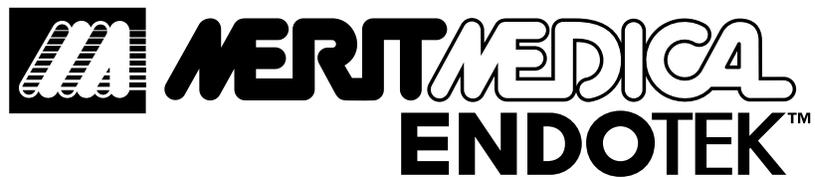


EndoMAXX™

Fully Covered Esophageal Stent

INSTRUCTIONS FOR USE



Fully Covered Esophageal Stent

DEVICE DESCRIPTION

The MERIT ENDOTEK™ EndoMAXX Fully Covered Esophageal Stent is comprised of two components: the radiopaque self-expanding Nitinol stent and the deployment catheter. The stent is completely covered with a biocompatible silicone membrane. The stent expansion results from the physical properties of the metal and the proprietary geometry. The stent is designed with a larger diameter at the distal and proximal ends to reduce the possibility of migration. The overall stent geometry is designed to minimize foreshortening upon expansion, thus facilitating improvement in deployment accuracy. The proximal and distal ends of the stent are threaded with a suture intended for use in proximal and distal repositioning of the stent. (See description under REPOSITIONING OF THE ESOPHAGEAL STENT).

The stent is deployed with a dedicated deployment catheter. The deployment catheter consists of two coaxial sheaths attached to a deployment handle. The handle permits one-handed positioning and deployment via a trigger mechanism. The exterior sheath serves to constrain the stent until the sheath is retracted during deployment. A radiopaque tip and marker on the inner shaft proximal to the stent aid the operator in determining stent position in relation to the deployment threshold. Once deployment is initiated, the stent can not be restrained. The stent can be repositioned proximally until the first deployment trigger is deployed for a two deployment trigger device or until the second deployment trigger is deployed for a three deployment trigger device. **This is the last point at which the operator can reposition the stent proximally by pulling the entire delivery catheter proximally.**

The inner tube of the coaxial sheath catheter contains a central lumen that will accommodate a 0.035" (0.89mm) guide wire. This feature is designed to allow safe guidance of the deployment catheter to the intended implant site while minimizing the risk of esophageal injury from the delivery system tip.

The complete Instructions for Use should be reviewed before using this system.

A patient card is included with the device.

INDICATIONS FOR USE

The MERIT ENDOTEK™ EndoMAXX Fully Covered Esophageal Stent is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors and for occlusion of esophageal fistulae.

MRI Conditional

Non-clinical testing has demonstrated that the EndoMAXX is MR Conditional for a single and for two-overlapped stents. A patient with this device can be scanned safely, immediately after placement under the following conditions:

- Static magnetic field of 3-tesla or less
- Maximum spatial gradient field of 720 Gauss/cm or less
- Maximum specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning

In non-clinical testing, the EndoMAXX stents (single and two-overlapped versions) produced a temperature rise of less than or equal to 3.2°C for single stent and 3.6°C for two-overlapped stents at a maximum specific absorption rate (SAR) of 2 W/kg for 15 minutes of MR scanning (i.e., per pulse sequence) in 1.5-tesla/64-MHz (Magnetom, Siemens Medical Solutions, Malvern, PA. Software Numaris/4, Version Syngo MR 2002 B DHHS Active-shielded, horizontal field scanner) and 3-Tesla/128-MHz (Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR systems. These temperature changes will not pose a hazard to a human subject under the conditions indicated above.

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the EndoMAXX stent. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 5mm relative to the size and shape of this implant when obtained using a 3-Tesla/128-MHz (Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system with a send-recv RF coil.

The safety of the deployment catheter in the MR environment has not been evaluated, and therefore, the deployment catheter should not be used within the MR environment.

CONTRAINDICATIONS

The MERIT ENDOTEK™ EndoMAXX Fully Covered Esophageal Stent is contraindicated in:

1. Patients with significantly abnormal coagulopathy.
2. Patients with necrotic, chronically bleeding or polypoid lesions.
3. Strictures that cannot be safely dilated to allow passage of the deployment catheter.
4. Esophageal fistulae or perforation that prevent secure stent placement.
5. Situations that require positioning the proximal end of the stent within 20mm of the upper esophageal sphincter.
6. Patients in whom endoscopic procedures cannot be safely performed.
7. Any use other than those specifically outlined under Indications for Use.

POTENTIAL COMPLICATIONS

Complications have been reported in the literature for esophageal stent placement with both silicone stents and expandable metal stents. These include, but are not necessarily limited to:

PROCEDURAL COMPLICATIONS:

- Bleeding
- Esophageal perforation
- Pain
- Aspiration

POST-STENT PLACEMENT COMPLICATIONS:

- Stent migration
- Perforation
- Bleeding
- Pain/foreign body sensation
- Occlusion due to lesion growth
- Obstruction related to food volume
- Infection
- Reflux
- Esophagitis
- Esophageal ulceration
- Edema
- Fever
- Fistula formation outside of normal disease progression
- Death with cause outside of normal disease progression

ADDITIONAL CAUTIONS AND WARNINGS

1. The MERIT ENDOTEK™ EndoMAXX Fully Covered Esophageal Stent should be used with caution after careful consideration of the following:

- Stent placement across the gastro-esophageal (GE) junction may increase migration risk and reflux.
- Stent placement may further compromise patients with significant cardiac or pulmonary conditions.
- Laser ablation of lesions with a stent in place could cause patient injury.
- Placement of a second stent within the lumen of another stent could significantly compromise the patency of the lumen.
- Placement of a stent in a very proximal location could cause discomfort or patient foreign body sensation.
- Stents placed to treat strictures where the proximal margins are located within 45mm of the upper esophageal sphincter may not fully expand, compromising the patency of the lumen.

2. If the stent is damaged or does not fully expand during implantation, remove the stent following the Instructions for Use.
3. Do not cut the stent or delivery catheter. The device should only be placed and deployed using the supplied catheter system.
4. Do not reposition the stent by grasping the stent covering. Always grasp the suture loop or the metal stent to reposition the stent and do not twist or rotate the stent unless the stent is being removed.
5. REUSE PRECAUTION STATEMENT – For single patient use only. Do not reuse or reprocess. Reuse or reprocessing may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse or reprocessing may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

INSTRUCTIONS FOR USE

Required Equipment:

- Endoscope
- 0.035" (0.89mm) stiff bodied, soft tipped guide wire, 180cm length minimum
- EndoMAXX Fully Covered Esophageal Stent of appropriate length and diameter
- Fluoroscopic imaging should be used to facilitate esophageal dilation if required prior to stent placement. Fluoroscopic imaging may also be used in addition to or in place of endoscopy to aid in accurate stent placement.

1. Locate Stenosis and Pre-Dilate as Necessary.

Pass an endoscope into the esophagus and beyond the esophageal stricture. If necessary, dilate the stricture until an endoscope can be passed.

WARNING: Do not attempt placement of the MERIT ENDOTEK™ EndoMAXX Fully Covered Esophageal Stent in patients with stenoses that cannot be dilated sufficiently to allow passage of an endoscope.

2. Estimate the Stenosis Length and Luminal Diameter.

This estimation may be performed by visual inspection via endoscopy or via fluoroscopy. To determine the stenosis length, measure the distance from the distal border of the narrowing to the proximal border while pulling back on the endoscope. A suitable length estimate may be obtained with a combination of endoscopy, fluoroscopy, and a radiopaque marker of known length that is adhered to the patient's chest. To determine the lumen diameter, estimate the diameter of the normal-appearing esophageal lumen proximal to the stenosis. An open biopsy forceps may be used for a reference guide. Alternatively, the stenosis length and luminal diameter may be measured by reviewing a recent CT scan of the narrowed esophageal lumen.

3. Identify Landmarks to Aid in Placement.

Endoscopically and/or fluoroscopically examine the lumen both proximal and distal to the stenosis. The stricture should be dilated to allow passage of an endoscope, or approximately 9mm (27F) minimum. Radiopaque markers may be placed on the patient's chest to assist in identifying the margins of the stenotic area.

4. Select the Appropriate Stent Size.

The physician should select a stent diameter following the complete endoscopic and fluoroscopic examination. To minimize the potential of stent migration, dilate the stricture ONLY if passage of the endoscope or the delivery system through the stricture lumen is not possible. Choose a stent long enough to completely bridge the target stenosis with a 27mm margin both proximally and distally. Because the MERIT ENDOTEK™ EndoMAXX Fully Covered Esophageal Stent will not significantly foreshorten when deployed it is not necessary to account for shortening.

5. Introduce the Guide Wire.

Place a 0.035" (0.89mm), stiff-bodied, soft-tipped guide wire through the endoscope and beyond the stenosis. The endoscope should be removed at this time while maintaining the position of the guide wire.

6. Inspect and Prepare the EndoMAXX Fully Covered Esophageal Stent.

This product is supplied non-sterile. Before opening the package, inspect the package for damage. Do not use if the package has been opened or damaged.

Carefully remove the device from the plastic tray by pulling up on the handle end lid tabs, lifting the hinged lid, and pulling the device from the tray. The tray does not need to be fully removed from the pouch, only the hinged end of the tray. (See Figure 1) Be careful to not pull or manipulate the deployment triggers during removal. Visually inspect the Esophageal Stent and the delivery catheter for any sign of damage. Do not use if there are any visible signs of damage.

The red safety on the handle is designed to prevent premature stent deployment and may remain on the device until the device is correctly positioned relative to the treatment site.

Lubricate the distal portion of the stent delivery catheter with water-soluble lubricant to aid in introduction. Backload the guide wire into the distal tip.

7. Positioning of EndoMAXX Fully Covered Esophageal Stent in Esophagus.

7.1 Under endoscopic visualization, advance the EndoMAXX Fully Covered Esophageal Stent over the guide wire through the stenosis. Stent positioning can be accomplished using fluoroscopy and/or endoscopy.

7.1.1 For stent placement across the GE Junction using endoscopy, advance the delivery catheter 27mm across the GE junction and into the stomach to ensure engagement of the anti-migration features of the deployed stent at the GE junction. Use endoscopy to visualize the green marker located on the catheter inner shaft at the proximal end of the stent. Ensure the distal end of the green marker is at least 27mm proximal to the proximal end of the stenosis.

When using fluoroscopy, visualize the radiopaque markers on the deployment catheter tip and inner shaft proximal to the stent. Align the proximal end of the radiopaque tip 27mm across the GE junction and into the stomach. Ensure the distal end of the proximal marker is at least 27mm proximal to the proximal end of the stenosis.

Continue to step 7.2 for further instructions.

7.1.2 For stent placement to treat a STRICTURE near the upper esophageal sphincter using endoscopy, visualize the green marker located on the catheter inner shaft at the proximal end of the stent. Align the distal end of the green marker 27mm proximal to the proximal end of the stenosis.

When using fluoroscopy, visualize the radiopaque markers on the deployment catheter tip and inner shaft proximal to the stent. Align the radiopaque marker located at the proximal end of the stent 27mm proximal to the proximal end of the stenosis and the tip marker at least 27mm distal to the stenosis.

Continue to step 7.2 for further instructions.

7.1.3 For stent placement to treat fistulae NOT INVOLVING A STRICTURE near the upper esophageal sphincter using endoscopy, visualize the green marker located on the catheter inner shaft at the proximal end of the stent. Align the distal end of the green marker at least 20mm distal to the upper esophageal sphincter which indicates the desired location for the most proximal end of the stent allowing adequate margin from the upper esophageal sphincter.

When using fluoroscopy, visualize the radiopaque markers on the deployment catheter tip and inner shaft proximal to the stent. Align the radiopaque marker located on the proximal end of the stent at least 20mm distal to the upper esophageal sphincter which indicates the desired location for the most proximal end of the stent allowing adequate margin from the upper esophageal sphincter.

The tip marker should be positioned distal to the fistula. Continue to step 7.2 for further instructions.

7.1.4 For all other stent placement locations, use endoscopy to visualize the green marker located on the catheter inner shaft at the proximal end of the stent. Align the distal end of the green marker 27mm proximal to the proximal end of the stenosis.

When using fluoroscopy, visualize the radiopaque markers on the deployment catheter tip and inner shaft proximal to the stent. Align the radiopaque marker

located at the proximal end of the stent 27mm proximal to the proximal end of the stenosis and the tip marker 27mm distal to the stenosis.

Continue to step 7.2 for further instructions.

7.2 Remove the red safety from the handle by pulling the tab in the arrow direction (away from the deployment catheter), taking care not to reposition the stent.

8. Deployment of stents

The deployment catheter has a handle with two or three (150 mm length only) deployment triggers to allow the user to deploy the stent in two or three steps (Fig 2 and Fig 3).

Hold the handle grip in the palm of your hand (Fig. 4). Using the index and middle finger, grasp the first deployment trigger. We recommend using two fingers, one on the top and bottom of the trigger for deployment.

Slowly retract the outer sheath by pulling back on the first deployment trigger until the deployment trigger touches the handle (Fig 5). The stent is now partially deployed. The stent is not reconstrainable, however, the stent may be repositioned proximally while holding the position of the deployment trigger and moving the deployment catheter as a unit. The stent may be repositioned proximally until the first deployment trigger has been deployed and before the second deployment trigger is deployed for a two deployment trigger device. For a three deployment trigger device, the stent may be repositioned proximally until the first and second deployment triggers have been deployed and before the third deployment trigger is deployed.

After confirming the position of the stent use your index and middle finger to grasp the second deployment trigger (Fig 6.)

Pull the second deployment trigger until it touches the first deployment trigger (Fig 7). Unless there is a third deployment trigger, the stent is now fully deployed. If there is a third deployment trigger, use your index and middle finger to grasp the third deployment trigger. Pull the third deployment trigger until it touches the second deployment trigger.

9. Assess Deployed Stent and Remove Deployment catheter.

Confirm endoscopically and fluoroscopically that the stent has completely deployed and expanded. Carefully remove the delivery catheter from within the expanded stent, using care not to move the stent with the distal tip of the delivery catheter. Dilation is not recommended. If the stent does not expand sufficiently or is not in the desired position, the stent may be removed as described below. Re-evaluate the size of the esophagus and choose an appropriate size device. Repeat stent implant with a new device.

REPOSITIONING OF THE ESOPHAGEAL STENT

The Merit EndoMAXX Fully Covered Esophageal Stent design allows for repositioning of the stent proximally or distally immediately after placement. The repositioning of the stent may be necessary in the event that the stent is not in a desirable location or improperly sized. Position the endoscope so that the proximal or distal flare of the stent is visible.

The EndoMAXX Fully Covered Esophageal Stent can be repositioned proximally or distally using a rat tooth forceps to grasp the suture loop at the proximal or distal end of the stent and carefully applying traction (Fig 8).

The purse-stringing effect releases the proximal or distal end of the stent from contact with the esophageal wall, thus facilitating atraumatic repositioning (Fig. 9).

As an alternative to grasping the suture loop, the stent may be repositioned by applying gentle traction to the proximal or distal end of the stent using grasping forceps such as alligator forceps. Open the forceps and carefully pass the forceps over the proximal or distal end of the

stent. One jaw should be positioned outside of the stent, between the stent and the luminal wall. The other jaw should be positioned inside the stent. Close the forceps over the metal stent, grasping as much of the metal stent as possible.

Do not grasp the covering of the stent alone without grasping the metal stent.

Gently apply traction to the metal stent to reposition the stent proximally or distally.

WARNING: The risks associated with repositioning the stent other than immediately after placement have not been evaluated in an animal or clinical model. Attempts to do so may result in tissue injury.

WARNING: Do not attempt repositioning by grasping the middle of the stent.

WARNING: Only rat tooth grasping forceps may be used to grasp the suture loop during repositioning and do not use rat tooth forceps to grasp the metal struts to reposition the stent.

WARNING: Do not rotate the stent using forceps if it is being repositioned proximally or distally.

REMOVAL OF THE ESOPHAGEAL STENT

The MERIT ENDOTEK™ EndoMAXX Fully Covered Esophageal Stent design allows for removal of the stent **immediately after placement only**. The removal of the stent may be necessary in the event that the stent is not in a desirable location or is improperly sized. Position the endoscope so that the suture loop at the proximal end of the stent is visible.

The EndoMAXX Fully Covered Esophageal Stent can be removed using rat tooth grasping forceps to grasp the suture loop at the proximal end of the stent and carefully applying traction (Fig. 8). The purse-stringing effect releases the proximal end of the stent from contact with the esophageal wall, thus facilitating atraumatic removal (Fig. 9).

WARNING: Do not attempt to reload or reconstrain a deployed or partially deployed self-expanding stent. If it becomes necessary to remove a partially deployed stent the entire system should be withdrawn en bloc. Do not attempt to advance the outer sheath to recompress the stent prior to withdrawing the system.

WARNING: Do not attempt removal by grasping the middle of the stent.

WARNING: The risks associated with removal of the stent other than immediately after placement have not been evaluated in an animal or clinical model. Attempts to do so may result in tissue injury.

POST-PROCEDURE MANAGEMENT

Patients should have P-A (postero-anterior) and lateral chest x-rays to record stent position. The patient should be observed for complications associated with endoscopy, esophageal dilatation and stent placement. The patient should be monitored closely for 24 hours post-implant and should receive only clear liquids during this period. Patients treated for esophago-respiratory fistula should receive no fluids or solid food by mouth until after sealing of the fistula has been confirmed.

Once proper positioning has been confirmed and the patient has been stabilized for 24 hours, the patient should be instructed to eat only in an upright position, avoid certain foods as appropriate, chew food thoroughly and to take fluids during and following meals.

In order to minimize complications of gastric reflux, patients with stents in the distal esophagus or across the GE junction should receive antacid treatment and should be advised to elevate their head while supine.

Patients should be scheduled for follow-up examinations as indicated to confirm proper positioning and stent patency within 90 days of implant. Patients should be advised that symptomatic dysphagia following stent placement could be an indication of tumor impingement or stent migration and that repeat endoscopy may be required.

PACKAGING AND LABELING

Inspect the MERIT ENDOTEK™ EndoMAXX Fully Covered Esophageal Stent, the delivery catheter and the packaging for damage prior to use. Confirm that the device is consistent with the package label. Discard and replace any damaged devices.

DO NOT ATTEMPT REPAIR

Contact MERIT ENDOTEK™ Customer Service at 1-800-356-3748 if the package has been opened or damaged.

STORAGE

Do not expose this device to conditions of extreme heat and humidity. Store the MERIT ENDOTEK™ EndoMAXX Fully Covered Esophageal Stent in a normal room temperature environment.

HOW SUPPLIED

The disposable, single-patient-use self-expanding stents are available, pre-mounted on the delivery catheter in a variety of configurations.

All of the esophageal stents are mounted on a delivery catheter.

WARNING: The MERIT ENDOTEK™ EndoMAXX Fully Covered Esophageal Stent is provided non-sterile.

DO NOT STERILIZE

Each packaged unit is intended for **SINGLE-PATIENT-USE ONLY.**

For more information or to arrange for a demonstration, contact MERIT ENDOTEK™ at 1-800-356-3748.

WARRANTY

The manufacturer warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness. Handling and storage of this device, as well as other factors relating to the patient, diagnosis, treatment, implant procedures, and other matters beyond the control of the manufacturer directly affect the device and the results obtained from its use. The manufacturer obligation under this warranty is limited to the replacement of this device; and the manufacturer shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device.

The manufacturer neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. The manufacturer assumes no liability with respect to devices that are reused, reprocessed, or resterilized, and makes no warranties, expressed or implied, including, but not limited to, merchantability or fitness for intended use, with respect to such device.

RX only: CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

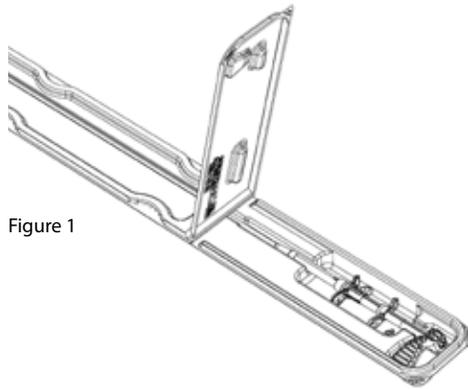


Figure 1

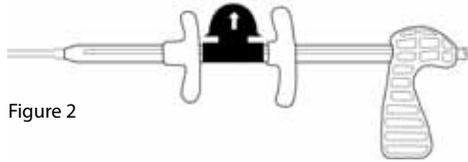


Figure 2

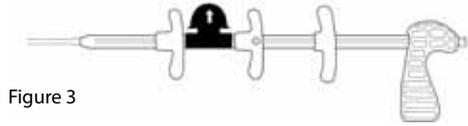


Figure 3

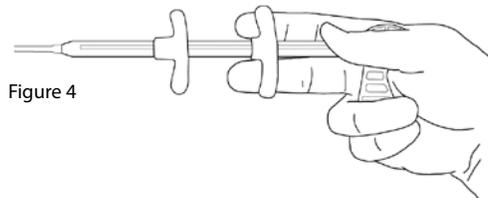


Figure 4

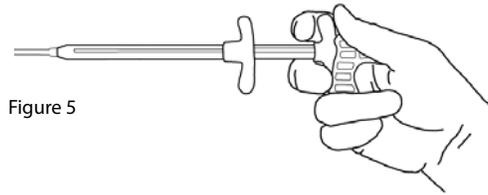


Figure 5

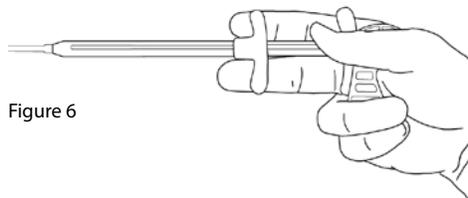


Figure 6

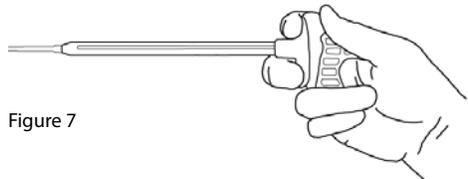


Figure 7

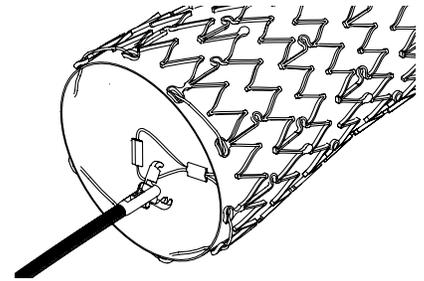


Figure 8

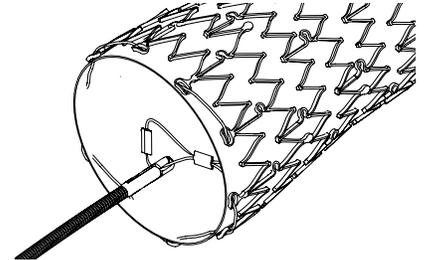


Figure 9



Single Use



MR Conditional



Manufacturer:
 Merit Medical Systems, Inc.
 South Jordan, Utah 84095 U.S.A. 1-801-253-1600
 www.merit.com
 U.S.A. Customer Service 1-800-356-3748