THERMORA by FAST Clinical

Thermal Submucosal Hemorrhoidopexy. A new option for hemorrhoidal disease.

An overview for the Seattle clinical team

PREPARED FOR
THE SEATTLE CLINICAL TEAM

FROM
MERIBEL HEALTH

DATE
MAY 2026

STATUS
CONFIDENTIAL

01 / THE TEAM

Inventors, operators, and clinicians behind the procedure.

AZ

Dr. Anmin Zheng

CO-FOUNDER, MERIBEL HEALTH

Built a multi-billion dollar medical device company listed on the Shanghai Stock Exchange. Leads strategic direction and IP strategy for the anoscope platform.

FS

Dr. Francesco Sias, MD

CO-INVENTOR & LEAD AUTHOR

Serial physician entrepreneur, Dr. Sias Medical Center (Cagliari, Italy). Developed the TSH technique and the proprietary anoscope. First author of the 248-patient 5-year case series.

SS

Stephen Song, MBA

CLINICAL KOL / BIZDEV

Senior medical device leadership at U.S. Surgical, ConMed, Johnson & Johnson, and Karl Storz Endoscopy. Bridges device, hospital, and surgeon networks.

GP

Gareth Pan

CEO & CO-FOUNDER

Operating lead for sales, clinical coordination, product, and partnerships. Owns the patient-direct GTM and the Seattle clinic build.

LM

Dr. Luca Milone, MD FACS

CO-INVENTOR & NYC TRIAL LEAD

Chief of General Surgery, The Brooklyn Hospital Center. Columbia New Technology Fellowship. Co-author on the published outcomes data and NYC controlled trial site lead.

PB

Dr. Peter Billing

SEATTLE CLINICAL ADVISOR

Performing surgeon and clinical operator for the Seattle Thermora clinic. Anchors the first FAST Clinical facility in the Pacific Northwest.

02 / THE DISEASE

Hemorrhoidal disease has high incidence and a real impact on quality of life worldwide.

Hemorrhoidal disease (HD) is the most common proctologic pathology in adults, affecting roughly one in six Western adults. It is the fourth leading outpatient gastrointestinal diagnosis in the United States and drives an estimated $350M–$2.5B in annual US spend.

17%
of adults in Western Europe report symptomatic hemorrhoids

3.5M
US ambulatory care visits per year for HD

20M
procedures performed globally each year (CAGR 10%)

45–65
age of peak incidence across both genders

Hemorrhoidectomy, the current surgical standard, is one of the most painful operations in the GI canon. Severe postoperative pain is reported in 20–40% of patients, recovery runs 2–4 weeks, and postoperative bleeding occurs in up to 10% of cases.

Sources: WHO 2019 procedure volume survey; published HD epidemiology literature; Sias & Milone (2025), Journal of Surgery.

03 / ANATOMY & GRADING

What we treat, and the grades where the evidence is strongest.

Internal hemorrhoids

Vascular cushions in the anal canal above the dentate line that have prolapsed or are causing bleeding. Graded I through IV by the Cleveland Clinic classification.

- Grade I: bleeding without prolapse
- Grade II: prolapse with spontaneous reduction
- Grade III: prolapse requiring manual reduction
- Grade IV: irreducible prolapse

Thermora indication

The published 248-patient cohort consisted of Grade II–III patients. Outcomes data is strongest at these grades.

GRADE II: 12% GRADE III: 88%

Grade IV remains a surgical hemorrhoidectomy indication. Thermora is positioned to take share from the conservative-care and banding population that has failed to resolve.

Reference: Sias F, Milone L. 2025. Thermal Submucosal Hemorrhoidopexy. J Surg 10:11513.

04 / THE STANDARD OF CARE

Milligan-Morgan hemorrhoidectomy: best long-term durability, real patient cost.

The Milligan-Morgan excisional hemorrhoidectomy remains the surgical reference standard because it is the most definitive intervention. The trade-off is a difficult recovery: 20–40% of patients report severe postoperative pain, narcotic use is common for 1–2 weeks, and patients lose multiple working days.

DIMENSION	HEMORRHOIDECTOMY	RUBBER-BAND LIGATION	THD / HAL	THERMORA (TSH)
Mechanism	Excises tissue	Strangulates tissue (necrosis)	Ligates feeding arteries	**Repositions tissue with thermal energy**
Sessions	Single OR procedure	3 sessions, ~6 weeks	Single OR procedure	**Single office visit**
Anesthesia	General or spinal	None	General / regional	**Light IV sedation**
Setting	Hospital / ASC	Office	Operating room	**Office-based clinic**
Recovery	2–4 weeks off work	Mild per session	~1–2 weeks	**Same or next day for most patients**
Severe post-op pain	20–40% of patients	Low	Moderate	**92% report zero pain in first 5 days**

Sources: Sias & Milone (2025); Cleveland Clinic clinical guidance; published comparative literature. US Aetna designated THD/HAL "investigational" in March 2025.

05 / A NEW TREATMENT OPTION

Repositioning, not removal.

Over the last two decades, surgical interventions for hemorrhoidal disease have evolved toward repositioning the hemorrhoidal cushions to their anatomical site rather than excising them. Thermora replaces sutured hemorrhoidopexy with radiofrequency energy to deliver volumetric reduction in a single office visit.

06 / HOW IT WORKS

A proprietary anoscope plus auto-sensing RF generator, in four reproducible steps.

1

Expose

The patented anoscope is inserted in the Sims position. Its operative windows align to the standard hemorrhoidal columns.

2

Deliver

An electrode is placed in the submucosa within 1 cm of the pectinate line. Low-intensity RF is delivered for 5–10 seconds per site.

3

Auto-stop

The auto-sensing generator terminates delivery when target tissue temperature is reached, producing visible whitening and volumetric retraction.

4

Rotate & complete

The anoscope is rotated 180° to address intermediate positions. The full procedure averages 10 minutes from insertion to discharge prep.

DURATION	SEDATION	POSITION	DISCHARGE
10 min	Midazolam 2mg	Left lateral	30–60 min

Procedure parameters per Sias & Milone (2025). Patents cover the anoscope geometry and simultaneous thermal coagulation across operative windows.

07 / PROCEDURE FOOTAGE

The procedure, unedited.

A reusable bipolar electrode coagulates the mucosa that falls into position in the anoscope windows. The auto-sensing generator terminates delivery when target tissue temperature is reached. Note the visible volumetric reduction at the conclusion of the procedure.

Confidential clinical footage. Patents cover the anoscope geometry and simultaneous thermal coagulation across operative windows.

08 / CLINICAL EVIDENCE

248 patients, 5 years of follow-up, peer-reviewed.

Sias & Milone published 5-year outcomes from a 248-patient single-center series (treated February 2016 – December 2022). 88% of the cohort was Grade III. Open-access in the Journal of Surgery, Gavin Publishers, 2025.

87%

of patients completely asymptomatic at 5 years. Remaining 12.9% treated with a localized repeat procedure.

92%

reported zero pain in the first 5 post-op days. Only 25 patients required analgesics beyond day 2.

0%

anal stenosis, fecal incontinence, urinary retention, or infection across the published cohort.

15.3%

minor bleeding (no intervention required)

2%

major bleeding, early in the learning curve

4%

hemorrhoidal thrombosis

12.9%

5-year retreatment rate

Sias F, Milone L. 2025. Thermal Submucosal Hemorrhoidopexy. J Surg 10:11513. Open access. Level IV evidence. Controlled trials planned at Brooklyn Hospital Center (NYC) and Paris.

09 / PATIENT ACQUISITION PLAN

A phased patient pipeline tied to FDA clearance and clinic capacity.

PHASE 1
Pre-FDA

- Focused on foundational content development to support SEO and paid search initiatives.

PHASE 2
Post-FDA, 0–3 months

- Launch of core marketing materials and initial patient acquisition efforts, and gather treatment insights.

PHASE 3
Post-FDA, 3–6 months

- Expansion into additional geographic markets.

10 / NEXT STEP

What we are aligning on with the Seattle clinical team this week.

1. Procedure protocol walk-through, anesthesia approach, and case selection criteria for the Seattle clinic.
2. Pre-FDA training and proctoring plan with Dr. Sias and Dr. Milone (Brooklyn).
3. Patient pipeline expectations for the first 90 days post-FDA, tied to the Phase 2 paid acquisition turn-on.
4. Outcomes tracking and clinical data collection at the Seattle site, supporting the Level I/II controlled trial work.