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Principal Investigator	Anastassia Amaro, MD
Study Title:	A Prospective, Randomized, Double-Blind, Sham- Controlled, Multi-Center Pivotal Study to Evaluate the Efficacy and Safety of Duodenal Mucosal Resurfacing Using the Revita® System in Subjects with Type 2 Diabetes on Insulin therapy

Purpose:
The purpose of this study is to demonstrate the efficacy and safety of the Fractyl DMR Procedure using the Revita System compared to a sham procedure. The Revita System is an endoscopic treatment consisting of a single catheter and console designed to lift the duodenal mucosa with saline followed by controlled circumferential hydrothermal ablation of the mucosa.

Brief Description
The Revita® system is being investigated to assess the efficacy of DMR versus Sham on improvement in Glycemic, Hepatic and Cardiovascular endpoints for patients with Type 2 Diabetes who are inadequately controlled with insulin therapy. Subjects randomized to the DMR procedure will be followed per protocol till 48 weeks post treatment. Subjects in the Sham treatment arm will be offered cross over to receive the DMR treatment at 48 weeks and will be followed per protocol for 24 weeks post treatment.

Eligibility
1. Age 21-70 years
2. Diagnosis of Type 2 Diabetes
3. Currently taking 20-60 units/day of basal insulin
4. HbA1c of 7.5-9.5%
5. Body Mass Index (BMI) of 28-40.

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