Instructions for Use

endOclear® with Collection Adapter
Catalog No. EC-100-01
STERILE

READ ALL INSTRUCTIONS BEFORE USE!

Federal (USA) law restricts this device to sale by or on the order of a physician. Single Use Device. Do not reстерилize.

PRODUCT DESCRIPTION
The endOclear® device (ECD) is a sterile single use device. The ECD wiper is a disk shaped wiper that can be used to clear away mucus, secretions and bacteria from the inside of the endotracheal tube (ETT).

The ECD Collection Adapter (BCA-1) is intended to be used with EC-100-01, and is a sterile single use device. The BCA-1 fits most standard adult endotracheal tubes (ETT).

INDICATION FOR USE
The ECD is indicated for the cleaning of endotracheal tubes sized 7mm to 9mm, where a humidification device is in use.

⚠️ WARNINGS AND PRECAUTIONS

- **Do NOT use in a dry ETT.**
- **Do not release the Safety Toggle (RED) until the device is properly positioned at the end of the ETT, as measured by length marking**
- **Do not deploy the wiper distal to the tip of the ETT.**
- **Do NOT use excessive force when removing the ECD. Wiping action should be gentle, and smooth. If any hard resistance is encountered, release the pressure on the trigger and carefully remove the device.**
- **Do NOT use the device if it is kinked, or appears damaged in any way.**
- **Do NOT use in ETT smaller than 7mm or larger than 9mm**

To avoid or minimize alveolar derecruitment, always make disconnections and connections to the ventilatory circuit (bronchoscopic or other device adapters) as rapidly but safely as possible.

Federal Law (USA) restricts this device to sale by or on the order of a physician. Do not use this device if package is damaged or opened. Do not use this device if it shows signs of damage, e.g., crimps, kinks, or crushed areas. This device is for single use only. **DO NOT REUSE. DO NOT RESTERILIZE.** Proper surgical procedures and techniques are necessarily the responsibility of the medical profession. These instructions are furnished for informational purposes only. Each user must evaluate the appropriate use of this device, case by case, based on medical training, experience, and the type of procedure employed. Dispose of used products in accordance with established hospital protocol for hazardous waste. Verify all user connections of this device are secure prior to use.
**Non-Sheath Technique**

1. Pre-oxygenate the patient.
2. Use universal precautions, specifically clean gloves and eye protection.
3. Check that the ETT is securely attached to the patient and note centimeter markings at the teeth or lip.
4. Open the Biofilm Collection Adapter (BCA-1), using clean technique.
5. Rapidly insert the BCA-1 between the endotracheal tube and the ventilator, with the ventilator connection superior and the insertion/collection port inferior.
6. Open the ECD package at the end where the handle of the device is located and remove the device.
7. Test device function by first pulling the red safety toggle back until it snaps into the handle. Next, deploy the ECD wiper using a syringe like motion of the handle, bringing the finger grips and thumb hole toward each other until the stop is reached. The distal cleaning member of the device should deploy to resemble a disk. Once appropriate function of the cleaning member is assured, return the finger grips and thumb hole to their nominal positions and reengage the red safety toggle by pushing it forward until it once again snaps into the handle. If the cleaning member does not deploy on testing, do not use the ECD and replace it with a new one.
8. Place a dollop of sterile lube (Surgilube® for example) over the end of the BCA-1 where the device is to be inserted.

**Usage and disposal**

1. Squeeze opposite sides of the distal sheath to open up the end of the sheath and slide the sheath over the BCA-1 while simultaneously inserting the tip of the ECD through the insertion port of the BCA-1.
2. Initially insert the device until the blue stop comes to rest against the BCA-1.
3. Continue to insert the device while visually matching up the centimeter markings on the ETTube with those on the device (do not insert more than 1 to 2 cm beyond these landmarks). The blue stop serves as a “drag” to prevent rapid insertion inadvertently beyond the end of the endotracheal tube.
4. Once the device is in position, pull the safety toggle (RED) back so that it snaps into the handle.
5. Holding the BCA-1 and the sheath with the other hand, clean the tube by deploying the cleaning member as in instruction number (8) above and then pulling the device out over approximately 3 to 5 seconds, timed with patient expiration. **Do not use excessive force to wipe the ETT clear.** ECD users should feel a smooth wiping action.
6. If at any time the device is difficult to remove, or cannot be removed from the ETT in the deployed position, release the thumb and finger grips and pull device back slightly. Then attempt redeployment and removal.
7. Once the tip of the device is withdrawn into the BCA-1, the adapter and device may be separated from the ventilator circuit and disposed of as a unit.
8. If factors indicate that a second pass is appropriate, the RED safety toggle must be reset and the device should be removed from the adapter and retracted into its sheath. Confirm that the wiper is in working order before attempting a second cleaning. **A second insertion should be done using a second BCA-1 adapter to avoid carrying previously cleared secretions back into the ETT.**
9. Alternatively, a new BCA cassette can be attached to the BCA-1. Steps (1) through (7) may then be repeated.
10. Biofilm and secretions should be handled following the hospital’s policy for contaminated waste. (ETT, suction catheter disposal)

**Protective-Sheath Technique**

1. Pre-oxygenate the patient.
2. Use universal precautions, specifically clean gloves and eye protection.
3. Check that the ETT is securely attached to the patient and note centimeter markings at the teeth or lip.
4. Open the Collection Adapter (BCA-1) using aseptic technique.
5. Rapidly insert the BCA-1 between the endotracheal tube and ventilator, with the ventilator connection superior and the insertion/collection port inferior.
6. Open the ECD package at the end where the handle of the device is located and remove the device.
7. Test device function by first pulling the red safety toggle back until it snaps into the handle. Next, deploy the ECD wiper using a syringe like motion of the handle, bringing the finger grips and thumb hole toward each other until the stop is reached. The distal cleaning member of the device should deploy to resemble a disk. Once appropriate function of the cleaning member is assured, return the finger grips and thumb hole to their nominal positions and reengage the red safety toggle by pushing it forward until it once again snaps into the handle. If the cleaning member does not deploy on testing, do not use the ECD and replace it with a new one.
8. Place the device alongside the ETT and match up the length markings on the ETT with those on the device.
9. Pinch the moveable stop (blue) and move it to set the appropriate length for device insertion.
   a. With closed suction systems, adjust the movable stop to position it at the most proximal location of the port through which the ECD will be inserted.
   b. With open suction, adjust the stop to position it at the most proximal location on the ETT or BCA-1 that corresponds to the site of insertion of the ECD.

**Usage and Disposal**

1. Put on sterile gloves and have an assistant remove the sterile sleeve protecting the ECD and grasp the device near the tip using the same hand that will later be used to fire the device.
2. Open the hinged port of the BCA-1 for insertion of the ECD
3. Place a dollop of sterile lube (Surgilube® for example) over the end of the BCA-1 where the device is to be inserted.
4. Insert the device through the BCA-1 into the ETT until the stop engages. **Do not over-insert beyond these landmarks.**
5. Once the device is positioned, pull the safety toggle (RED) back so that it snaps into the handle.
6. At the end of patient or ventilator inspiration, deploy the ECD wiper using a syringe-like motion, bringing the finger grips and thumb hole toward each other until the stop is reached.
7. **Holding the ETT with the other hand,** clean the tube by pulling the device out over approximately three to five seconds, timed with patient expiration. **Do NOT use excessive force to wipe the ETT clear.** ECD users should feel a smooth wiping action.
8. If at any time the device is difficult to remove, or cannot be removed from the ETT in the deployed position, release the thumb and finger grips and pull the device back slightly. Then attempt redeployment and removal.
9. Once the tip of the device is withdrawn into the BCA-1, the adapter and device may be separated from the ventilator circuit and disposed of as a unit. (If the BCA-1 is not used, as the wiper becomes visible in the ETT outside of the patient, be prepared to use a 4x4 to capture the sections and biofilm that are removed from the ETT.)
10. If factors indicate that a second pass is appropriate, the RED safety toggle must be reset and the device should be removed from the adapter and retracted fully. Confirm that the wiper is in working order before attempting a second cleaning. A **second insertion should be done using a second BCA-1 adapter to avoid carrying previously cleared secretions back into the ETT.** If not using an adapter, the tip of the ECD may be wiped clean using a 4x4 and sterile lubricant. **Do NOT use alcohol on the wiper.**
11. Alternatively, a new BCA cassette can be attached to the BCA-1. Steps (2) through (9) may then be repeated.
12. Biofilm and secretions should be handled following the Hospital’s policy for contaminated waste. (ETT, Suction Catheter Disposal)

**WARRANTY**

ENDOCLEAR LLC warrants the instrument against defects in material and workmanship subject to the conditions that the instrument has been used in accordance with its operating instructions at all times.

The end customer shall bear the cost of transportation and risk of return shipments.

Opening the equipment or performance of any repairs or modifications to the equipment by unauthorized persons shall release ENDOCLEAR LLC from any liability for its performance. Any such opening, repair, or modification performed during the warranty period shall void all warranties expressed or implied.

Representations and warranties made by any person, including but not limited to dealers and representatives of ENDOCLEAR LLC which are inconsistent or in conflict with the terms of this limited warranty, shall not be binding upon ENDOCLEAR LLC unless reduced to writing and approved by an expressly authorized officer of ENDOCLEAR LLC.

This limited warranty is the complete and exclusive statement of warranty which ENDOCLEAR LLC agrees to provide with respect to this product and it shall supersede all prior and contemporaneous oral or written agreements, understandings, proposals, and communications pertaining to the subject matter hereof.

**Manufactured for:**

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