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Patient Information Leaflet

The RESET System

What is the RESET System used for?

The RESET® System is intended to be used as an adjunct therapy to lifestyle and/or medication(s) for the management of morbid obesity and/or obesity in the presence of at least one concurrent cardiometabolic risk factor, e.g. type 2 diabetes and/or dyslipidemia and to prevent contact of ingested nutrients with the mucosal lining of the duodenum and proximal jejunum (for the RESET® Liner). The RESET® System is intended for patients ≥ 21 and ≤ 65 years old.

What is the Indication of Use?

The RESET® System is indicated for the management of morbid obesity in adult patients with BMI ≥40 kg/m2 or patients with BMI ≥30 kg/m2 with at least one concurrent cardiometabolic risk factor, e.g. type 2 diabetes or dyslipidemia.

Product Description and Intended Purpose

The RESET System is intended to be used as an adjunct therapy to lifestyle and/or medication(s) for the management of morbid obesity and/or obesity in the presence of at least one concurrent cardiometabolic risk factor, e.g., type 2 diabetes and/or dyslipidemia. It is also intended to prevent contact of ingested nutrients with the mucosal lining of the duodenum and proximal jejunum (via the RESET Liner) in patients described above in order to promote weight loss, weight-loss mediated glycemic control and to minimize the likelihood of obesity-related complications such as cardiovascular disease and/or deterioration of underlying type 2 diabetes.
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Implant Duration

The RESET® Liner is intended for an implant duration of 9 months.

Special Operating Instructions

Only physicians trained in therapeutic endoscopic techniques should use this product.

Contraindications

The RESET Liner is contraindicated in the following subjects:

- Patients <21 years old and patients >65 years old due to lack of relevant clinical data
- Patient with BMI>55 kg/m2 due to lack of relevant clinical data
- Women who are pregnant or plan to become pregnant while implanted with the RESET Liner.
- Previous GI surgery that could preclude the ability to place the RESET Liner or affect the function of the RESET Liner or abnormal GI anatomical finding that could preclude the ability to place the RESET Liner or affect the function of the RESET Liner
- Known history of liver disease (e.g., viral, autoimmune, cirrhosis etiology, but not including incidental fatty liver)
- Known history of renal disease (e.g., kidney stones)
- Prior history of an abscess requiring hospitalization, intravenous antibiotics or drainage
- Previous treatment for severe liver disease and/or biliary tract disease, including but not limited to, surgery, bile duct dilatation, and stent placement
- Diagnosis of type 1 diabetes mellitus or having any history of ketoacidosis
- Male patients with serum creatinine (Cr) >1.5 mg/dl or female patients with Cr >1.4 mg/dl
- Iron deficiency anemia <12 Hb
- Uncorrectable bleeding diathesis, platelet dysfunction, thrombocytopenia with platelet count less than 100,000/microliter, or known coagulopathy
- Height < 152 cm (5 feet)
- History of pancreatitis, including gallstone related pancreatitis (subsequent to which has cholecystectomy)
- Diagnosis of autoimmune connective tissue disorder (e.g. lupus erythematosus, scleroderma)
- Active or recent (less than 12 months) gastroesophageal reflux disease (GERD)
- Thyroid disease unless controlled with medication
- Currently taking prescription antithrombotic therapy (e.g. anticoagulant or antiplatelet agent) within 10 days prior to RESET Liner implant.
- Inability to discontinue drugs known to affect GI motility (e.g. metoclopramide), prescription or over-the-counter weight loss medication(s), Proton Pump Inhibitor (PPI), Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), aspirin, ibuprofen, and other anti-inflammatory medication for study duration, medications known to cause significant weight gain or weight loss (e.g. chemotherapeutics), supplements that are known or suspected to increase bleeding risk (e.g. Gingko biloba, Ginseng, Vitamins C & E, Turmeric, St. John's wort, Evening primrose oil, Feverfew, and Green Tea Extract)
- Allergy or hypersensitivity to cephalosporins or penicillin and all equivalent antibiotics
- Active H. pylori

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- History of Crohn's disease, atresias or untreated stenoses
- Abnormal pathologies or conditions of the gastrointestinal tract, including ulcers or upper gastrointestinal bleeding conditions, esophageal or gastric varices.
- Poor dentition not allowing complete chewing of food
- History or observation of psychological disorder or behavior which could preclude compliance to the RESET Liner.
- Any condition that increases red cell turnover, such as thalassemia
- Existence of (>5 cm string test) Pseudomonas aeruginosa, Stenotrophomonas maltophilia and/or Klebsiella pneumoniae serotype K1 and K2 as a result of oral swab
- A known sensitivity to nickel, titanium or stainless steel

Potential Adverse Events

As with all endoscopic and/or implant procedures, serious injury or death can occur.
Your physician will discuss all possible complications and adverse events with your patient. Complications that may result from the use of this product include the risks associated with the medications and methods utilized in the endoscopic procedure, anesthesia risks, the risks associated with any endoscopic procedure, the risks associated with the RESET® Delivery System, RESET® Liner, and the risks associated with the patient's degree of intolerance to a foreign object placed in the duodenum.

Any complication that could possibly be related to RESET® System must be reported quickly to your physician.

Potential complications related to the device include:

- Adverse patient reaction, e.g. allergic, rash, acute cytotoxicity)
- Alopecia
- Aspiration, Adynamic ileus
- Biliary Disease which could lead to Hepatic Abscess
- Bleeding – Major, Minor
- Environmental contamination
- Dehydration/headache/Hyper- Hypotension
- Delayed/difficult delivery or retrieval resulting in prolonged anesthesia
- Diarrhea
- Dizziness
- Esophageal/Oropharyngeal Perforation
- Esophageal scratch
- Esophageal Tear
- Flatulence/bloating
- Gallstones/cholecystitis
- GERD, Esophagitis
- Hepatic Abscess (HA)
- Hypoglycemia or Hyperglycemia
- Illness/injury
- Infection (Other than HA)
- Intestinal intussusceptions
- Irritation, tissue damage, Pseudopolyps, inflammation
- Nausea/Vomiting, Weakness
- Pain (Major)
- Pain (Minor)
- Pancreatitis, biliary disease
- Perforation
- Personnel contamination
- Prolonged anesthesia
- Reduced efficacy
- Surgical Procedure needed
- Toxic Response
- Ulceration
- Vitamin and Mineral Deficiency, Constipation, dehydration, diarrhea
- Second endoscopic procedure needed

Potential complications during the treatment period may include:

- Infections due to implant of non-sterile device.
- Cytotoxic and allergic reactions due device incompatibility.
- Abdominal pain and constipation, nausea, and vomiting related to intolerance of the implanted device.
- Hyperglycemia and hypoglycemia due improper glucose control during implant.
- Vitamin and mineral deficiency due to possible malabsorption Known risks as it pertains to endoscopy and general anesthesia

Potential complications during and after RESET Liner removal may include

- Hepatic abscess - a hepatic abscess may form
- **Biliary Disease which could lead to Hepatic Abscess**
- Bleeding - in rare cases, significant bleeding that may result in surgery and/or transfusion may occur
- GI tract laceration
- Oropharyngeal perforation
- Esophageal perforation
- Gastric perforation
- Bowel perforation
- Adynamic ileus
- Infection with and without fever

- Pancreatitis (with or without bile duct blockage)
- Biliary disease/cholelithiasis
- Inability to remove RESET® Liner endoscopically, resulting in surgical removal
- Prolonged procedure time
- Complications associated with an endoscopic procedure (i.e., sore throat or deep vein thrombosis)
- Headache
- Alopecia
- Abdominal pain
- Pain– flank/back
- GERD
- Hypoglycemia
- Hyperglycemia
- Concurrent illness
- Diarrhea
- Constipation
- Serum chemistry changes
- Vitamin and mineral deficiency
- Liner migration/rotation
- Nausea/vomiting
- Weakness

MRI Information

A patient with the RESET® Liner can be scanned safely immediately after placement under the following conditions:

MRI Safety Information

MR Conditional

The **RESET Liner** is MR Conditional. A patient with the **RESET Liner** may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Parameter	***Condition of Use/Information***
Static Magnetic Field Strength (T)	1.5-Tesla and 3.0-Tesla
Static Magnetic Field Orientation	Horizontal
Maximum Spatial Field Gradient (T/m and gauss/cm)	5-T/m (500-gauss/cm)
RF Excitation Polarization	Circularly Polarized (CP) (i.e., Quadrature-Transmission)
Transmit RF Coil	Any transmit RF coil may be used
Receive RF Coil	Any receive-only RF coil may be used
MR System Operating Mode	Normal Operating Mode
Maximum Whole Body Averaged SAR (W/kg)	2-W/kg (Normal Operating Mode)
Scan Duration and Wait Time	Whole body averaged SAR of 2-W/kg for 60 minutes of continuous RF exposure (i.e., per pulse sequence or back-to-back sequences/series without breaks)

MR Image Artifact	The presence of the RESET Liner may produce an MR image artifact. Imaging protocol modifications may be necessary to compensate for the MR image artifact.

Material Information

RESET Liner

Materials	*Weight (g)*	*% Composition*
ePTFE and FEP	1.50	56.4%
NiTi	.84	31.6%
304 Stainless Steel	0.26	9.8%
UHMWPE	0.03	1.12%
Platinum	0.02	0.88%
Iridium	<0.01	<.0.1%

RESET Delivery System (not including RESET Liner)

Materials	*Weight (g)*	*% Composition*
Acrylonitrile Butadiene Styrene (ABS) AX98567H	63.10	49.98%
304 Stainless Steel	26.70	21.15%
PEBAX 7033	9.5	7.5%
70% Petrothene LR734001	7.42	5.88%
Acrylonitrile Butadiene Styrene (ABS) Lustran 348	3.90	3.09%
30% Petrothene NA951000	3.18	2.52%
Polycarbonate	1.20	0.95%
Copper C12200	1.00	0.79%
Polypropylene (RTP 199 X 106730)	1.00	0.79%
NiTi	0.12	0.1%
Vestamid ML21	0.10	0.1%
ETR Silicone Elastomer	0.06	0.05%
UHMWPE	<0.01	<0.1%
Cool Grey (HCGYO 390-3)	<0.01	<0.1%
Teal (UN5011)	<0.01	<0.1%
Ink Tosh STB EC Black w/ 25% C1 Hardener	<0.01	<0.1%
PTFE Lubriskin Coating (or eq)	<0.01	<0.1%

Remainder accounted for by adhesive/primer

Implant Card

You must keep a record of your implant. You will be provided with a patient implant card. An explanation of the symbols found on your Implant Card is given below.

Precautions and Warnings

Pre-procedural precautions

- Please do not take anticoagulants (aspirin, heparin, NSAIDs, etc.) for 10 days prior to RESET® Liner placement and for the duration of treatment.
- Individuals with known allergies or hypersensitivity to ceftriaxone, cephalosporins or penicillins should seek an equivalent, long-acting, broad-spectrum antibiotic. Please see antibiotic package insert for full prescribing information and details.
- Please take an over-the-counter H2-receptor antagonist, 40mg/BID from two-weeks prior to when the RESET® Liner is implanted to two weeks after the RESET® Liner is explanted.

Post-procedural Precautions

- Immediately contact the doctor in case of fever, shivering, or pain to ensure that the patient is treated in due time in case of a hepatic abscess.
- Daily monitoring of the body temperature is recommended to identify any potential infection resulting in hepatic abscess.
- Certain foods (such as seeds and nuts) or lack of adequate hydration can interfere with the proper functioning of the RESET® Liner. Therefore, do not eat seeds and nuts and follow the diet regimen outlined by your physician. If a soft food diet is not applied,
- Food could shift the device, causing bleeding.
- The Delivery System Deployment Ball is left in the body and passes naturally, without need for retrieval, within 24 hours.

Explanation of Symbols on Implant Card

	Patient Name or patient ID
	Date of Implantation
	Name and Address of the implanting healthcare institution/provider
	Manufacturer
	Information website for patients
Device Type	Duodenal-Jejunal Bypass Liner
	Medical Device
	Catalog Number
	Lot Number
	Unique device identifier

Safety and Clinical Performance

For the Summary of Safety and Clinical Performance (SSCP) please visit https://eu.morphicmed.com and, once operational, https://ec.europa.eu/tools/eudamed/#/screen/home

Vigilance

For product information, serious incident reports, complaints or general feedback, contact a Morphic
DE: +49 30 40 50 45 33 10
US: +1 (781) 357 3300
Email: CustomerService@MorphicMed.com

Any serious incident that has occurred in relation to the RESET® System should be reported to Morphic Medical and the competent authority of the Member State in which the user and/or patient is established.

Contact Information

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