

Duodenal Mucosal Resurfacing Procedure Training and Implementation



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BACKGROUND

- The duodenum plays a key role in regulating metabolism and is known to be dysfunctional early in the development of metabolic disease such as type 2 diabetes (T2D).
- Revita[®] duodenal mucosal resurfacing (DMR) is a non-pharmacologic, investigational, endoscopic treatment which hydrothermally ablates the duodenal mucosa to restore the metabolic functionality of the duodenum in people with T2D.
- Revita is an investigational device in the US, which has received breakthrough status, and has been evaluated in over 300 patients to date with favorable safety and metabolic benefits observed. As part of the currently enrolling, global, pivotal Revitalize 1 trial for Revita, competency-based training and implementation have evolved to support scalable education of advanced-endoscopist investigators.
- Here, we describe the current Revita endoscopist training program, demonstrate alignment with ASGE* training and effectiveness principles,^{1,2} and provide evidence that training methodology has led to acceptable and consistent safety outcomes in Revitalize 1.**

METHODS AND RESULTS

Figure 1

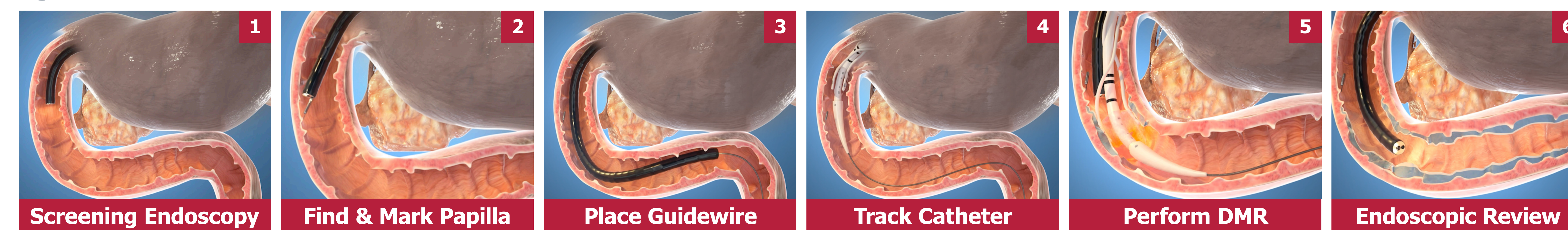


Figure 1. Revita Procedure Workflow and Core Competencies.

The training program consists of three core elements aligned with ASGE principles of effective teaching to enhance proficiency toward safe and efficacious execution of the Revita procedure: 1) Didactic Fractyl Health-led overview of the Revita system, procedure, and core competencies; 2) Hands-on tracking of the Revita catheter through the Revita training simulator (Figure 2); and 3) Fractyl Health-supported live-patient cases focused on the successful execution of the Revita procedure and demonstration of core competencies. Training success was defined as completion of the full program with demonstration of competency in core endoscopy skills and troubleshooting techniques. Procedural success was defined as performing ablations along the anatomical length of the duodenum from immediately beyond the ampulla of Vater to the ligament of Treitz, while minimizing longitudinal gaps between areas of ablated mucosa.

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Figure 2. The Revita DMR Training Simulator and Catheter.

The Revita simulator was developed and validated to complement the didactic component of the training program. The simulator mimics human duodenal anatomy and endoscopic forces to support the development of endoscopic skills necessary to successfully perform the Revita procedure (Figure 1).

Tables 1 and 2. Revitalize 1 Baseline Characteristics and Adverse Events.

The Revita training program, including the Revita simulator, was employed to train advanced therapeutic endoscopists as investigators in Revitalize 1 in 6 centers in the US and EU. All centers successfully completed training in ~3 hours within 2 weeks of their first patient case. To date, nine open-label patients have been treated with 100% procedural success. Baseline characteristics are consistent with uncontrolled T2D despite multiple glucose-lowering medications and insulin (Table 1). Adverse events (AEs) were mild and resolved without sequelae (Table 2). No long-term device- or procedure-related AEs, no device- or procedure-related serious AEs, and no unanticipated AEs have been observed to date.

Table 1

Demographics and Baseline Characteristics	n=9
Sex, % male	66.7
Age, years, median (min, max)	60 (45, 68)
HbA1c, % (min, max)	8.5 (7.6, 9.1)
Body weight, kg, median (min, max)	96 (85, 128)
Diabetes duration, years, median (min, max)	13 (7, 24)



Figure 2

Table 2

AEs Definitely or Probably Related to Device and/or Procedure	n
Sore throat	2
Abdominal bloating	1
Abdominal pain	1

CONCLUSIONS

- Three core elements of the ASGE-aligned Revita training program, inclusive of the Revita simulator, are scalable and have been reproducibly employed to train advanced therapeutic endoscopists to safely perform the Revita procedure with 100% procedural success thus far.**
- Results thus far suggest Revita appears to be a safe, broadly accessible, and disease-modifying approach to treat metabolic disease, such as T2D, via therapeutic endoscopy.³⁻⁸**

*American Society for Gastrointestinal Endoscopy
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