

Tracheobronchial Stent System

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

The MERIT ENDOTEK AERomini Tracheobronchial Stent System is comprised of two components: the radiopaque self-expanding nitinol stent and the delivery system. The stent is completely covered with a biocompatible polyurethane membrane. The stent expansion results from the physical properties of the metal and the proprietary geometry. The stent is designed with a constant diameter throughout its entire length. The overall stent geometry is designed to maintain a constant length over the entire range of possible diameters. As a result of this unique design the stent has virtually no foreshortening, thus facilitating the selection of the appropriate stent length.

The stents are deployed with a dedicated delivery system. The delivery system consists of two coaxial sheaths. The exterior sheath serves to constrain the stent until the sheath is retracted during deployment. The stent remains constrained by the delivery system until the trigger is pulled beyond the white deployment threshold mark located between the trigger and hand grip. This feature allows for repositioning of the stent proximally. A radiopaque tip and marker on the inner shaft aid the operator in determining stent position in relation to the deployment threshold mark, where repositioning or en bloc withdrawal is no longer possible. The inner tube of the coaxial sheath delivery system contains a central lumen that will accommodate a 0.035" guide wire. This



feature is designed to allow safe guidance of the delivery system to the intended implant site while minimizing the risk of airway injury from the delivery system tip.

The stent and delivery system are provided STERILE using an ethylene oxide (EO) process.

MRI SAFETY INFORMATION

Non-clinical testing demonstrated that the AERomini is MR Conditional. A patient with this device can be safely scanned in an MR system under the following conditions:

- Static magnetic field of 1.5T and 3.0T only
- Maximum spatial gradient magnetic field of 4,000 Gauss/cm (40-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg (Normal Operating Mode)

Under the scan conditions defined, the AERomini is expected to produce a maximum temperature rise of 2.2°C after 15-minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 5 mm from the AERomini when imaged using a gradient echo pulse sequence and a 3Tesla MRI system. The artifact does not obscure the device lumen.

INDICATIONS FOR USE

The MERIT ENDOTEK AERomini Tracheobronchial Stent System is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

WARNING: The safety and effectiveness of the device for use in the vascular system has not been established and can result in serious harm and/or death.

CONTRAINDICATIONS

The MERIT ENDOTEK AERomini Tracheobronchial Stent System is contraindicated for:

1. Tracheobronchial obstruction with a luminal diameter that cannot be dilated to at least 75% of the nominal diameter of the selected stent.
2. Patients for whom bronchoscopic procedures are contraindicated.
3. Any use other than those specifically outlined under Indications for Use.

POTENTIAL COMPLICATIONS

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

PROCEDURAL COMPLICATIONS:

- Stent misplacement
- Bleeding
- Tracheobronchial perforation and pneumothorax
- Retrosternal Pain
- Aspiration
- Hypoxia
- Infection

POST-STENT PLACEMENT COMPLICATIONS:

- Stent migration
- Occlusion due to mucous accumulation
- Occlusion due to tumor in-growth or overgrowth at stent ends
- Occlusion due to granulomatous tissue formation
- Chronic cough
- Partial stent fractures
- Recurrent obstructive dyspnea related to stent occlusion or migration

- Tracheobronchial wall ulceration, perforation and hemorrhage
- Infection and septic shock
- Aponia
- Death

ADDITIONAL CAUTIONS AND WARNINGS

1. The MERIT ENDOTEK AERomini Tracheobronchial Stent System should be used with caution and only after careful consideration in patients with:
 - Extended clotting times or coagulopathies
 - Prior pneumonectomy
 - Active acute inflammation in the airway lumen
 - A tumor related stenosis adjacent to a major vessel
2. If the stent becomes fractured or does not fully expand during implantation, remove the stent following the Instructions for use.
3. Do not use the stent for treatment of lesions where placement of the device may obstruct a functioning major sidebranch.
4. Do not cut the stent or the delivery system. The device should only be placed and deployed using the supplied delivery system.
5. Do not use a kinked bronchoscope, endotracheal tube or introducer sheath as this may increase the force necessary to deploy the device and may cause a deployment failure or delivery system breakage.
6. Do not deploy the stent inside of the bronchoscope.
7. Do not reposition the stent by pushing on the stent with the bronchoscope.
8. Do not insert a rigid bronchoscope through the stent lumen after deployment.
9. When using a rigid bronchoscope, do not allow the bronchoscope to abrade the stent.
10. Use caution when withdrawing the MERIT ENDOTEK AERomini Tracheobronchial Stent System back into the bronchoscope, endotracheal tube, or introducer sheath once the device is fully introduced. Withdrawing the stent back into the bronchoscope, endotracheal tube, or introducer sheath may cause damage to the device, premature deployment, deployment failure, and/or delivery system separation. If removal prior to deployment is necessary, do not reuse the stent or delivery system.
11. Do not reposition the stent by grasping the polyurethane covering. Always grasp the suture or stent connector to reposition the stent and do not twist or rotate the stent or metal strut unless the stent is being removed.
12. If the lesion mass is reduced significantly, (as may occur with radiation therapy or chemotherapy) there is an increased chance of migration. If this occurs, removal of the stent should be considered.
13. There is an increased risk of stent migration when the stent has been implanted in patients with narrowing at the distal end of the lesion relative to the proximal end (conical or funnel shaped lesion). Physicians should consider monitoring these patients for up to 72 hours after stent placement and may wish to verify final placement using chest x-ray.

STENT DIAMETER SIZING TABLE (TABLE 1)	
DEVICE SIZING	
Labeled Device Diameter (mm)	Recommended Lumen Diameter (mm)
6	4.5-5.5

STENT DIAMETER SIZING TABLE (TABLE 2)		
Labeled Device Diameter (mm)	Labeled Length 10mm	Labeled Length 15mm
	Stenosis Length (mm)	Stenosis Length (mm)
6	10	15

STENT SELECTION

- Prior to implantation of the MERIT ENDOTEK AERomini Tracheobronchial Stent System, the physician should refer to the Sizing Table (Table 1 & 2) and read the Instructions for Use.
- When used in the treatment of stenotic or obstructive lesions, placement of the stent should immediately follow the opening of the airway by whatever means appropriate and be confirmed by fluoroscopy and/or bronchoscopy. The device must be sized in accordance with the Sizing Table (Table 1 & 2) using accurate measurement techniques.
- Proper placement of the device should be monitored and confirmed using bronchoscopy and/or fluoroscopy.

REQUIRED EQUIPMENT

- Bronchoscope
- 0.035" (0.89mm) stiff bodied, soft tipped guide wire, 180cm length minimum (optional).
- Fluoroscopic imaging should be used to facilitate tracheobronchial 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.
- Grasping forceps

INSTRUCTIONS FOR USE

MERIT ENDOTEK recommends that the operator follow the directions outlined below.

1. Locate Stenosis and Pre-Dilate as Necessary.

2. Estimate the Stenosis Length and Luminal Diameter.

This estimation may be performed by visual inspection via bronchoscopy or via fluoroscopy.

Measuring the length: If possible, advance the scope to the distal end of the lesion, pause and observe the anatomy. Grasp the proximal end of the scope and do not release your grasp. Retract the scope until the proximal end of the lesion can be visualized. With your opposite hand grasp the proximal end of the scope near the patient's mouth while maintaining your initial grip. It is important to always maintain the initial grasp mark on the scope during visual measurement because this will provide you with the initial point of reference to conduct the length measurement. Once the distal and proximal limits are identified it is possible to measure the lesion length and select the appropriate size stent. If there are depth measurement markings on the scope these can be used to measure the actual lesion length. Once the measurement is completed the appropriate length stent can be selected. Be sure to review the directions for use regarding sizing the diameter before choosing the final device. To determine the lumen diameter, estimate the diameter of the normal-appearing tracheobronchial 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 tracheobronchial lumen.

3. Identify Landmarks to Aid in Placement.

Bronchoscopically examine the lumen distal to the stenosis, noting the distance to any branches. Examine the stenotic area fluoroscopically. The stricture should be dilated to approximately 75% of the normal lumen diameter. Radiopaque markers may be placed on the patient's chest to assist in identifying the margins of the stenotic area.

4. Select the Appropriate Covered Stent Size.

Choose a stent long enough to completely bridge the target stenosis. Choose the stent diameter to approximate the size of the normal proximal lumen but do not exceed the desired final diameter by more than 2mm. If possible, avoid choosing a stent that would cross side branches when placed. See Sizing Table (Table 1 & 2).

5. Introduce the Guide Wire (optional).

Place a 0.035" (0.89mm), stiff-bodied, soft-tipped guide wire through the bronchoscope and beyond the stenosis.

6. Inspect and prepare the MERIT ENDOTEK AERomini Tracheobronchial Stent System.

This product is supplied sterile. Before opening the package, inspect the package for damage. Do not use if the package has been opened or damaged. Visually inspect the Tracheobronchial Stent System for any sign of damage. Do not use if it has any visible signs of damage.

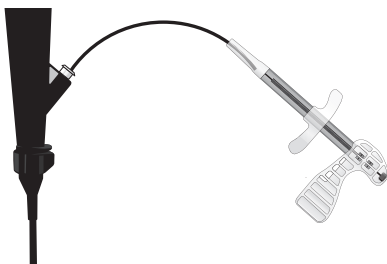
Open the label end of the box. Carefully open the box and pouch. Remove the delivery system from the plastic tray by pulling up on the handle end lid tabs, lifting the hinged lid, and pulling the device from the tray. The tray does not need to be fully removed from the pouch, only the hinged end of the tray.

A red safety is located adjacent to the delivery system trigger. The red safety on the delivery system is designed to prevent premature stent deployment and may remain on the delivery system until it is correctly positioned relative to the treatment size.

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

7. Introduce the stent delivery system through the 2.8 mm or greater working channel of the bronchoscope.

Alternatively, the stent delivery system may be placed over a guide wire, without using the bronchoscope working channel.



8. Ensure stent has completely exited the distal channel of the bronchoscope by visualizing the green proximal marker.



9. Positioning of MERIT ENDOTEK AERomini Tracheobronchial Stent System in Airway.

Under bronchoscopic visualization, the green proximal marker on the delivery system will be aligned with the proximal end of the stent. When using fluoroscopy, visualize the radiopaque markers on the delivery system tip and inner shaft so that the stenosis is centered between them. These markers indicate the ends of the stent. The stent will not foreshorten upon deployment.

10. Deployment of Stent.

Hold the hand grip in the palm of your hand (Fig. 1). Using the index and middle finger, grasp the trigger.

Slowly retract the outer sheath by pulling back on the trigger (Fig. 2) until the trigger touches the hand grip. The stent is now fully deployed. Carefully remove the delivery system without disturbing the position of the stent.

Monitor the stent deployment under fluoroscopy, while maintaining the identified stricture margins centered between the delivery system radiopaque markers. If necessary, stop deployment and adjust the stent position proximally. The stent may be repositioned proximally while holding the position of the trigger and moving the delivery system as a unit. The stent may be repositioned proximally until the trigger is pulled beyond the white deployment threshold mark located between the trigger and hand grip.

11 . Assess Deployed Stent and Remove Delivery System.

Confirm bronchoscopically and fluoroscopically that the stent has completely deployed and expanded. Carefully remove the delivery system from within the expanded stent, using care not to move the stent with the distal tip of the delivery system. If the stent appears to be damaged or is not evenly and fully deployed, it should be removed following the directions for use to remove the stent. Dilation is not recommended.

WARNING: Conservative medical practice suggests that stents not be repositioned distally. 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.

REMOVAL & REPOSITIONING OF THE TRACHEOBRONCHIAL STENT

The MERIT ENDOTEK AEROmini stent can be repositioned or removed using grasping forceps. For removal of the stent, long jawed forceps such as alligator or rat-tooth forceps are recommended. For repositioning the stent proximally, only an atraumatic grasper, such as alligator forceps, should be used. Do not use rat tooth or biopsy forceps (duck-billed forceps) to reposition the stent. Open the forceps and carefully pass the forceps over the end of the stent at the location of one of stent connectors. One jaw should be positioned outside of the stent, between the stent and the luminal wall. The other jaw should be positioned inside of the stent (Fig. 3). Close the forceps over the stent connector, grasping as much of the stent connector as possible. Do not grasp the cover of the stent. Gently rotate the forceps one quarter of a turn as traction is applied. Slowly extract the stent (Fig. 4). Use this technique for stent removal only. Do not rotate the stent if it is being repositioned proximally.

For a stent with a repositioning aid (blue colored braided suture) the MERIT ENDOTEK AEROmini stent can be removed with an atraumatic forceps by grasping the suture adjacent to the knot and carefully applying traction (Fig. 5). This will relieve tension on the proximal end of the stent, thus facilitating removal (Fig. 6).

CAUTION: If the suture is used to reposition the stent proximally, the stent should be examined carefully to assure that it has fully expanded after repositioning. In the event that some compression remains at the proximal end it may be necessary to expand the stent with a balloon catheter.

WARNING: Clinical data for stent removal in humans was limited to a clinical study of 51 patients with malignancies. Thirteen devices were removed after 30 days; 6 devices were removed after 60 days; and 2 devices were removed after 90 days. During this clinical study, there was no tissue in-growth into the lumen of the stent reported.

PACKAGING AND LABELING

Inspect the MERIT ENDOTEK AEROmini Tracheobronchial Stent System 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 TO 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 AEROmini Tracheobronchial Stent System in a normal room temperature environment.

HOW SUPPLIED

Product not made with natural rubber latex.

The disposable, single-patient-use self-expanding stents are mounted on a 7.9 F delivery system. The working length is 110 cm.

The MERIT ENDOTEK AEROmini Tracheobronchial Stent System is provided STERILE using an ethylene oxide (EO) process.

DO NOT RESTERILIZE

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

REUSE PRECAUTION STATEMENT

Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization 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, reprocessing or resterilization 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.

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.

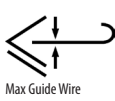
Rx ONLY : CAUTION: Federal (U.S.A) law restricts this device to sale by or on the order of a physician.



Single Use



MR Conditional



Max Guide Wire



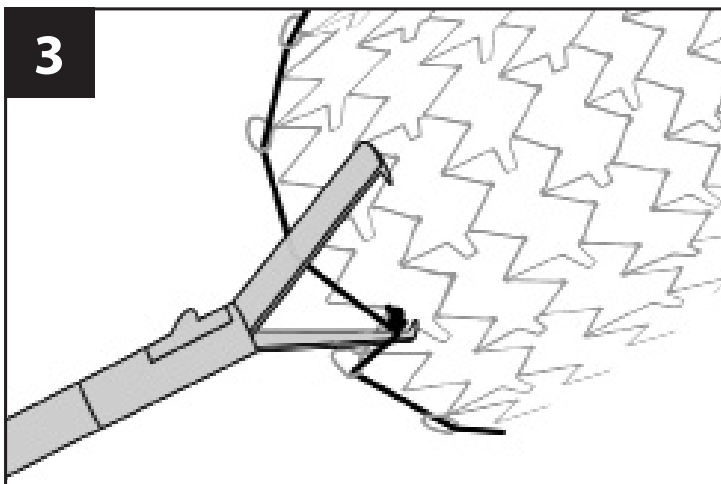
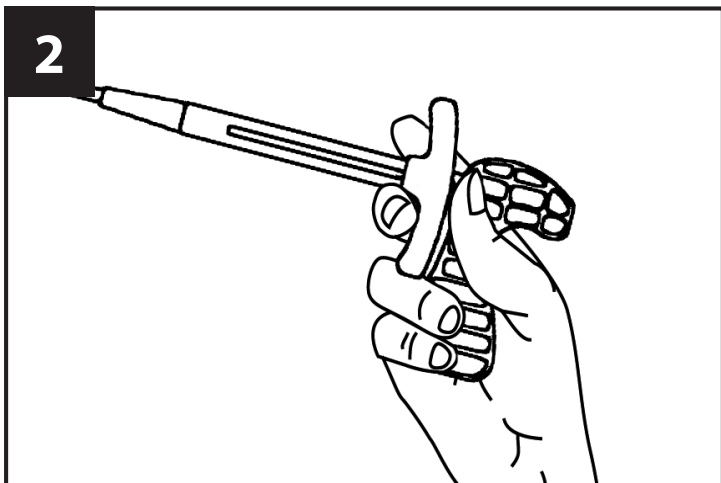
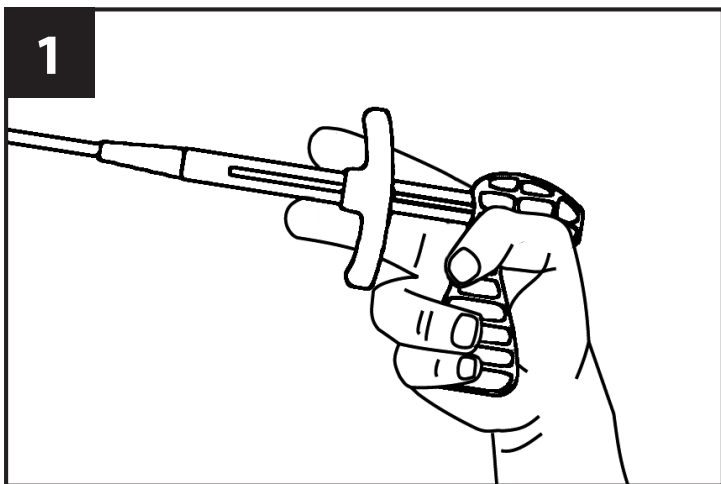
Do not use if package is damaged



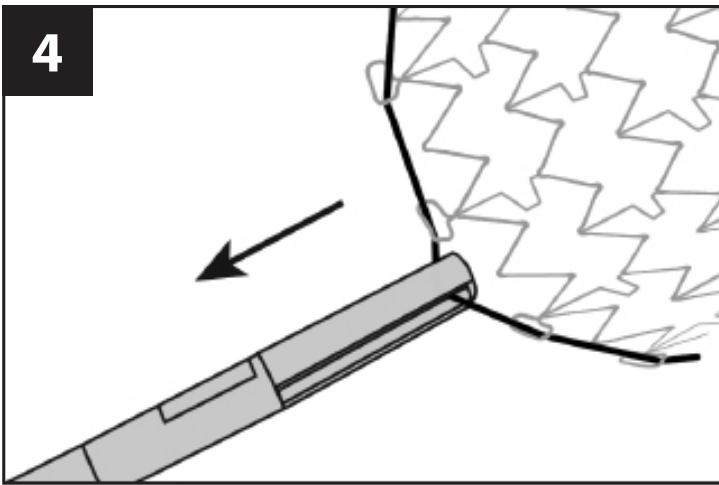
Caution: Consult accompanying documents

STERILE EO

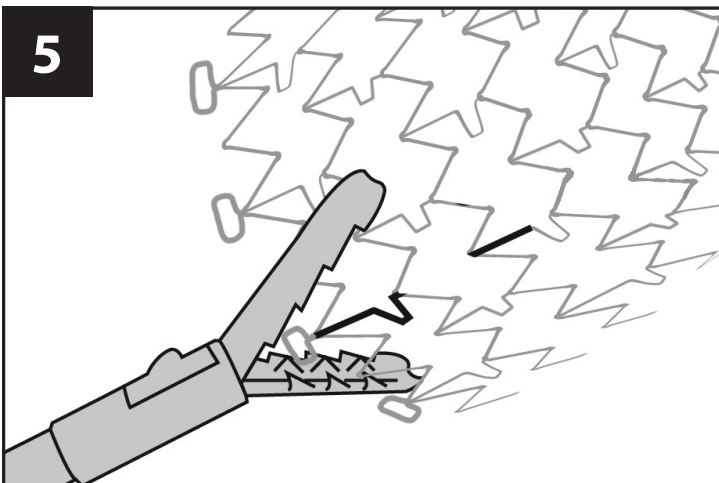
Sterilized using ethylene oxide



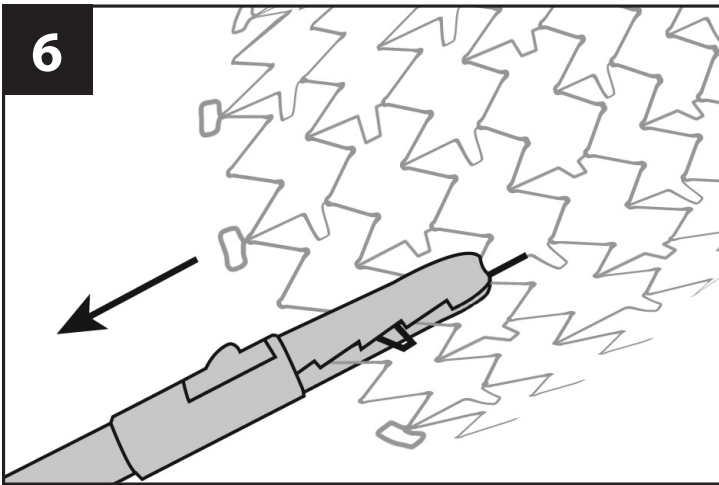
4



5



6



Manufacturer:

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



Authorized Representative:

Merit Medical Ireland Ltd,
Parkmore Business Park West, Galway, Ireland
European Customer Service by Country:
Belgium 0800 72906; France 0800 916030; Germany 0800 1820871;
Ireland 091 703700; Neth. 0800 0228184; U.K. 0800 973115