Instructions for Use

endOclear® Restore2™
Catalog No. EC-350-0001
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 resterilize.

PRODUCT DESCRIPTION
The endOclear® Restore2™ endotracheal tube cleaner (Restore2) is a sterile single use device. The Restore2 wiper is a radially expanding squared edged wiper that can be used to clear away mucus, secretions and bacteria from the inside of the endotracheal tube (ETT). The attached Collection Adapter (BCA) fits most standard adult endotracheal tubes (ETT).

INDICATION FOR USE
The Restore2 is indicated for the cleaning of Adult endotracheal tubes sized **7mm to 8.5mm**, where a humidification device is in use.

⚠ WARNINGS AND PRECAUTIONS

- **Do NOT use excessive force when removing the Restore2. Wiping action should be gentle, and smooth. If any hard resistance is encountered, release the pressure on the syringe and carefully remove the device.**
- **Do NOT use the device if appears damaged in any way.**
- **Do NOT use in ETT smaller than 7mm or larger than 8.5mm**
- **Do NOT cut ETT while Restore2 device is attached**
- **Do NOT overinflate (Syringes included are for use with 7.0-7.5 or 8.0-8.5 ETT only). Use specific syringe for specific ETT size.**
- **Do NOT insert past the appropriate centimeter depth marking.**

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.

USAGE INSTRUCTIONS

Set Up

1. First perform endotracheal tube (ETT) suctioning with either a closed or open suction catheter according to AARC guidelines.
2. Check that the ETT is secure and note centimeter markings at the lip or teeth.
3. Using universal precautions and clean gloves, remove the Restore2 with Collection Adapter (BCA) from the sterile pouch.
4. Select the appropriate syringe (Red Label - 7.0-7.5 attached to wiper in package, or Blue Label 8.0-8.5). Connect to the Restore2 catheter as needed and test the wiper by firing the syringe completely and depressing. Withdraw plunger fully and depress fully. Assure that the cleaning member inflates. Note that it may not inflate symmetrically outside of the ETT. This is normal. Withdraw the syringe fully and confirm that the balloon spontaneously returns to its unexpanded position tight against the catheter.
5. Rapidly insert the BCA and Restore2 between the endotracheal tube and the ventilator, with the ventilator connection superior and the insertion port for the Restore2 device inferior.
6. Advance the Restore2 into the ETT taking care to align the centimeter markings on the Restore2 catheter with the visible centimeter markings on the ETT. In most cases on uncut ETTs, the catheter may be fully inserted. **Do not over-insert.**
7. Hold the BCA adapter and Restore2 sheath with one hand. At the end of patient or ventilator inspiration, completely fire the syringe and pull the Restore2 cleaning member back into the BCA over 3 to 5 seconds. **Do NOT use excessive force to wipe the ETT clear**. Restore2 users should feel a smooth wiping action.
8. If the device cannot be pulled back, release the syringe and remove the catheter. Recheck the inflation volume (above) that is recommended and repeat the procedure without fully depressing the syringe. If the device still cannot be pulled back, release the syringe and remove the catheter. Abort the procedure. Remove the BCA and reconnect the ventilator. Fiber optic bronchoscopy may be recommended.
9. The BCA and Restore2 can be removed from the ventilator circuit as a unit and discarded according hospital policy for hazardous waste.
10. If factors indicate the need for a second pass the Restore2 can be removed from the BCA and withdrawn into its protective sheath. Confirm function of the cleaning member by temporary re-inflation and deflation. Repeat the cleaning procedure in steps 7 through 11 above.
11. If endotracheal tube obstruction is still considered, evaluate other means of investigation such as fiber-optic bronchoscopy.

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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