Appendix M. MAUDE and Medical Device Recall Reports

This appendix gives results from the US Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE)[2] and Medical Device Recalls[1] databases, in Table M1 through Table M3.

Table M1. US Food and Drug Administration Medical Device Recall Reports[1]

Recall Number	Product Description	Trade Name	Recall Class	Center	Center Classification Date	Termination	Firm Name	Manufacturer Recall Reason
Z-1805-2020	Obalon Balloon System with Model 4300 Touch Dispenser Touchscreen; Software version 02.00.00.0076	Obalon Balloon System with 4300 Touch Dispenser	2	CDRH	4/28/2020	NR	Obalon Therapeutics Inc	During initial set-up and/or replacement of the dispenser batteries, the touch dispenser touchscreen can inadvertently lose calibration. This issue can also occur if the touchscreen is pressed when the device is powered on in preparation for a balloon administration. As a result, the touchscreen can become unresponsive and balloon inflation cannot be initiated.

Table M2. Reports on Intragastric Balloon Devices from the FDA MAUDE Database[2]

Note: Key information is presented in this table, but detailed event descriptions are available at the FDA MAUDE database.

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3005099803-2024-00169	1/3/2024	Injury	Apollo Endosurgery, Inc	1/31/2024	LTI	Orbera365 Intragastric Balloon System	Use of Device Problem; Migration	Abdominal Pain; Vomiting; Obstruction/ Occlusion
3005099803-2024-00078	1/5/2024	Injury	Apollo Endosurgery, Inc	1/31/2024	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Use of Device Problem	No Clinical Signs, Symptoms or Conditions
3005099803-2024-00251	1/7/2024	Injury	Apollo Endosurgery, Inc	1/31/2024	LTI	Orbera365 Intragastric Balloon System	Use of Device Problem; Adverse Event Without Identified Device or Use Problem	Abdominal Pain; Cardiac Arrest; Perforation; Pneumonia; Sepsis; Post Operative Wound Infection
3005099803-2024-00170	10/23/2023	Injury	Apollo Endosurgery, Inc	1/26/2024	LTI	BIB Intragastric Balloon System	Inflation Problem; Difficult to Remove; Use of Device Problem	Pain
3005099803-2024-00175	11/9/2023	Malfunction	Apollo Endosurgery	1/26/2024	LTI	BIB Intragastric Balloon System	Material Separation; Difficult to Advance	No Clinical Signs, Symptoms or Conditions
3012638928-2024-02991	12/6/2023	Malfunction	Spatz Fgia Inc.	1/22/2024	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	Abdominal Pain; Vomiting
3012638928-2024-02989	1/3/2024	Malfunction	Spatz Fgia Inc.	1/22/2024	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	Insufficient Information

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3005099803-2023-07189	12/26/2023	Injury	Apollo Endosurgery, Inc.	1/19/2024	LTI	Orbera365 Intragastric Balloon System	Burst Container or Vessel; Use of Device Problem	Vomiting
3005099803-2024-00038	8/15/2023	Injury	Apollo Endosurgery, Inc	1/17/2024	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Migration	No Clinical Signs, Symptoms or Conditions
3005099803-2024-00062	11/20/2023	Injury	Apollo Endosurgery, Inc	1/17/2024	LTI	BIB Intragastric Balloon System	Inflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2024-02987	12/5/2023	Malfunction	Spatz Fgia Inc.	1/17/2024	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3005099803-2023-07171	7/31/2023	Injury	Apollo Endosurgery, Inc	1/16/2024	LTI	BIB Intragastric Balloon System	Inflation Problem	Nausea; Pain
3005099803-2024-00037	9/4/2023	Injury	Apollo Endosurgery, Inc	1/16/2024	LTI	BIB Intragastric Balloon System	Deflation Problem; Use of Device Problem	No Clinical Signs, Symptoms or Conditions
3005099803-2024-00043	10/28/2023	Injury	Apollo Endosurgery, Inc	1/16/2024	LTI	BIB Intragastric Balloon System	Inflation Problem	Nausea; Pain; Vomiting
3005099803-2024-00061	10/31/2023	Injury	Apollo Endosurgery, Inc	1/16/2024	LTI	BIB Intragastric Balloon System	Inflation Problem	Abdominal Pain; Nausea
3005099803-2024-00028	11/7/2023	Injury	Apollo Endosurgery, Inc.	1/16/2024	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Use of Device Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3005099803-2023-07168	12/9/2023	Injury	Apollo Endosurgery	1/16/2024	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Use of Device Problem	No Clinical Signs, Symptoms or Conditions
3005099803-2023-07169	12/17/2023	Malfunction	Apollo Endosurgery	1/16/2024	LTI	BIB Intragastric Balloon System	Material Integrity Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2024-02990	1/3/2024	Malfunction	Spatz Fgia Inc.	1/16/2024	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02983	12/4/2023	Malfunction	Spatz Fgia Inc.	1/15/2024	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3005099803-2023-07151	8/1/2023	Injury	Apollo Endosurgery	1/12/2024	LTI	BIB Intragastric Balloon System	Inflation Problem; Use of Device Problem	Abdominal Pain; Vomiting
3012638928-2023-02977	10/5/2023	Malfunction	Spatz Fgia Inc.	1/11/2024	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02980	11/29/2023	Malfunction	Spatz Fgia Inc.	1/11/2024	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3005099803-2023-07131	9/30/2023	Injury	Apollo Endosurgery, Inc	1/9/2024	LTI	Orbera365 Intragastric Balloon System	Adverse Event Without Identified Device or Use Problem	Erosion; Pyrosis/ Heartburn; Nausea; Vomiting
3005099803-2023-07068	12/6/2023	Malfunction	Apollo Endosurgery, Inc	1/5/2024	LTI	Orbera365 Intragastric Balloon System	Material Separation; Difficult to Advance	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3005099803-2023-07056	12/9/2023	Injury	Apollo Endosurgery Inc.,	1/5/2024	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Use of Device Problem	No Clinical Signs, Symptoms or Conditions
3005099803-2023-07076	12/11/2023	Malfunction	Apollo Endosurgery Inc.,	1/5/2024	LTI	Orbera365 Intragastric Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02970	7/28/2023	Malfunction	Spatz Fgia Inc.	1/4/2024	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02969	8/23/2023	Malfunction	Spatz Fgia Inc.	1/4/2024	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02968	9/5/2023	Malfunction	Spatz Fgia Inc.	1/4/2024	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02971	9/13/2023	Malfunction	Spatz Fgia Inc.	1/4/2024	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02967	9/19/2023	Malfunction	Spatz Fgia Inc.	1/4/2024	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02964	10/25/2023	Malfunction	Spatz Fgia Inc.	1/4/2024	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02966	10/25/2023	Malfunction	Spatz Fgia Inc.	1/4/2024	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2023-02965	11/14/2023	Malfunction	Spatz Fgia Inc.	1/4/2024	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02962	11/28/2023	Injury	Spatz Fgia Inc.	1/4/2024	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Patient Device Interaction Problem; Air/ Gas in Device	Abdominal Pain
3005099803-2023-07041	12/10/2023	Malfunction	Apollo Endosurgery	1/4/2024	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Migration	No Clinical Signs, Symptoms or Conditions
3005099803-2023-07042	12/11/2023	Injury	Apollo Endosurgery	1/4/2024	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Use of Device Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02961	10/25/2023	Malfunction	Spatz Fgia Inc.	1/3/2024	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Vomiting
3012638928-2023-02959	9/27/2023	Malfunction	Spatz Fgia Inc.	1/1/2024	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02956	10/9/2023	Injury	Spatz Fgia Inc.	12/28/2023	LTI	Spatz3 Adjustable Balloon System	Improper or Incorrect Procedure or Method	Laceration(s)
3005099803-2023-06938	11/27/2023	Malfunction	Apollo Endosurgery	12/28/2023	LTI	Orbera365 Intragastric Balloon System	Fluid/ Blood Leak	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3005099803-2023-06814	11/10/2023	Injury	Apollo Endosurgery	12/27/2023	LTI	BIB Intragastric Balloon System	Deflation Problem; Use of Device Problem; Material Integrity Problem	Vomiting
3005099803-2023-06813	8/11/2023	Injury	Apollo Endosurgery	12/26/2023	LTI	BIB Intragastric Balloon System	Inflation Problem; Use of Device Problem	Inflammation; Nausea; Vomiting; Paresthesia
3005099803-2023-06894	10/24/2023	Malfunction	Apollo Endosurgery	12/26/2023	LTI	BIB Intragastric Balloon System	Material Separation; Detachment of Device or Device Component	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02955	11/23/2023	Malfunction	Spatz Fgia Inc.	12/26/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02954	11/22/2023	Malfunction	Spatz Fgia Inc.	12/24/2023	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	Abdominal Pain; Nausea; Vomiting
3012638928-2023-02951	11/15/2023	Malfunction	Spatz Fgia Inc.	12/21/2023	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	Insufficient Information
3012638928-2023-02952	11/21/2023	Malfunction	Spatz Fgia Inc.	12/21/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02953	11/22/2023	Malfunction	Spatz Fgia Inc.	12/21/2023	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	Insufficient Information

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2023-02979	7/18/2023	Malfunction	Spatz Fgia Inc.	12/17/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02946	10/25/2023	Malfunction	Spatz Fgia Inc.	12/17/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02948	11/1/2023	Malfunction	Spatz Fgia Inc.	12/17/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02978	11/2/2023	Malfunction	Spatz Fgia Inc.	12/17/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3005099803-2023-06691	11/15/2023	Malfunction	Apollo Endosurgery Inc.,	12/15/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Use of Device Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02944	11/1/2023	Malfunction	Spatz Fgia Inc.	12/13/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02945	11/14/2023	Malfunction	Spatz Fgia Inc.	12/13/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3005099803-2023-06549	9/27/2023	Malfunction	Apollo Endosurgery, Inc.	12/11/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Use of Device Problem; Migration	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02942	10/6/2023	Malfunction	Spatz Fgia Inc.	12/11/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2023-02949	11/10/2023	Malfunction	Spatz Fgia Inc.	12/11/2023	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	Abdominal Pain; Nausea; Vomiting
3012638928-2023-02950	11/15/2023	Malfunction	Spatz Fgia Inc.	12/11/2023	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	Abdominal Pain; Eructate; Nausea
3005099803-2023-06590	10/15/2023	Injury	Apollo Endosurgery	12/8/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Use of Device Problem	No Clinical Signs, Symptoms or Conditions
3005099803-2023-06569	10/14/2023	Malfunction	Apollo Endosurgery, Inc.	12/7/2023	LTI	Orbera365 Intragastric Balloon System	Fluid/ Blood Leak; Inflation Problem	No Clinical Signs, Symptoms or Conditions
3005099803-2023-06589	11/6/2023	Injury	Apollo Endosurgery, Inc	12/7/2023	LTI	Orbera Intragastric Balloon System	Inflation Problem	Pain; Discomfort
3005099803-2023-06558	7/31/2023	Injury	Apollo Endosurgery, Inc	12/6/2023	LTI	BIB Intragastric Balloon System	Inflation Problem	Nausea; Pain
3012638928-2023-02938	11/8/2023	Malfunction	Spatz Fgia Inc.	12/4/2023	LTI	Spatz3 Adjustable Balloon System	Inflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-0230-00228	NR	Malfunction	Apollo Endosurgery, Inc	12/1/2023	LTI	Bib¿ Intragastric Balloon System	Inflation Problem	Abdominal Pain; Nausea; Vomiting; Obstruction/ Occlusion
3006722112-2023-00226	3/9/2020	Malfunction	Apollo Endosurgery, Inc	11/30/2023	LTI	Orbera® Intragastric Balloon System	Inflation Problem	Abdominal Pain; Vomiting

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2023-00227	NR	Malfunction	Apollo Endosurgery, Inc	11/30/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3012638928-2023-02947	10/31/2023	Malfunction	Spatz Fgia Inc.	11/28/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00223	7/13/2023	Malfunction	Apollo Endosurgery, Inc.	11/27/2023	LTI	Orbera Intragastric Balloon	Patient-Device Incompatibility	Dehydration; Fatigue; Nausea; Vomiting
3006722112-2023-00224	10/25/2023	Malfunction	Apollo Endosurgery, Inc.	11/27/2023	LTI	Orbera Intragastric Balloon	Patient-Device Incompatibility	Fatigue; Vomiting
3006722112-2023-00222	10/23/2023	Injury	Apollo Endosurgery, Inc.	11/17/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Fluid/ Blood Leak; Migration or Expulsion of Device; Unintended Deflation	Abdominal Pain; Failure of Implant; Obstruction/ Occlusion
3012638928-2023-02941	11/5/2023	Malfunction	Spatz Fgia Inc.	11/16/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02935	NR	Malfunction	Spatz Fgia Inc.	11/16/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration or Expulsion of Device	Vomiting
3012638928-2023-02931	10/11/2023	Malfunction	Spatz Fgia Inc.	11/15/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2023-02939	11/5/2023	Malfunction	Spatz Fgia Inc.	11/12/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02940	11/8/2023	Malfunction	Spatz Fgia Inc.	11/12/2023	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00216	9/13/2023	Malfunction	Apollo Endosurgery, Inc.	11/10/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Fluid/ Blood Leak; Migration or Expulsion of Device; Unintended Deflation	Failure of Implant
3006722112-2023-00221	10/10/2023	Malfunction	Apollo Endosurgery, Inc.	11/10/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Fluid/ Blood Leak; Migration or Expulsion of Device; Unintended Deflation	Failure of Implant
3006722112-2023-00218	10/20/2023	Malfunction	Apollo Endosurgery, Inc.	11/10/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Fluid/ Blood Leak; Migration or Expulsion of Device; Unintended Deflation	Failure of Implant

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2023-00215	9/21/2023	Malfunction	Apollo Endosurgery, Inc.	11/8/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Fluid/ Blood Leak; Migration or Expulsion of Device; Unintended Deflation	Failure of Implant
3012638928-2023-02934	9/29/2023	Malfunction	Spatz Fgia Inc.	11/8/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00214	10/16/2023	Malfunction	Apollo Endosurgery, Inc.	11/8/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Fluid/ Blood Leak; Migration or Expulsion of Device; Unintended Deflation	Failure of Implant
3012638928-2023-02936	10/25/2023	Malfunction	Spatz Fgia Inc.	11/8/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02932	10/20/2023	Malfunction	Spatz Fgia Inc.	11/7/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02933	10/20/2023	Malfunction	Spatz Fgia Inc.	11/7/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02930	9/17/2023	Malfunction	Spatz Fgia Inc.	11/6/2023	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility	Abdominal Pain; Nausea; Vomiting; Constipation

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2023-02927	10/1/2023	Injury	Spatz Fgia Inc.	11/5/2023	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility	Abdominal Pain; Pyrosis/ Heartburn; Vomiting
3006722112-2023-00212	9/30/2023	Malfunction	Apollo Endosurgery, Inc.	11/3/2023	LTI	Orbera Intragastric Balloon	Patient-Device Incompatibility	Abdominal Pain; Dehydration; Nausea; Vomiting; Abdominal Cramps
3012638928-2023-02924	9/15/2023	Malfunction	Spatz Fgia Inc.	10/29/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00208	8/30/2023	Malfunction	Apollo Endosurgery, Inc.	10/27/2023	LTI	Orbera Intragastric Balloon	Inflation Problem; Air/ Gas in Device	Failure of Implant
3006722112-2023-00219	3/5/2023	Malfunction	Apollo Endosurgery, Inc	10/26/2023	LTI	Orbera Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2023-00220	7/25/2023	Malfunction	Apollo Endosurgery, Inc.	10/26/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3012638928-2023-02923	9/27/2023	Malfunction	Spatz Fgia Inc.	10/26/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00202	9/18/2023	Malfunction	Apollo Endosurgery, Inc.	10/25/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2023-02919	9/19/2023	Injury	Spatz Fgia Inc.	10/25/2023	LTI	Spatz3 Adjustable Balloon System	Improper or Incorrect Procedure or Method	Perforation of Esophagus
3006722112-2023-00205	9/18/2023	Malfunction	Apollo Endosurgery, Inc	10/23/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2023-00210	NR	Malfunction	Apollo Endosurgery, Inc	10/19/2023	LTI	Orbera Intragastric Balloon System	Insufficient Information	Nausea; Vomiting; Obstruction/ Occlusion
3006722112-2023-00209	NR	Malfunction	Apollo Endosurgery, Inc	10/19/2023	LTI	Orbera365 Intragastric Balloon System	Inflation Problem	Dehydration; Nausea; Vomiting
3012638928-2023-02929	9/14/2023	Malfunction	Spatz Fgia Inc.	10/16/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration or Expulsion of Device	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00204	9/12/2023	Malfunction	Apollo Endosurgery, Inc	10/12/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Leak/ Splash; Unintended Deflation	Failure of Implant
3006722112-2023-00203	9/8/2023	Malfunction	Apollo Endosurgery, Inc	10/10/2023	LTI	Orbera Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3012638928-2023-02917	9/14/2023	Malfunction	Spatz Fgia Inc.	10/10/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2023-00200	7/13/2023	Malfunction	Apollo Endosurgery, Inc	10/9/2023	LTI	Orbera Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2023-00199	8/14/2023	Malfunction	Apollo Endosurgery, Inc	10/9/2023	LTI	Orbera Intragastric Balloon System	Inflation Problem	Failure of Implant
3006722112-2023-00196	9/28/2023	Malfunction	Apollo Endosurgery, Inc	10/9/2023	LTI	Orbera Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Bowel Perforation
3006722112-2023-00201	NR	Malfunction	Apollo Endosurgery, Inc	10/9/2023	LTI	Orbera Intragastric Balloon System	Adverse Event Without Identified Device or Use Problem	Cardiac Arrest; Nausea; Vomiting; Syncope/ Fainting
3006722112-2023-00193	9/2/2023	Malfunction	Apollo Endosurgery, Inc.	10/6/2023	LTI	Orbera Intragastric Balloon	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2023-00189	NR	Malfunction	Apollo Endosurgery, Inc.	10/6/2023	LTI	Orbera 365 Intragastric Balloon	Adverse Event Without Identified Device or Use Problem	Pyrosis/ Heartburn; Failure of Implant; Nausea; Vomiting
3012638928-2023-02915	8/25/2023	Malfunction	Spatz Fgia Inc.	10/5/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00186	NR	Malfunction	Apollo Endosurgery, Inc.	10/3/2023	LTI	Orbera Intragastric Balloon	Adverse Event Without Identified Device or Use Problem	Pyrosis/ Heartburn; Failure of Implant; Inflammation; Nausea; Vomiting

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2023-00194	8/24/2023	Malfunction	Apollo Endosurgery, Inc	10/2/2023	LTI	Orbera Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2023-00190	9/5/2023	Malfunction	Apollo Endosurgery, Inc.	10/2/2023	LTI	Orbera Intragastric Balloon	Compatibility Problem	Anemia; Gastritis; Failure of Implant; Low Oxygen Saturation; Gastrointestinal Hemorrhage
3006722112-2023-00188	NR	Malfunction	Apollo Endosurgery, Inc	10/2/2023	LTI	Orbera Intragastric Balloon System	Insufficient Information	Appropriate Clinical Signs, Symptoms, Conditions Term/ Code Not Available
3006722112-2023-00187	NR	Malfunction	Apollo Endosurgery, Inc	10/2/2023	LTI	Orbera Intragastric Balloon System	Migration	Abdominal Pain; Obstruction/ Occlusion
3006722112-2023-00198	4/24/2023	Malfunction	Apollo Endosurgery, Inc.	9/29/2023	LTI	Orbera Intragastric Balloon	Deflation Problem; Unintended Deflation	Failure of Implant
3012638928-2023-02909	4/12/2023	Injury	Spatz Fgia Inc.	9/28/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration or Expulsion of Device	Obstruction/ Occlusion
3012638928-2023-02913	7/27/2023	Injury	Spatz Fgia Inc.	9/28/2023	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Patient Device Interaction Problem; Air/ Gas in Device	Stomach Ulceration

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2023-02912	8/4/2023	Malfunction	Spatz Fgia Inc.	9/28/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02914	8/27/2023	Malfunction	Spatz Fgia Inc.	9/27/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02911	3/17/2023	Malfunction	Spatz Fgia Inc.	9/26/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02910	6/29/2023	Malfunction	Spatz Fgia Inc.	9/26/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00163	7/17/2023	Malfunction	Apollo Endosurgery, Inc	9/21/2023	LTI	Orbera Intragastric Balloon	Inflation Problem	Failure of Implant
3006722112-2023-00184	4/25/2023	Malfunction	Apollo Endosurgery, Inc.	9/19/2023	LTI	Orbera Intragastric Balloon	Inflation Problem; Air/ Gas in Device	Failure of Implant
3006722112-2023-00182	6/28/2023	Malfunction	Apollo Endosurgery, Inc.	9/19/2023	LTI	Orbera Intragastric Balloon	Inflation Problem; Air/ Gas in Device	Failure of Implant
3006722112-2023-00183	7/14/2023	Malfunction	Apollo Endosurgery, Inc.	9/19/2023	LTI	Orbera Intragastric Balloon	Inflation Problem; Air/ Gas in Device	Failure of Implant
3006722112-2023-00185	7/16/2023	Malfunction	Apollo Endosurgery, Inc.	9/19/2023	LTI	Orbera Intragastric Balloon	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2023-00192	NR	Malfunction	Apollo Endosurgery, Inc	9/18/2023	LTI	Orbera Intragastric Balloon System	Migration	Perforation of Esophagus
3006722112-2023-00191	6/17/2023	Malfunction	Apollo Endosurgery, Inc	9/15/2023	LTI	Orbera365 Intragastric Balloon System	Inflation Problem; Insufficient Information	Failure of Implant
3006722112-2023-00180	7/21/2023	Malfunction	Apollo Endosurgery, Inc.	9/15/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Fluid/ Blood Leak; Migration or Expulsion of Device; Unintended Deflation	Failure of Implant
3006722112-2023-00181	8/22/2023	Malfunction	Apollo Endosurgery, Inc.	9/15/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3012638928-2023-02907	8/7/2023	Malfunction	Spatz Fgia Inc.	9/14/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02908	8/21/2023	Malfunction	Spatz Fgia Inc.	9/14/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02903	8/14/2023	Malfunction	Spatz Fgia Inc.	9/13/2023	LTI	Spatz3 Adjustable Balloon System	Inflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2023-02904	7/31/2023	Malfunction	Spatz Fgia Inc.	9/12/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02906	8/9/2023	Malfunction	Spatz Fgia Inc.	9/12/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration or Expulsion of Device	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02902	8/11/2023	Malfunction	Spatz Fgia Inc.	9/11/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02905	8/16/2023	Malfunction	Spatz Fgia Inc.	9/10/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration or Expulsion of Device	Abdominal Pain; Diarrhea; Nausea; Vomiting
3006722112-2023-00170	7/19/2023	Malfunction	Apollo Endosurgery, Inc.	9/8/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant; Vomiting
3012638928-2023-02901	7/19/2023	Malfunction	Spatz Fgia Inc.	9/8/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00172	7/31/2023	Malfunction	Apollo Endosurgery, Inc.	9/8/2023	LTI	Orbera 365 Intragastric Balloon	Insufficient Information	Insufficient Information
3012638928-2023-02896	8/1/2023	Malfunction	Spatz Fgia Inc.	9/7/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2023-02900	8/9/2023	Malfunction	Spatz Fgia Inc.	9/7/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02897	8/1/2023	Malfunction	Spatz Fgia Inc.	9/6/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02895	8/7/2023	Malfunction	Spatz Fgia Inc.	9/4/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00168	7/19/2023	Malfunction	Apollo Endosurgery, Inc.	9/1/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2023-00169	8/4/2023	Malfunction	Apollo Endosurgery, Inc.	9/1/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2023-00175	7/1/2023	Malfunction	Apollo Endosurgery, Inc	8/30/2023	LTI	Orbera365 Intragastric Balloon System	Increase in Pressure	Dehydration; Diarrhea; Vomiting; Pancreatitis; Unspecified Kidney or Urinary Problem
3006722122-2023-00167	7/17/2023	Malfunction	Apollo Endosurgery, Inc.	8/30/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Fluid/ Blood Leak; Migration or Expulsion of Device; Unintended Deflation	Failure of Implant

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2023-00166	8/1/2023	Malfunction	Apollo Endosurgery, Inc.	8/30/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722122-2023-00178	9/1/2022	Malfunction	Apollo Endosurgery, Inc.	8/28/2023	LTI	Orbera 365 Intragastric Balloon	Patient-Device Incompatibility; Patient Device Interaction Problem	Dehydration; Failure of Implant
3006722112-2023-00177	2/2/2023	Malfunction	Apollo Endosurgery, Inc.	8/28/2023	LTI	Orbera 365 Intragastric Balloon	Patient-Device Incompatibility; Patient Device Interaction Problem	Dehydration; Failure of Implant; Vomiting
3006722112-2023-00173	4/20/2023	Malfunction	Apollo Endosurgery, Inc	8/28/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Unintended Deflation	Failure of Implant
3012638928-2023-02899	6/9/2023	Malfunction	Spatz Fgia Inc.	8/28/2023	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00174	7/3/2023	Malfunction	Apollo Endosurgery, Inc	8/28/2023	LTI	Orbera365 Intragastric Balloon System	Partial Blockage	Abdominal Pain; Pyrosis/ Heartburn; Failure of Implant; Nausea; Obstruction/ Occlusion
3006722112-2023-00176	7/6/2023	Malfunction	Apollo Endosurgery, Inc	8/28/2023	LTI	Orbera365 Intragastric Balloon System	Increase in Pressure	Abdominal Pain; Nausea; Pancreatitis

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2023-02898	7/6/2023	Malfunction	Spatz Fgia Inc.	8/28/2023	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	No Clinical Signs, Symptoms or Conditions
3006722122-2023-00165	7/31/2023	Malfunction	Apollo Endosurgery, Inc.	8/28/2023	LTI	Orbera 365 Intragastric Balloon	Inflation Problem	Fever; Failure of Implant
3006722112-2023-00161	3/8/2023	Malfunction	Apollo Endosurgery, Inc.	8/25/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Fluid/ Blood Leak; Migration or Expulsion of Device; Unintended Deflation	Failure of Implant; Vomiting
3006722112-2023-00162	5/25/2023	Malfunction	Apollo Endosurgery, Inc.	8/25/2023	LTI	Orbera 365 Intragastric Balloon	Inflation Problem	Failure of Implant
3006722122-2023-00163	7/17/2023	Malfunction	Apollo Endosurgery, Inc.	8/25/2023	LTI	Orbera Intragastric Balloon	Inflation Problem	Failure of Implant
3006722112-2023-00164	7/19/2023	Malfunction	Apollo Endosurgery, Inc.	8/25/2023	LTI	Orbera Intragastric Balloon	Inflation Problem	Failure of Implant
3012638928-2023-02894	7/25/2023	Malfunction	Spatz Fgia Inc.	8/23/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Nausea
3012638928-2023-02887	NR	Injury	Spatz Fgia Inc.	8/23/2023	LTI	Spatz3 Adjustable Balloon System	Adverse Event Without Identified Device or Use Problem	Coma
3012638928-2023-02892	5/2/2023	Malfunction	Spatz Fgia Inc.	8/22/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2023-02890	6/6/2023	Malfunction	Spatz Fgia Inc.	8/22/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02893	7/25/2023	Malfunction	Spatz Fgia Inc.	8/22/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02888	5/2/2023	Malfunction	Spatz Fgia Inc.	8/21/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Discomfort
3006722112-2023-00158	5/26/2023	Malfunction	Apollo Endosurgery, Inc.	8/21/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Fluid/ Blood Leak; Migration or Expulsion of Device; Unintended Deflation	Failure of Implant
3006722112-2023-00157	7/26/2023	Malfunction	Apollo Endosurgery, Inc.	8/21/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Fluid/ Blood Leak; Migration or Expulsion of Device; Unintended Deflation	Failure of Implant
3012638928-2023-02883	7/21/2023	Malfunction	Spatz Fgia Inc.	8/20/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02884	7/21/2023	Malfunction	Spatz Fgia Inc.	8/20/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722122-2023-00156	6/21/2023	Malfunction	Apollo Endosurgery, Inc.	8/18/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722122-2023-00155	7/9/2023	Malfunction	Apollo Endosurgery, Inc.	8/18/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3012638928-2023-02829	4/26/2023	Malfunction	Spatz Fgia Inc.	8/17/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02881	6/6/2023	Malfunction	Spatz Fgia Inc.	8/16/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration or Expulsion of Device	No Clinical Signs, Symptoms or Conditions
3006722122-2023-00153	7/14/2023	Malfunction	Apollo Endosurgery, Inc.	8/16/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722122-2023-00159	7/13/2023	Malfunction	Apollo Endosurgery, Inc.	8/15/2023	LTI	Orbera 365 Intragastric Balloon	Separation Problem; Premature Separation	Failure of Implant
3006722112-2023-00150	6/14/2023	Malfunction	Apollo Endosurgery, Inc.	8/14/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2023-02880	7/13/2023	Malfunction	Spatz Fgia Inc.	8/13/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
MW5135363	2/23/1962	Death	Apollo Endosurgery, Inc	8/12/2023	LTI	Orbera Gastric Balloon	Adverse Event Without Identified Device or Use Problem	Unspecified Infection; Pain; Perforation
3006722112-2023-00151	5/30/2023	Malfunction	Apollo Endosurgery, Inc.	8/11/2023	LTI	Orbera Intragastric Balloon System	Inflation Problem	Failure of Implant
3006722112-2023-00152	7/2/2023	Malfunction	Apollo Endosurgery, Inc.	8/11/2023	LTI	Orbera Intragastric Balloon System	Inflation Problem	Failure of Implant
3006722112-2023-00148	7/9/2023	Malfunction	Apollo Endosurgery, Inc.	8/11/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Migration or Expulsion of Device; Unintended Deflation	Failure of Implant
3012638928-2023-02876	6/21/2023	Malfunction	Spatz Fgia Inc.	8/10/2023	LTI	Spatz3 Adjustable Balloon System	Air/ Gas in Device	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02878	7/3/2023	Malfunction	Spatz Fgia Inc.	8/10/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2023-02875	1/11/2023	Injury	Spatz Fgia Inc.	8/9/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Patient-Device Incompatibility; Patient Device Interaction Problem	Abdominal Pain
3012638928-2023-02873	4/18/2023	Malfunction	Spatz Fgia Inc.	8/9/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00149	6/13/2023	Malfunction	Apollo Endosurgery, Inc	8/9/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3012638928-2023-02877	7/5/2023	Malfunction	Spatz Fgia Inc.	8/9/2023	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00147	7/11/2023	Malfunction	Apollo Endosurgery, Inc	8/9/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3012638928-2023-02874	5/24/2023	Malfunction	Spatz Fgia Inc.	8/8/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02871	NR	Malfunction	Spatz Fgia Inc.	8/8/2023	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	Abdominal Pain; Discomfort

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2023-02869	5/25/2023	Malfunction	Spatz Fgia Inc.	8/6/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02872	7/7/2023	Malfunction	Spatz Fgia Inc.	8/6/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02867	5/2/2023	Malfunction	Spatz Fgia Inc.	8/3/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02863	5/11/2023	Injury	Spatz Fgia Inc.	8/3/2023	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	Abdominal Pain; Nausea; Pancreatitis
3012638928-2023-02868	5/26/2023	Malfunction	Spatz Fgia Inc.	8/3/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00146	3/21/2023	Malfunction	Apollo Endosurgery, Inc.	8/1/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Fluid/ Blood Leak; Migration or Expulsion of Device; Migration; Unintended Deflation	Failure of Implant
3012638928-2023-02865	7/3/2023	Malfunction	Spatz Fgia Inc.	7/31/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2023-00143	6/19/2023	Malfunction	Apollo Endosurgery, Inc.	7/28/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3012638928-2023-02858	6/22/2023	Malfunction	Spatz Fgia Inc.	7/26/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00144	6/30/2023	Injury	Apollo Endosurgery, Inc.	7/26/2023	LTI	Orbera Intragastric Balloon	Patient-Device Incompatibility; Patient Device Interaction Problem	Abdominal Pain; Failure of Implant; Nausea; Vomiting; Appropriate Clinical Signs, Symptoms, Conditions Term/ Code Not Available
3012638928-2023-02855	6/21/2023	Malfunction	Spatz Fgia Inc.	7/24/2023	LTI	Spatz3 Adjustable Balloon System	Inflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02860	6/29/2023	Malfunction	Spatz Fgia Inc.	7/24/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00141	2/6/2023	Malfunction	Apollo Endosurgery, Inc.	7/21/2023	LTI	Orbera 365 Intragastric Balloon	Migration or Expulsion of Device; Expulsion	Failure of Implant
3012638928-2023-02861	6/16/2023	Malfunction	Spatz Fgia Inc.	7/20/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02859	6/27/2023	Malfunction	Spatz Fgia Inc.	7/20/2023	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2023-02854	6/1/2023	Injury	Spatz Fgia Inc.	7/19/2023	LTI	Spatz3 Adjustable Balloon System	Inadequate or Insufficient Training; Improper or Incorrect Procedure or Method; Misassembly by Users	Laceration(s); Perforation of Esophagus
3006722112-2023-00140	6/15/2023	Malfunction	Apollo Endosurgery, Inc.	7/19/2023	LTI	Orbera Intragastric Balloon	Separation Problem; Premature Separation	Failure of Implant
3006722112-2023-00142	6/22/2023	Malfunction	Apollo Endosurgery, Inc.	7/18/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Fluid/ Blood Leak; Migration or Expulsion of Device; Unintended Deflation	Failure of Implant
3012638928-2023-02853	2/17/2023	Malfunction	Spatz Fgia Inc.	7/16/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02850	6/14/2023	Malfunction	Spatz Fgia Inc.	7/13/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02852	4/24/2023	Malfunction	Spatz Fgia Inc.	7/11/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2023-02845	5/12/2023	Malfunction	Spatz Fgia Inc.	7/11/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration or Expulsion of Device	Constipation
3006722112-2023-00139	6/12/2023	Malfunction	Apollo Endosurgery, Inc.	7/10/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3012638928-2023-02849	6/5/2023	Malfunction	Spatz Fgia Inc.	7/5/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02848	6/13/2023	Malfunction	Spatz Fgia Inc.	7/5/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02846	5/30/2023	Malfunction	Spatz Fgia Inc.	7/3/2023	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	Abdominal Pain; Dehydration; Nausea; Vomiting
3012638928-2023-02841	5/23/2023	Injury	Spatz Fgia Inc.	6/29/2023	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility	Nausea; Vomiting
3006722112-2023-00132	5/25/2023	Injury	Apollo Endosurgery, Inc.	6/23/2023	LTI	Orbera 365 Intragastric Balloon	Difficult to Remove	Laceration(s) of Esophagus; Perforation of Esophagus
3006722112-2023-00136	NR	Malfunction	Apollo Endosurgery, Inc	6/21/2023	LTI	Orbera Intragastric Balloon System	Inflation Problem	Nausea; Vomiting; Pancreatitis

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2023-02847	5/30/2023	Malfunction	Spatz Fgia Inc.	6/20/2023	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	Abdominal Pain
3012638928-2023-02844	6/7/2023	Malfunction	Spatz Fgia Inc.	6/20/2023	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	Abdominal Pain; Nausea
3012638928-2023-02839	5/25/2023	Malfunction	Spatz Fgia Inc.	6/19/2023	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	Abdominal Pain; Nausea
3006722112-2023-00128	7/1/2022	Malfunction	Apollo Endosurgery, Inc	6/16/2023	LTI	Orbera Intragastric Balloon System	Migration or Expulsion of Device; Migration	Perforation
3006722112-2023-00131	3/23/2023	Malfunction	Apollo Endosurgery, Inc	6/16/2023	LTI	Orbera Intragastric Balloon System	Migration	Abdominal Pain; Failure of Implant; Sepsis; Hernia; Obstruction/ Occlusion
3006722112-2023-00130	5/12/2023	Malfunction	Apollo Endosurgery, Inc	6/16/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Unintended Deflation	Failure of Implant
3006722112-2023-00111	5/21/2023	Malfunction	Apollo Endosurgery, Inc.	6/16/2023	LTI	Orbera Intragastric Balloon	Deflation Problem; Unintended Deflation	Abdominal Pain; Failure of Implant
3012638928-2023-02838	5/18/2023	Malfunction	Spatz Fgia Inc.	6/15/2023	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	Nausea; Vomiting

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2023-02836	4/23/2023	Malfunction	Spatz Fgia Inc.	6/13/2023	LTI	Spatz3 Adjustable Balloon System	Insufficient Information	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02837	5/20/2023	Malfunction	Spatz Fgia Inc.	6/13/2023	LTI	Spatz3 Adjustable Balloon System	Insufficient Information	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00126	5/16/2023	Malfunction	Apollo Endosurgery, Inc	6/6/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Unintended Deflation	Failure of Implant
3006722112-2023-00124	5/6/2023	Malfunction	Apollo Endosurgery, Inc	6/5/2023	LTI	Orbera365 Intragastric Balloon System	Migration	Abdominal Pain; Dehydration; Nausea; Vomiting; Obstruction/ Occlusion; Kidney Infection
3006722112-2023-00118	NR	Malfunction	Apollo Endosurgery, Inc.	6/5/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Unintended Deflation	Abdominal Pain; Failure of Implant
3006722112-2023-00112	2/10/2023	Malfunction	Apollo Endosurgery, Inc	6/2/2023	LTI	Orbera Intragastric Balloon System	Deflation Problem; Leak/ Splash; Unintended Deflation	Failure of Implant
3006722112-2023-00116	3/10/2023	Malfunction	Apollo Endosurgery, Inc	6/2/2023	LTI	Orbera Intragastric Balloon System	Inflation Problem	Failure of Implant
3006722112-2023-00117	4/10/2023	Malfunction	Apollo Endosurgery, Inc	6/2/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Leak/ Splash; Unintended Deflation	Failure of Implant

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2023-00115	4/20/2023	Malfunction	Apollo Endosurgery, Inc	6/2/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Unintended Deflation	Failure of Implant
3006722112-2023-00120	4/28/2023	Malfunction	Apollo Endosurgery, Inc	6/2/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Unintended Deflation	Failure of Implant
3006722112-2023-00119	5/4/2023	Malfunction	Apollo Endosurgery, Inc	6/2/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2023-00108	3/29/2023	Malfunction	Apollo Endosurgery, Inc.	5/31/2023	LTI	Orbera Intragastric Balloon	Deflation Problem; Unintended Deflation	Failure of Implant
3006722112-2023-00114	4/22/2023	Malfunction	Apollo Endosurgery, Inc.	5/30/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Unintended Deflation	Failure of Implant; Vomiting
3006722112-2023-00109	5/2/2023	Malfunction	Apollo Endosurgery, Inc.	5/26/2023	LTI	Orbera Intragastric Balloon	Deflation Problem; Mechanical Problem; Unintended Deflation	Failure of Implant
3012638928-2023-02831	4/14/2023	Malfunction	Spatz Fgia Inc.	5/24/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Abdominal Pain
3006722112-2023-00107	4/4/2023	Malfunction	Apollo Endosurgery, Inc.	5/23/2023	LTI	Obera Intragastric Balloon	Patient Device Interaction Problem	Vomiting; Perforation of Esophagus

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2023-00105	4/4/2023	Malfunction	Apollo Endosurgery, Inc.	5/19/2023	LTI	Orbera Intragastric Balloon	Deflation Problem; Unintended Deflation	Failure of Implant
3006722112-2023-00102	4/8/2023	Malfunction	Apollo Endosurgery, Inc.	5/19/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Unintended Deflation	Failure of Implant
3006722112-2023-00103	NR	Malfunction	Apollo Endosurgery, Inc	5/17/2023	LTI	Orbera Intragastric Balloon System	Inflation Problem	Hypersensitivity/ Allergic reaction
3012638928-2023-02821	3/7/2023	Malfunction	Spatz Fgia Inc.	5/16/2023	LTI	Spatz3 Adjustable Balloon System	Insufficient Information	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00085	3/20/2023	Malfunction	Apollo Endosurgery, Inc	5/15/2023	LTI	Orbera Intragastric Balloon System	Deflation Problem; Unintended Deflation	Failure of Implant
3006722112-2023-00093	4/10/2023	Malfunction	Apollo Endosurgery, Inc	5/15/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Unintended Deflation	Failure of Implant
3006722112-2023-00089	NR	Malfunction	Apollo Endosurgery, Inc	5/15/2023	LTI	Orbera Intragastric Balloon System	Inflation Problem; Air/ Gas in Device	Failure of Implant
3006722112-2023-00084	3/26/2023	Malfunction	Apollo Endosurgery, Inc.	5/12/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Unintended Deflation	Failure of Implant
3012638928-2023-02833	4/19/2023	Malfunction	Spatz Fgia Inc.	5/10/2023	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	Abdominal Pain; Nausea; Vomiting

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2023-02834	5/7/2023	Malfunction	Spatz Fgia Inc.	5/9/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02830	4/6/2023	Malfunction	Spatz Fgia Inc.	5/7/2023	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00083	4/13/2023	Malfunction	Apollo Endosurgery, Inc.	5/5/2023	LTI	Orbera Intragastric Balloon System	Adverse Event Without Identified Device or Use Problem	Abdominal Pain; Vomiting; Aspiration Pneumonitis
3012638928-2023-02820	4/14/2023	Malfunction	Spatz Fgia Inc.	5/1/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00080	2/18/2023	Malfunction	Apollo Endosurgery, Inc.	4/28/2023	LTI	Orbera Intragastric Balloon	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2023-00081	4/1/2023	Malfunction	Apollo Endosurgery, Inc.	4/28/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Unintended Deflation	Failure of Implant
3012638928-2023-02828	1/18/2023	Malfunction	Spatz Fgia Inc.	4/27/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02825	1/18/2023	Malfunction	Spatz Fgia Inc.	4/27/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2023-02817	3/11/2023	Malfunction	Spatz Fgia Inc.	4/27/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00091	3/24/2023	Malfunction	Apollo Endosurgery, Inc	4/26/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Unintended Deflation	Failure of Implant
3006722112-2023-00092	3/24/2023	Malfunction	Apollo Endosurgery, Inc	4/26/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Unintended Deflation	Failure of Implant
3012638928-2023-02813	6/15/2022	Malfunction	Spatz Fgia Inc.	4/24/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02815	1/15/2023	Malfunction	Spatz Fgia Inc.	4/24/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Discomfort
3012638928-2023-02824	1/18/2023	Malfunction	Spatz Fgia Inc.	4/24/2023	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	Discomfort
3012638928-2023-02814	3/29/2023	Malfunction	Spatz Fgia Inc.	4/24/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00079	1/19/2023	Malfunction	Apollo Endosurgery, Inc.	4/21/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Unintended Deflation	Abdominal Pain; Failure of Implant

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2023-00078	2/13/2023	Malfunction	Apollo Endosurgery, Inc.	4/21/2023	LTI	Orbera 365 Intragastric Balloon	Adverse Event Without Identified Device or Use Problem; Migration	Abdominal Pain; Failure of Implant; Perforation
3012638928-2023-02822	1/29/2023	Malfunction	Spatz Fgia Inc.	4/20/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02823	3/10/2023	Malfunction	Spatz Fgia Inc.	4/20/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02812	3/27/2023	Malfunction	Spatz Fgia Inc.	4/19/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration or Expulsion of Device	Abdominal Pain; Diarrhea; Nausea; Vomiting
3012638928-2023-02816	NR	Malfunction	Spatz Fgia Inc.	4/19/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration or Expulsion of Device	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00073	3/2/2023	Malfunction	Apollo Endosurgery, Inc.	4/18/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Unintended Deflation	Failure of Implant
3006722112-2023-00066	1/8/2023	Malfunction	Apollo Endosurgery, Inc.	4/17/2023	LTI	Orbera 365 Intragastric Balloon	Insufficient Information	Necrosis
3006722112-2023-00069	3/5/2023	Malfunction	Apollo Endosurgery, Inc	4/17/2023	LTI	Orbera 365 Intragastric Balloon	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2023-00070	3/21/2023	Malfunction	Apollo Endosurgery, Inc.	4/17/2023	LTI	Orbera 365 Intragastric Balloon	Unintended Deflation	Failure of Implant
3006722112-2023-00071	NR	Malfunction	Apollo Endosurgery, Inc.	4/17/2023	LTI	BIB System Intragastric Balloon	Air/ Gas in Device	Failure of Implant
3012638928-2023-02808	9/13/2022	Malfunction	Spatz Fgia Inc.	4/13/2023	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00074	NR	Malfunction	Apollo Endosurgery, Inc	4/12/2023	LTI	Orbera® Intragastric Balloon System	Obstruction of Flow	Obstruction/ Occlusion
3006722112-2023-00067	3/3/2023	Malfunction	Apollo Endosurgery, Inc	4/4/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Unintended Deflation	Failure of Implant
3006722112-2023-00065	3/14/2023	Malfunction	Apollo Endosurgery, Inc	4/4/2023	LTI	Orbera Intragastric Balloon System	No Apparent Adverse Event	Abdominal Pain; Flatus; Pyrosis/ Heartburn
3012638928-2023-02806	3/10/2023	Malfunction	Spatz Fgia Inc.	4/3/2023	LTI	Spatz3 Adjustable Balloon System	Insufficient Information	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00068	12/1/2022	Malfunction	Apollo Endosurgery, Inc.	3/31/2023	LTI	Orbera Intragastric Balloon System	Inflation Problem	Abdominal Pain; Failure of Implant
3006722112-2023-00063	2/6/2023	Malfunction	Apollo Endosurgery, Inc	3/31/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2023-00057	2/13/2023	Malfunction	Apollo Endosurgery, Inc	3/31/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3012638928-2023-02810	3/23/2023	Malfunction	Spatz Fgia Inc.	3/28/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02811	3/23/2023	Malfunction	Spatz Fgia Inc.	3/28/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02798	2/3/2023	Malfunction	Spatz Fgia Inc.	3/26/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00055	2/20/2023	Malfunction	Apollo Endosurgery, Inc	3/24/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Unintended Deflation	Failure of Implant
3012638928-2023-02801	2/18/2023	Malfunction	Spatz Fgia Inc.	3/20/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02805	NR	Injury	Spatz Fgia Inc.	3/20/2023	LTI	Spatz3 Adjustable Balloon System	Obstruction of Flow	Abdominal Pain; Nausea; Constipation
3006722112-2023-00060	10/25/2022	Malfunction	Apollo Endosurgery, Inc	3/17/2023	LTI	Orbera Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2023-00052	1/31/2023	Malfunction	Apollo Endosurgery, Inc	3/17/2023	LTI	BIB Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-0230-00053	3/9/2023	Malfunction	Apollo Endosurgery, Inc	3/17/2023	LTI	Orbera Intragastric Balloon System	Inflation Problem	Failure of Implant
3006722112-2023-00059	12/18/2022	Malfunction	Apollo Endosurgery, Inc	3/16/2023	LTI	Orbera Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3012638928-2023-02803	2/24/2023	Malfunction	Spatz Fgia Inc.	3/16/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00050	2/25/2023	Malfunction	Apollo Endosurgery, Inc	3/16/2023	LTI	Orbera Intragastric Balloon System	Inflation Problem	Abdominal Pain; Pyrosis/ Heartburn
3006722112-2023-00058	NR	Malfunction	Apollo Endosurgery, Inc	3/16/2023	LTI	Orbera Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Gastritis; Failure of Implant
3012638928-2023-02800	1/26/2023	Malfunction	Spatz Fgia Inc.	3/15/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00048	12/25/2023	Malfunction	Apollo Endosurgery, Inc	3/15/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2023-02795	10/29/2022	Malfunction	Spatz Fgia Inc.	3/14/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration or Expulsion of Device	No Clinical Signs, Symptoms or Conditions
16528829	1/13/2023	Malfunction	Apollo Endosurgery, Inc.	3/13/2023	LTI	Orbera Intragastric Balloon System	Inadequacy of Device Shape and/or Size	Abdominal Pain
3012638928-2023-02792	1/13/2023	Malfunction	Spatz Fgia Inc.	3/9/2023	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	Nausea; Vomiting
3012638928-2023-02790	2/3/2023	Malfunction	Spatz Fgia Inc.	3/9/2023	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02789	2/5/2023	Malfunction	Spatz Fgia Inc.	3/6/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration or Expulsion of Device	Abdominal Pain
3012638928-2023-02802	2/27/2023	Malfunction	Spatz Fgia Inc.	3/2/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02785	1/31/2023	Malfunction	Spatz Fgia Inc.	2/28/2023	LTI	Spatz3 Adjustable Balloon System	Insufficient Information	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00047	2/2/2023	Malfunction	Apollo Endosurgery, Inc	2/24/2023	LTI	Orbera365 Intragastric Balloon System	Adverse Event Without Identified Device or Use Problem; Insufficient Information	Renal Failure; Vomiting

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2023-00049	NR	Malfunction	Apollo Endosurgery, Inc	2/24/2023	LTI	Orbera Intragastric Balloon System	Adverse Event Without Identified Device or Use Problem	Fever; Pain
3006722112-2023-00046	3/5/2022	Malfunction	Apollo Endosurgery, Inc	2/23/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2023-00042	2/11/2023	Malfunction	Apollo Endosurgery, Inc	2/23/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2023-00041	2/16/2023	Malfunction	Apollo Endosurgery, Inc.	2/23/2023	LTI	Obera Intragastric Balloon Systems	Fluid/ Blood Leak; Migration	Abdominal Pain; Failure of Implant
3006722112-2023-00043	2/20/2023	Malfunction	Apollo Endosurgery, Inc	2/23/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2023-00044	1/30/2023	Malfunction	Apollo Endosurgery, Inc	2/22/2023	LTI	Orbera365 Intragastric Balloon System	Fluid/ Blood Leak	Perforation of Esophagus
3006722112-2023-00037	2/9/2023	Malfunction	Apollo Endosurgery, Inc.	2/22/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2023-00036	2/10/2023	Malfunction	Apollo Endosurgery, Inc	2/22/2023	LTI	Orbera Intragastric Balloon System	Partial Blockage; Obstruction of Flow	Dehydration; Failure of Implant; Vomiting; Obstruction/ Occlusion
3006722112-2023-00035	12/1/2023	Malfunction	Apollo Endosurgery, Inc	2/22/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2023-00021	1/15/2023	Malfunction	Apollo Endosurgery, Inc	2/21/2023	LTI	Bib¿ Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2023-00026	1/24/2023	Malfunction	Apollo Endosurgery, Inc	2/21/2023	LTI	Orbera365 Intragastric Balloon System	No Apparent Adverse Event	Dehydration; Vomiting
3006722112-2023-00022	1/26/2023	Malfunction	Apollo Endosurgery, Inc	2/21/2023	LTI	Orbera Intragastric Balloon System	Inflation Problem	Failure of Implant
3006722112-2023-00031	NR	Malfunction	Apollo Endosurgery, Inc	2/21/2023	LTI	Bib¿ Intragastric Balloon System	Deflation Problem; Unintended Deflation	Abdominal Pain; Pyrosis/ Heartburn; Perforation of Vessels; Vomiting
3006722112-2023-00038	NR	Death	Apollo Endosurgery, Inc	2/21/2023	LTI	Orbera Intragastric Balloon System	Adverse Event Without Identified Device or Use Problem	Perforation
3012638928-2023-02783	12/21/2022	Malfunction	Spatz Fgia Inc.	2/20/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Abdominal Pain

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2023-02784	1/19/2023	Malfunction	Spatz Fgia Inc.	2/20/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02766	10/18/2022	Malfunction	Spatz Fgia Inc.	2/16/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Abdominal Pain
3006722112-2023-00030	NR	Malfunction	Apollo Endosurgery, Inc	2/16/2023	LTI	Orbera Intragastric Balloon System	Partial Blockage	Failure of Implant; Nausea; Pain; Vomiting; Obstruction/ Occlusion
3006722112-2023-00029	NR	Malfunction	Apollo Endosurgery, Inc	2/16/2023	LTI	Orbera® Intragastric Balloon System	Inflation Problem	Failure of Implant
3012638928-2023-02776	12/25/2022	Malfunction	Spatz Fgia Inc.	2/15/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00023	2/10/2022	Malfunction	Apollo Endosurgery, Inc	2/14/2023	LTI	Orbera Intragastric Balloon System	Patient-Device Incompatibility	Failure of Implant; Pain; Implant Pain
3006722112-2023-00034	11/1/2022	Malfunction	Apollo Endosurgery, Inc	2/14/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2023-00028	1/18/2023	Malfunction	Apollo Endosurgery, Inc	2/14/2023	LTI	Orbera365 Intragastric Balloon System	Infusion or Flow Problem; Unintended Deflation	Failure of Implant

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2023-00032	1/26/2023	Malfunction	Apollo Endosurgery, Inc	2/14/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Unintended Deflation	Failure of Implant
3012638928-2023-02779	2/26/2022	Malfunction	Spatz Fgia Inc.	2/13/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02778	11/20/2022	Malfunction	Spatz Fgia Inc.	2/13/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Abdominal Pain
3012638928-2023-02786	2/3/2023	Malfunction	Spatz Fgia Inc.	2/9/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02775	9/27/2022	Malfunction	Spatz Fgia Inc.	2/8/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02773	11/27/2022	Malfunction	Spatz Fgia Inc.	2/8/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02777	12/26/2022	Malfunction	Spatz Fgia Inc.	2/8/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02780	2/10/2022	Malfunction	Spatz Fgia Inc.	2/7/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02768	1/10/2023	Malfunction	Spatz Fgia Inc.	2/7/2023	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	Abdominal Pain; Nausea; Vomiting

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
MW5114745	NR	Injury	Apollo Endosurgery Costa Rica S.R.L.	2/6/2023	LTI	Orbera Intra Gastric Balloon	Improper or Incorrect Procedure or Method	Appropriate Clinical Signs, Symptoms, Conditions Term/ Code Not Available
3006722112-2023-00024	NR	Malfunction	Apollo Endosurgery, Inc	2/3/2023	LTI	Orbera Intragastric Balloon System	Inflation Problem	Abdominal Pain; Failure of Implant; Perforation of Vessels; Pancreatitis
3006722112-2023-00025	NR	Malfunction	Apollo Endosurgery, Inc	2/3/2023	LTI	Orbera Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2023-00020	7/28/2022	Malfunction	Apollo Endosurgery, Inc	2/2/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2023-00019	9/26/2022	Malfunction	Apollo Endosurgery, Inc	2/2/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3012638928-2023-02769	11/2/2022	Malfunction	Spatz Fgia Inc.	2/2/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00005	11/8/2022	Malfunction	Apollo Endosurgery, Inc	2/2/2023	LTI	Orbera365 Intragastric Balloon System	Pressure Problem	Neuralgia
3006722112-2023-00017	12/22/2022	Malfunction	Apollo Endosurgery, Inc	2/2/2023	LTI	Orbera365 Intragastric Balloon System	Fluid/ Blood Leak; Reflux within Device	Gastritis; Nausea; Obstruction/ Occlusion

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2023-00007	1/13/2023	Malfunction	Apollo Endosurgery, Inc	2/2/2023	LTI	Orbera Intragastric Balloon System	Inflation Problem; Air/ Gas in Device	Abdominal Pain; Failure of Implant
3012638928-2023-02764	8/15/2022	Malfunction	Spatz Fgia Inc.	2/1/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00001	11/4/2022	Malfunction	Apollo Endosurgery, Inc	2/1/2023	LTI	Orbera365 Intragastric Balloon System	Adverse Event Without Identified Device or Use Problem	Abdominal Pain; Perforation; Vomiting
3006722112-2023-00015	11/21/2022	Malfunction	Apollo Endosurgery, Inc	2/1/2023	LTI	Orbera Intragastric Balloon System	Inflation Problem	Failure of Implant
3006722112-2023-00016	12/10/2022	Malfunction	Apollo Endosurgery, Inc	2/1/2023	LTI	Orbera Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2023-00003	1/12/2023	Malfunction	Apollo Endosurgery, Inc	2/1/2023	LTI	Orbera Intragastric Balloon System	Inflation Problem	Nausea; Vomiting
3006722112-2023-00018	NR	Malfunction	Apollo Endosurgery, Inc	1/28/2023	LTI	Orbera Intragastric Balloon System	Appropriate Term/ Code Not Available	Vomiting; Stomach Ulceration
3006722112-2023-00014	NR	Malfunction	Apollo Endosurgery, Inc	1/25/2023	LTI	Orbera Intragastric Balloon System	Appropriate Term/ Code Not Available	Abdominal Pain; Bowel Perforation

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2023-00006	NR	Malfunction	Apollo Endosurgery, Inc	1/24/2023	LTI	Orbera Intragastric Balloon System	Deflation Problem; Migration or Expulsion of Device; Migration; Unintended Deflation	Abdominal Pain; Vomiting; Obstruction/ Occlusion
3006722112-2023-00012	NR	Malfunction	Apollo Endosurgery, Inc	1/23/2023	LTI	Orbera Intragastric Balloon System	Appropriate Term/ Code Not Available	Failure of Implant; Pain; Vomiting; Constipation
3006722112-2023-00013	NR	Malfunction	Apollo Endosurgery, Inc	1/23/2023	LTI	Orbera Intragastric Balloon System	No Apparent Adverse Event	Abdominal Pain; Diarrhea; Nausea; Constipation
3012638928-2023-02762	12/15/2022	Malfunction	Spatz Fgia Inc.	1/18/2023	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02761	12/20/2022	Malfunction	Spatz Fgia Inc.	1/18/2023	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	Abdominal Pain
3012638928-2023-02765	1/6/2023	Malfunction	Spatz Fgia Inc.	1/18/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02758	12/15/2022	Injury	Spatz Fgia Inc.	1/17/2023	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility	Abdominal Pain; Nausea; Vomiting

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2023-00002	10/26/2022	Malfunction	Apollo Endosurgery, Inc	1/13/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Abdominal Pain; Failure of Implant
3006722112-2022-00134	11/22/2022	Malfunction	Apollo Endosurgery, Inc	1/13/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2022-00136	12/13/2022	Malfunction	Apollo Endosurgery, Inc	1/13/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2022-00135	12/20/2022	Malfunction	Apollo Endosurgery, Inc	1/13/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Migration or Expulsion of Device; Migration; Unintended Deflation	Failure of Implant
3006722112-2022-00137	12/26/2022	Malfunction	Apollo Endosurgery, Inc	1/13/2023	LTI	Orbera Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2022-00133	10/7/2022	Malfunction	Apollo Endosurgery, Inc	1/11/2023	LTI	Orbera Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2022-00132	10/26/2022	Malfunction	Apollo Endosurgery, Inc	1/11/2023	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3012638928-2023-02760	11/17/2022	Malfunction	Spatz Fgia Inc.	1/11/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2023-02757	12/6/2022	Malfunction	Spatz Fgia Inc.	1/11/2023	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2022-00131	12/13/2022	Malfunction	Apollo Endosurgery, Inc	1/11/2023	LTI	Orbera Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2022-00126	2/8/2022	Malfunction	Apollo Endosurgery, Inc	12/29/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Unintended Deflation	Failure of Implant
3006722112-2022-00127	9/7/2022	Malfunction	Apollo Endosurgery, Inc.	12/29/2022	LTI	Orbera365 Intragastric Balloon System	Insufficient Information	Obstruction/ Occlusion
3012638928-2022-02751	12/5/2022	Injury	Spatz Fgia Inc.	12/29/2022	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility	Abdominal Pain; Nausea; Vomiting
3012638928-2022-02755	12/7/2022	Malfunction	Spatz Fgia Inc.	12/21/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2022-02750	11/24/2022	Malfunction	Spatz Fgia Inc.	12/20/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Abdominal Pain
3012638928-2022-02749	11/12/2022	Injury	Spatz Fgia Inc.	12/18/2022	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility	Abdominal Pain; Stomach Ulceration
3012638928-2022-02753	11/4/2022	Malfunction	Spatz Fgia Inc.	12/15/2022	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	Abdominal Pain; Vomiting
3012638928-2022-02754	12/3/2022	Malfunction	Spatz Fgia Inc.	12/15/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Abdominal Pain
3006722112-2022-00130	NR	Malfunction	Apollo Endosurgery, Inc.	12/15/2022	LTI	Orbera Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Abdominal Pain; Failure of Implant
3006722112-2022-00116	10/10/2022	Malfunction	Apollo Endosurgery, Inc	12/14/2022	LTI	Orbera Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2022-00128	10/19/2022	Malfunction	Apollo Endosurgery, Inc	12/14/2022	LTI	Orbera365 Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2022-00117	10/20/2022	Malfunction	Apollo Endosurgery, Inc	12/14/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Mechanical Problem; Unintended Deflation	Failure of Implant
3006722112-2022-00118	10/23/2022	Malfunction	Apollo Endosurgery, Inc	12/14/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2022-00125	10/30/2022	Malfunction	Apollo Endosurgery, Inc	12/14/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2022-00101	7/27/2022	Malfunction	Apollo Endosurgery, Inc.	12/13/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2022-00121	9/9/2022	Malfunction	Apollo Endosurgery, Inc.	12/13/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant; Laceration(s) of Esophagus
3006722112-2022-00120	9/13/2022	Malfunction	Apollo Endosurgery, Inc.	12/13/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2022-00123	9/19/2022	Malfunction	Apollo Endosurgery, Inc.	12/13/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2022-00100	9/23/2022	Malfunction	Apollo Endosurgery, Inc.	12/13/2022	LTI	Orbera365 Intragastric Balloon System	Inflation Problem	Failure of Implant
3006722112-2022-00122	10/7/2022	Malfunction	Apollo Endosurgery, Inc.	12/13/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2022-00119	10/19/2022	Malfunction	Apollo Endosurgery, Inc.	12/13/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2022-00124	10/22/2022	Malfunction	Apollo Endosurgery, Inc.	12/13/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Unintended Deflation	Failure of Implant
3006722112-2022-00114	10/24/2022	Malfunction	Apollo Endosurgery, Inc.	12/13/2022	LTI	Orbera Intragastric Balloon System	Infusion or Flow Problem	Abdominal Pain; Vomiting
3012638928-2022-02748	11/7/2022	Malfunction	Spatz Fgia Inc.	12/13/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Abdominal Pain
3012638928-2022-02744	11/13/2022	Malfunction	Spatz Fgia Inc.	12/13/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2022-00129	12/11/2022	Malfunction	Apollo Endosurgery, Inc.	12/13/2022	LTI	Orbera Intragastric Balloon System	Inflation Problem	Abdominal Pain; Failure of Implant
3012638928-2022-02440	10/10/2021	Malfunction	Spatz Fgia Inc.	12/8/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02502	11/4/2021	Malfunction	Spatz Fgia Inc.	12/8/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02521	2/1/2022	Malfunction	Spatz Fgia Inc.	12/8/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration or Expulsion of Device	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02498	2/12/2022	Injury	Spatz Fgia Inc.	12/8/2022	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility	Abdominal Pain
3012638928-2022-02514	2/13/2022	Injury	Spatz Fgia Inc.	12/8/2022	LTI	Spatz3 Adjustable Balloon System	Adverse Event Without Identified Device or Use Problem	Pancreatitis
3012638928-2022-02620	6/24/2022	Malfunction	Spatz Fgia Inc.	12/8/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02739	5/10/2022	Malfunction	Spatz Fgia Inc.	12/7/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2022-02738	6/15/2022	Malfunction	Spatz Fgia Inc.	12/7/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02752	12/1/2022	Malfunction	Spatz Fgia Inc.	12/7/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02454	NR	Malfunction	Spatz Fgia Inc.	12/7/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration or Expulsion of Device	Abdominal Pain
3012638928-2022-02519	NR	Malfunction	Spatz Fgia Inc.	12/7/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02735	NR	Malfunction	Spatz Fgia Inc.	12/7/2022	LTI	Spatz3 Adjustable Balloon System	Air/ Gas in Device	Abdominal Pain
3012638928-2021-02442	12/10/2021	Malfunction	Spatz Fgia Inc.	12/6/2022	LTI	Spatz3 Adjustable Balloon System	Leak/ Splash; Therapeutic or Diagnostic Output Failure	Failure of Implant; Vomiting
3006722112-2022-00096	7/1/2022	Malfunction	Apollo Endosurgery, Inc.	12/6/2022	LTI	Orbera Intragastric Balloon System	Inflation Problem	Failure of Implant
3006722112-2022-00094	8/18/2022	Malfunction	Apollo Endosurgery, Inc.	12/6/2022	LTI	Orbera365 Intragastric Balloon System	Inflation Problem	Failure of Implant

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2022-00113	9/13/2022	Malfunction	Apollo Endosurgery, Inc.	12/6/2022	LTI	Orbera Intragastric Balloon System	Inflation Problem	Failure of Implant
3006722112-2022-00099	9/22/2022	Malfunction	Apollo Endosurgery, Inc.	12/6/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2022-00111	9/30/2022	Malfunction	Apollo Endosurgery, Inc.	12/6/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2022-00108	10/17/2022	Malfunction	Apollo Endosurgery, Inc.	12/6/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2022-00112	10/18/2022	Malfunction	Apollo Endosurgery, Inc.	12/6/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Unintended Deflation	Failure of Implant; Vomiting
3006722112-2022-00110	10/18/2022	Malfunction	Apollo Endosurgery, Inc.	12/6/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2022-00115	10/20/2022	Malfunction	Apollo Endosurgery, Inc.	12/6/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Inflation Problem; Unintended Deflation	Failure of Implant

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2022-00107	10/21/2022	Malfunction	Apollo Endosurgery, Inc.	12/6/2022	LTI	Orbera Intragastric Balloon System	Inflation Problem	Abdominal Pain; Flatus; Nausea; Vomiting
3012638928-2022-02737	5/11/2022	Malfunction	Spatz Fgia Inc.	12/5/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02736	10/19/2022	Malfunction	Spatz Fgia Inc.	12/1/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02745	9/6/2022	Injury	Journeylite Physicians	11/29/2022	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility	Abdominal Pain; Dehydration; Vomiting
3012638928-2022-02472	9/28/2022	Injury	True You Weight Loss (Atlanta)	11/29/2022	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility	Abdominal Pain; Dehydration; Electrolyte Imbalance
3012638928-2022-02476	10/18/2021	Malfunction	Spatz Fgia Inc.	11/24/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02529	3/12/2022	Malfunction	Spatz Fgia Inc.	11/24/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02531	3/21/2022	Malfunction	Spatz Fgia Inc.	11/24/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02533	3/26/2022	Malfunction	Spatz Fgia Inc.	11/24/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2022-02660	7/20/2022	Malfunction	Spatz Fgia Inc.	11/24/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Vomiting
3012638928-2022-02707	9/29/2022	Malfunction	Spatz Fgia Inc.	11/24/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02733	11/6/2022	Malfunction	Spatz Fgia Inc.	11/23/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration or Expulsion of Device	Abdominal Pain
3012638928-2022-02728	NR	Malfunction	Spatz Fgia Inc.	11/22/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02723	8/15/2022	Malfunction	Spatz Fgia Inc.	11/21/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration or Expulsion of Device	Abdominal Pain
3012638928-2022-02724	10/24/2022	Malfunction	Spatz Fgia Inc.	11/21/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration or Expulsion of Device	Abdominal Pain
3012638928-2022-02693	5/31/2022	Injury	Spatz Fgia Inc.	11/17/2022	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility	Dehydration; Nausea; Vomiting
3012638928-2022-02690	6/16/2022	Injury	Spatz Fgia Inc.	11/17/2022	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility	Abdominal Pain; Diarrhea; Nausea; Vomiting; Syncope/ Fainting

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2022-02695	8/23/2022	Injury	Spatz Fgia Inc.	11/17/2022	LTI	Spatz3 Adjustable Balloon System	Adverse Event Without Identified Device or Use Problem	Abdominal Pain; Pain; Aspiration Pneumonitis; Cough
3012638928-2022-02681	8/28/2022	Injury	Spatz Fgia Inc.	11/17/2022	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility	Abdominal Pain; Nausea; Vomiting
3012638928-2022-02718	8/29/2022	Malfunction	Spatz Fgia Inc.	11/17/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02734	9/10/2022	Malfunction	Spatz Fgia Inc.	11/17/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02720	9/14/2022	Malfunction	Spatz Fgia Inc.	11/17/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02719	9/23/2022	Malfunction	Spatz Fgia Inc.	11/17/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02721	10/10/2022	Malfunction	Spatz Fgia Inc.	11/17/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02715	9/19/2022	Malfunction	Spatz Fgia Inc.	11/16/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02714	10/13/2022	Malfunction	Spatz Fgia Inc.	11/16/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2022-02732	9/30/2022	Malfunction	Spatz Fgia Inc.	11/10/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration	Vomiting; No Clinical Signs, Symptoms or Conditions
3012638928-2022-02713	10/3/2022	Injury	Spatz Fgia Inc.	11/10/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration	Abdominal Pain
3012638928-2022-02740	10/31/2022	Malfunction	Spatz Fgia Inc.	11/10/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02711	8/2/2022	Malfunction	Spatz Fgia Inc.	11/4/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02705	9/15/2022	Malfunction	Spatz Fgia Inc.	11/3/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02710	8/6/2022	Malfunction	Spatz Fgia Inc.	11/2/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration or Expulsion of Device	Abdominal Pain
3012638928-2022-02709	9/23/2022	Malfunction	Spatz Fgia Inc.	11/2/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02704	9/19/2022	Malfunction	Spatz Fgia Inc.	10/26/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2022-00102	2/28/2020	Malfunction	Apollo Endosurgery, Inc.	10/20/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Unintended Deflation	Increased Appetite
3006722112-2022-00103	10/1/2020	Malfunction	Apollo Endosurgery, Inc.	10/20/2022	LTI	Orbera365 Intragastric Balloon System	Migration or Expulsion of Device; Migration	Abdominal Pain; Perforation
3006722112-2022-00106	11/20/2020	Malfunction	Apollo Endosurgery, Inc.	10/20/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Abdominal Pain; Failure of Implant
3006722112-0220-00104	1/15/2021	Malfunction	Apollo Endosurgery, Inc.	10/20/2022	LTI	Orbera365 Intragastric Balloon System	Leak/ Splash	Abdominal Pain
3006722112-2022-00105	3/28/2022	Malfunction	Apollo Endosurgery, Inc.	10/20/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3012638928-2022-02697	8/3/2022	Malfunction	Spatz Fgia Inc.	10/13/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02698	8/12/2022	Malfunction	Spatz Fgia Inc.	10/13/2022	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	Abdominal Pain
3012638928-2022-02700	8/19/2022	Malfunction	Spatz Fgia Inc.	10/13/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2022-02696	8/24/2022	Malfunction	Spatz Fgia Inc.	10/13/2022	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	Abdominal Pain
3012638928-2022-02689	9/14/2022	Malfunction	Spatz Fgia Inc.	10/13/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02699	9/15/2022	Malfunction	Spatz Fgia Inc.	10/13/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02686	5/30/2022	Malfunction	Spatz Fgia Inc.	10/6/2022	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	Abdominal Pain
3012638928-2022-02687	8/30/2022	Malfunction	Spatz Fgia Inc.	10/6/2022	LTI	Spatz3 Adjustable Balloon System	Air/ Gas in Device	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02683	NR	Malfunction	Spatz Fgia Inc.	10/6/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2022-00089	8/10/2022	Malfunction	Apollo Endosurgery, Inc.	10/5/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Leak/ Splash; Unintended Deflation	Gastrointestinal Regurgitation
3006722112-2022-00098	6/9/2022	Malfunction	Apollo Endosurgery, Inc.	10/4/2022	LTI	Orbera365 Intragastric Balloon System	Adverse Event Without Identified Device or Use Problem	Abdominal Pain

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2022-00097	8/12/2022	Malfunction	Apollo Endosurgery, Inc.	10/4/2022	LTI	Orbera Intragastric Balloon System	Leak/ Splash	Failure of Implant
3006722112-2022-00093	8/20/2022	Malfunction	Apollo Endosurgery, Inc	10/4/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Unintended Deflation	Increased Appetite
3006722112-2022-00090	8/16/2022	Malfunction	Apollo Endosurgery, Inc.	9/30/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3012638928-2022-02677	8/24/2022	Malfunction	Spatz Fgia Inc.	9/29/2022	LTI	Spatz3 Adjustable Balloon System	Air/ Gas in Device	Abdominal Pain; Vomiting
3012638928-2022-02680	NR	Malfunction	Spatz Fgia Inc.	9/29/2022	LTI	Spatz3 Adjustable Balloon System	Migration or Expulsion of Device	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02675	7/21/2022	Malfunction	Spatz Fgia Inc.	9/28/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02673	8/15/2022	Malfunction	Spatz Fgia Inc.	9/28/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02672	8/10/2022	Malfunction	Spatz Fgia Inc.	9/25/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2022-02671	8/26/2022	Malfunction	Spatz Fgia Inc.	9/23/2022	LTI	Spatz3 Adjustable Balloon System	Air/ Gas in Device	Abdominal Pain
3012638928-2022-02670	8/25/2022	Malfunction	Spatz Fgia Inc.	9/20/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration	Abdominal Pain; Vomiting
3012638928-2022-02664	7/30/2022	Injury	Spatz Fgia Inc.	9/12/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration or Expulsion of Device	Abdominal Pain
3006722112-2022-00091	4/2/2022	Malfunction	Apollo Endosurgery, Inc.	9/7/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2022-00092	8/2/2022	Malfunction	Apollo Endosurgery, Inc.	9/7/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Unintended Deflation	Failure of Implant
3012638928-2022-02668	8/16/2022	Injury	Spatz Fgia Inc.	9/7/2022	LTI	Spatz3 Adjustable Balloon System	Adverse Event Without Identified Device or Use Problem	Abdominal Pain
3006722112-2022-00079	6/9/2022	Malfunction	Apollo Endosurgery, Inc.	8/30/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2022-00084	NR	Malfunction	Apollo Endosurgery, Inc.	8/30/2022	LTI	Orbera Intragastric Balloon	Fluid/ Blood Leak	Fever; Hemorrhage/ Bleeding; Nausea; Pain; Vomiting

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2022-00078	NR	Malfunction	Apollo Endosurgery, Inc.	8/30/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3012638928-2022-02655	7/21/2022	Malfunction	Spatz Fgia Inc.	8/28/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2022-00082	7/6/2022	Malfunction	Apollo Endosurgery, Inc.	8/23/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Unintended Deflation	Failure of Implant
3006722112-2022-00076	7/15/2022	Malfunction	Apollo Endosurgery, Inc.	8/23/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem	Failure of Implant
3006722112-2022-00081	7/27/2022	Malfunction	Apollo Endosurgery, Inc.	8/23/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Unintended Deflation	Abdominal Pain
3012638928-2022-02669	8/15/2022	Malfunction	Spatz Fgia Inc.	8/21/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02662	7/23/2022	Malfunction	Spatz Fgia Inc.	8/18/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02657	7/13/2022	Malfunction	Spatz Fgia Inc.	8/16/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2022-00080	7/20/2022	Malfunction	Apollo Endosurgery, Inc.	8/16/2022	LTI	Orbera Intragastric Balloon System	Inflation Problem	Failure of Implant
3012638928-2022-02658	7/25/2022	Malfunction	Spatz Fgia Inc.	8/15/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02661	7/25/2022	Malfunction	Spatz Fgia Inc.	8/15/2022	LTI	Spatz3 Adjustable Balloon System	Migration	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02652	7/13/2022	Malfunction	Spatz Fgia Inc.	8/11/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02641	1/27/2022	Malfunction	Spatz Fgia Inc.	8/3/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02644	2/21/2022	Malfunction	Spatz Fgia Inc.	8/3/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02645	4/8/2022	Malfunction	Spatz Fgia Inc.	8/3/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02643	4/14/2022	Malfunction	Spatz Fgia Inc.	8/3/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02642	6/20/2022	Malfunction	Spatz Fgia Inc.	8/3/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2022-00071	6/27/2022	Malfunction	Apollo Endosurgery, Inc.	8/3/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Appropriate Clinical Signs, Symptoms, Conditions Term/ Code Not Available
3012638928-2022-02659	7/25/2022	Malfunction	Spatz Fgia Inc.	8/2/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2022-00077	NR	Malfunction	Apollo Endosurgery, Inc.	8/1/2022	LTI	Orbera Intragastric Balloon System	Inflation Problem	Abdominal Pain; Nausea; Vomiting
3012638928-2022-02656	6/26/2022	Malfunction	Spatz Fgia Inc.	7/30/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02634	6/17/2022	Malfunction	Spatz Fgia Inc.	7/28/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2022-00075	5/10/2022	Malfunction	Apollo Endosurgery, Inc.	7/26/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2022-00070	5/26/2022	Malfunction	Apollo Endosurgery, Inc.	7/26/2022	LTI	Orbera Intragastric Balloon System	Inflation Problem	Abdominal Pain; Failure of Implant; Pain
3006722112-2022-00074	6/17/2022	Malfunction	Apollo Endosurgery, Inc.	7/26/2022	LTI	Orbera365 Intragastric Balloon System	Expulsion	Hemorrhage/ Bleeding; Gastrointestinal Hemorrhage

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2022-02647	7/23/2021	Malfunction	Spatz Fgia Inc.	7/25/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02651	6/13/2022	Malfunction	Spatz Fgia Inc.	7/25/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2022-00066	5/13/2022	Malfunction	Apollo Endosurgery, Inc.	7/21/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Abdominal Pain
3012638928-2022-02650	6/13/2022	Malfunction	Spatz Fgia Inc.	7/20/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Abdominal Pain
3012638928-2022-02615	6/14/2022	Malfunction	Spatz Fgia Inc.	7/15/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2022-00061	4/22/2022	Malfunction	Apollo Endosurgery, Inc.	7/13/2022	LTI	Orbera Intragastric Balloon System	Inflation Problem	Failure of Implant
3006722112-2022-00060	6/2/2022	Malfunction	Apollo Endosurgery, Inc.	7/13/2022	LTI	Orbera Intragastric Balloon System	Inflation Problem	Abdominal Pain; Pain
3006722112-2022-00073	6/6/2022	Malfunction	Apollo Endosurgery, Inc.	7/13/2022	LTI	Orbera Intragastric Balloon System	Infusion or Flow Problem	Abdominal Pain; Nausea; Vomiting

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2022-00063	6/10/2022	Malfunction	Apollo Endosurgery, Inc.	7/13/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Vomiting
3012638928-2022-02646	6/13/2022	Malfunction	Spatz Fgia Inc.	7/13/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02648	7/5/2022	Malfunction	Spatz Fgia Inc.	7/13/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2022-00072	NR	Malfunction	Apollo Endosurgery, Inc.	7/8/2022	LTI	Orbera Intragastric Balloon System	Inflation Problem	Insufficient Information
3012638928-2022-02632	6/28/2022	Malfunction	Spatz Fgia Inc.	7/7/2022	LTI	Spatz3 Adjustable Balloon System	Migration or Expulsion of Device; Migration	Abdominal Pain
3012638928-2022-02639	7/4/2022	Malfunction	Spatz Fgia Inc.	7/7/2022	LTI	Spatz3 Adjustable Balloon System	Infusion or Flow Problem; Air/ Gas in Device	Abdominal Pain
3006722112-2022-00068	6/23/2022	Malfunction	Apollo Endosurgery, Inc.	7/6/2022	LTI	Orbera365 Intragastric Balloon System	Inflation Problem; Mechanical Problem	Abdominal Pain; Vomiting; Appropriate Clinical Signs, Symptoms, Conditions Term/ Code Not Available
3012638928-2022-02622	6/24/2022	Malfunction	Spatz Fgia Inc.	7/5/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2022-02633	6/29/2022	Malfunction	Spatz Fgia Inc.	7/5/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02621	5/28/2021	Malfunction	Spatz Fgia Inc.	7/4/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2022-00067	11/18/2021	Malfunction	Apollo Endosurgery, Inc.	7/1/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Insufficient Information
3012638928-2022-02612	2/12/2022	Malfunction	Spatz Fgia Inc.	6/28/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02607	6/9/2022	Malfunction	Spatz Fgia Inc.	6/28/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02618	6/23/2022	Malfunction	Spatz Fgia Inc.	6/28/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02609	5/10/2022	Malfunction	Spatz Fgia Inc.	6/23/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02600	5/24/2022	Malfunction	Spatz Fgia Inc.	6/23/2022	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	Abdominal Pain; Vomiting

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2022-02613	5/26/2022	Malfunction	Spatz Fgia Inc.	6/23/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02614	6/20/2022	Malfunction	Spatz Fgia Inc.	6/23/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02598	4/10/2022	Malfunction	Spatz Fgia Inc.	6/21/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2022-00064	4/11/2022	Malfunction	Apollo Endosurgery, Inc.	6/21/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3012638928-2022-02608	5/20/2022	Malfunction	Spatz Fgia Inc.	6/21/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02599	5/21/2022	Malfunction	Spatz Fgia Inc.	6/21/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02601	5/21/2022	Malfunction	Spatz Fgia Inc.	6/21/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02606	6/6/2022	Malfunction	Spatz Fgia Inc.	6/21/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2022-00054	4/6/2022	Malfunction	Apollo Endosurgery, Inc.	6/20/2022	LTI	Orbera Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2022-00051	5/5/2022	Malfunction	Apollo Endosurgery, Inc	6/20/2022	LTI	Orbera365 Intragastric Balloon System	Inflation Problem	Failure of Implant
3006722112-2022-00055	5/16/2022	Malfunction	Apollo Endosurgery, Inc.	6/20/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2022-00058	5/22/2022	Malfunction	Apollo Endosurgery, Inc.	6/20/2022	LTI	Orbera365 Intragastric Balloon System	Inflation Problem	Failure of Implant; Vomiting
3006722112-2022-00057	5/22/2022	Malfunction	Apollo Endosurgery, Inc.	6/20/2022	LTI	Orbera365 Intragastric Balloon System	Inflation Problem	Failure of Implant; Vomiting
3006722112-2022-00059	5/24/2022	Malfunction	Apollo Endosurgery, Inc.	6/20/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Unintended Deflation	Failure of Implant
3006722112-2022-00062	5/31/2022	Malfunction	Apollo Endosurgery, Inc	6/20/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem	Appropriate Clinical Signs, Symptoms, Conditions Term/ Code Not Available
3012638928-2022-02604	5/27/2022	Malfunction	Spatz Fgia Inc.	6/17/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration	Abdominal Pain

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2022-02605	6/3/2022	Malfunction	Spatz Fgia Inc.	6/17/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2022-00056	6/5/2022	Malfunction	Apollo Endosurgery, Inc.	6/17/2022	LTI	Orbera Intragastric Balloon System	Insufficient Information	Abdominal Pain; Nausea; Vomiting; Abdominal Distention
3006722112-2022-00046	5/10/2022	Malfunction	Apollo Endosurgery, Inc.	6/15/2022	LTI	BIB System Intragastric Balloon System	Inflation Problem	Failure of Implant
3006722112-2022-00049	5/18/2022	Malfunction	Apollo Endosurgery, Inc.	6/15/2022	LTI	Orbera Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2022-00053	NR	Malfunction	Apollo Endosurgery, Inc.	6/15/2022	LTI	Orbera Intragastric Balloon System	Insufficient Information	Hemorrhage/ Bleeding
3006722112-2022-00045	4/22/2022	Malfunction	Apollo Endosurgery, Inc.	6/14/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3012638928-2022-02591	4/16/2022	Malfunction	Spatz Fgia Inc.	6/12/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02596	4/19/2022	Malfunction	Spatz Fgia Inc.	6/12/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2022-02595	4/26/2022	Malfunction	Spatz Fgia Inc.	6/12/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02594	5/28/2022	Malfunction	Spatz Fgia Inc.	6/12/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Abdominal Pain
3012638928-2022-02586	12/28/2021	Malfunction	Spatz Fgia Inc.	6/9/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2022-00050	4/30/2022	Malfunction	Apollo Endosurgery, Inc.	6/9/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2022-00048	5/5/2022	Malfunction	Apollo Endosurgery, Inc.	6/9/2022	LTI	Orbera Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant
3012638928-2022-02585	5/11/2022	Injury	Spatz Fgia Inc.	6/9/2022	LTI	Spatz3 Adjustable Balloon System	Adverse Event Without Identified Device or Use Problem	Aspiration/ Inhalation
3012638928-2022-02580	5/10/2022	Malfunction	Spatz Fgia Inc.	6/8/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02587	5/16/2022	Malfunction	Spatz Fgia Inc.	6/2/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2022-02582	10/8/2021	Malfunction	Spatz Fgia Inc.	5/31/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02583	11/12/2021	Malfunction	Spatz Fgia Inc.	5/31/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02584	1/15/2022	Malfunction	Spatz Fgia Inc.	5/31/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02579	3/22/2022	Malfunction	Spatz Fgia Inc.	5/29/2022	LTI	Spatz3 Adjustable Balloon System	Air/ Gas in Device	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02581	5/5/2022	Malfunction	Spatz Fgia Inc.	5/29/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02570	4/26/2022	Malfunction	Spatz Fgia Inc.	5/26/2022	LTI	Spatz3 Adjustable Balloon System	Migration	Abdominal Pain
3012638928-2022-02575	5/2/2022	Malfunction	Spatz Fgia Inc.	5/26/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2022-00043	NR	Malfunction	Apollo Endosurgery, Inc.	5/26/2022	LTI	Orbera Intragastric Balloon System	Material Perforation	Abdominal Pain; Pyrosis/ Heartburn; Pain; Vomiting; Perforation of Esophagus

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2022-00044	NR	Malfunction	Apollo Endosurgery, Inc.	5/26/2022	LTI	Orbera Intragastric Balloon System	Adverse Event Without Identified Device or Use Problem	Dehydration; Fever; Nausea; Pain; Vomiting; Ulcer
3012638928-2022-02571	4/29/2022	Malfunction	Spatz Fgia Inc.	5/24/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02573	NR	Malfunction	Spatz Fgia Inc.	5/24/2022	LTI	Spatz3 Adjustable Balloon System	Migration	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02564	1/28/2022	Malfunction	Spatz Fgia Inc.	5/21/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02561	3/14/2022	Malfunction	Spatz Fgia Inc.	5/20/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2022-00040	3/21/2022	Malfunction	Apollo Endosurgery, Inc.	5/20/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Unintended Deflation	Failure of Implant
3012638928-2022-02560	3/3/2022	Malfunction	Spatz Fgia Inc.	5/19/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02558	3/16/2022	Malfunction	Spatz Fgia Inc.	5/19/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02565	12/28/2021	Malfunction	Spatz Fgia Inc.	5/18/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2022-02563	4/6/2021	Malfunction	Spatz Fgia Inc.	5/17/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02559	3/23/2022	Malfunction	Spatz Fgia Inc.	5/16/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Abdominal Pain
3012638928-2022-02562	3/9/2022	Malfunction	Spatz Fgia Inc.	5/15/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02557	3/25/2022	Malfunction	Spatz Fgia Inc.	5/15/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02554	4/14/2022	Malfunction	Spatz Fgia Inc.	5/15/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02566	12/20/2021	Malfunction	Spatz Fgia Inc.	5/12/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02555	4/12/2022	Malfunction	Spatz Fgia Inc.	5/10/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2022-00041	4/13/2022	Malfunction	Apollo Endosurgery, Inc.	5/10/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Unintended Deflation	Vomiting
3012638928-2022-02552	3/8/2022	Malfunction	Spatz Fgia Inc.	5/9/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2022-02553	4/6/2022	Malfunction	Spatz Fgia Inc.	5/8/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2022-00039	3/26/2022	Malfunction	Apollo Endosurgery, Inc.	5/7/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Unintended Deflation	Failure of Implant
3012638928-2022-02551	4/9/2022	Malfunction	Spatz Fgia Inc.	5/4/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02547	1/26/2022	Malfunction	Spatz Fgia Inc.	5/3/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Abdominal Pain
3012638928-2022-02548	3/23/2022	Malfunction	Spatz Fgia Inc.	5/3/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02549	4/1/2022	Malfunction	Spatz Fgia Inc.	5/3/2022	LTI	Spatz3 Adjustable Balloon System	Air/ Gas in Device	Abdominal Pain
3012638928-2022-02526	NR	Malfunction	Spatz Fgia Inc.	5/3/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2022-00036	2/15/2022	Malfunction	Apollo Endosurgery, Inc.	4/28/2022	LTI	Orbera® Intragastric Balloon System	Adverse Event Without Identified Device or Use Problem	Abdominal Pain; Vomiting; Ulcer
3006722112-2022-00035	2/24/2022	Malfunction	Apollo Endosurgery, Inc.	4/28/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Unintended Deflation	Failure of Implant

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722122-0220-00038	3/30/2022	Malfunction	Apollo Endosurgery, Inc.	4/28/2022	LTI	BIB System Intragastric Balloon System	Inflation Problem	Abdominal Pain
3012638928-2022-02545	12/27/2021	Malfunction	Spatz Fgia Inc.	4/26/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Vomiting
3012638928-2022-02544	3/2/2022	Malfunction	Spatz Fgia Inc.	4/26/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02537	3/17/2022	Malfunction	Spatz Fgia Inc.	4/26/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02535	3/24/2022	Injury	Spatz Fgia Inc.	4/26/2022	LTI	Spatz3 Adjustable Balloon System	Patient Device Interaction Problem	Stomach Ulceration
3012638928-2022-02536	3/25/2022	Injury	Spatz Fgia Inc.	4/26/2022	LTI	Spatz3 Adjustable Balloon System	Adverse Event Without Identified Device or Use Problem; Patient Device Interaction Problem	Stomach Ulceration
3012638928-2022-02541	4/4/2022	Malfunction	Spatz Fgia Inc.	4/26/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Output Problem	Insufficient Information
3012638928-2022-02540	NR	Malfunction	Spatz Fgia Inc.	4/25/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2022-02534	3/24/2022	Malfunction	Spatz Fgia Inc.	4/17/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02527	1/20/2022	Malfunction	Spatz Fgia Inc.	4/13/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02528	2/25/2022	Malfunction	Spatz Fgia Inc.	4/11/2022	LTI	Spatz3 Adjustable Balloon System	Air/ Gas in Device	Abdominal Pain
3012638928-2022-02522	3/1/2022	Malfunction	Spatz Fgia Inc.	4/11/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Abdominal Pain
3012638928-2022-02530	3/21/2022	Malfunction	Spatz Fgia Inc.	4/11/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02532	3/21/2022	Malfunction	Spatz Fgia Inc.	4/11/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02525	1/7/2022	Malfunction	Spatz Fgia Inc.	4/10/2022	LTI	Spatz3 Adjustable Balloon System	Air/ Gas in Device	Abdominal Pain
3012638928-2022-02523	2/1/2022	Malfunction	Spatz Fgia Inc.	4/10/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Abdominal Pain
3012638928-2022-02524	12/27/2022	Malfunction	Spatz Fgia Inc.	4/10/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Abdominal Pain

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2022-00034	3/9/2022	Malfunction	Apollo Endosurgery, Inc.	4/6/2022	LTI	BIB System Intragastric Balloon	Inflation Problem	Nausea; Abdominal Distention
3006722112-2022-00037	3/9/2022	Malfunction	Apollo Endosurgery, Inc.	4/6/2022	LTI	Bib® Intragastric Balloon System	Inflation Problem	Nausea; Abdominal Distention
3012638928-2022-02520	1/19/2022	Malfunction	Spatz Fgia Inc.	4/5/2022	LTI	Spatz3 Adjustable Balloon System	Migration or Expulsion of Device	No Clinical Signs, Symptoms or Conditions
3006722112-2022-00032	2/20/2022	Malfunction	Apollo Endosurgery, Inc.	3/28/2022	LTI	Orbera Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3012638928-2022-02509	12/21/2021	Malfunction	Spatz Fgia Inc.	3/23/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Abdominal Pain
3012638928-2022-02501	2/21/2022	Malfunction	Spatz Fgia Inc.	3/23/2022	LTI	Spatz3 Adjustable Balloon System	Fluid/ Blood Leak	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02510	1/7/2022	Malfunction	Spatz Fgia Inc.	3/21/2022	LTI	Spatz3 Adjustable Balloon System	Fluid/ Blood Leak	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02511	2/4/2022	Malfunction	Sptaz Fgia Inc.	3/21/2022	LTI	Spatz3 Adjustable Balloon System	Fluid/ Blood Leak	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2022-02513	2/16/2022	Malfunction	Spatz Fgia Inc.	3/21/2022	LTI	Spatz3 Adjsutable Balloon System	Deflation Problem; Migration or Expulsion of Device	Abdominal Pain
3012638928-2022-02512	2/16/2022	Malfunction	Spatz Fgia Inc.	3/21/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02507	2/28/2022	Malfunction	Spatz Fgia Inc.	3/21/2022	LTI	Spatz3 Adjustable Balloon System	Tear, Rip or Hole in Device Packaging	No Clinical Signs, Symptoms or Conditions
3006722112-2022-00028	1/19/2022	Malfunction	Apollo Endosurgery, Inc.	3/15/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	
3006722112-2022-00029	1/21/2022	Malfunction	Apollo Endosurgery, Inc.	3/15/2022	LTI	Orbera Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant; Vomiting
3006722112-2022-00026	2/7/2022	Malfunction	Apollo Endosurgery, Inc.	3/8/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3012638928-2022-24445	12/7/2021	Malfunction	Spatz Fgia Inc.	3/7/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02487	12/17/2021	Malfunction	Spatz Fgia Inc.	3/7/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2022-02486	12/20/2021	Malfunction	Spatz Fgia Inc.	3/7/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Abdominal Pain
3012638928-2022-02506	2/23/2022	Malfunction	Spatz Fgia Inc.	3/7/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2022-00025	11/3/2021	Malfunction	Apollo Endosurgery, Inc.	3/4/2022	LTI	BIB System Intragastric Balloon System	Appropriate Term/ Code Not Available	Abdominal Pain; Failure of Implant; Obstruction/ Occlusion
3006722112-2022-00022	11/10/2021	Malfunction	Apollo Endosurgery, Inc.	3/3/2022	LTI	Orbera Intragastric Balloon System	Insufficient Information	Hemorrhage/ Bleeding; Low Blood Pressure/ Hypotension; Nausea; Vomiting; Ulcer
3006722112-2022-00021	1/23/2022	Malfunction	Apollo Endosurgery, Inc.	3/3/2022	LTI	BIB System Intragastric Balloon System	Inflation Problem	Failure of Implant
3006722112-2022-00024	1/26/2022	Malfunction	Apollo Endosurgery, Inc.	3/3/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant; Cramp(s)/ Muscle Spasm(s)
3006722112-2022-00020	12/3/2021	Malfunction	Apollo Endosurgery, Inc.	3/2/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2022-00019	12/7/2021	Malfunction	Apollo Endosurgery, Inc.	3/2/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Unintended Deflation	Failure of Implant; Vomiting

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2022-00031	1/31/2022	Malfunction	Apollo Endosurgery, Inc.	3/2/2022	LTI	Orbera365 Intragastric Balloon System	Inflation Problem	Failure of Implant; Vomiting
3006722112-2022-00023	2/1/2022	Malfunction	Apollo Endosurgery, Inc.	3/2/2022	LTI	Orbera Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Dehydration; Failure of Implant; Vomiting
MW5107793	11/9/2021	Injury	Apollo Endosurgery Costa Rica S.R.L.	2/28/2022	LTI	Orbera Endoscopy/ Orbera	Unexpected Therapeutic Results	Hemorrhage/ Bleeding; Nausea; Shock; Dizziness
3012638928-2021-02421	9/14/2021	Malfunction	Spatz Fgia Inc.	2/27/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Abdominal Pain
3012638928-2022-02484	11/5/2021	Malfunction	Spatz Fgia Inc.	2/27/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Abdominal Pain
3012638928-2022-02436	12/8/2021	Malfunction	Spatz Fgia Inc.	2/27/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02490	12/16/2021	Malfunction	Spatz Fgia Inc.	2/27/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02489	12/20/2021	Malfunction	Spatz Fgia Inc.	2/27/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2022-02494	12/27/2021	Malfunction	Spatz Fgia Inc.	2/27/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02493	12/28/2021	Malfunction	Spatz Fgia Inc.	2/27/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02492	1/12/2022	Malfunction	Spatz Fgia Inc.	2/27/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02491	1/13/2022	Malfunction	Spatz Fgia Inc.	2/27/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02495	1/31/2022	Malfunction	Spatz Fgia Inc.	2/27/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02497	2/11/2022	Malfunction	Spatz Fgia Inc.	2/27/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Abdominal Pain
3012638928-2022-02496	2/12/2022	Malfunction	Spatz Fgia Inc.	2/27/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02499	2/14/2022	Malfunction	Spatz Fgia Inc.	2/27/2022	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	Abdominal Pain
3012638928-2022-02500	2/16/2022	Malfunction	Spatz Fgia Inc.	2/27/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2022-02503	2/18/2022	Malfunction	Spatz Fgia Inc.	2/27/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02485	12/20/2022	Malfunction	Spatz Fgia Inc.	2/27/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Abdominal Pain
3012638928-2022-02477	5/15/2021	Malfunction	Spatz Fgia Inc.	2/21/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02478	8/23/2021	Malfunction	Spatz Fgia Inc.	2/21/2022	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Infusion or Flow Problem	Abdominal Pain
3012638928-2022-02483	12/7/2021	Malfunction	Spatz Fgia Inc.	2/21/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02482	12/16/2021	Malfunction	Spatz Fgia Inc.	2/21/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02481	12/27/2021	Malfunction	Spatz Fgia Inc.	2/21/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Abdominal Pain
3012638928-2022-02488	1/12/2022	Malfunction	Spatz Fgia Inc.	2/21/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2022-00018	1/24/2022	Malfunction	Apollo Endosurgery, Inc.	2/17/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3012638928-2022-02742	NR	Death	Spatz Fgia Inc.	2/16/2022	LTI	Spatz3 Adjustable Balloon System	Insufficient Information; Patient Device Interaction Problem	Abdominal Pain; Perforation
3012638928-2021-02395	5/19/2021	Malfunction	Spatz Fgia Inc.	2/15/2022	LTI	Spatz3 Adjustable Balloon System	Migration; Unintended Deflation	Failure of Implant
3012638928-2021-02396	7/30/2021	Malfunction	Spatz Fgia Inc.	2/15/2022	LTI	Spatz3 Adjustable Balloon System	Migration or Expulsion of Device; Unintended Deflation	Vomiting
3012638928-2021-02453	10/22/2021	Malfunction	Spatz Fgia Inc.	2/15/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2021-02397	11/10/2021	Malfunction	Spatz Fgia Inc.	2/15/2022	LTI	Spatz3 Adjustable Balloon System	Unintended Deflation	Failure of Implant
3012638928-2021-02405	11/19/2021	Malfunction	Spatz Fgia Inc.	2/15/2022	LTI	Spatz3 Adjustable Balloon System	Unintended Deflation	Failure of Implant
3012638928-2021-02434	11/25/2021	Malfunction	Spatz Fgia Inc.	2/15/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2021-02430	11/29/2021	Malfunction	Spatz Fgia Inc.	2/15/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2021-02427	12/14/2021	Malfunction	Spatz Fgia Inc.	2/15/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02475	12/21/2021	Malfunction	Spatz Fgia Inc.	2/15/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02463	12/27/2021	Malfunction	Spatz Fgia Inc.	2/15/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02461	12/29/2021	Malfunction	Spatz Fgia Inc.	2/15/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Abdominal Pain
3012638928-2021-02457	1/8/2022	Malfunction	Spatz Fgia Inc.	2/15/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02467	1/16/2022	Malfunction	Spatz Fgia Inc.	2/15/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Abdominal Pain
3012638928-2022-02470	1/28/2022	Malfunction	Spatz Fgia Inc.	2/15/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Abdominal Pain

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012632889-2021-02439	4/9/2021	Malfunction	Spatz Fgia Inc.	2/6/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration or Expulsion of Device	Abdominal Pain
3012638928-2021-02429	7/23/2021	Malfunction	Spatz Fgia Inc.	2/6/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2021-02414	11/12/2021	Malfunction	Spatz Fgia Inc.	2/6/2022	LTI	Spatz3 Adjustable Balloon System	Material Rupture	Insufficient Information
3012638928-2022-02466	12/18/2021	Malfunction	Spatz Fgia Inc.	2/6/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration or Expulsion of Device	Abdominal Pain
3012638928-2022-02464	1/10/2022	Malfunction	Spatz Fgia Inc.	2/6/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Insufficient Information
3012638928-2022-02471	1/20/2022	Malfunction	Spatz Fgia Inc.	2/6/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02469	1/21/2022	Malfunction	Spatz Fgia Inc.	2/6/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02468	1/25/2022	Malfunction	Spatz Fgia Inc.	2/6/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Abdominal Pain

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2022-00016	1/12/2022	Malfunction	Apollo Endosurgery, Inc.	1/26/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2022-00017	1/17/2022	Malfunction	Apollo Endosurgery, Inc.	1/26/2022	LTI	Orbera® Intragastric Balloon System	Inflation Problem	Failure of Implant; Vomiting
3012638928-2021-02449	9/2/2021	Malfunction	Spatz Fgia Inc.	1/20/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration or Expulsion of Device	No Clinical Signs, Symptoms or Conditions
3012638928-2021-02437	9/3/2021	Malfunction	Spatz Fgia Inc.	1/20/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2021-02451	9/24/2021	Malfunction	Spatz Fgia Inc.	1/20/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2021-02435	10/25/2021	Malfunction	Spatz Fgia Inc.	1/20/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2021-02428	10/30/2021	Malfunction	Spatz Fgia Inc.	1/20/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2021-02431	11/3/2021	Malfunction	Spatz Fgia Inc.	1/20/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2021-02426	11/8/2021	Malfunction	Spatz Fgia Inc.	1/20/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2021-02423	11/22/2021	Malfunction	Spatz Fgia Inc.	1/20/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Migration or Expulsion of Device	No Clinical Signs, Symptoms or Conditions
3012638928-2021-02425	11/24/2021	Malfunction	Spatz Fgia Inc.	1/20/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Appropriate Clinical Signs, Symptoms, Conditions Term/ Code Not Available
3012638928-2021-02432	11/29/2021	Malfunction	Spatz Fgia Inc.	1/20/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2021-02433	11/29/2021	Malfunction	Spatz Fgia Inc.	1/20/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2021-02443	12/6/2021	Malfunction	Spatz Fgia Inc.	1/20/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2021-02454	12/6/2021	Malfunction	Spatz Fgia Inc.	1/20/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02460	12/13/2021	Malfunction	Spatz Fgia Inc.	1/20/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2022-02459	12/25/2021	Malfunction	Spatz Fgia Inc.	1/20/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2021-02447	1/3/2022	Malfunction	Spatz Fgia Inc.	1/20/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3012638928-2022-02462	1/12/2022	Malfunction	Spatz Fgia Inc.	1/20/2022	LTI	Spatz3 Adjustable Balloon System	Patient-Device Incompatibility; Air/ Gas in Device	Abdominal Pain
3006722112-2022-00012	10/4/2021	Malfunction	Apollo Endosurgery, Inc.	1/19/2022	LTI	Orbera365 Intragastric Balloon System	Insufficient Information	Vomiting
3006722112-2022-00015	11/23/2021	Malfunction	Apollo Endosurgery, Inc.	1/19/2022	LTI	Orbera365 Intragastric Balloon System	Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2022-00014	12/16/2021	Malfunction	Apollo Endosurgery, Inc.	1/19/2022	LTI	Orbera® Intragastric Balloon System	Insufficient Information	Dehydration; Nausea; Pain; Vomiting
3006722112-2022-00013	1/11/2022	Malfunction	Apollo Endosurgery, Inc.	1/19/2022	LTI	Orbera365 Intragastric Balloon System	Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3012638928-2021-02422	11/11/2021	Malfunction	Spatz Fgia Inc.	1/18/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2022-00011	12/30/2021	Malfunction	Apollo Endosurgery, Inc.	1/12/2022	LTI	Orbera Intragastric Balloon System	Insufficient Information	Flatus; Vomiting

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2021-02424	12/4/2021	Malfunction	Spatz Fgia Inc.	1/11/2022	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	No Clinical Signs, Symptoms or Conditions
3006722112-2022-00010	12/27/2021	Malfunction	Apollo Endosurgery, Inc.	1/10/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2022-00008	11/9/2021	Malfunction	Apollo Endosurgery, Inc.	1/7/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2022-00006	11/23/2021	Malfunction	Apollo Endosurgery, Inc.	1/7/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2022-00005	12/1/2021	Malfunction	Apollo Endosurgery, Inc.	1/7/2022	LTI	Orbera Intragastric Balloon System	Inflation Problem	Failure of Implant; Nausea; Vomiting; Obstruction/ Occlusion
3006722112-2022-00003	12/17/2021	Malfunction	Apollo Endosurgery, Inc.	1/7/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2022-00004	12/17/2021	Malfunction	Apollo Endosurgery, Inc.	1/7/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2022-00007	12/21/2021	Malfunction	Apollo Endosurgery, Inc.	1/7/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Abdominal Pain; Failure of Implant; Vomiting; Obstruction/ Occlusion
3006722112-2022-00009	12/23/2021	Malfunction	Apollo Endosurgery, Inc.	1/7/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant; Vomiting
3006722112-2022-00001	9/20/2021	Malfunction	Apollo Endosurgery, Inc.	1/6/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2022-00002	12/14/2021	Malfunction	Apollo Endosurgery, Inc.	1/6/2022	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
MW5106299	11/9/2021	Injury	Apollo Endosurgery Costa Rica S.R.L.	12/27/2021	LTI	Orbera	Adverse Event Without Identified Device or Use Problem	Cardiac Arrest; Hemorrhage/ Bleeding; Nausea; Dizziness
3012628928-2021-02409	10/26/2021	Malfunction	Spatz Fgia Inc.	12/26/2021	LTI	Spatz3 Adjustable Balloon System	Unintended Deflation	Failure of Implant; Pain
3012638928-2021-00241	10/31/2021	Malfunction	Spatz Fgia Inc.	12/26/2021	LTI	Spatz3 Adjustable Balloon System	Unintended Deflation	Failure of Implant
3012638928-2021-02406	11/8/2021	Malfunction	Spatz Fgia Inc.	12/26/2021	LTI	Spatz3 Adjustable Balloon System	Deflation Problem	Insufficient Information

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2021-02408	11/20/2021	Malfunction	Spatz Fgia Inc.	12/26/2021	LTI	Spatz3 Adjustable Balloon System	Deflation Problem; Leak/ Splash	Appropriate Clinical Signs, Symptoms, Conditions Term/ Code Not Available
3012638928-2021-02417	11/20/2021	Malfunction	Spatz Fgia Inc.	12/26/2021	LTI	Spatz3 Adjustable Balloon System	Insufficient Information	Appropriate Clinical Signs, Symptoms, Conditions Term/ Code Not Available
3012638928-2021-02416	11/26/2021	Malfunction	Spatz Fgia Inc.	12/26/2021	LTI	Spatz3 Adjustable Balloon System	Output Problem	Appropriate Clinical Signs, Symptoms, Conditions Term/ Code Not Available
3006722112-2021-00129	12/20/2021	Malfunction	Apollo Endosurgery, Inc.	12/21/2021	LTI	Orbera® Intragastric Balloon System	Obstruction of Flow	Ischemia
3012638928-2021-02399	10/1/2021	Malfunction	Spatz Fgia Inc.	12/20/2021	LTI	Spatz3 Adjustable Balloon System	Output Problem	Abdominal Pain
3012638928-2021-02401	10/4/2021	Malfunction	Spatz Fgia Inc.	12/20/2021	LTI	Spatz3 Adjustable Balloon System	Output Problem	Insufficient Information
3006722112-2021-00125	11/10/2021	Malfunction	Apollo Endosurgery, Inc.	12/20/2021	LTI	Orbera® Intragastric Balloon System	Inflation Problem	Abdominal Pain; Failure of Implant
3012638928-2021-02403	11/16/2021	Malfunction	Spatz Fgia Inc.	12/20/2021	LTI	Spatz3 Adjustable Balloon System	Adverse Event Without Identified Device or Use Problem	Appropriate Clinical Signs, Symptoms, Conditions Term/ Code Not Available
3012638928-2021-02402	11/17/2021	Malfunction	Spatz Fgia Inc.	12/20/2021	LTI	Spatz3 Adjustable Balloon System	Unintended Deflation	Failure of Implant

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2021-02392	10/25/2021	Malfunction	Spatz Fgia Inc.	12/14/2021	LTI	Spatz3 Adjustable Balloon System	Biofilm coating in Device; Deflation Problem	Failure of Implant
3012638928-2021-02393	10/31/2021	Malfunction	Spatz Fgia Inc.	12/14/2021	LTI	Spatz3 Adjustable Balloon System	Leak/ Splash	Insufficient Information
3012638928-2021-02394	11/3/2021	Malfunction	Spatz Fgia Inc.	12/14/2021	LTI	Spatz3 Adjustable Balloon System	Leak/ Splash	Insufficient Information
3006722112-2021-00123	11/19/2021	Malfunction	Apollo Endosurgery, Inc.	12/14/2021	LTI	Orbera Intragastric Balloon System	Inflation Problem	Failure of Implant
3006722112-2021-00124	12/2/2021	Malfunction	Apollo Endosurgery, Inc.	12/14/2021	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Failure to Deflate	Failure of Implant; Obstruction/ Occlusion
3006722112-2021-00120	11/12/2021	Malfunction	Apollo Endosurgery, Inc.	12/9/2021	LTI	Orbera365 Intragastric Balloon System	Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2021-00121	11/20/2021	Malfunction	Apollo Endosurgery, Inc.	12/9/2021	LTI	Orbera Intragastric Balloon System	Deflation Problem	Erosion; Hemorrhage/ Bleeding; Failure of Implant
3006722112-2021-00122	NR	Malfunction	Apollo Endosurgery, Inc.	12/9/2021	LTI	Orbera® Intragastric Balloon System	Deflation Problem	Pyrosis/ Heartburn; Nausea; Vomiting; Pancreatitis
3012638928-2021-02388	10/16/2020	Malfunction	Spatz Fgia Inc.	12/8/2021	LTI	Spatz3 Adjustable Balloon System	Output Problem	Appropriate Clinical Signs, Symptoms, Conditions Term/ Code Not Available

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3012638928-2021-02382	7/31/2021	Malfunction	Spatz Fgia Inc.	12/8/2021	LTI	Spatz3 Adjustable Balloon System	Insufficient Information	Appropriate Clinical Signs, Symptoms, Conditions Term/ Code Not Available
3006722112-2021-00118	10/23/2021	Malfunction	Apollo Endosurgery, Inc.	12/8/2021	LTI	Orbera Intragastric Balloon System	Fluid/ Blood Leak; Mechanical Problem	Failure of Implant
3006722112-2021-00119	11/14/2021	Malfunction	Apollo Endosurgery, Inc.	12/8/2021	LTI	Orbera365 Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant; Vomiting; Obstruction/ Occlusion
3012638928-2021-02381	9/2/2021	Malfunction	Spatz Fgia Inc.	12/4/2021	LTI	Spatz3 Adjustable Balloon System	Output Problem	Insufficient Information
3012638928-2021-02380	9/27/2021	Malfunction	Spatz Fgia Inc.	11/30/2021	LTI	Spatz3 Adjustable Balloon System	Output Problem	Insufficient Information
3006722112-2021-00112	11/4/2021	Malfunction	Apollo Endosurgery, Inc.	11/18/2021	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2021-00113	11/5/2021	Malfunction	Apollo Endosurgery, Inc.	11/18/2021	LTI	Orbera365 Intragastric Balloon System	Inflation Problem	Failure of Implant
3006722112-2021-00111	NR	Malfunction	Apollo Endosurgery, Inc.	11/17/2021	LTI	Orbera Intragastric Balloon System	Inflation Problem	Failure of Implant; Nausea; Vomiting

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2021-00117	11/10/2021	Malfunction	Apollo Endosurgery, Inc.	11/16/2021	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2021-00115	11/10/2021	Malfunction	Apollo Endosurgery, Inc.	11/16/2021	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Fluid/ Blood Leak; Unintended Deflation	Abdominal Pain; Pyrosis/ Heartburn
3006722112-2021-00107	10/4/2021	Malfunction	Apollo Endosurgery, Inc.	11/2/2021	LTI	Orbera Intragastric Balloon System	Adverse Event Without Identified Device or Use Problem	Dehydration; Vomiting; Malaise
3006722112-2021-00110	10/25/2021	Malfunction	Apollo Endosurgery, Inc.	11/2/2021	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Unintended Deflation	Failure of Implant
3006722112-2021-00108	10/14/2021	Malfunction	Apollo Endosurgery, Inc.	11/2/2021	LTI	Orbera Intragastric Balloon System	Insufficient Information	Pancreatitis
3006722112-2021-00109	NR	Malfunction	Apollo Endosurgery, Inc.	11/2/2021	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Unintended Deflation	Failure of Implant
3006722112-2021-00095	9/29/2021	Malfunction	Apollo Endosurgery, Inc.	10/28/2021	LTI	Orbera365 Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant
3006722112-2021-00093	10/2/2021	Malfunction	Apollo Endosurgery, Inc.	10/28/2021	LTI	Orbera Intragastric Balloon System	Inflation Problem	Failure of Implant

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2021-00098	10/2/2021	Malfunction	Apollo Endosurgery, Inc.	10/28/2021	LTI	Orbera365 Intragastric Balloon System	Inflation Problem	Failure of Implant
3006722112-2021-00104	10/5/2021	Malfunction	Apollo Endosurgery, Inc.	10/28/2021	LTI	Orbera Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant
3006722112-2021-00105	NR	Malfunction	Apollo Endosurgery, Inc.	10/28/2021	LTI	Orbera365 Intragastric Balloon System Directions	Fluid/ Blood Leak	Abdominal Pain; Failure of Implant; Nausea; Vomiting
3006722112-2021-00094	9/18/2021	Malfunction	Apollo Endosurgery, Inc.	10/26/2021	LTI	Orbera Intragastric Balloon System	Migration	Failure of Implant; Perforation
3006722112-2021-00091	7/9/2021	Malfunction	Apollo Endosurgery, Inc.	10/22/2021	LTI	Orbera Intragastric Balloon System	Migration	Abdominal Pain; Vomiting; Obstruction/ Occlusion
3006722112-2021-00099	9/20/2021	Malfunction	Apollo Endosurgery, Inc.	10/22/2021	LTI	Orbera Intragastric Balloon System	Insufficient Information	Malaise
3006722112-2021-00096	9/24/2021	Malfunction	Apollo Endosurgery, Inc.	10/22/2021	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Migration; Failure to Deflate	Airway Obstruction; Failure of Implant
3006722112-2021-00097	9/24/2021	Malfunction	Apollo Endosurgery, Inc.	10/22/2021	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Migration	Airway Obstruction; Failure of Implant

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2021-00092	10/1/2021	Malfunction	Apollo Endosurgery, Inc.	10/22/2021	LTI	Orbera365 Intragastric Balloon System	Deflation Problem; Unintended Deflation	Failure of Implant
3006722112-2021-00103	9/2/2021	Malfunction	Apollo Endosurgery, Inc.	10/21/2021	LTI	Orbera365 Intragastric Balloon System	Inflation Problem	Abdominal Pain; Failure of Implant; Vomiting
3006722112-2021-00090	9/25/2021	Malfunction	Apollo Endosurgery, Inc.	10/21/2021	LTI	Orbera Intragastric Balloon System	Inflation Problem	Insufficient Information
3006722112-2021-00084	9/3/2021	Malfunction	Apollo Endosurgery, Inc.	10/20/2021	LTI	Orbera365 Intragastric Balloon System	Inflation Problem	Failure of Implant
3006722112-2021-00086	6/7/2021	Malfunction	Apollo Endosurgery, Inc.	10/8/2021	LTI	Orbera365 Intragastric Balloon System	Inflation Problem	Failure of Implant
3006722112-2021-00089	8/28/2021	Malfunction	Apollo Endosurgery, Inc.	10/8/2021	LTI	Orbera365 Intragastric Balloon System	Unintended Deflation	Failure of Implant; Vomiting
3006722112-2021-00088	8/9/2021	Malfunction	Apollo Endosurgery, Inc.	9/30/2021	LTI	Orbera365 Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant
3006722112-2021-00085	9/1/2021	Malfunction	Apollo Endosurgery, Inc.	9/29/2021	LTI	Orbera365 Intragastric Balloon System	Inflation Problem; Migration or Expulsion of Device	Abdominal Pain; Fatigue; Failure of Implant
3006722112-2021-00082	7/10/2021	Malfunction	Apollo Endosurgery, Inc.	9/20/2021	LTI	Orbera Intragastric Balloon System	Deflation Problem	Abdominal Pain; Failure of Implant; Vomiting

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2021-00083	8/18/2021	Malfunction	Apollo Endosurgery, Inc.	9/16/2021	LTI	Orbera365 Intragastric Balloon System	Deflation Problem	Abdominal Pain; Failure of Implant; Vomiting
3006722122-2021-00078	NR	Malfunction	Apollo Endosurgery, Inc.	9/15/2021	LTI	Orbera365 Intragastric Balloon System	Inflation Problem; Migration	Abdominal Pain; Failure of Implant; Nausea; Vomiting
3006722112-2021-00079	7/15/2021	Malfunction	Apollo Endosurgery, Inc.	9/2/2021	LTI	Orbera Intragastric Balloon System	Inflation Problem	Failure of Implant; Pain
3006722112-2021-00077	7/22/2021	Malfunction	Apollo Endosurgery, Inc.	9/2/2021	LTI	Orbera365 Intragastric Balloon System	Migration or Expulsion of Device	Failure of Implant; Vomiting
3006722112-2021-00080	8/18/2021	Malfunction	Apollo Endosurgery, Inc.	9/2/2021	LTI	Orbera Intragastric Balloon System	Inflation Problem	Failure of Implant; Vomiting; Obstruction/ Occlusion
3006722112-2021-00076	7/20/2021	Malfunction	Apollo Endosurgery, Inc.	8/31/2021	LTI	Orbera365 Intragastric Balloon System	Inflation Problem	Failure of Implant; Pain; Vomiting
3006722112-2021-00075	7/26/2021	Malfunction	Apollo Endosurgery, Inc.	8/31/2021	LTI	Orbera365 Intragastric Balloon System	Inflation Problem	Failure of Implant; Pain; Vomiting
3006722112-2021-00081	8/10/2021	Malfunction	Apollo Endosurgery, Inc.	8/26/2021	LTI	Orbera365 Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2021-00074	2/2/2021	Malfunction	Apollo Endosurgery, Inc.	8/25/2021	LTI	Orbera Intragastric Balloon System	Inflation Problem; Adverse Event Without Identified Device or Use Problem	Failure of Implant
3006722112-2021-00073	7/19/2021	Malfunction	Apollo Endosurgery, Inc.	8/23/2021	LTI	Orbera365 Intragastric Balloon System	Fluid/ Blood Leak; Unintended Deflation	Failure of Implant
3006722112-2021-00072	6/19/2021	Malfunction	Apollo Endosurgery, Inc.	8/23/2021	LTI	Orbera Intragastric Balloon System	Inflation Problem	Abdominal Pain; Failure of Implant; Vomiting
3006722112-2021-00069	4/25/2021	Malfunction	Apollo Endosurgery, Inc.	8/18/2021	LTI	Orbera Intragastric Balloon System	Insufficient Information	Abdominal Pain; Failure of Implant
3006722112-2021-00067	7/8/2021	Malfunction	Apollo Endosurgery, Inc.	8/10/2021	LTI	Orbera365 Intragastric Balloon System	Adverse Event Without Identified Device or Use Problem	Perforation of Esophagus
3006722112-2021-00070	7/16/2021	Malfunction	Apollo Endosurgery, Inc.	8/10/2021	LTI	Orbera365 Intragastric Balloon System	Deflation Problem	Failure of Implant
3006722112-2021-00064	4/10/2021	Malfunction	Apollo Endosurgery, Inc.	8/4/2021	LTI	Orbera365 Intragastric Balloon System	Patient-Device Incompatibility	Failure of Implant; Vomiting; Obstruction/ Occlusion
3006722112-2021-00066	NR	Injury	Apollo Endosurgery, Inc.	7/29/2021	LTI	Orbera Intragastric Balloon System	Insufficient Information	Failure of Implant; Perforation; Perforation of Esophagus

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2021-00065	NR	Death	Apollo Endosurgery, Inc.	7/29/2021	LTI	Orbera® Intragastric Balloon System	Insufficient Information	Insufficient Information
3006722112-2021-00068	6/24/2021	Malfunction	Apollo Endosurgery, Inc.	7/22/2021	LTI	Orbera365 Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant; Vomiting
3006722112-2021-00038	5/24/2021	Malfunction	Apollo Endosurgery, Inc.	7/13/2021	LTI	Orbera365 Intragastric Balloon System	Mechanical Problem	Failure of Implant; Nausea; Vomiting
3006722112-2021-00055	5/3/2021	Malfunction	Apollo Endosurgery, Inc.	7/6/2021	LTI	Orbera365 Intragastric Balloon System	Inflation Problem	Nausea; Vomiting
3006722112-2021-00056	6/2/2021	Malfunction	Apollo Endosurgery, Inc.	6/29/2021	LTI	Orbera365 Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant
3006722112-2021-00053	5/21/2021	Malfunction	Apollo Endosurgery, Inc.	6/22/2021	LTI	Orbera365 Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant
3006722112-2021-00050	4/15/2021	Malfunction	Apollo Endosurgery, Inc.	6/22/2021	LTI	Orbera365 Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant
3006722112-2021-00062	NR	Injury	Apollo Endosurgery Costa Rica, Srl	6/22/2021	LTI	Intragastric Balloon System	Patient-Device Incompatibility	Nausea; Pain; Abdominal Distention; Pancreatitis
3006722112-2021-00046	NR	Malfunction	Apollo Endosurgery, Inc.	6/14/2021	LTI	Orbera Intragastric Balloon System	Patient-Device Incompatibility	Failure of Implant

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2021-00049	1/29/2021	Malfunction	Apollo Endosurgery, Inc.	6/10/2021	LTI	Orbera365 Intragastric Balloon System	Patient-Device Incompatibility	Failure of Implant; Pain; Vomiting
3006722112-2021-00047	3/30/2021	Malfunction	Apollo Endosurgery, Inc.	6/8/2021	LTI	Orbera365 Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant
3006722112-2021-00048	5/14/2021	Malfunction	Apollo Endosurgery, Inc.	6/8/2021	LTI	Orbera365 Intragastric Balloon System	Patient-Device Incompatibility	Failure of Implant; Pain; Vomiting
3006722112-2021-00051	4/14/2021	Malfunction	Apollo Endosurgery, Inc.	6/2/2021	LTI	Orbera Intragastric Balloon System	Patient-Device Incompatibility	Vomiting
3006722112-2021-00042	5/10/2021	Malfunction	Apollo Endosurgery, Inc.	6/2/2021	LTI	Orbera365 Intragastric Balloon System	Fluid/ Blood Leak	Abdominal Pain; Failure of Implant; Implant Pain
3006722112-2021-00039	1/25/2021	Injury	Apollo Endosurgery, Inc.	6/1/2021	LTI	Orbera Intragastric Balloon System	Adverse Event Without Identified Device or Use Problem	Abdominal Pain; Vomiting
3006722112-2021-00032	2/5/2021	Malfunction	Apollo Endosurgery, Inc.	5/24/2021	LTI	Orbera Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant
3006722112-2021-00037	4/16/2021	Malfunction	Apollo Endosurgery, Inc.	5/19/2021	OCW	Orbera Intragastric Balloon System	Patient-Device Incompatibility	Eructate; Flatus; Abdominal Distention
3006722112-2021-00041	4/1/2021	Malfunction	Apollo Endosurgery, Inc.	5/12/2021	LTI	Orbera 365 Intragastric Balloon	Fluid/ Blood Leak	Failure of Implant

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2021-00040	3/4/2021	Malfunction	Apollo Endosurgery, Inc.	5/11/2021	LTI	Orbera Intragastric Balloon System	Fluid/ Blood Leak; Inflation Problem	Failure of Implant
3006722112-2021-00031	4/7/2021	Injury	Apollo Endosurgery, Inc.	5/7/2021	OCZ	BIB Removal Tool Wire Grasper	Mechanical Problem; Device Damaged by Another Device	No Clinical Signs, Symptoms or Conditions
3006722112-2021-00029	3/15/2021	Malfunction	Apollo Endosurgery, Inc.	4/21/2021	LTI	Orbera365 Intragastric Balloon System	Deflation Problem	Failure of Implant
3006722112-2021-00024	2/25/2021	Injury	Apollo Endosurgery, Inc.	4/16/2021	LTI	Orbera 365 Intragastric Balloon	Adverse Event Without Identified Device or Use Problem	Eructate; Pyrosis/ Heartburn; Nausea; Vertigo; Vomiting; Abdominal Distention
3006722112-2021-00021	3/19/2021	Malfunction	Apollo Endosurgery, Inc.	4/16/2021	LTI	Orbera Intragastric Balloon System	Inflation Problem; Air/ Gas in Device	Diarrhea; Nausea; Vomiting; Abdominal Distention
3006722112-2021-00026	3/11/2021	Injury	Apollo Endosurgery, Inc.	4/8/2021	LTI	Orbera365 Intragastric Balloon System	Difficult to Remove	Obstruction/ Occlusion
3006722112-2021-00022	3/4/2021	Malfunction	Apollo Endosurgery, Inc.	4/1/2021	LTI	Orbera Intragastric Balloon System	Mechanical Problem	Failure of Implant
MW5100421	2/23/2021	Malfunction	Apollo Endosurgery Inc	3/30/2021	LTI	Orbera Balloon	Adverse Event Without Identified Device or Use Problem	Nausea; Pain; Vomiting; Pressure Sores; Sleep Dysfunction; Weight Changes

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2021-00018	11/17/2020	Malfunction	Apollo Endosurgery	3/22/2021	LTI	Orbera Intragastric Balloon System	Patient-Device Incompatibility	Failure of Implant
3006722112-2021-00019	2/18/2021	Malfunction	Apollo Endosurgery, Inc.	3/19/2021	LTI	Orbera 365 Intragastric Balloon	Patient-Device Incompatibility	Failure of Implant
3006722112-2021-00014	NR	Death	Apollo Endosurgery, Inc.	3/19/2021	LTI	Orbera Intragastric Balloon System	Insufficient Information	Perforation; Insufficient Information
3006722112-2021-00017	12/22/2020	Malfunction	Apollo Endosurgery, Inc.	3/11/2021	LTI	Orbera365 Intragastric Balloon System	Patient-Device Incompatibility	Failure of Implant; Vomiting; Ulcer; Obstruction/ Occlusion
3006722112-2021-00013	1/25/2021	Malfunction	Apollo Endosurgery, Inc.	3/10/2021	LTI	Orbera Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant
3006722112-2021-00016	12/10/2020	Malfunction	Apollo Endosurgery	3/10/2021	LTI	Orbera365 Intragastric Balloon System	Patient-Device Incompatibility	Failure of Implant; Vomiting; Obstruction/ Occlusion
3006722112-2021-00012	1/23/2021	Malfunction	Apollo Endosurgery, Inc.	3/5/2021	LTI	Orbera365 Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant
3006722112-2021-00010	10/1/2019	Injury	Apollo Endosurgery	3/1/2021	LTI	Orbera Intragastric Balloon	Adverse Event Without Identified Device or Use Problem	Dehydration; Vomiting; Obstruction/ Occlusion
3006722112-2021-00011	1/23/2021	Injury	Apollo Endosurgery, Inc.	2/23/2021	OCW	Orbera Intragastric Balloon	Fluid/ Blood Leak	Failure of Implant; Stomach Ulceration

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2021-00009	1/16/2021	Malfunction	Apollo Endosurgery	2/16/2021	LTI	Orbera365 Intragastric Balloon System	Human-Device Interface Problem	Failure of Implant
3006722112-2021-00008	1/19/2021	Malfunction	Apollo Endosurgery	2/16/2021	LTI	Orbera Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant
3006722112-2021-00006	1/8/2021	Injury	Apollo Endosurgery	2/3/2021	LTI	Orbera Intragastric Balloon System	Insufficient Information	Perforation of Esophagus
3006722112-2021-00005	1/15/2021	Injury	Apollo Endosurgery	2/3/2021	LTI	Orbera Intragastric Balloon System	Adverse Event Without Identified Device or Use Problem	Dehydration; Nausea; Vomiting; Malaise
3006722112-2021-00007	NR	Injury	Apollo Endosurgery	1/28/2021	LTI	Orbera Intragastric Balloon System	Patient-Device Incompatibility	Abdominal Pain; Nausea; Vomiting; Constipation; Pancreatitis
3006722112-2021-00004	1/4/2021	Malfunction	Apollo Endosurgery	1/27/2021	LTI	Orbera Intragastric Balloon System	Fluid/ Blood Leak	Obstruction/ Occlusion
3006722112-2021-00003	12/24/2020	Malfunction	Apollo Endosurgery	1/20/2021	LTI	Orbera Intragastric Balloon System	Patient-Device Incompatibility	Vomiting
3006722112-2021-00001	9/28/2020	Malfunction	Apollo Endosurgery	1/11/2021	LTI	Orbera Intragastric Balloon System	Patient-Device Incompatibility	Failure of Implant; Nausea; Pain; Vomiting
3006722112-2021-00002	11/15/2020	Malfunction	Apollo Endosurgery	1/11/2021	LTI	Orbera365 Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2020-00134	11/25/2020	Injury	Apollo Endosurgery	1/8/2021	LTI	Orbera365 Intragastric Balloon System	Patient-Device Incompatibility	Perforation; Sepsis; Vomiting
3006722112-2020-00133	NR	Malfunction	Apollo Endosurgery	1/5/2021	LTI	Orbera365 Intragastric Balloon System	Fluid/ Blood Leak; Migration or Expulsion of Device	Abdominal Pain
3006722112-2020-00132	9/12/2020	Injury	Apollo Endosurgery	12/28/2020	LTI	Orbera365 Intragastric Balloon System	Adverse Event Without Identified Device or Use Problem	Abdominal Pain; Perforation; Vomiting; Abdominal Cramps; Hematemesis
3006722112-2020-00130	10/31/2020	Malfunction	Apollo Endosurgery	12/21/2020	LTI	Orbera Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant
3006722112-2020-00128	10/24/2020	Injury	Apollo Endosurgery	12/17/2020	LTI	Orbera Intragastric Balloon System	Adverse Event Without Identified Device or Use Problem	Pancreatitis
3006722112-2020-00123	11/14/2020	Death	Apollo Endosurgery	12/16/2020	LTI	Orbera Intragastric Balloon System	Adverse Event Without Identified Device or Use Problem	Nausea; Vomiting; Bowel Perforation
3006722112-2020-00124	10/29/2020	Malfunction	Apollo Endosurgery	12/15/2020	LTI	Orbera Intragastric Balloon System	Patient-Device Incompatibility	Pain
3006722112-2020-00121	10/10/2020	Malfunction	Apollo Endosurgery	12/8/2020	LTI	Orbera Intragastric Balloon System	Patient-Device Incompatibility	Abdominal Pain; Vomiting

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2020-00120	10/25/2020	Malfunction	Apollo Endosurgery	12/1/2020	LTI	BIB System Intragastric Balloon	Fluid/ Blood Leak; Migration or Expulsion of Device	Abdominal Pain; Failure of Implant; Nausea; Vomiting
3006722112-2020-00115	10/9/2020	Injury	Apollo Endosurgery	11/23/2020	LTI	Orbera® Intragastric Balloon System	Patient-Device Incompatibility	Vomiting
3006722112-2020-00118	10/28/2020	Malfunction	Apollo Endosurgery	11/23/2020	LTI	Orbera Intragastric Balloon System	Patient-Device Incompatibility	Abdominal Pain
3006722112-2020-00114	7/29/2020	Malfunction	Apollo Endosurgery	11/20/2020	LTI	Orbera Intragastric Balloon System	Difficult to Remove; Short Fill	Failure of Implant
MW5097989	9/28/2020	Injury	Apollo Endosurgery, Inc.	11/19/2020	LTI	Orbera	Failure to Deflate	Abdominal Pain; Nausea; Vomiting
3006722112-2020-00110	9/25/2020	Malfunction	Apollo Endosurgery	11/17/2020	LTI	Orbera Intragastric Balloon System	Patient-Device Incompatibility	Failure of Implant
3006722112-2020-00111	9/30/2020	Malfunction	Apollo Endosurgery	11/17/2020	LTI	Orbera Intragastric Balloon System Directions	Patient-Device Incompatibility	Failure of Implant
3006722112-2020-00107	7/19/2020	Death	Apollo Endosurgery	11/10/2020	LTI	BIB System Intragastric Balloon	Insufficient Information	Insufficient Information
3006722112-2020-00112	10/1/2019	Malfunction	Apollo Endosurgery	11/9/2020	LTI	Orbera365 Intragastric Balloon System	Fluid/ Blood Leak	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2020-00109	9/29/2020	Malfunction	Apollo Endosurgery	11/9/2020	LTI	Orbera Intragastric Balloon System	Patient-Device Incompatibility	Abdominal Pain; Vomiting
3006722112-2020-00105	9/28/2020	Malfunction	Apollo Endosurgery	11/4/2020	LTI	Orbera365 Intragastric Balloon System	Fluid/ Blood Leak	No Clinical Signs, Symptoms or Conditions
3006722112-2020-00104	9/12/2020	Malfunction	Apollo Endosurgery	11/4/2020	LTI	Orbera365 Intragastric Balloon System	Fluid/ Blood Leak	No Clinical Signs, Symptoms or Conditions
3006722112-2020-00106	NR	Injury	Apollo Endosurgery	10/30/2020	LTI	Orbera Intragastric Balloon System	Insufficient Information	Nausea; Vomiting
3006722112-2020-00101	5/6/2020	Malfunction	Apollo Endosurgery	10/26/2020	LTI	Orbera365 Intragastric Balloon System	Fluid/ Blood Leak	No Clinical Signs, Symptoms or Conditions
3006722112-2020-00102	4/29/2020	Malfunction	Apollo Endosurgery	10/26/2020	LTI	Orbera365 Intragastric Balloon System	Fluid/ Blood Leak; Migration or Expulsion of Device	No Clinical Signs, Symptoms or Conditions
3006722112-2020-00100	5/13/2020	Malfunction	Apollo Endosurgery	10/26/2020	LTI	Orbera365 Intragastric Balloon System	Fluid/ Blood Leak; Migration or Expulsion of Device	No Clinical Signs, Symptoms or Conditions
3006722112-2020-00099	9/15/2020	Malfunction	Apollo Endosurgery	10/26/2020	LTI	BIB System Intragastric Balloon	Patient-Device Incompatibility	No Clinical Signs, Symptoms or Conditions
3006722112-2020-00098	8/28/2020	Injury	Apollo Endosurgery	10/23/2020	LTI	Orbera Intragastric Balloon System	Fluid/ Blood Leak; Insufficient Information	Obstruction/ Occlusion; Insufficient Information

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2020-00108	9/24/2020	Malfunction	Apollo Endosurgery	10/22/2020	LTI	Orbera365 Intragastric Balloon System	Migration or Expulsion of Device	No Clinical Signs, Symptoms or Conditions
3006722112-2020-00097	7/24/2020	Malfunction	Apollo Endosurgery	10/21/2020	LTI	Orbera Intragastric Balloon System	Patient-Device Incompatibility	Abdominal Pain; Vomiting
3006722112-2020-00092	5/6/2020	Malfunction	Apollo Endosurgery	10/13/2020	LTI	Orbera Intragastric Balloon System	Patient-Device Incompatibility	Abdominal Pain; Vomiting; Abdominal Distention
3006722112-2020-00103	8/29/2020	Malfunction	Apollo Endosurgery	10/13/2020	LTI	Orbera365 Intragastric Balloon System	Fluid/ Blood Leak	No Clinical Signs, Symptoms or Conditions
3006722112-2020-00090	6/22/2020	Injury	Apollo Endosurgery	10/12/2020	LTI	BIB System Intragastric Balloon	Adverse Event Without Identified Device or Use Problem	Abdominal Pain; Perforation
3006722112-2020-00089	9/8/2020	Malfunction	Apollo Endosurgery	10/6/2020	LTI	Orbera 365 Intragastric Balloon System	Patient-Device Incompatibility	No Clinical Signs, Symptoms or Conditions
3006722112-2020-00088	NR	Injury	Apollo Endosurgery	10/6/2020	LTI	Orbera Intragastric Balloon System	Adverse Event Without Identified Device or Use Problem	Vomiting
3006722112-2020-00091	NR	Injury	Apollo Endosurgery	10/6/2020	LTI	Orbera Intragastric Balloon System	Patient-Device Incompatibility	Pancreatitis
3006722112-2020-00087	8/26/2020	Malfunction	Apollo Endosurgery	10/5/2020	LTI	Orbera 365 Intragastric Balloon System	Fluid/ Blood Leak	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2020-00086	8/29/2020	Malfunction	Apollo Endosurgery	9/30/2020	LTI	BIB System Intragastric Balloon	Patient-Device Incompatibility	Appropriate Clinical Signs, Symptoms, Conditions Term/ Code Not Available
3005722112-2020-00084	6/26/2020	Malfunction	Apollo Endosurgery	9/18/2020	LTI	Orbera Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant; Appropriate Clinical Signs, Symptoms, Conditions Term/ Code Not Available
3006722112-2020-00082	6/16/2020	Malfunction	Apollo Endosurgery	9/17/2020	LTI	Orbera Intragastric Balloon System	Fluid/ Blood Leak	Appropriate Clinical Signs, Symptoms, Conditions Term/ Code Not Available
3006722112-2020-00083	7/7/2020	Injury	Apollo Endosurgery	9/17/2020	LTI	Orbera Intragastric Balloon System	Adverse Event Without Identified Device or Use Problem	Vomiting; Increased Sensitivity
3006722112-2020-00077	1/12/2020	Malfunction	Apollo Endosurgery	9/16/2020	LTI	Orbera Intragastric Balloon System	Patient-Device Incompatibility	Pain; Vomiting
3006722112-2020-00080	3/7/2020	Malfunction	Apollo Endosurgery	9/16/2020	LTI	Orbera Intragastric Balloon System	Patient-Device Incompatibility	Pain; Vomiting
3006722112-2020-00076	3/9/2020	Malfunction	Apollo Endosurgery	9/16/2020	LTI	Orbera Intragastric Balloon System	Off-Label Use; Patient-Device Incompatibility	Pain; Vomiting
3006722112-2020-00081	3/27/2020	Malfunction	Apollo Endosurgery	9/16/2020	LTI	Orbera Intragastric Balloon System	Patient-Device Incompatibility	Pain; Vomiting

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2020-00078	6/17/2020	Malfunction	Apollo Endosurgery	9/16/2020	LTI	Orbera Intragastric Balloon System	Patient-Device Incompatibility	Pain
3006722112-2020-00079	7/25/2020	Malfunction	Apollo Endosurgery	9/16/2020	LTI	Orbera Intragastric Balloon System	Patient-Device Incompatibility	Appropriate Clinical Signs, Symptoms, Conditions Term/ Code Not Available
3006722112-2020-00074	3/26/2020	Malfunction	Apollo Endosurgery	9/8/2020	LTI	Orbera Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant; Appropriate Clinical Signs, Symptoms, Conditions Term/ Code Not Available
3006722112-2020-00075	4/10/2020	Injury	Apollo Endosurgery	9/8/2020	LTI	Orbera Intragastric Balloon System	Adverse Event Without Identified Device or Use Problem	Pain; Abdominal Distention
3006722112-2020-00073	5/23/2020	Malfunction	Apollo Endosurgery	9/8/2020	LTI	Orbera Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant; No Known Impact Or Consequence To Patient
3006722112-2020-00072	NR	Injury	Apollo Endosurgery	9/8/2020	LTI	Orbera Intragastric Balloon System	Adverse Event Without Identified Device or Use Problem	Nausea; Vomiting
3006722112-2020-00071	2/3/2020	Death	Apollo Endosurgery	9/2/2020	LTI	Orbera Intragastric Balloon System	Adverse Event Without Identified Device or Use Problem	Sudden Cardiac Death
MW5096356	8/28/2020	Injury	Apollo Endosurgery Inc	8/31/2020	LTI	Orbera	Appropriate Term/ Code Not Available	Obstruction/ Occlusion; Foreign Body In Patient
3006722112-2020-00065	7/9/2020	Malfunction	Apollo Endosurgery, Inc.	8/18/2020	LTI	Orbera365 Intragastric Balloon	Patient-Device Incompatibility	Patient Problem/ Medical Problem

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2020-00070	NR	Malfunction	Apollo Endosurgery, Inc.	8/6/2020	LTI	Orbera365 Intragastric Balloon System	Patient-Device Incompatibility	No Code Available
3006722112-2020-00069	1/31/2020	Malfunction	Apollo Endosurgery, Inc.	8/4/2020	LTI	Orbera Intragastric Balloon System	Patient-Device Incompatibility	Nausea; Vomiting; Abdominal Distention
3006722112-2020-00064	6/18/2020	Malfunction	Apollo Endosurgery, Inc.	7/20/2020	LTI	Orbera 365 Intragastric Balloon System	Patient-Device Incompatibility	Patient Problem/ Medical Problem
3006722112-2020-00062	6/24/2020	Malfunction	Apollo Endosurgery, Inc.	7/20/2020	LTI	BIB System Intragastric Balloon	Patient-Device Incompatibility	Patient Problem/ Medical Problem
3006722112-2020-00063	6/24/2020	Malfunction	Apollo Endosurgery, Inc.	7/20/2020	LTI	Orbera Intragastric Balloon System	Patient-Device Incompatibility	Pain; Vomiting
3006722112-2020-00061	5/2/2020	Malfunction	Apollo Endosurgery, Inc.	7/20/2020	LTI	Orbera 365 Intragastric Balloon System	Fluid/ Blood Leak	Nausea; Vomiting
3006722112-2020-00059	5/11/2020	Malfunction	Apollo Endosurgery, Inc.	6/10/2020	LTI	Orbera Intragastric Balloon	Fluid/ Blood Leak	No Known Impact Or Consequence To Patient
3006722112-2020-00058	5/6/2020	Malfunction	Apollo Endosurgery, Inc.	6/8/2020	LTI	Orbera Intragastric Balloon System	Fluid/ Blood Leak	Patient Problem/ Medical Problem
3006722112-2020-00057	5/2/2020	Malfunction	Apollo Endosurgery, Inc.	6/4/2020	LTI	Orbera Intragastric Balloon System	Fluid/ Blood Leak; Migration or Expulsion of Device	Nausea; Vomiting

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2020-00056	4/30/2020	Injury	Apollo Endosurgery, Inc.	6/2/2020	LTI	BIB System Intragastric Balloon	Adverse Event Without Identified Device or Use Problem	Nausea; Pain; Obstruction/ Occlusion
3006722112-2020-00055	2/4/2020	Injury	Apollo Endosurgery, Inc.	5/30/2020	LTI	Orbera Intragastric Balloon System	Adverse Event Without Identified Device or Use Problem	Internal Organ Perforation
3006722112-2020-00053	4/9/2020	Malfunction	Apollo Endosurgery, Inc.	5/22/2020	LTI	Orbera 365 Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant
3006722112-2020-00049	1/29/2020	Injury	Apollo Endosurgery, Inc.	4/13/2020	LTI	Orbera 365 Intragastric Balloon System	Adverse Event Without Identified Device or Use Problem	Hypersensitivity/ Allergic reaction; Pain
3006722112-2020-00050	3/6/2020	Malfunction	Apollo Endosurgery, Inc.	4/13/2020	LTI	Orbera 365 Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant
3006722112-2020-00047	3/11/2020	Injury	Apollo Endosurgery, Inc.	4/9/2020	LTI	Orbera Intragastric Balloon System	Adverse Event Without Identified Device or Use Problem	Syncope; Dyspnea; Pain; No Code Available
3006722112-2020-00048	3/8/2020	Injury	Apollo Endosurgery, Inc.	4/7/2020	LTI	Orbera Intragastric Balloon System	Adverse Event Without Identified Device or Use Problem	Pain; Vomiting
3006722112-2020-00045	1/12/2020	Injury	Apollo Endosurgery, Inc.	4/7/2020	LTI	Orbera Intragastric Balloon System	Patient-Device Incompatibility	Pain; Vomiting
3006722112-2020-00043	1/28/2020	Malfunction	Apollo Endosurgery, Inc.	4/7/2020	LTI	Orbera 365 Intragastric Balloon System	Fluid/ Blood Leak	Nausea; Vomiting

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2020-00039	2/19/2020	Malfunction	Apollo Endosurgery, Inc.	3/17/2020	LTI	Orbera 365 Intragastric Balloon System	Fluid/ Blood Leak; Migration or Expulsion of Device	Weight Changes; Patient Problem/ Medical Problem
3006722112-2020-00042	2/19/2020	Injury	Apollo Endosurgery, Inc.	3/17/2020	LTI	Orbera Intragastric Balloon System	Adverse Event Without Identified Device or Use Problem	Nausea; Pain; Vomiting; Abdominal Cramps
3006722112-2020-00044	2/20/2020	Malfunction	Apollo Endosurgery, Inc.	3/17/2020	LTI	Orbera 365 Intragastric Balloon System	Fluid/ Blood Leak; Migration or Expulsion of Device	Malaise
3006722112-2020-00038	NR	Injury	Apollo Endosurgery, Inc.	3/9/2020	LTI	Orbera® Intragastric Balloon System	Adverse Event Without Identified Device or Use Problem	Dehydration; Nausea; Pain; Vomiting; Abdominal Cramps
3006722112-2020-00035	12/29/2019	Malfunction	Apollo Endosurgery, Inc.	3/9/2020	LTI	Orbera® Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant
3006722112-2020-00037	1/5/2020	Malfunction	Apollo Endosurgery, Inc.	3/9/2020	LTI	Orbera® Intragastric Balloon System	Patient-Device Incompatibility	Nausea; Pain; Vomiting
3006722112-2020-00040	2/3/2020	Malfunction	Apollo Endosurgery, Inc.	3/9/2020	LTI	Orbera® Intragastric Balloon System	Patient-Device Incompatibility	Pain; Vomiting; Abdominal Distention
3006722112-2020-00036	2/13/2020	Malfunction	Apollo Endosurgery, Inc.	3/9/2020	LTI	Bib¿ System Intragastric Balloon	Fluid/ Blood Leak	Failure of Implant
3006722112-2020-00034	NR	Malfunction	Apollo Endosurgery, Inc.	3/9/2020	LTI	Orbera365® Intragastric Balloon	Fluid/ Blood Leak	Failure of Implant

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2020-00033	NR	Malfunction	Apollo Endosurgery, Inc.	3/9/2020	LTI	Orbera365® Intragastric Balloon	Fluid/ Blood Leak	Failure of Implant
3006722112-2020-00030	12/2/2019	Malfunction	Apollo Endosurgery, Inc.	3/3/2020	LTI	Orbera 365 Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant
3006722112-2020-00031	12/15/2019	Malfunction	Apollo Endosurgery, Inc.	3/3/2020	LTI	Orbera Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant
3006722112-2020-00032	1/27/2020	Injury	Apollo Endosurgery, Inc.	3/3/2020	LTI	Orbera 365 Intragastric Balloon System	Adverse Event Without Identified Device or Use Problem	Nausea; Vomiting; Patient Problem/ Medical Problem
3006722112-2020-00029	12/23/2019	Malfunction	Apollo Endosurgery, Inc.	3/3/2020	LTI	Orbera® Intragastric Balloon System	Patient-Device Incompatibility	Pain; Vomiting
3006722112-2020-00028	11/5/2019	Malfunction	Apollo Endosurgery, Inc.	2/24/2020	LTI	Orbera Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant
3006722112-2020-00025	11/5/2019	Malfunction	Apollo Endosurgery, Inc.	2/24/2020	LTI	Orbera Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant; Nausea; Vomiting
3006722112-2020-00023	12/16/2019	Malfunction	Apollo Endosurgery, Inc.	2/24/2020	LTI	Orbera Intragastric Balloon System	Fungus in Device Environment; Patient-Device Incompatibility	Pain; Vomiting
3006722112-2020-00027	12/17/2019	Malfunction	Apollo Endosurgery, Inc.	2/24/2020	LTI	Orbera Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2020-00024	12/27/2019	Malfunction	Apollo Endosurgery, Inc.	2/24/2020	LTI	Orbera Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant
3006722112-2020-00018	1/25/2020	Injury	Apollo Endosurgery, Inc.	2/24/2020	LTI	Orbera® Intragastric Balloon System	Patient-Device Incompatibility	Aspiration/ Inhalation; Ischemia; Necrosis; Pain; Vomiting
3006722112-2020-00022	1/28/2020	Injury	Apollo Endosurgery, Inc.	2/24/2020	LTI	Bib¿ System Intragastric Balloon	Detachment of Device or Device Component	Perforation of Esophagus
3006722112-2020-00026	12/7/2019	Malfunction	Apollo Endosurgery, Inc.	2/24/2020	LTI	Orbera® Intragastric Balloon System	Patient-Device Incompatibility	Pain; Vomiting
MW5093139	2/4/2020	Injury	Appollo Endosurgery Costa Rica S.R.L.	2/19/2020	LTI	Orbera	Adverse Event Without Identified Device or Use Problem	Perforation
3006722112-2020-00019	1/24/2020	Injury	Apollo Endosurgery, Inc.	2/10/2020	LTI	Orbera365 Intragastric Balloon System	Patient-Device Incompatibility	Nausea; Pain; Vomiting
3006722112-2020-00015	12/14/2019	Malfunction	Apollo Endosurgery, Inc.	2/3/2020	LTI	Orbera365® Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant
3006722112-2020-00016	12/15/2019	Malfunction	Apollo Endosurgery, Inc.	2/3/2020	LTI	Orbera365 Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant
3006722112-2020-00013	1/3/2020	Malfunction	Apollo Endosurgery, Inc.	2/3/2020	LTI	Orbera365® Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2020-00014	1/7/2020	Malfunction	Apollo Endosurgery, Inc.	2/3/2020	LTI	Orbera365® Intragastric Balloon System	Fluid/ Blood Leak	Failure of Implant
3006722112-2020-00009	1/17/2020	Malfunction	Apollo Endosurgery, Inc.	1/31/2020	LTI	Orbera365® Intragastric Balloon System	Fluid/ Blood Leak; Migration or Expulsion of Device	Failure of Implant
3006722112-2020-00012	10/9/2019	Injury	Apollo Endosurgery, Inc.	1/27/2020	LTI	Orbera365 Intragastric Balloon System	Patient-Device Incompatibility	Dehydration; Vomiting
3006722112-2020-00010	11/14/2019	Malfunction	Apollo Endosurgery, Inc.	1/22/2020	LTI	Orbera365® Intragastric Balloon System	Patient-Device Incompatibility	Inflammation; Vomiting
3006722112-2019-00195	10/6/2019	Injury	Apollo Endosurgery, Inc.	1/13/2020	LTI	Orbera Intragastric Balloon System Us	Patient-Device Incompatibility; Adverse Event Without Identified Device or Use Problem	Gastritis; Inflammation; Nausea; Vomiting; Weakness
3006722112-2020-00006	11/30/2019	Malfunction	Apollo Endosurgery, Inc.	1/13/2020	LTI	Orbera Intragastric Balloon System	Patient-Device Incompatibility	Pain; Vomiting
3006722112-2020-00005	12/13/2019	Injury	Apollo Endosurgery, Inc.	1/13/2020	LTI	Orbera Intragastric Balloon System	Patient-Device Incompatibility	Vomiting
3006722112-2020-00003	12/2/2019	Malfunction	Apollo Endosurgery, Inc.	1/9/2020	LTI	Orbera365® Intragastric Balloon System	Fluid/ Blood Leak	No Consequences Or Impact To Patient

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2020-00001	NR	Malfunction	Apollo Endosurgery, Inc.	1/6/2020	LTI	Orbera365 Intragastric Balloon System	Patient-Device Incompatibility	Pain; Vomiting
3006722112-2019-00205	11/26/2019	Malfunction	Apollo Endosurgery, Inc.	1/3/2020	LTI	Orbera® Intragastric Balloon System	Fluid/ Blood Leak; Leak/ Splash	Failure of Implant
3006722112-2019-00182	9/21/2019	Malfunction	Apollo Endosurgery, Inc.	12/16/2019	LTI	Orbera® Intragastric Balloon System	Patient-Device Incompatibility	Pain; Vomiting
3006722112-2019-00185	10/5/2019	Malfunction	Apollo Endosurgery, Inc.	12/16/2019	LTI	Orbera® Intragastric Balloon System	Fluid/ Blood Leak; Leak/ Splash	Failure of Implant
3006722112-2019-00198	11/12/2019	Malfunction	Apollo Endosurgery, Inc.	12/16/2019	LTI	BIB System Intragastric Balloon	Material Split, Cut or Torn	No Code Available
3006722112-2019-00203	11/24/2019	Malfunction	Apollo Endosurgery, Inc.	12/16/2019	LTI	Orbera 365 Intragastric Balloon System	Leak/ Splash	Discharge; Patient Problem/ Medical Problem
3006722112-2019-00178	NR	Injury	Apollo Endosurgery, Inc.	12/16/2019	LTI	Orbera® Intragastric Balloon System	Adverse Event Without Identified Device or Use Problem	Dehydration; Nausea; Vomiting; Patient Problem/ Medical Problem
3006722112-2019-00174	NR	Malfunction	Apollo Endosurgery, Inc.	12/16/2019	LTI	Orbera365 Intragastric Balloon System	Fluid/ Blood Leak; Leak/ Splash	No Code Available
3006722112-2019-00190	11/7/2019	Malfunction	Apollo Endosurgery, Inc.	12/10/2019	LTI	BIB System Intragastric Balloon	Detachment of Device or Device Component	No Code Available

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2019-00191	11/7/2019	Malfunction	Apollo Endosurgery, Inc.	12/10/2019	LTI	BIB System Intragastric Balloon	Detachment of Device or Device Component	No Code Available
3006722112-2019-00121	4/19/2019	Malfunction	Apollo Endosurgery, Inc.	5/22/2019	LTI	BIB System Intragastric Balloon	Patient-Device Incompatibility	Vomiting
3006722112-2019-00062	9/3/2018	Malfunction	Apollo Endosurgery, Inc.	2/22/2019	LTI	BIB System Intragastric Balloon	Patient-Device Incompatibility	Patient Problem/ Medical Problem

Table M3. Reports on Endoscopic Sleeve Gastroplasty Devices from the FDA MAUDE Database[2]

Note: Key information is presented in this table, but detailed event descriptions are available at the FDA MAUDE database.

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2021-00059	NR	Malfunction	Apollo Endosurgery Costa Rica, Srl	6/18/2021	OCW	Endoscopic Suturing System	Adverse Event Without Identified Device or Use Problem; Insufficient Information	Hematoma; Nausea; Vomiting
3006722112-2021-00060	NR	Injury	Apollo Endosurgery Costa Rica, Srl	6/18/2021	OCW	Endoscopic Suturing System	Adverse Event Without Identified Device or Use Problem; Insufficient Information	Abdominal Pain; Hematoma; Perforation of Esophagus; Pancreatitis; Stomach Ulceration
3006722112-2022-00033	NR	Malfunction	Apollo Endosurgery, Inc.	3/28/2022	OCW	ESS Endoscopic Suturing System	Insufficient Information	Hemorrhage/ Bleeding; Myocardial Infarction
3005099803-2024-00031	12/11/2023	Malfunction	Apollo Endosurgery, Inc	1/10/2024	OCW	Overstitch Endoscopic Suture System	Break; Device-Device Incompatibility; Difficult to Open or Close; Material Twisted/ Bent	No Clinical Signs, Symptoms or Conditions
3005099803-2023-07079	12/14/2023	Malfunction	Apollo Endosurgery Inc.,	1/9/2024	OCW	Overstitch Endoscopic Suture System	Failure to Align	No Clinical Signs, Symptoms or Conditions
3005099803-2023-07021	11/23/2023	Malfunction	Apollo Endosurgery	1/3/2024	OCW	Overstitch Endoscopic Suture System	Failure to Align; Difficult to Open or Close	No Clinical Signs, Symptoms or Conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2023-00159	7/3/2023	Malfunction	Apollo Endosurgery, Inc.	8/25/2023	OCW	Overstitch Endoscopic Suture System	No Apparent Adverse Event; Insufficient Information	Insufficient Information; Appropriate Clinical Signs, Symptoms, Conditions Term/ Code Not Available
17224403	2/8/2023	Malfunction	Apollo Endosurgery, Inc.	6/29/2023	HCF	Overstitch Endoscopic Suturing System	Mechanical Problem; Failure to Cut	Tissue Breakdown
17001751	5/10/2023	Malfunction	Apollo Endosurgery, Inc.	5/25/2023	HCF	Overstitch Endoscopic Suturing System	Activation, Positioning or Separation Problem	No Clinical Signs, Symptoms or Conditions
14134966	3/15/2022	Malfunction	Apollo Endosurgery, Inc.	4/18/2022	OCW	Overstitch Endoscopic Suturing System	Failure to Align	No Clinical Signs, Symptoms or Conditions
13652741	1/11/2022	Malfunction	Apollo Endosurgery, Inc.	3/2/2022	OCW	Overstitch Endoscopic Suturing System	Material Twisted/ Bent	Insufficient Information
3006722112-2021-00102	NR	Malfunction	Apollo Endosurgery, Inc.	10/26/2021	OCW	Overstitch Endoscopic Suturing System	Insufficient Information	Dysphagia/ Odynophagia
3006722112-2021-00100	NR	Malfunction	Apollo Endosurgery, Inc.	10/22/2021	OCW	Overstitch Endoscopic Suturing System	Insufficient Information	Abdominal Pain; Nausea; Vomiting
3006722112-2021-00101	NR	Malfunction	Apollo Endosurgery, Inc.	10/22/2021	OCW	Overstitch Endoscopic Suturing System	Mechanical Problem	Perforation

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2021-00087	NR	Malfunction	Apollo Endosurgery, Inc.	9/20/2021	OCW	Overstitch Endoscopic Suturing System	Insufficient Information	Abdominal Pain; Fever; Vomiting; Gastrointestinal Hemorrhage
3006722112-2021-00071	6/8/2021	Malfunction	Apollo Endosurgery, Inc.	8/4/2021	OCW	Overstitch Endoscopic Suturing System	Appropriate Term/ Code Not Available	Pneumonia; Respiratory Tract Infection
3006722112-2021-00057	6/5/2021	Malfunction	Apollo Endosurgery, Inc.	7/6/2021	OCW	Overstitch Endoscopic Suturing System	Insufficient Information	Failure of Implant
3006722112-2021-00044	5/12/2021	Malfunction	Apollo Endosurgery, Inc.	6/29/2021	OCW	Overstitch Endoscopic Suturing System	Mechanical Problem; Mechanical Jam	Appropriate Clinical Signs, Symptoms, Conditions Term/ Code Not Available
3006722112-2021-00052	5/25/2021	Malfunction	Apollo Endosurgery, Inc.	6/23/2021	LTI	Overstitch Endoscopic Suturing System	Mechanical Jam	Perforation
3006722112-2021-00045	NR	Injury	Apollo Endosurgery, Inc.	6/18/2021	OCW	Overstitch Endoscopic Suturing System	Insufficient Information	Bowel Perforation
3006722112-2021-00058	4/13/2021	Malfunction	Apollo Endosurgery, Inc.	6/14/2021	OCW	Overstitch Endoscopic Suturing System	Entrapment of Device; Difficult to Remove	Device Embedded In Tissue or Plaque
3006722112-2020-00113	10/19/2020	Injury	Apollo Endosurgery	11/19/2020	OCW	Overstitch Endoscopic Suturing System	Entrapment of Device; Difficult to Remove	Device Embedded In Tissue or Plaque

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2019-00172	9/16/2019	Malfunction	Apollo Endosurgery, Inc.	1/3/2020	OCW	Overstitch Endoscopic Suturing System	Entrapment of Device; Detachment of Device or Device Component; Mechanical Jam; Positioning Problem	Suture Abrasion; Patient Problem/ Medical Problem
3006722112-2019-00197	10/1/2019	Malfunction	Apollo Endosurgery, Inc.	12/16/2019	OCW	Overstitch Endoscopic Suturing System	Entrapment of Device; Difficult to Remove; Mechanical Jam	Suture Abrasion; Patient Problem/ Medical Problem
12165605	7/9/2021	Malfunction	Apollo Endosurgery, Inc.	7/14/2021	OCW	Overstitch Endoscopic Suturing System Needle Driver And Anchor Exchange	Physical Resistance/ Sticking	Insufficient Information
3005099803-2023-07140	12/19/2023	Malfunction	Apollo Endosurgery	1/10/2024	OCW	Overstitch Sx Endoscopic Suture System	Entrapment of Device; Detachment of Device or Device Component; Device-Device Incompatibility	No Clinical Signs, Symptoms or Conditions
3005099803-2023-07020	12/6/2023	Malfunction	Apollo Endosurgery, Inc	1/4/2024	OCW	Overstitch Sx Endoscopic Suture System	Entrapment of Device	No Clinical Signs, Symptoms or Conditions
3005099803-2023-06588	10/3/2023	Malfunction	Apollo Endosurgery, Inc.	12/7/2023	OCW	Overstitch Sx Endoscopic Suture System	Device-Device Incompatibility; Difficult to Open or Close	No Clinical Signs, Symptoms or Conditions
3006722112-2023-00061	3/2/2023	Malfunction	Apollo Endosurgery, Inc	3/31/2023	OCW	Overstitch Sx Endoscopic Suturing System	Insufficient Information	Perforation of Esophagus

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2023-00129	3/1/2023	Malfunction	Apollo Endosurgery, Inc	5/26/2023	OCW	Overstitch Sx¿ Endoscopic Suturing System	Adverse Event Without Identified Device or Use Problem	Failure of Implant; Liver Damage/ Dysfunction; Pancreatitis; Unspecified Kidney or Urinary Problem
3006722112-2023-00217	10/11/2023	Malfunction	Apollo Endosurgery, Inc.	11/3/2023	OCW	Overstitch Endoscopic Suture System	Material Integrity Problem	Insufficient Information; Appropriate Clinical Signs, Symptoms, Conditions Term/ Code Not Available
3006722112-2023-00211	10/8/2023	Injury	Apollo Endosurgery, Inc.	11/2/2023	OCW	Overstitch Endoscopic Suture System	Insufficient Information	Failure of Implant; Pneumonia; Sepsis
3006722112-2023-00195	6/29/2023	Malfunction	Apollo Endosurgery, Inc.	9/20/2023	OCW	Overstitch Endoscopic Suture System	Difficult to Remove; Activation, Positioning or Separation Problem	Insufficient Information; Appropriate Clinical Signs, Symptoms, Conditions Term/ Code Not Available
3006722112-2023-00179	12/12/2022	Malfunction	Apollo Endosurgery, Inc.	9/15/2023	OCW	Overstitch Endoscopic Suture System	Material Perforation; Mechanical Jam	Laceration(s) of Esophagus

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2023-00125	4/28/2023	Malfunction	Apollo Endosurgery, Inc.	6/12/2023	OCW	Overstitch Endoscopic Suture System	Mechanical Problem	Appropriate Clinical Signs, Symptoms, Conditions Term/ Code Not Available
3006722112-2023-00086	NR	Malfunction	Apollo Endosurgery, Inc	5/15/2023	OCW	Overstitch Endoscopic Suture System	Adverse Event Without Identified Device or Use Problem	Perforation of Vessels; Bowel Perforation
3006722112-2023-00075	NR	Malfunction	Apollo Endosurgery, Inc	4/12/2023	OCW	Overstitch Endoscopic Suture System	Migration	Perforation
3006722112-2023-00076	NR	Malfunction	Apollo Endosurgery, Inc	4/10/2023	OCW	Overstitch Endoscopic Suture System	Migration	Peritonitis
3006722112-2023-00072	NR	Malfunction	Apollo Endosurgery, Inc	3/31/2023	OCW	Overstitch Endoscopic Suture System	Migration or Expulsion of Device; Migration	Syncope/ Fainting; Gastrointestinal Hemorrhage
3006722112-2023-00056	NR	Malfunction	Apollo Endosurgery, Inc	3/15/2023	OCW	Overstitch Endoscopic Suture System	No Apparent Adverse Event	Gastrointestinal Hemorrhage
3006722112-2023-00008	10/25/2022	Malfunction	Apollo Endosurgery, Inc	2/2/2023	OCW	Overstitch Endoscopic Suture System	No Apparent Adverse Event	Hemorrhage/ Bleeding; Vomiting
3006722112-2022-00138	9/12/2022	Death	Apollo Endosurgery, Inc	1/13/2023	OCW	Overstitch Endoscopic Suture System	Adverse Event Without Identified Device or Use Problem	Pulmonary Embolism; Cardiac Arrest

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2023-00206	9/24/2023	Malfunction	Apollo Endosurgery, Inc	10/30/2023	OCW	Overstitch Endoscopic Suturing System	Adverse Event Without Identified Device or Use Problem	Cardiac Arrest
3006722112-2023-00197	NR	Malfunction	Apollo Endosurgery, Inc	10/9/2023	OCW	Overstitch Endoscopic Suturing System	Adverse Event Without Identified Device or Use Problem	Hemorrhage/ Bleeding
3006722112-2023-00171	8/14/2023	Malfunction	Apollo Endosurgery, Inc.	9/8/2023	OCW	Overstitch Endoscopic Suturing System	Premature Separation	Failure of Implant
3006722112-2023-00154	7/18/2023	Malfunction	Apollo Endosurgery, Inc.	8/15/2023	OCW	Overstitch Endoscopic Suturing System	Entrapment of Device; Difficult to Remove	Device Embedded In Tissue or Plaque
3006722112-2023-00145	2/8/2023	Malfunction	Apollo Endosurgery, Inc	7/21/2023	OCW	Overstitch Endoscopic Suturing System	Material Perforation	Laceration(s) of Esophagus
3006722112-2023-00134	6/12/2022	Malfunction	Apollo Endosurgery, Inc	6/27/2023	OCW	Overstitch Endoscopic Suturing System	Migration	Abdominal Pain; Diarrhea; Perforation; Vomiting
3006722112-2023-00138	NR	Malfunction	Apollo Endosurgery, Inc	6/27/2023	OCW	Overstitch Endoscopic Suturing System	Adverse Event Without Identified Device or Use Problem	Hemorrhage/ Bleeding; Ulcer
3006722112-2023-00135	NR	Malfunction	Apollo Endosurgery, Inc	6/21/2023	OCW	Overstitch Endoscopic Suturing System	Adverse Event Without Identified Device or Use Problem	Pulmonary Embolism; Hemorrhage/ Bleeding; Nausea; Pain

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2023-00137	NR	Malfunction	Apollo Endosurgery, Inc	6/21/2023	OCW	Overstitch Endoscopic Suturing System	Fluid/ Blood Leak	Appropriate Clinical Signs, Symptoms, Conditions Term/ Code Not Available
3006722112-2023-00133	NR	Malfunction	Apollo Endosurgery, Inc	6/21/2023	OCW	Overstitch Endoscopic Suturing System	Migration	Hemorrhage/ Bleeding; Pain; Ulcer; Pancreatitis
3006722112-2023-00113	5/5/2023	Malfunction	Apollo Endosurgery, Inc.	6/5/2023	OCW	Overstitch Endoscopic Suturing System	Difficult to Fold, Unfold or Collapse; Unintended Collision	Appropriate Clinical Signs, Symptoms, Conditions Term/ Code Not Available
3006722112-2023-00110	4/19/2023	Malfunction	Apollo Endosurgery, Inc	6/5/2023	OCW	Overstitch Endoscopic Suturing System	Insufficient Information; Loosening of Implant Not Related to Bone-Ingrowth	Appropriate Clinical Signs, Symptoms, Conditions Term/ Code Not Available
3006722112-2023-00127	NR	Malfunction	Apollo Endosurgery, Inc	5/31/2023	OCW	Overstitch Endoscopic Suturing System	Insufficient Information	Hemorrhage/ Bleeding
3006722112-2023-00123	NR	Malfunction	Apollo Endosurgery, Inc	5/30/2023	OCW	Overstitch Endoscopic Suturing System	Appropriate Term/ Code Not Available	Chest Pain; Fever; Hemorrhage/ Bleeding; Implant Pain
3006722112-2023-00122	NR	Malfunction	Apollo Endosurgery, Inc	5/30/2023	OCW	Overstitch Endoscopic Suturing System	Adverse Event Without Identified Device or Use Problem	Hemorrhage/ Bleeding; Liver Damage/ Dysfunction; Pain

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2023-00106	NR	Malfunction	Apollo Endosurgery, Inc	5/23/2023	OCW	Overstitch Endoscopic Suturing System	Adverse Event Without Identified Device or Use Problem	Fistula; Hemorrhage/ Bleeding; Perforation; Ulcer
3006722112-2023-00090	4/24/2023	Malfunction	Apollo Endosurgery, Inc.	5/19/2023	OCW	Overstitch Endoscopic Suturing System	Mechanical Problem; Mechanical Jam	Appropriate Clinical Signs, Symptoms, Conditions Term/ Code Not Available
3006722112-2023-00100	NR	Malfunction	Apollo Endosurgery, Inc	5/18/2023	OCW	Overstitch Endoscopic Suturing System	Adverse Event Without Identified Device or Use Problem	Pulmonary Embolism; Hemorrhage/ Bleeding; Perforation
3006722112-2023-00104	NR	Malfunction	Apollo Endosurgery, Inc	5/18/2023	OCW	Overstitch Endoscopic Suturing System	Adverse Event Without Identified Device or Use Problem	Hemorrhage/ Bleeding; Pancreatitis
3006722112-2023-00101	NR	Malfunction	Apollo Endosurgery, Inc	5/18/2023	OCW	Overstitch Endoscopic Suturing System	Mechanical Problem	Hemorrhage/ Bleeding; Perforation of Esophagus
3006722112-2023-00121	NR	Malfunction	Apollo Endosurgery, Inc	5/18/2023	OCW	Overstitch Endoscopic Suturing System	Insufficient Information	Fistula; Sepsis
3006722112-2023-00098	NR	Malfunction	Apollo Endosurgery, Inc	5/17/2023	OCW	Overstitch Endoscopic Suturing System	Adverse Event Without Identified Device or Use Problem	Pulmonary Embolism; Dehydration; Thrombosis/ Thrombus
3006722112-2023-00099	NR	Malfunction	Apollo Endosurgery, Inc	5/17/2023	OCW	Overstitch Endoscopic Suturing System	Adverse Event Without Identified Device or Use Problem; Migration	Abdominal Pain; Hemorrhage/ Bleeding; Ulcer

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2023-00097	NR	Malfunction	Apollo Endosurgery, Inc	5/16/2023	OCW	Overstitch Endoscopic Suturing System	Partial Blockage	Obstruction/ Occlusion; Thrombosis/ Thrombus
3006722112-2023-00096	NR	Malfunction	Apollo Endosurgery, Inc	5/16/2023	OCW	Overstitch Endoscopic Suturing System	Leak/ Splash	Hemorrhage/ Bleeding
3006722112-2023-00095	NR	Malfunction	Apollo Endosurgery, Inc	5/16/2023	OCW	Overstitch Endoscopic Suturing System	Migration	Vomiting; Obstruction/ Occlusion
3006722112-2023-00094	NR	Malfunction	Apollo Endosurgery, Inc	5/16/2023	OCW	Overstitch Endoscopic Suturing System	Adverse Event Without Identified Device or Use Problem	Abdominal Pain; Perforation of Esophagus
3006722112-2023-00087	NR	Malfunction	Apollo Endosurgery, Inc	5/15/2023	OCW	Overstitch Endoscopic Suturing System	Material Perforation; Migration	Abdominal Pain; Perforation of Vessels; Bowel Perforation
3006722112-2023-00082	4/11/2023	Malfunction	Apollo Endosurgery, Inc.	5/12/2023	OCW	Overstitch Endoscopic Suturing System	No Apparent Adverse Event; Insufficient Information	Insufficient Information; Appropriate Clinical Signs, Symptoms, Conditions Term/ Code Not Available
3006722112-2023-00088	NR	Malfunction	Apollo Endosurgery, Inc	5/12/2023	OCW	Overstitch Endoscopic Suturing System	Patient Device Interaction Problem	Perforation of Esophagus

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2023-00039	NR	Malfunction	Apollo Endosurgery, Inc	2/21/2023	OCW	Overstitch Endoscopic Suturing System	Adverse Event Without Identified Device or Use Problem	Perforation; Perforation of Vessels; Perforation of Esophagus
3006722112-2023-00027	12/15/2022	Malfunction	Apollo Endosurgery, Inc	2/14/2023	OCW	Overstitch Endoscopic Suturing System	Difficult to Insert; Difficult to Advance	Appropriate Clinical Signs, Symptoms, Conditions Term/ Code Not Available
3006722112-2023-00004	1/4/2023	Malfunction	Apollo Endosurgery, Inc	1/31/2023	OCW	Overstitch Endoscopic Suturing System	Material Perforation	Hemorrhage/ Bleeding
3006722112-2023-00010	NR	Malfunction	Apollo Endosurgery, Inc	1/25/2023	OCW	Overstitch Endoscopic Suturing System	Adverse Event Without Identified Device or Use Problem	Post Operative Wound Infection
3006722112-2022-00088	8/12/2022	Malfunction	Apollo Endosurgery, Inc.	9/6/2022	OCW	Overstitch Endoscopic Suturing System	Adverse Event Without Identified Device or Use Problem	Gastrointestinal Hemorrhage
3006722112-2022-00065	4/25/2022	Malfunction	Apollo Endosurgery, Inc.	6/21/2022	OCW	Overstitch Endoscopic Suturing System	Adverse Event Without Identified Device or Use Problem	Pain; Malaise; Cramp(s)/ Muscle Spasm(s)
3006722112-2022-00047	NR	Malfunction	Apollo Endosurgery, Inc.	5/27/2022	OCW	Overstitch Endoscopic Suturing System	Appropriate Term/ Code Not Available	Appropriate Clinical Signs, Symptoms, Conditions Term/ Code Not Available

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2022-00042	4/5/2022	Malfunction	Apollo Endosurgery, Inc.	5/7/2022	OCW	Overstitch Endoscopic Suturing System	Mechanical Problem	Appropriate Clinical Signs, Symptoms, Conditions Term/ Code Not Available
3006722112-2022-00030	2/16/2022	Malfunction	Apollo Endosurgery, Inc.	3/17/2022	OCW	Overstitch Endoscopic Suturing System	Mechanical Problem; Detachment of Device or Device Component	Perforation
3006722112-2022-00027	2/10/2022	Malfunction	Apollo Endosurgery, Inc.	3/8/2022	OCW	Overstitch Endoscopic Suturing System	Mechanical Problem; Mechanical Jam	Perforation
3006722112-2021-00116	NR	Malfunction	Apollo Endosurgery, Inc.	12/8/2021	OCW	Overstitch Endoscopic Suturing System	Insufficient Information	Nausea; Vomiting; Gastrointestinal Hemorrhage
3006722112-2021-00114	NR	Malfunction	Apollo Endosurgery, Inc.	11/17/2021	OCW	Overstitch Endoscopic Suturing System	Adverse Event Without Identified Device or Use Problem	Hematoma; Genital Bleeding
3006722112-2020-00007	1/9/2020	Malfunction	Apollo Endosurgery, Inc.	1/20/2020	OCW	Overstitch Endoscopic Suturing System	Difficult to Remove	Patient Problem/ Medical Problem
3006722112-2020-00002	11/19/2019	Malfunction	Apollo Endosurgery, Inc.	1/7/2020	OCW	Overstitch Endoscopic Suturing System	Difficult to Remove	Patient Problem/ Medical Problem
3006722112-2019-00176	9/25/2019	Malfunction	Apollo Endosurgery, Inc.	12/16/2019	OCW	Overstitch Endoscopic Suturing System	Material Integrity Problem; Material Twisted/ Bent	No Code Available

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem
3006722112-2019-00193	11/6/2019	Malfunction	Apollo Endosurgery, Inc.	12/10/2019	OCW	Overstitch Endoscopic Suturing System	Insufficient Information	No Code Available
3006722112-2022-00083	NR	Malfunction	Apollo Endosurgery, Inc.	8/30/2022	OCW	Overstitch Endoscopic Suture System	Insufficient Information	Hemorrhage/ Bleeding; Pain

Appendix M References

1. US Food and Drug Administration. Medical Device Recalls. 2024; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm. Accessed February 2023.

2. US Food and Drug Administration. MAUDE - Manufacturer and User Facility Device Experience. 2024; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM. Accessed February 27, 2023.