

AEROSIZER®

Tracheobronchial Stent Sizing Device

 Review Instructions For Use
Before Using This System.

 Single Use Only

 Non-sterile

CONTENTS

Instructions for Use3

IMPORTANT PRODUCT INFORMATION

Please read this information carefully before using the **MERIT ENDOTEK™ AEROSIZER®**. Failure to properly follow the instructions may result in serious clinical consequences.

CAUTION: Federal law (USA) restricts this device to sale by or on 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



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ENDOTEK™.

DEVICE DESCRIPTION

The **MERIT ENDOTEK™ AEROSIZER®** is comprised of the retractable sizing arms, a shaft, and a three ring handle (one for the thumb, the other two for the fingers). When the three-ring handle is contracted, a stiff wire is pulled through the shaft which in turn opens the sizing arms. The appropriate **MERIT ENDOTEK™ AERO®** or **AERO DV®** Stent diameter size is determined by observing the indication window located on the handle when the sizing arms of the **AEROSIZER®** lightly contact the walls of the lumen (**AERO®** Stent sizes 10mm - 18mm). For lumen wall diameters greater than 18mm, the **AEROSIZER®** can aid in determining the nominal lumen size by fully actuating the sizing arms (18mm) and visually comparing them to the normal lumen diameter. Markers are provided in 1cm increments at the distal end of the **AEROSIZER®** and at the proximal end of the **AEROSIZER®** below the handle. The appropriate **MERIT ENDOTEK™ AERO®** or **AERO DV®** Stent length is determined by referring to these length markers. The **AEROSIZER®** is designed for easy tracking through the working channel of a flexible bronchoscope or through a rigid bronchoscope (Figure 1).

INDICATIONS FOR USE

The **AEROSIZER®** is indicated for use in selecting the appropriate diameter and length of **AERO® Tracheobronchial** or **AERO DV®** Stents. This is a single use device and is only to be inserted temporarily into the patient during the sizing procedure.

CONTRAINDICATIONS

The **MERIT ENDOTEK™ AEROSIZER®** Stent Sizing Device is contraindicated for:

1. Any other use not specified in the Indications for Use
2. Re-use

POTENTIAL COMPLICATIONS

Potential complications include, but are not necessarily limited to:

PROCEDURAL COMPLICATIONS:

- Complications associated with bronchoscopy

ADDITIONAL CAUTIONS AND WARNINGS

1. The **AEROSIZER®** Stent Sizing Device should be used with caution and only after careful consideration in patients for which bronchoscopy is indicated.
2. This device is only intended to be used through a ≥ 2 mm working channel of a flexible or rigid bronchoscope. Do not attempt to introduce this device into the airways by itself or through an endotracheal tube or introducer sheath.

Attempting to introduce the device into the airways by itself can potentially cause:

- Abrasion
 - Bleeding
 - Vocal cord trauma
 - Perforation, tear or laceration of airway
 - Epistaxis
 - Throat pain
 - Laryngospasm
 - Hoarseness
3. This device is only intended to be used as a secondary stent sizing tool to support more traditional methods of lumen measurement such as CT scan, balloon sizing and visual sizing by an experienced operator.
 4. Do not use a kinked or damaged bronchoscope as this may increase the force necessary to actuate the device and may cause actuation failure or device breakage.
 5. Do not withdraw the **AEROSIZER®** back into the bronchoscope when the sizing arms are open. Withdrawing the **AEROSIZER®** back into the bronchoscope when the sizing arms are open may cause damage to both the device and the bronchoscope. It may also cause device actuation failure and/or device separation. If removal of the device is necessary prior to measuring, make certain the sizing arms are closed.

CAUTION: If the device is damaged, remove the device and do not attempt to reuse. If the device is damaged and it cannot be removed from the bronchoscope, the device and the bronchoscope can be removed en bloc.

6. Do not rotate the **AEROSIZER®** when the sizing arms are open. Rotating the **AEROSIZER®** when the sizing arms are open may cause damage to both the device and the bronchoscope. It may also cause device actuation failure, device deformation, and/or device separation. If removal of the device is necessary prior to measuring, make certain the sizing arms are closed.

RECOMMENDED INSTRUCTIONS FOR USE

1. Locate Stenosis and Pre-Dilate if Necessary.

Pass a flexible or rigid bronchoscope into the airway and beyond the stricture. If the bronchoscope cannot be passed through the stricture, dilate the stricture using a balloon catheter dilator until a bronchoscope can be passed. Keep the bronchoscope past the stricture for Step 2.

WARNING: Do not attempt insertion of the **AEROSIZER®** in patients with stenoses that cannot be dilated sufficiently to allow passage of a bronchoscope.

2. How to Read the Color Scale Window.

Squeeze the handle GENTLY until the sizing arms are seen to be slightly touching the walls of the lumen. When the normal lumen wall diameter is greater than 18mm the fully actuated sizing arms will not touch the lumen wall and can be used as a visual reference for sizing the lumen. Note the color (diameter) indicated in the handle window. Refer to TABLE 1 for color-to-diameter correlation and TABLE 2 for recommended stent diameter placement.

TABEL 1. MERIT ENDOTEK™ **AEROSIZER®** Stent Sizing Table

SCALE	DIAMETER (mm)	COLOR AT DISTAL END OF WINDOW
8	8	BLACK
10	10	RED
12	12	BLUE
14	14	GREEN
16	16	YELLOW
18	18	WHITE

3. Determine the Diameter of the Normal Lumen Distal to the Stricture.

Insert the **AEROSIZER®** through the working channel of the flexible or rigid bronchoscope. When the sizing arms have exited the distal end of the bronchoscope, locate the sizing arms in an area of normal lumen diameter. This is an area distal to the stent target site. With the sizing arms located in an area of normal lumen diameter, squeeze the handle GENTLY until the sizing arms are seen to be slightly touching the walls of

the lumen (Figure 2). When the normal lumen wall diameter is greater than 18mm the fully actuated sizing arms will not touch the lumen wall and can be used as a visual reference for sizing the lumen (Figure 3). Note the color (diameter) indicated in the handle window. After the color (diameter) has been noted, close the sizing arms by gently releasing the handle. Refer to TABLE 1 for color to diameter correlation.

CAUTION: For exceptionally large tracheas, the sizing arms might not reach the walls of the lumen when fully actuated. In this case, visual sizing by an experienced operator is required. The normal lumen diameter can be estimated by comparing the fully actuated sizing arms (18mm) to the normal lumen diameter.

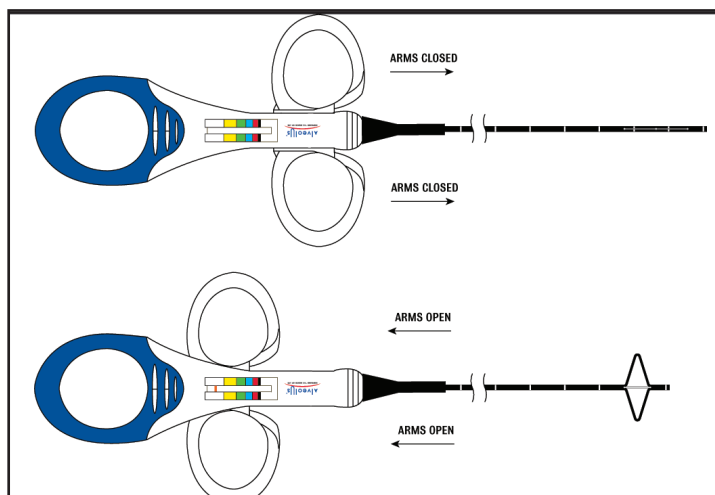


Figure 1.

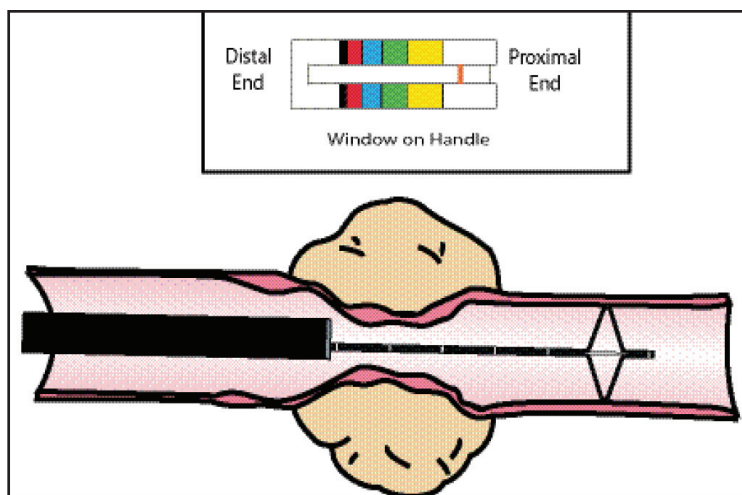


Figure 2.

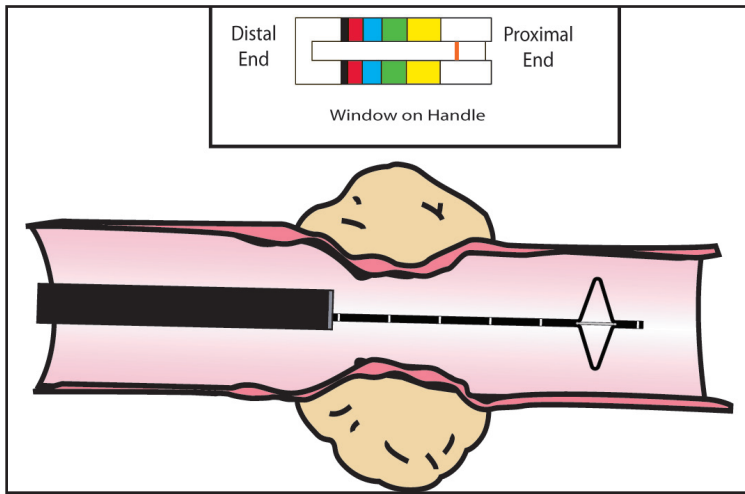


Figure 3.

WARNING: Make certain the sizing arms are only slightly touching the lumen wall when observing the color indicated in the handle window. The sizing arms can transmit enough force to the lumen wall to extend or temporarily dilate the tissue locally.

4. Determine the Diameter of the Lumen at the Stricture before Dilation or Debulking.

Close the sizing arms by gently releasing the handle. Slowly retract the flexible or rigid bronchoscope and the **AEROSIZER**[®] proximally until even with the most narrowed portion of the stricture. Squeeze the handle GENTLY until the sizing arms are seen to be slightly touching the walls of the lumen (Figure 4). Note the color (diameter) indicated in the handle window. After the color (diameter) has been noted, close the sizing arms by gently releasing the handle. Apply the same technique to record color (diameter) at different locations inside the stricture. If the color (diameter) varies, the physician should refer to the Sizing Tables located in the **AERO**[®] and **AERO DV**[®] Instructions for Use. Refer to TABLE 1 for **AEROSIZER**[®] color-to-diameter correlation.

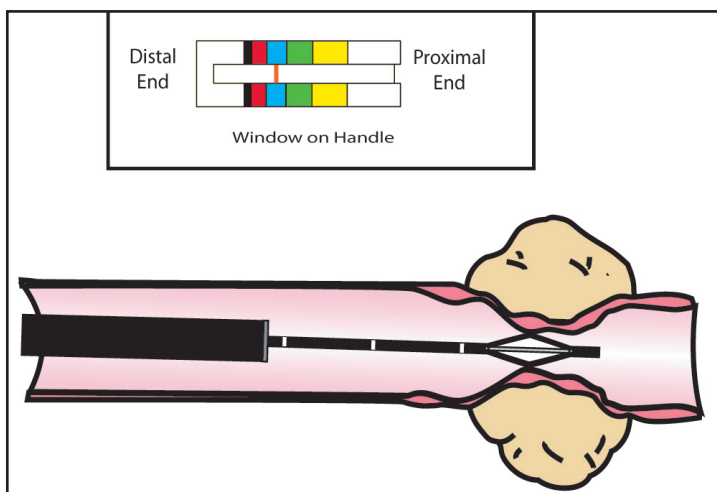


Figure 4.

5. Determine the Diameter of the Normal Lumen Proximal to the Stricture.

Close the sizing arms by gently releasing the handle. Slowly retract the flexible or rigid bronchoscope and the **AEROSIZER**[®] proximally until the sizing arms are located in an area of normal lumen diameter. This is an area proximal to the target stent site. With the sizing arms located in an area of normal lumen diameter, squeeze the handle GENTLY until the sizing arms are seen to be slightly touching the walls of the lumen (Figure 5). When the normal lumen wall diameter is greater than 18mm the fully actuated sizing arms will not touch the lumen wall and can be used as a visual reference for sizing the lumen (Figure 6). Note the color (diameter) indicated in the handle window. After the color (diameter) has been noted, close the sizing arms by gently releasing the handle. Refer to TABLE 1 for color-to-diameter correlation.

CAUTION: For exceptionally large tracheas, the sizing arms might not reach the walls of the lumen when fully actuated. In this case, visual sizing by an experienced operator is required. The normal lumen diameter can be estimated by comparing the fully actuated sizing arms (18mm) to the normal lumen diameter.

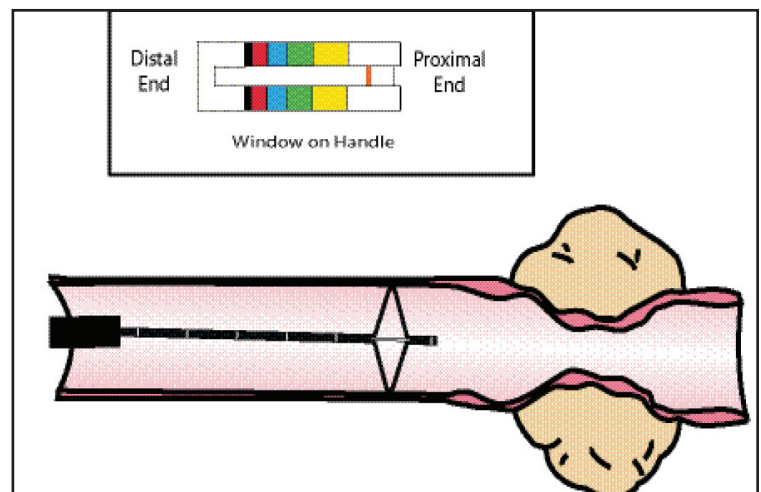


Figure 5.

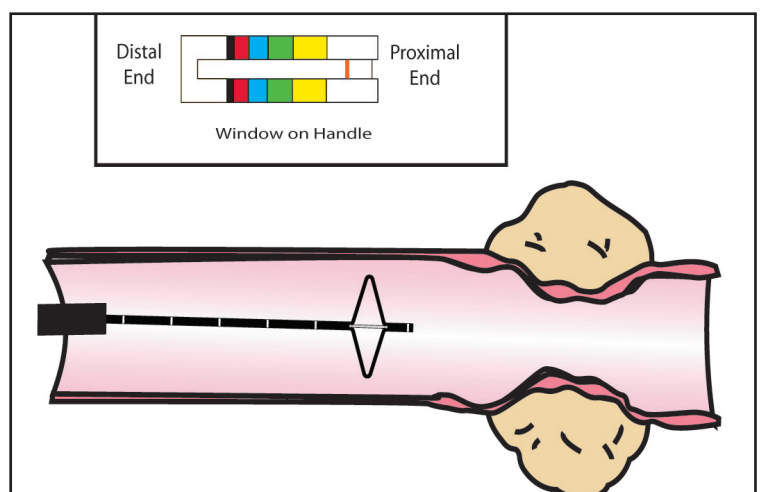


Figure 6.

6. Determine the Length of the Stricture.

Using the Distal Length Markers.

With the sizing arms closed and the **AEROSIZER**[®] tip flush with the distal end of the bronchoscope, advance the bronchoscope to the distal end of the stricture. Align the distal length marker located at the distal end of the device and the distal end of the bronchoscope evenly with the distal end of the stricture. While holding the device stationary, slowly retract the flexible or rigid bronchoscope proximally through the stricture until the distal end of the bronchoscope is even with the proximal end of the stricture. Note the number of length markers that are passed on the distal end of the device while retracting the bronchoscope from the distal end of the stricture to the proximal end of the stricture. Each marker represents 1cm (Figure 7).

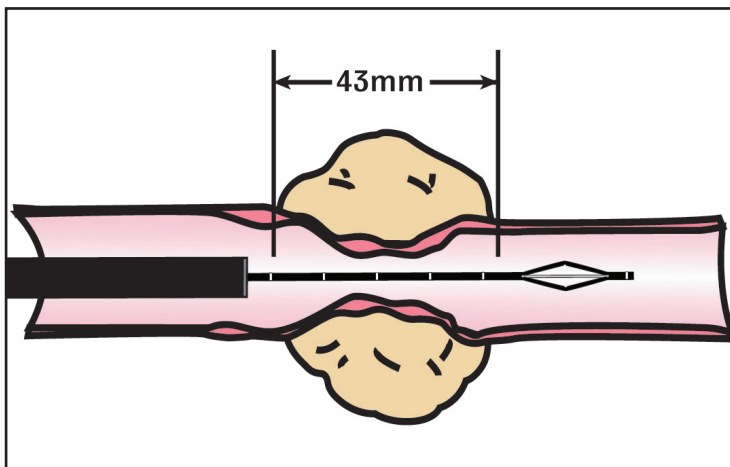


Figure 7.

Using the Proximal Length Markers.

With the sizing arms closed and the **AEROSIZER**[®] tip flush with the distal end of the bronchoscope, advance the bronchoscope to the distal end of the stricture. Align the distal length marker located at the distal end of the device and the distal end of the bronchoscope evenly with the distal end of the stricture. Note the proximal length marker that is aligned with the proximal end of the working channel of the bronchoscope. While holding the sizing device stationary, slowly retract the bronchoscope proximally through the stricture until the distal end of the bronchoscope is even with the proximal end of the stricture. Note the number of length markers that are passed on the proximal end of the device while retracting the bronchoscope from the distal end of the stricture to the proximal end of the stricture. Each marker represents 1cm.

7. Device Removal.

Close the sizing arms and carefully remove the **AEROSIZER**[®] from the working channel of the bronchoscope.

TABEL 2. Stent Diameter Recommendation

	Healthy Lumen Diameter (mm)	Stricture Diameter	* Recommended Stent Diameter
Trachea	>18	14	dilate or debulk
	>18	16	20
	>18	18	20
	18	12 or less	dilate or debulk
	18	14	18
	18	16	18
	16	10 or less	dilate or debulk
	16	12	16
	16	14	16
Bronchus	14	10 or less	dilate or debulk
	14	12	14
	12	8 or less	dilate or debulk
	12	10	12
	10	6 or less	dilate or debulk
	10	8	10

* MERIT ENDOTEK™ recognizes that the practice of medicine varies from physician to physician and institution to institution; and therefore, the tables above are provided as a suggested guideline.

WARNING: Using an **AERO**[®] stent in tracheas with a normal lumen diameter that measures greater than 20mm is not recommended.

8. Sizing the Stent from the Diameters and the Lengths Recorded. Prior to implantation of the **AERO**[®], the physician should refer to the Sizing Table (Table 1) located on page 5 in the **AERO**[®] Instructions for Use. The **AERO**[®] Stent must be sized in accordance with the Sizing Table and confirmed by using accurate measurement techniques such as CT scan, balloon sizing and visual sizing by an experienced operator.

WARNING: Do not attempt to place an **AERO**[®] Stent in a stricture that is not in accordance with the Sizing Table located in the **AERO**[®] Instructions for Use.

PACKAGING AND LABELING

Inspect the **AEROSIZER**[®] Stent Sizing Device 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 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 **AEROSIZER**[®] in a normal room temperature environment.

HOW SUPPLIED

The **AEROSIZER**[®] is a disposable, non-sterile, single-patient-use medical device. The **AEROSIZER**[®] has a nominal diameter (OD) of 1.6mm. The working length of the delivery system is 90cm. The overall length of the device is approximately 110cm. For more information or to arrange for a demonstration, contact MERIT ENDOTEK[™] at the telephone number shown above.

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

CAUTION: The **AEROSIZER**[®] is provided non-sterile. Do not use if the outer package is opened or damaged. Each packaged unit is intended for **SINGLE-PATIENT USE ONLY**.

WARNING: The safety and effectiveness of this device for use in the vascular system have not been established.

WARNING: Do not use this device when the **AEROSIZER**[®] sizing arms cannot be verified visually with an endoscopic field of view. Do not use this device when the **AEROSIZER**[®] size indicator cannot be verified visually.

WARRANTY

MERIT ENDOTEK[™], Inc. 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 MERIT ENDOTEK[™], Inc. directly affect the device and the results obtained from its use. The MERIT ENDOTEK[™], Inc. obligation under this warranty is limited to the replacement of this device, and MERIT ENDOTEK[™] shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device. MERIT ENDOTEK[™] neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. MERIT ENDOTEK[™] 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.