FRACTYL

Revita® System

INSTRUCTIONS FOR USE - ENGLISH

System Use Description

The Revita Catheter and the Line Set are provided sterile and for single use only. The devices are not implantable or reusable. The Catheter and Line Set are used with the Revita Console, which is an electromechanical device that controls the ablation cycle and circulates hot and cold fluid to the Catheter via the Line Set. The Revita System is used in a suitably equipped endoscopy suite. The catheter contacts the patient's digestive tract (mouth to duodenum) for approximately 45-60 minutes, which is the duration of a typical Duodenal Mucosal Resurfacing (DMR) procedure. It is important to note that product use, treatment delivered, and method for delivery are the same across indications. Consult Operator's Manual for more information on set-up and use.

Indications for Use

The Revita System is a hydrothermal ablation system of the duodenal mucosa with insulin-sensitizing properties intended as an adjunct to diet and exercise to:

- improve glycemic control in patients with Type 2 diabetes who have preserved pancreatic beta cell function and whose diabetes is poorly controlled despite oral and/or injectable glucose lowering medications and/or long-acting insulin therapy;
- reduce liver fat in patients with Type 2 diabetes and non-alcoholic fatty liver disease;
- improve insulin sensitivity in insulin-resistant women with PCOS, and this effect is known to improve ovulation rates in PCOS.

Patient Contraindications

The use of the Fractyl Revita DMR System is excluded in patients with the following conditions:

- Diagnosed with Type 1 Diabetes or with a recent history of ketoacidosis
- More than one severe hypoglycemic event within the past year, as defined by need for third-party assistance
- Active H.pylori infection (Patients with active H. pylori may be treated if they receive treatment for H. pylori first.)
- Previous gastrointestinal (GI) surgery that could affect the ability to treat the duodenum such as subjects who have had a Billroth II, Roux-en-Y gastric bypass, or other similar procedures or conditions
- Duodenal abnormalities that would interfere with the ability to ablate the length of the post-papillary duodenum to the ligament of Treitz, such as diverticuli, cysts, or erosive duodenitis.
- History of chronic or recent history of acute pancreatitis (within the past year)
- Known acute hepatitis or other active acute liver disease
- Symptomatic gallstones or symptomatic kidney stones, acute cholecystitis
- Known active coagulopathy, or current upper GI bleeding conditions such as ulcers, gastric varices, strictures, or congenital or acquired intestinal telangiectasia
- Use of anticoagulation therapy (such as warfarin) which cannot be discontinued for 7 days before and 14 days after the procedure
- Active systemic infection
- General contraindications to deep sedation or general anesthesia (e.g., ASA score 3 or 4) or to upper GI endoscopy

Special Patient Populations

The Revita System has not been studied in the following populations, and the risk/benefit ratio should be carefully considered by the clinician before using the Revita System in such patients:

- Patients with known intestinal autoimmune disease, as evidenced by a positive Anti-GAD test, including Celiac or Crohn's disease, or pre-existing symptoms of lupus erythematosus, scleroderma or other autoimmune connective tissue disorder affecting the small intestine
- Patients taking P2Y12 inhibitors (clopidogrel, pasugrel, ticagrelor)
- Patients actively taking NSAID (non-steroidal anti-inflammatory drugs)
- Patients taking corticosteroids or drugs known to affect GI motility (e.g. Metoclopramide)
- Pregnant women

Precautions

- Patients who are using anti-diabetic drugs that may expose them to hypoglycemia should actively monitor blood glucose levels.
- Therapy with the Revita System, like other insulin sensitizers, may result in ovulation in some premenopausal anovulatory women. As a result, these patients may be at an increased risk for pregnancy after Revita DMR. Adequate contraception in all premenopausal women is recommended after Revita DMR.

Information for Patients

Therapy with the Revita System, like other treatments that lower insulin levels, may result in ovulation in some women who were previously having troubles with their ovulatory cycles. As a result, these patients may be at an increased risk for pregnancy after Revita DMR. Conversation about the potential for pregnancy and use of adequate contraception is recommended in all premenopausal women after Revita DMR.

Risks

The following potential risks are associated with the procedure:

- abscess formation
- abdominal pain, tightness and cramping
- bleeding
- delayed gastric emptying
- dental injury
- diarrhea
- difficulty swallowing
- fever
- gastric dumping syndrome
- headache
- hypoxia
- infection
- injury to esophagus
- nausea
- non-healing ulcer
- nutritional mal-absorption
- pancreatitis
- perforation
- pneumoperitoneum
- pulmonary aspiration
- sore throat
- stomach or duodenal mucosa stricture and obstruction
- structural damage to the GI tract
- worsening dysglycemic symptoms including hypoglycemia
- release of an egg from an ovary in a woman (ovulation) leading to unplanned pregnancy

Materials and Equipment

- Revita Catheter
- Revita Line Set
- Console Umbilical
- Console

Inspection Prior to Use

Prior to use, inspect the Revita Catheter and Line Set packaging for damage or breach of the sterile packaging seal(s). These products have been inspected and sterilized using Ethylene Oxide gas prior to shipment. Prior to use all equipment to be used during the procedure should be carefully examined to ensure there is no damage and that it functions properly.

CAUTION: The Revita Catheter and Line Set are designed and intended for single patient usage only. Do not re-sterilize and/or reuse Revita catheters.

Potential risks associated with re-sterilization and reuse include:

- Sterility of a reprocessed and re-sterilized devices cannot be assured resulting in potential for infection or disease transfer
- Reduced integrity of the balloon may result in leak or burst
- The integrity of the needles may degrade and cause injury
- Fittings used to connect the catheter and line set may degrade causing leaks and improper performance
- Reuse may prevent the catheter from meeting its performance requirements leading to potential injury

Cleaning and Disinfection

Refer to the Revita Console Operator's Manual for cleaning instructions for the console and reusable console umbilical.

System Set Up and Procedure

Refer to the Revita Console Operator's Manual for details on system preparation and operation. The Revita System is to be used only under the supervision of a Fractyl Field Representative. The following outlines the required procedure sequence.

CAUTION: In the event of device or system failure, the system will default to a safe state. If this occurs, retract the catheter needles and remove the device from the patient. Do not use the Revita System until proper performance is verified by a Fractyl Field Representative.

Prepare Console for Use

1. Power up console and complete the system set up and operational checks per the Revita Console Operator's Manual.
2. Using sterile technique, remove Line Set from packaging.
3. Attach Line Set to the console ensuring proper orientation and ensure all connections are secure.
4. Prepare and attach saline fluid for injection.
5. Attach a vacuum source and canister to the console via the Line Set.

Prepare Revita Catheter for Use

1. Using sterile technique, open the packaging leaving the Revita Catheter in the package tray.
2. Following the touchscreen prompts, attach the Revita Catheter to the console, umbilical, and Line Set.
3. Attach the Revita Catheter luer connectors to three 10mL syringes and place syringes in cradle on console.
4. Follow the touchscreen prompts to verify the Revita Catheter for proper balloon inflation, needle action, and vacuum function. Then prime the Revita Catheter lines with saline by running an injection cycle.

Track Revita Catheter to the Duodenum

1. Complete a screening endoscopy using an endoscope capable of reaching the distal duodenum such as a pediatric colonoscope.
2. Insert a .035" guidewire through the working channel of the endoscope and withdraw the scope leaving the guidewire in the duodenum.
3. Lubricate exterior of Revita Catheter with silicone or other lubricant as commonly used in GI endoscopic procedures.
4. Pass the Revita Catheter trans-orally over the previously placed guidewire to the distal duodenum using fluoroscopy to assist placement.

Perform Mucosal Lifting and Hot Fluid Ablations

CAUTION: Avoid the ampulla during this procedure. If the Revita Catheter does not function properly, turn off the vacuum, deflate the balloon, retract the needles and remove.

1. Insert the endoscope into the proximal duodenum.
2. Position the Revita Catheter balloon just distal to the ampulla under endoscopic visualization.
3. Position the endoscope just proximal to the balloon.
4. Aspirate with the endoscope and follow the touchscreen prompts to inflate the balloon, advance the needles and complete mucosal lifting with saline injection.
5. After injection follow touchscreen prompts to withdraw needles, release vacuum and deflate balloon.
6. Reposition catheter approximately 1cm distally or as needed to create a contiguous lifted region.
7. Repeat steps 4, 5, and 6 until required length of duodenum has been lifted.

CAUTION: It may be necessary to repeat mucosal lifting in the same location or perform localized touch up with an injection needle based on visual assessment to achieve thorough coverage.

8. Retract the balloon into the desired treatment region which has been fully lifted under direct endoscopic visualization.
9. Run the ablation cycle via the touchscreen on the console.
10. Reposition the Revita Catheter and endoscope just distal to the ablated region and repeat steps 4-9 for subsequent mucosal lifts and ablations.

CAUTION: Avoid ablating the same area twice or overlapping ablations.

11. Continue the process of lifting and ablating until the ligament of Treitz is reached.
12. Once the procedure is complete remove the guidewire, the Revita Catheter, and endoscope from the patient.
13. Dispose of the Revita Catheter and Line Set per hospital procedures for bio-hazardous waste disposal.

CAUTION: At the conclusion of the procedure a thorough endoscopic evaluation of the GI tract should be completed to ensure there are no abnormalities.

FRACTYL

Fractyl Laboratories, Inc.
17 Hartwell Avenue
Lexington MA, 02421
USA
Tel.: +1-781-902-8800

EC REP

HealthLink Europe Services
BV De Tweeling 20-22
5215 MC 's-Hertogenbosch
The Netherlands
Tel: +31-13-5479300

PATENT: Fractyl.com/patents/

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