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 slightly larger diameter near the distal and proximal ends to minimize the possibility of migration. 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 shortening, 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. In addition, the procedure can be aborted and the entire system can be withdrawn en bloc at any time before the trigger is pulled. The device should only be used with a kinked bronchoscope, endotracheal tube or introducer sheath as this may increase the force necessary to deploy the device and/or delivery system separation. If removal prior to deployment is necessary, do not reuse the stent or delivery system.

The MERIT ENDOTEK AEROMini Tracheobronchial Stent System is comprised of two components: the radiopaque self-expanding nitinol stent and the delivery system. The stent and delivery system are provided STERILE using an ethylene oxide (EO) process.

The safety and effectiveness of the device for use regarding sizing the diameter before choosing the final device. To maintain the initial grasp mark on the scope during visual measurement is necessary, do not reuse the stent or delivery system.

Measuring the length: Advance the scope to the distal end of the lesion, and may wish to verify final placement using chest x-ray. If there is adequate clearance before proceeding with the stent placement. Grasping forceps

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.
- 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.

INSTRUCTIONS FOR USE

1. Locate Stenosis and Pre-Dilate as Necessary.
   - Pass a bronchoscope into the airway beyond the tracheobronchial stricture. If necessary, dilate the stricture using a balloon catheter dilator until a bronchoscope can be passed.
   - When selecting a rigid tube for placement of the device with rigid bronchoscopy, select a tracheal tube that has an internal diameter of not less than 11.5mm to allow sufficient clearance for the delivery system and a flexible or rigid bronchoscope. The physician should confirm that there is adequate clearance before proceeding with the stent placement.

2. Estimate the Stenosis Length and Luminal Diameter.
   - This estimation may be performed by visual inspection via bronchoscopy or via fluoroscopy.
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 strictures 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 with a 5 mm margin both proximally and distally. 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.
   Place a 0.035" (0.89mm), stiff-bodied, soft-tipped guide wire through the bronchoscope and beyond the stenosis. The bronchoscope should be removed at this time while maintaining the position of the guide wire.

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 it if there any visible signs of damage.

   Open the label end of the box. Carefully open 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 watersoluble lubricant to aid in introduction. Backload the guide wire into the distal end of the delivery system.

   Under bronchoscopic visualization, advance the stent over the guide wire through the stenosis. Direct visualization of the green proximal marker on the delivery system will provide a guide for placement. The proximal end of the deployed stent will be aligned with this green marker. 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.

8. 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.

   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. Distal 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, longjawed forceps such as alligator or rat-tooth forceps are recommended. For repositioning the stent proximally, only an atrumatic 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 atrumatic 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

   The disposable, single-patient-use self-expanding stents are available, premounted on a 12 F delivery system with 70 cm working length.

   Product not made with natural rubber latex.

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

   DO NOT RESTERLIZE

   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.

Product not made with natural rubber latex.