

AERO DV[®]

Tracheobronchial Direct Visualization Stent System

 Review Instructions For Use Before Using This System.

 Single Use Only

 Non-sterile

 MR Conditional

CONTENTS

Instructions for Use.....3

IMPORTANT PRODUCT INFORMATION

Please read this information carefully before using the **MERIT ENDOTEK[™] AERO DV[®] Tracheobronchial Direct Visualization Stent System**. Failure to properly follow the instructions may result in serious clinical consequences.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.



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



US and foreign patents issued and pending

DEVICE DESCRIPTION

The **MERIT ENDOTEK™ AERO DV® 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 mechanical 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 stent ends are slightly vaulted inwardly in order to minimize possible airway injury from the stent edges. 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 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. Once deployment is initiated, the stent can not be reconstrained. An indicator on the handle mechanism provides the operator with visual feedback when the stent has been deployed to 50% of its length. **This is the last point at which the operator can reposition the stent proximally by pulling the entire delivery catheter proximally.** The stent remains constrained by the delivery system until it is deployed beyond the indicator marker (approximately 50% of its length). 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 stent has been deployed beyond 50% of its length.** The inner tube of the coaxial sheath catheter contains a central lumen that will accommodate a bronchoscope with 5.2mm or smaller insertion tube diameter. This feature is designed to allow safe guidance of the delivery system to the intended implant site over the bronchoscope. All testing has been preformed using a bronchoscope with an insertion tube diameter of 5.2mm and working length of 550mm.

A window in the delivery catheter at the proximal end of the stent provides the ability to visualize the proximal end of the intended treatment site using a bronchoscope. This feature aids in the proper alignment of the proximal end of the stent relative to the intended treatment site. The central lumen of the delivery catheter also allows the bronchoscope to be advanced through the distal end of the delivery catheter, enabling visualization of the distal end of the treatment site.

The stent and delivery system are provided non-sterile. For user sterilization information, see the section in these Instructions for Use, under the heading **Sterilization Information**. The complete Instructions for Use should be reviewed before using this system.

Non-clinical testing has demonstrated that the AERO® Tracheobronchial Stent System is MR Conditional. It can be scanned safely under the following conditions:

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

In non-clinical testing, the **AERO DV® Tracheobronchial Stent System** produced a temperature rise of less than 1.8°C at a maximum specific absorption rate (SAR) of 3 W/kg for 15 minutes of MR scanning in a 3-tesla MR system using a transmit/receive body coil (excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI) MR scanner. 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 AERO DV® stent. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

INDICATIONS FOR USE

The **MERIT ENDOTEK™ AERO DV® Tracheobronchial Direct Visualization 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 severe harm and/or death.

CONTRAINDICATIONS

The **MERIT ENDOTEK™ AERO DV® Tracheobronchial Direct Visualization 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 **MERIT ENDOTEK™ AERO DV® Tracheobronchial Direct Visualization 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 over-growth at stent ends
- Occlusion due to granulomaous 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™ AERO DV® Tracheobronchial Stent Technology 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 MERIT ENDOTEK™ AERO DV® stent for treatment of lesions where placement of the device may obstruct a functioning major side branch.
4. Do not cut the stent or the delivery catheter. The device should only be placed and deployed using the supplied catheter 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 catheter breakage.
6. Do not use a bronchoscope which has bumps or kinks from previous use or repair as this may increase the friction between the bronchoscope and inner sheath or stent and may result in premature stent deployment.
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.

STENT DIAMETER SIZING TABLE (TABLE 1)

DEVICE SIZING	
Labeled Device Diameter (mm)	Normal Proximal Lumen Diameter (mm) (1)
12	9.0 - 11.5
14	10.5 - 13.5
16	12.0 - 15.5
18	13.5 - 17.5
20	15.5-19.5

- (1) Recommended device diameter oversizing relative to the healthy native lumen diameter is approximately 2mm.
 (2) Labeled device lengths are nominal.

STENT LENGTH SIZING TABLE (TABLE 2)

DEVICE SIZING					
Labeled Stent Diameter (mm)	Labled Length 20mm	Labled Length 30mm	Labled Length 40mm	Labled Length 60mm	Labled Length 80mm
	Stenosis Length (mm)				
12	5.7	15.7	25.7	N/A	N/A
14	5.7	15.7	25.7	N/A	N/A
16	N/A	N/A	21.4	41.3	61.2
18	N/A	N/A	22	42	62.3
20	N/A	N/A	22.5	38.2	59.2

10. Do not withdraw the **MERIT ENDOTEK™ AERO DV® Tracheobronchial Stent Technology System** delivery catheter back into endotracheal tube, or introducer sheath once the device is fully introduced. Withdrawing the delivery catheter back into the endotracheal tube, or introducer sheath may cause damage to the device, premature deployment, deployment failure, and/or catheter separation. If removal prior to deployment is necessary, do not reuse the **MERIT ENDOTEK™ AERO DV® Tracheobronchial Stent System** or delivery device.
11. Do not reposition the stent by grasping the polyurethane covering. Always grasp the metal strut 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) 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 SELECTION

- Prior to implantation of the **MERIT ENDOTEK™ AERO DV®** stent, the physician should refer to the Sizing Table (Table 1) on the previous pages and read the Instructions for Use.
- When used in the treatment of stenotic or obstructive lesions, placement of the **MERIT ENDOTEK™ AERO DV®** luminal dilation confirmed by fluoroscopy and/or bronchoscopy. The device must be sized in accordance with the Sizing Table (Table 1) using accurate measurement techniques.
- Proper placement of the device should be monitored and confirmed using bronchoscopy and/or fluoroscopy.

INSTRUCTIONS FOR USE

Required Equipment:

- Bronchoscope with an insertion tube diameter of 5.2mm or smaller and working length of 550mm or longer OR Rigid Tracheal Tube WITHOUT universal connector with a maximum length of 270mm
- **AERO DV® Tracheobronchial Stent** of appropriate length and diameter

Optional Equipment:

- Fluoroscopic imaging may be used to facilitate airway lumen dilation if required prior to stent placement. Fluoroscopic imaging may also be used in addition to bronchoscopy to aid in accurate stent placement. **MERIT ENDOTEK™** recognizes that the practice of medicine varies from physician to physician and institution to institution; and therefore, the following is provided as a suggested guideline, and not as strict procedural guidance.

1. Locate Stenosis and Pre-Dilate as Necessary.

Pass a bronchoscope into the airway beyond the tracheobronchial stricture. If necessary, dilate the stricture to a diameter equal to the diameter of the delivery device catheter or approximately 10.0mm (30F) minimum using a balloon catheter dilator.

When selecting a rigid tube for placement of the stent with rigid bronchoscopy select a tracheal tube that has an internal diameter of not less than 10.0mm to allow sufficient clearance between the delivery system and the rigid tube. The physician should confirm that there is adequate clearance before proceeding with the stent placement.

WARNING: Do not attempt placement of the **MERIT ENDOTEK™ AERO DV® Tracheobronchial Stent System** in patients with stenoses that cannot be dilated sufficiently to allow passage of the delivery catheter.

2. Estimate the Stenosis Length and Luminal Diameter.

This estimation may be performed by visual inspection via bronchoscopy or via fluoroscopy. When measuring the length: advance the scope to the distal end of the lesion, pause and observe the anatomy. Once familiar with the landmark of the distal end of the lesion advance the scope an additional 5mm. (If there are measurement markers on the scope they can be used to verify this length). At this point, remove any kinks or extra bends in the bronchoscope as it may result in incorrect estimation of stent length. Grasp the proximal end of the scope at the mouth piece or nostril and do not release your grasp. Retract the scope until the proximal end of the lesion can be visualized. Continue retracting the scope until it is positioned 5mm proximal to the lesion site. With your opposite hand grasp the proximal end of the scope at the mouth piece or nostril 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. While selecting the stent length consider that the stent should not be blocking any side branches which should remain open. Review the Instructions 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. When using rigid bronchoscopy, the OD of the rigid tube may give a far more accurate measurement of diameter. 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. The stricture should be dilated to approximately 75% of the nominal stent 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 5mm margin both proximally and distally. Ideally, the stricture should be in between the two dog-bone flanges of the stent. 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. Avoid choosing a stent that would cross side branches when placed. See Sizing Table (Table 1).

5. Inspect and Prepare the AERO DV® Tracheobronchial Stent System.

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. Visually inspect the Tracheobronchial Stent System for any sign of damage. Do not use if it has any visible signs of damage. Carefully remove the device from the shipping support tube backing card. NOTE: The AERO DV® Tracheobronchial Stent System is supplied with a plastic shipping support tube in the inner lumen. This shipping support tube MUST be removed prior to insertion into the patient. Carefully remove the plastic shipping support tube from the inner lumen of the delivery catheter by slowly pulling the mandrel proximally through the device handle. The plastic trigger guard 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.

6. Load the AERO DV® Tracheobronchial Stent System.

6.1 Using Flexible Bronchoscope

Load the flexible bronchoscope into the proximal end of the delivery catheter. Use caution when advancing the bronchoscope through the catheter in order to prevent damage to or movement of the stent. Advance the bronchoscope through the delivery device until the catheter handle is adjacent to the bronchoscope handle. Rotate the device relative to the bronchoscope so that the window at the proximal end of the stent will be positioned towards the patient's chin and thus towards the anterior tracheal wall upon advancement into the anatomy.

6.2 Using Rigid Tracheal Tube

Load the telescope (video rod) of the rigid bronchoscope into the proximal end of the delivery catheter. Use caution when advancing the telescope through the catheter in order to prevent damage to

or movement of the stent. Advance the telescope through the delivery device until the catheter handle is adjacent to the telescope handle (proximal end).

Lubricate the distal portion of the stent delivery catheter with water-soluble lubricant to aid in introduction.

7. Positioning of AERO DV® Tracheobronchial Stent in Airway.

7.1 Using Flexible Bronchoscope

The flexible bronchoscope will be used as a guide to place the **AERO DV® Tracheobronchial Stent System** into the airway. Under bronchoscopic visualization, advance the bronchoscope, with the AERO DV® Tracheobronchial Stent System loaded on the proximal end, through the vocal cords, into the trachea. Visualize vocal cords during insertion to confirm that there is no damage to the bronchoscope during the loading of Stent System.

7.2 Using Rigid Tracheal Tube

Remove the universal connector of the rigid tracheal tube if it is there. The telescope will be used as a guide to place the AERO DV® Tracheobronchial Stent System into the airway. Under visualization, advance the telescope, with the AERO DV® Tracheobronchial Stent System loaded on the proximal end, into airway.

If patient's blood oxygen saturation level falls below the acceptable limit, remove the stent system with telescope en bloc. If stent is deployed more than 50% of its length, complete deployment before removing stent system.

Using bronchoscopy, visualize the distal end of the lesion. While maintaining the position of the bronchoscope, use the bronchoscope as a guide to advance the **AERO DV® Tracheobronchial Stent System** over the bronchoscope until the tip of the catheter can be visualized using bronchoscopy. Using the depth markings on the proximal end of the bronchoscope, continue to advance the delivery catheter 5mm distally. This step aligns the distal end of the stent 5mm distal to the distal edge of the stricture. While maintaining the position of delivery catheter, retract the bronchoscope proximally until the delivery catheter window is visualized using bronchoscopy. For a 360° view, rotate the delivery catheter relative to the bronchoscope while maintaining the same axial position of the bronchoscope and the delivery catheter. Now, maintaining the position of delivery catheter, advance the bronchoscope until you can see the distal end of the stent. The stent is now in proper position for deployment (Fig. 1) Visualization through the proximal window is not possible once stent deployment is initiated, therefore it is important to

endoscopically establish an anatomical landmark at the desired location of the distal end of the stent prior to stent deployment. Positioning of the distal end of the stent relative to this distal anatomical landmark should be confirmed after stent deployment is initiated, but prior to 50% deployment, to enable proximal positioning. Remove the plastic trigger guard from the handle by pulling the tab on the proximal end, taking care not to reposition the stent.

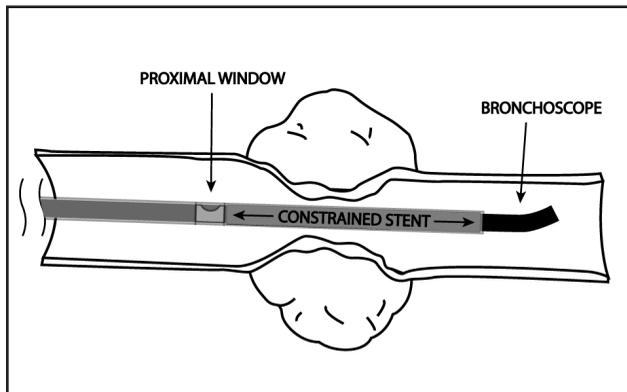


Figure 1.

8. Deployment of stents 60mm and shorter in length.

Place the handle of the delivery system in the palm of your hand (Figure 2). Wrap your ring and pinky finger around the base of the handle to form a 'pistol grip.' Then rest the tips of the index and middle finger on the deployment trigger.

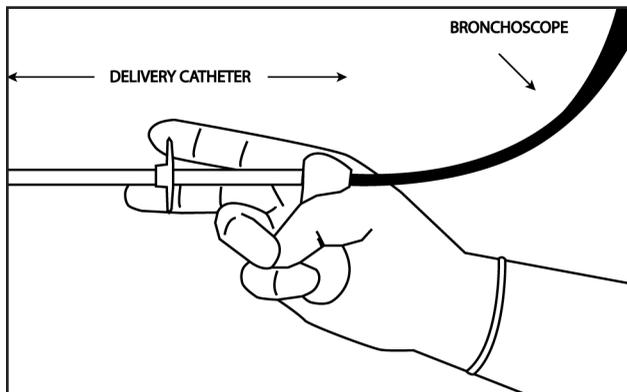


Figure 2.

Slowly pull back the deployment trigger until the trigger touches the handle. This action will withdraw the outer sheath, deploying the stent (Fig. 3). Carefully remove the delivery system without disturbing the position of the stent.

IMPORTANT: While deploying the stent, pull back slightly on the handle to create a back tension to prevent the device from creeping forward. This action counters the tendency of the stricture to pull the expanding stent forward.

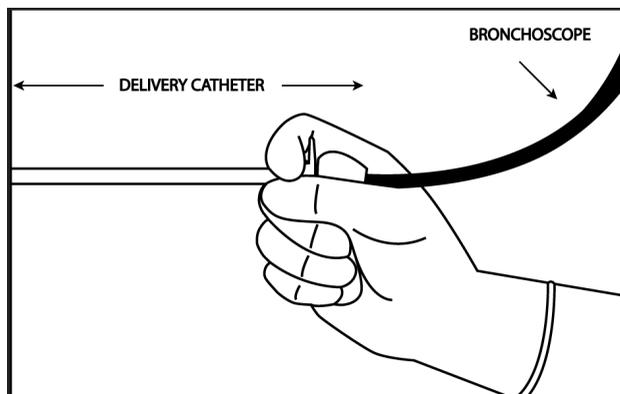


Figure 3.

Monitor the stent being deployed via bronchoscopy segment by segment. Retract the bronchoscope slightly, if necessary, to constantly visualize the stent deployment. If necessary, stop deployment and adjust the stent position proximally. The stent may be repositioned proximally until the distal end of the stent aligns with the previously identified distal anatomical landmark while holding the position of the deployment handle and moving the delivery system as a unit. The stent may be repositioned proximally until it has been deployed to approximately 50% of its length. The indicator for 50% deployment is located on the proximal end of the catheter.

9. Deployment of stents longer than 60mm.

The delivery device for stents greater than 60mm in length has a handle with 2 deployment triggers which allows the user to deploy the stent in two steps (Fig. 4).

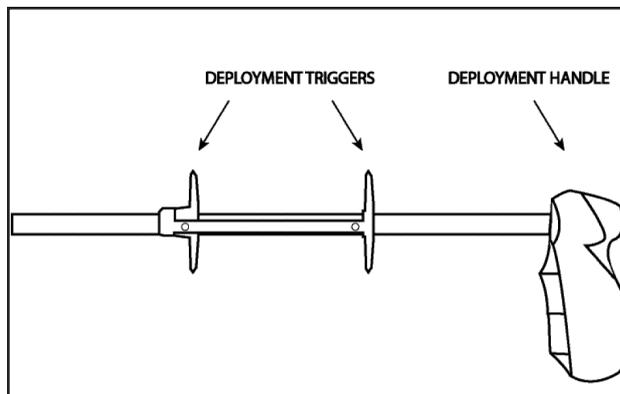


Figure 4.

Place the handle of the delivery system in the palm of your hand (Fig. 5). Wrap your ring and pinky finger around the base of the handle to form a 'pistol grip.' Then rest the tips of the index and middle finger on the first deployment trigger.

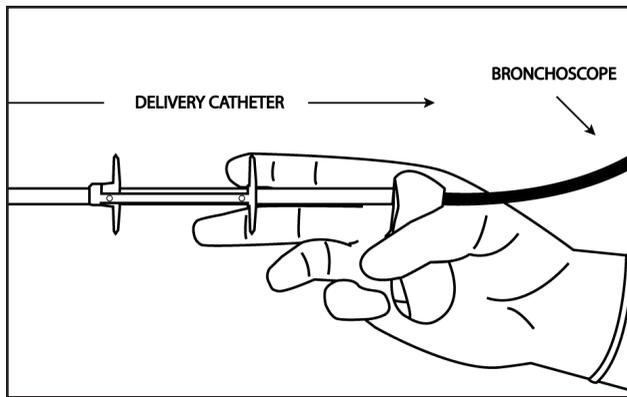


Figure 5.

Slowly pull back the first deployment trigger until the trigger touches the handle. This action will withdraw the outer sheath, deploying the stent to approximately 50% of its length (Fig. 6).

IMPORTANT: While deploying the stent, *pull back slightly on the handle to create a back tension to prevent the device from creeping forward.* This action counters the tendency of the stricture to pull the expanding stent forward.

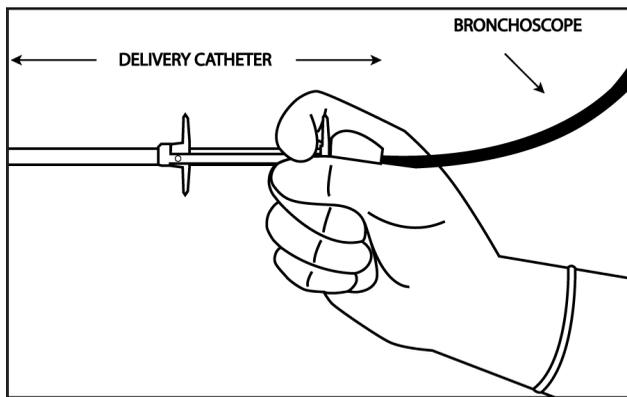


Figure 6.

After confirming the position of the stent, rest your index and middle finger on the second deployment trigger (Fig. 7).

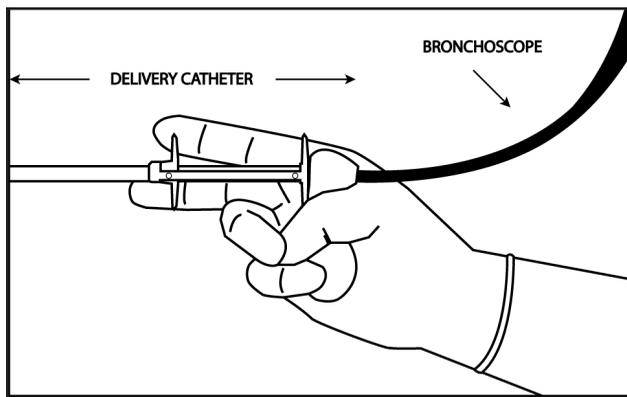


Figure 7.

Pull back the second deployment trigger until the trigger touches the handle. The stent is now fully deployed (Fig. 8).

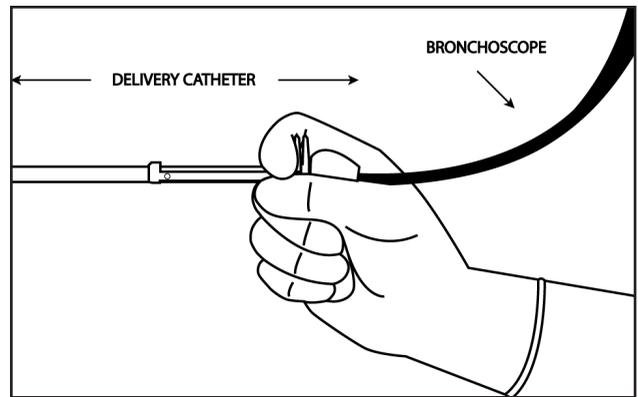


Figure 8.

10. Assess Deployed Stent and Remove Delivery System.

Confirm bronchoscopically that the stent has completely deployed and expanded. The stent placement may also be visualized endoscopically if desired. Carefully remove the bronchoscope together with delivery catheter from the patient, using care not to move the stent. The delivery catheter may be removed from the bronchoscope by pulling the bronchoscope proximally through the lumen of the delivery catheter. If the stent appears to be damaged or is not evenly and fully deployed, it should be removed following the Instructions 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 to recompress the stent prior to withdrawing the system.

REPOSITIONING OF THE TRACHEOBRONCHIAL STENT

The **AERO DV® Tracheobronchial Stent** design allows for repositioning of the stent proximally immediately after placement. Repositioning distally is not recommended. The repositioning of the stent may be necessary in the event that the stent is not in the desired location or is improperly sized. Position the bronchoscope so that the proximal end of the stent is visible. 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 **AS THIS MAY FRACTURE OR TEAR THE COVER OF THE STENT.** Open the forceps and carefully pass the forceps over the end of the stent at the location of one of the 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. Close the forceps over the stent connector, grasping as much of the stent connector as possible. Do not grasp the cover of the stent. **Do not rotate the stent.** Gently apply traction to reposition the stent proximally.

For a stent with a repositioning/removal aid (blue colored braided suture) the AERO DV® Tracheobronchial Stent can be repositioned

with a rat-tooth forceps by grasping the suture adjacent to the knot and carefully applying traction. The purse-stringing effect releases the proximal end of the stent from contact with luminal wall, thus facilitating atraumatic repositioning. Be certain to collapse the stent sufficiently to prevent injury to tissue.

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. Dilation is not recommended.

WARNING: Do not attempt to reposition the stent by grasping middle or distal end of the stent.

WARNING: Rat tooth forceps may only be used to grasp the suture knot during repositioning. Do not use rat tooth or biopsy forceps to grasp the metal struts or polyurethane covering to reposition the stent.

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. There were no reports of tissue in-growth into the lumen of the stent.

REMOVAL OF THE TRACHEOBRONCHIAL STENT

The **MERIT ENDOTEK™ AERO DV® Tracheobronchial Stent** design allows for removal of the stent proximally immediately after placement. The removal of the stent may be necessary in the event that the stent is not in the desired location or improperly sized. Position the bronchoscope so that the proximal end of the stent is visible. Open the forceps and carefully pass the forceps over the end of the stent at the location of one of the 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. 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. Use this technique for stent removal only. For a stent with a repositioning/removal aid (blue colored braided suture) the **AERO DV® Tracheobronchial Stent** can be removed with a rat-tooth forceps by grasping the suture adjacent to the knot and carefully applying traction. The purse-stringing effect releases the proximal end of the stent from contact with the luminal wall, thus facilitating atraumatic removal. Be certain to collapse the stent sufficiently to prevent injury to tissue.

WARNING: Do not attempt to remove the stent by grasping middle or distal end of the stent.

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. There were no reports of tissue in-growth into the lumen of the stent.

PACKAGING AND LABELING

Inspect the **MERIT ENDOTEK™ AERO DV® Tracheobronchial Stent Technology 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 1-800-35-MERIT (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™ AERO DV® Tracheobronchial Stent System** in a normal room temperature environment.

HOW SUPPLIED

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

WARNING: The **MERIT ENDOTEK™ AERO DV® Tracheobronchial Stent System** is provided non-sterile.

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

STERILIZATION INFORMATION

If the user facility desires to sterilize the device prior to use the following information should be used as guidance.

Preconditioning Exposure parameters:

100° ± 10° F at 50% RH for 20 hours minimum
Maximum time between pre-conditioning and sterilization equals 30 minutes

EtO Process Cycle Parameters:

100% EtO for 10 hours minimum at 600 – 650 mg/L (to achieve 11" Hg. Pressure rise)
Product temperature monitored at 140° F maximum

Post Process Aeration:

110° ± 10° F at ambient RH for 24 hours minimum

This sterilization process has been validated using the half-cycle method in conformance with ANSI/AAMI/ISO 11135:1994 by **MERIT ENDOTEK™** to provide a SAL of 10⁻⁶. Proper aeration will result in EtO residuals, ECH residuals and EG residuals below those required by ISO 10993-7. Because **MERIT ENDOTEK™** cannot assure proper calibration and validation of the user

equipment and process, sterility is the responsibility of the user.

DO NOT RESTERILIZE

For more information or to arrange for a demonstration, contact MERIT ENDOTEK™ at the telephone number shown on the previous page.

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.