

AeroClear[®] aerosol evacuator

Instructions for Use

Intended Use:

The AeroClear aerosol evacuator intended for use to evacuate aerosols and fluids generated by surgical instruments from the nasal cavity during surgical procedures. The aerosols and fluids can consist of liquids, gases, and/or suspended particulates. The AeroClear aerosol evacuator is intended for use under the direction of a licensed health care provider.

Device Description:

The kit includes the aerosol evacuator that has a white suction connector attached to tubing that terminates in a beveled end. Inserted on this tubing is a yellow foam seal (14 mm diameter) and a black positioning ring; both can slide along the tubing. A spare larger foam seal (18 mm diameter) and male connector are also supplied. When surgery is performed in one nasal cavity, the AeroClear is placed in the contralateral cavity and connected to facility suction.

Warnings:

- If the distal end of the tubing becomes occluded the suction flow and aerosol evacuation will diminish: free the tubing and reposition the distal end of the tubing.
- If the distal end of the tubing becomes clogged with solid matter withdraw the device and the end can be trimmed off to restore an open end. Trim the end to mimic the beveled end.
- If the distal end of the evacuator is in a pool of liquid the suction flow and aerosol evacuation will diminish until the liquid clears the device. Thus, avoid placement in pools of liquid or pause the use of aerosol generating instruments until the device is cleared.
- Verify the vacuum connection is leak free, otherwise suction flow and aerosol evacuation will be diminished.
- If the foam seal is dislodged or the tubing slides out of the foam seal during the procedure, reposition the device following the instructions below for placing a device. Verify the tubing is free of any kinks as that may reduce suction flow and aerosol evacuation.
- The product shall be disposed of in compliance with pertinent government regulations regarding Medical Devices.

Precautions:

- Carefully read the Instructions for use prior to application.
- Single Use Only.
- Sterility not guaranteed if package is damaged or opened. Discard damaged or open packages.
- Expiration Date: This device should not be used after the end of the year and month shown.
- To prevent product contamination prior to application, always follow aseptic techniques.

Instructions:

1. Peel open the pouch to remove its contents.
2. Examine the nose endoscopically to ensure that there is adequate space to place the AeroClear tubing.
3. Visually assess the size of the nostril to determine if the larger foam seal is appropriate and replace seals if so determined.
4. Decongest the nose, if necessary, to facilitate placement of the tubing.
5. Determine the positioning of the open beveled end of the tubing based on the available space such that it will not get occluded or is in a pool of liquid. Any suspended location from just inside the vestibule, slightly protruding from the foam seal, to any location on the nasal floor will be suitable for creating the suction flow. The following instructions are for placing the tubing end just into the nasopharynx where it can be visualized with an endoscope. These instructions are to be adapted for other locations more proximal to the foam seal should the location in the nasopharynx not be accessible.
6. Slide the yellow foam seal close to the black positioning ring.
7. Place the beveled end of the tubing along the floor of the nose which will provide adequate space and stability for the tubing along its length. Make sure the beveled end is pointing upward.
8. Use 2 fingers and a rolling action to radially compress the foam seal and reduce its diameter as you insert it into the nostril. The entire Foam Seal should sit JUST inside the nostril tip, with the clear tubing running through its center. Release the foam once it is inside the nostril and it will expand and conform to the nostril shape and seal it from air exchange.
9. Place a zero- or 30-degree endoscope in the opposite (open) nostril and into the nasopharynx to

confirm the placement of the clear tubing, and to ensure that it is sitting at the back of the nasal cavity without touching the nasal walls or nasopharyngeal mucosa. If you cannot see the tubing, slowly continue to push the tubing into the nose through the lumen of the foam seal. Make sure the beveled end of the tubing is not in contact with tissue.

10. Once the tubing is well positioned, move the black positioning ring against the outside of the foam seal to prevent the tubing from moving, and to also identify the proper length of tubing to be retained within the nose. During surgery you can check the black ring to make sure it remains snug against the yellow foam seal, thus ensuring proper placement of the tubing, and a functioning AeroClear.
11. Attach the white suction connector to the suction device of choice. Use the supplied male connector as needed to connect 2 female suction connectors. Suction pressure of 200 mm of Hg is adequate for proper suction effect. Higher suction is acceptable and will only result in greater flow and even faster site clearance or if multiple instruments are connected to the same suction source.
12. Once you have completed surgery on one side, gently remove the yellow foam seal from the nostril along with the tubing and black positioning ring.
13. Try not to alter the position of the foam seal and positioning ring to help with accurate placement into the opposite nostril, as there will be symmetry between right and left sides of the nose. Repeat the steps above to insert the AeroClear into the opposite nostril and ensure proper function.
14. At the end of the surgery, remove the AeroClear completely from the nose, including the yellow foam and entire length of tubing, and discard properly in a suitable medical waste receptacle.

How Supplied:

The device is terminally sterilized by gamma irradiation. See individual carton label for carton quantity.

Storage and Handling:

The AeroClear aerosol evacuator does not require any special storage conditions. Once product package is opened, contents may be subject to contamination. Discard any unused product after opening.

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



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 Made in USA.
 Patent Pending.

Symbol	Description	Store at room temperature
Rx ONLY	CAUTION: Federal (U.S.) law restricts this device to sale by or on the order of a physician	
#	Quantity Symbol: numeral in symbol (in place of #) indicates the quantity of units in package.	
⚠	Caution: See Instructions for Use	
STERILE R	Sterilized by Irradiation	
S	Single Use Only. Do not reuse.	
R	Do Not Re-sterilize	
D	Do Not Use if Package is Damaged	
	Manufacturer	
REF	Catalog Number	
LOT	Lot Number	
	Expiration Date (Use By). This device should not be used after the end of the year and month shown.	