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المحترمين


الأفاضل / ملاك جميع المؤسسات الصحية الخاصة

تحية طيبة .. وبعد ،،،

الموضوع :- منتجات التخسيس الخاصة بأنظمة بالون المعدة

بالإشارة إلى الموضوع أعلاه ، مرفق لكم بالفي تفاصيل الأجهزة الخاصة بنظام بالون المعدة لجميع الأنواع المستخدمة ...
يرجى من جميع المؤسسات الصحية الخاصة المعنية بالموضوع ضرورة الاستفادة عن النوع المستخدم لديها، مع التأكيد بأن إستخدام مثل هذه الأنظمة تتم فقط عن طريق أطباء الامراض الباطنية والجراحة تخصص الجهاز الهضمي من درجة إختصاصي فأعلى وذلك للاهمية .




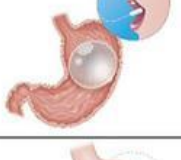
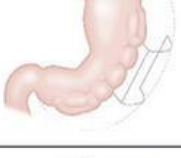



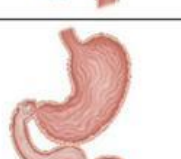
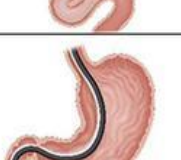
شاكرين لكم حسن تعاونكم معنا دائماً .


الدكتور / مازن بن جواد الخابوري

مدير عام المديرية العامة للمؤسسات الصحية الخاصة



نسخة مع التحية مدراء دوائر المؤسسات الصحية الخاصة بالمحافظات لعمل اللازم والافادة

Primary EMBTs	Illustrations	Description	Efficacy	SAE Rate	FDA Status
Orbera Gastric Balloon (Apollo Endosurgery, Austin, TX)		<ul style="list-style-type: none"> - Single fluid-filled balloon - Endoscopic placement and removal - Filled with 400-700 cc of saline 	11.3% TWL at 1 year ⁶⁶	1.6% Migration, perforation, death ⁶⁶	<ul style="list-style-type: none"> - Approved in 2015 - BMI 30-40 kg/m² - Age 22 or older
Obalon Balloon System (Obalon Therapeutics, Carlsbad, CA)		<ul style="list-style-type: none"> - Gas-filled balloon - Swallowable placement and endoscopic removal - Three balloons administered over 9- to 12-week period - Each balloon filled with 250 cc of a nitrogen mix gas 	10% TWL at 6 months ⁶⁷	0.15% Severe pain, perforation ⁶⁷	<ul style="list-style-type: none"> - Approved in 2016 - BMI 30-40 kg/m² - Age 22 or older
Spatz3 Adjustable Balloon System (Spatz Medical, Great Neck, NY)		<ul style="list-style-type: none"> - Single fluid-filled balloon with a connecting tube for volume adjustment - Endoscopic placement and removal - Filled with 400-550 cc of saline with methylene blue - Volume may be adjusted down to 300 cc or up to 800 cc 	14.9% TWL at 8 months ¹⁰⁵	5.3% Persistent accommodati ve GI symptoms ¹⁰⁵	<ul style="list-style-type: none"> - Under FDA review - Pivotal trial completed
Ellipse Balloon (Allurion Technologies, Wellesley, MA)		<ul style="list-style-type: none"> - Single fluid-filled balloon - Swallowable with fluoroscopic guidance for placement and self-emptying mechanism at 4 months for removal - Filled with 550 cc of saline 	Data pending pivotal trial	N/A	<ul style="list-style-type: none"> - Under FDA review - Pivotal trial completed
Primary Obesity Surgery Endoluminal (POSE) (USGI Medical, San Clemente, CA)		<ul style="list-style-type: none"> - One of the applications of the Incisionless Operating Platform (IOP) - Endoscopic plications of the fundus (traditional) or gastric body (distal) 	13.2% at 12-15 months (traditional) ⁷⁹ 15-17.8% TWL at 6 and 12 months (distal) ^{80,107,108}	3.2% Chest pain, low-grade fever, extragastric bleeding and hepatic abscess ⁷⁹	<ul style="list-style-type: none"> - Cleared in 2006 for tissue apposition
Endoscopic Sutured/Sleeve Gastroplasty (ESG) (Apollo Endosurgery, Austin, TX)		<ul style="list-style-type: none"> - One of the applications of the Overstitch Endoscopic Suturing System - Endoscopic suturing along the greater curvature of the stomach to create a sleeve-like structure 	16.5% TWL at 1 year ⁷³	2.2% Severe pain, nausea, GI bleeding, leak, fluid collection ⁷³	<ul style="list-style-type: none"> - Cleared in 2008 for tissue apposition - In U.S. clinical trial
Aspiration Therapy (Aspire Bariatrics, King of Prussia, PA)		<ul style="list-style-type: none"> - A 26-French gastrostomy tube with 15 cm internal fenestrated drainage catheter - Endoscopic placement and removal - Patients aspirate 25% to 30% of ingested calories at 30 minutes after meals 	17.8% TWL at 1 year ⁸¹	4.1% Buried bumper, peritonitis, severe pain, ulcer, product malfunction ⁸¹	<ul style="list-style-type: none"> - Approved in 2016 - BMI 35-55 kg/m² - Age 22 or older
Transpyloric Shuttle (BAROnova Inc, Goleta, CA)		<ul style="list-style-type: none"> - A spherical bulb tethered to a smaller cylindrical bulb - Endoscopic placement and removal - Located across the pylorus creating intermittent obstruction 	9.5% TWL at 1 year ¹⁰⁶	2.8% Device impaction, esophageal rupture, pneumothora x, pain, ulcer, vomiting ¹⁰⁶	<ul style="list-style-type: none"> - Approved in 2019 - Currently unavailable
Duodenal-jejunal Bypass Liner (GI Dynamics, Boston, MA)		<ul style="list-style-type: none"> - A 60 cm fluoropolymer liner anchored at the duodenal bulb and ending at the jejunum - Endoscopic placement and removal 	Data pending pivotal trial	N/A	<ul style="list-style-type: none"> - Not currently FDA approved - In U.S. clinical trial
Duodenal Mucosal Resurfacing (Fractyl, Lexington, MA)		<ul style="list-style-type: none"> - Endoscopic thermal ablation of the duodenal mucosa using a balloon filled with heated water 	Data pending pivotal trial	N/A	<ul style="list-style-type: none"> - Not currently FDA approved - In U.S. clinical trial

