EVT24 Medical Device for Gastrointestinal Leaks

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JOHNS HOPKINS MEDICINE

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Background

Perforations causing leakage of pus in the gastrointestinal (GI) tract are common and negatively affect patient health.

Endoscopic Vacuum Therapy (EVT) is a treatment developed to treat this condition. Current EVT procedures are complex, and current EVT devices require frequent replacement throughout the perforation's healing time.

An updated EVT device should be inexpensive, simple to deploy, and capable of remaining in the body for extended periods of time without replacement.

Objectives

- Improve current EVT device (Eso-Sponge®) used in Europe
- Decrease deployment procedure's time and complexity
- Increase device's longevity after deployment

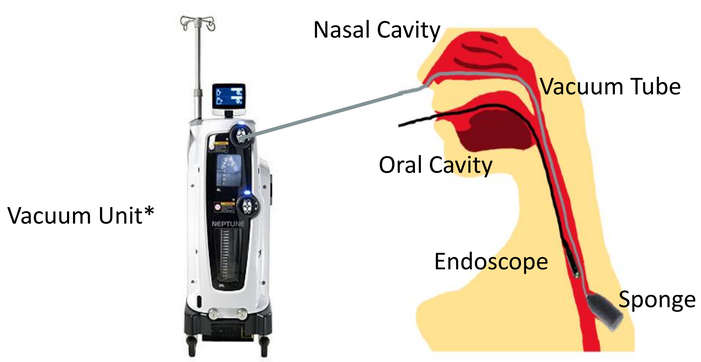
Solution

The EVT device consists of a sponge which is compressed into a gelatin capsule and attached to a vacuum tube.

Two potential sponges can be used. The first sponge contains a polyurethane core for compressibility and a bioabsorbable PLGA outer layer that serves as a buffer to tissue ingrowth.

The second sponge is a polyurethane sponge coated in polyethylene glycol (PEG). The PEG coating prevents tissue growth from attaching to the sponge, extending the lifetime of the sponge in the perforation.

Once the sponge is deployed in the target region, the gelatin capsule dissolves, allowing the sponge to expand and fill the entire volume of the perforation while a vacuum drains infectious fluid.



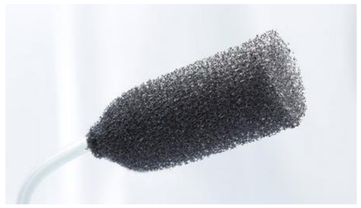
Design Attributes

- 6mm diameter capsule
- Expands to 25mm diameter
- Less than 10-minute procedure time
- Over 7-day operational life

*Image taken from product websites (B. Braun for Eso-Sponge, Stryker for vacuum unit)

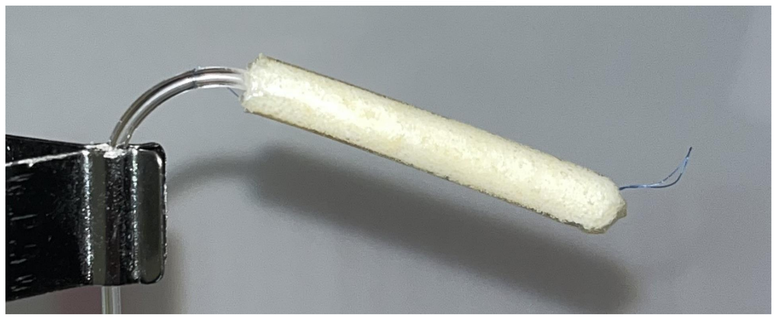
Devices

Eso-Sponge®*



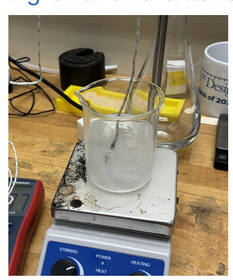
EVT24 Intermediary

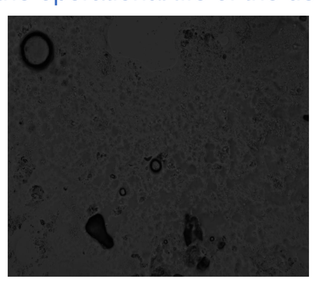
EVT24 Final



Sponge

One solution to this problem (left) of tissue ingrowth is to envelop a polyurethane sponge with a bioabsorbable layer in the form of a PLGA scaffold (right). The PLGA provides a bioabsorbable buffer to tissue ingrowth and extends the operational life of the device.





Polyethylene glycol (PEG) has been shown to prevent proteins from adhering to materials. A PEG coating permits the sponge to remain longer in the body without excessive tissue ingrowth.

Casing

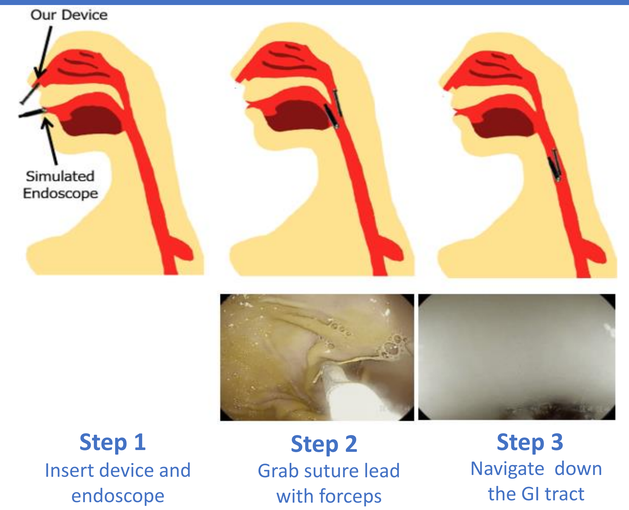
Mix Gelatin Solution

Dip Mold Into Solution

Allow Casing to Cure

Remove Casing From Mold

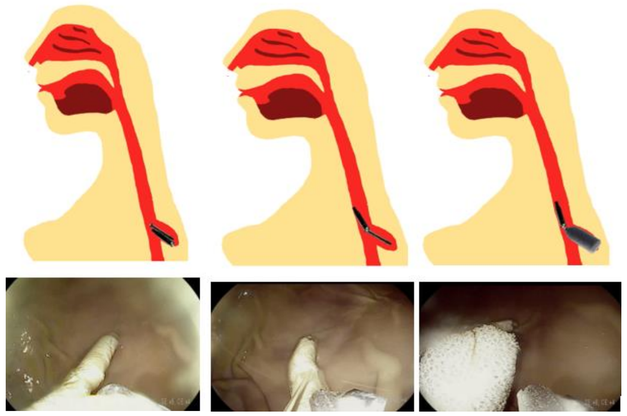
Procedure



Step 1
Insert device and endoscope

Step 2
Grab suture lead with forceps

Step 3
Navigate down the GI tract



Step 4
Insert the device into the perforation

Step 5
Dissolve casing with saline

Step 6
Monitor device's expansion

Requirements

Requirement	Solution	Completion
Procedure Time under an Hour	Gelation Casing and Simplified Procedure	✓
Endoscopic Deployment	Suture Guide	✓
Remain in Body for a Week	Bioabsorbable Layer and Tissue Repellent Coating (Unverified)	–
Active Vacuum	Vacuum Tube	✓
Mass Production	Dip Molding	✓
FDA Approval	In Vitro Testing	–

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