



**INDICATION:**

Sil.Flex TC Pads are intended for use between the tracheostomy tube neck flange and patient to provide a stable, comfortable interface between flange and patient.

**⚠ WARNINGS:**

Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.  
 • Do not use this product if you have not been trained or are not proficient in changing tracheostomy tubes.

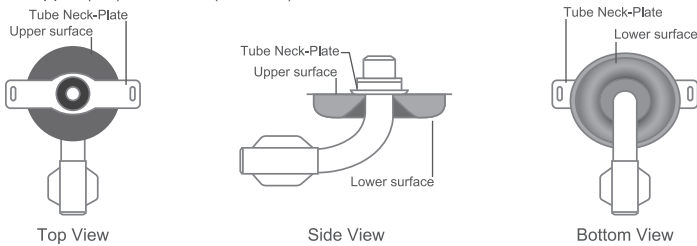
- Sterile unless package is opened or damaged.

**⚠ CAUTIONS:**

- Read and understand the contents of this insert and demonstrate proficiency in the application of this device prior to use.
- Inspect the Sil.Flex TC Pad before placement. If damaged, do not use.
- Periodically check for correct position of the Sil.Flex TC Pad.
- Do not use any hydrocarbon-based substance on any part of the Sil.Flex TC Pad.
- Sil.Flex TC Pads should be discarded after a maximum 30 day period, or should tracheostomy care dictate more frequent changes.
- Sil.Flex TC Pads are single patient use products and are not intended to be reprocessed and used on multiple patients.
- To obtain best performance from Sil.Flex TC Pads, use within 2 years from the week listed in the lot code (YYWW).

**PRODUCT FEATUERS:**

1. Manufactured from a non-filled gel silicone that is encapsulated in a polyurethane film to specific requirements.
2. An upper (flat) and lower (concave) surfaces.



The flat upper surface is designed to rest against the tracheostomy tube neck-plate (flange) while the concave lower surface rests against the neck.

- Seal around tracheostomy tubes from 8.0 to 16.0 mm outside diameter.
- Offered in 5.0 mm and 10.0 mm thicknesses.

**INSTRUCTIONS FOR USE:**

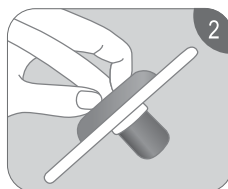
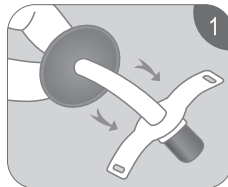
**⚠ Do not use this product if you have not been trained or are not proficient in changing tracheostomy tubes.**

**Note:** Placement of the Sil.Flex TC Pad on to the tracheostomy tube should be done prior to insertion of the tube. Although it is possible to stretch the pad over the tracheostomy neck-plate (flange) while the tube is in place, excessive force may be required which could traumatize the stoma site. The preferred and recommended installation technique is to place pad onto the tube prior to insertion in to the stoma.

1. Inspect package for damage. Discard product if package is damaged or package seal has been broken.
- Installation instructions 2 – 9 need to be performed by using aseptic technique.**
2. Remove the pad from the package and inspect for damage. Discard if product is ripped, torn or it shows any indication of defect.
3. Open and inspect the tracheostomy tube to be laced.
4. The flat side (side with printing) is designed to rest against the tracheostomy tube neck plate. To place the pad on the tube, slide the tube through the center hole of the pad until the flat side rest against the neck-plate.

**Note:** The pad has been designed to accommodate a tube outside diameter of 8.0 – 16.0 mm. The use of a water based lubricant can facilitate the installation of the pad on to the tube.

**⚠ Do not use any hydrocarbon-based substance on any part of the Sil.Flex TC Pad.**



5. Prepare the tracheostomy tube with installed Sil.Flex TC Pad as instructed by the manufacturer of the tracheostomy tube.
6. After preparing the patient, it is recommended that the stoma site be cleaned and prepared according to your institution policy and procedure for tracheostomy care.
7. Remove the "old" tracheostomy tube and place the "new" tube with installed Sil.Flex TC Pad according to your institution policy and procedure for tracheostomy tube change.
8. According to your institution policy and procedure for tracheostomy care, lightly tighten the tracheostomy strap and inspect the pad.  
**Note:** The pad should not exhibit excessive compression. It should be slightly compressed to allow stabilization of the tube.
9. Periodically check the position and condition of the Sil.Flex TC Pad. Routine tracheostomy care should include the removal of any secretions between pad and neck-plate as well as pad and patient neck. The use of an absorptive pad may be required.
10. Should the Sil.Flex TC Pad require removal without removal of the tube, the pad may be cut away from the tube. The non-filled gel silicone is very viscous and will not flow freely from the pad.
11. When using the Sil.Flex TC Pad to decrease air leak around the stoma site during tracheostomy tube weaning or during speech therapy, apply mild pressure to the neck-plate area adjacent to the pad. This will improve the seal between pad and neck which will direct more gas to the larynx.

**⚠ Sil.Flex TC Pads should be discarded after a maximum 30 day period, or should tracheostomy care dictate more frequent changes.**

**CLEANING:**

Care should be taken while cleaning the Sil.Flex TC Pad to avoid damage.

The pad may be cleaned with:

- a) A mild non hydrocarbon based detergent or;
- b) A diluted hydrogen peroxide solution (equal amounts of 3% hydrogen peroxide and sterile distilled water) or;
- c) A 70% isopropyl alcohol prep pad.

To clean:

1. Remove the pad from the tube.
2. Gently wash the pad with a soft brush, prep pad, lint-free cloth or with hand.
3. As required, rinse with sterile water and dry the pad.
4. Before placement back on the tube always inspect the pad for damage. If present, discard.

**SANITIZATION:**

Clean the Sil.Flex TC Pad as instructed above.

Sanitization may be obtained with the use of either:

- a) A 3% USP hydrogen peroxide solution; or
- b) A 65% ethyl alcohol gel without out fragrance or other additives; or
- c) Cold disinfection solution approved for used on medical equipment

To sanitize:

1. Clean the Sil.Flex TC Pad as instructed above.
2. 3% USP Hydrogen Peroxide solution:
  - 2.1. Submerge the pad in the solution for 30 minutes.
  - 2.2. Thoroughly rinse the pad with sterile water.
  - 2.3. Dry with a sterile sponge or allow to air dry before use.
3. 60% ethyl alcohol gel
  - 3.1. Apply the gel to the pad ensuring that the pad is thoroughly coated.
  - 3.2. As required, rinse the pad with sterile water.
  - 3.3. Dry with a sterile sponge or allow to air dry before use.
4. Cold disinfection solution - follow disinfection solution manufacture procedure.
5. Before placement back on the tube always inspect the pad for damage. If present, discard.



Designed by A Plus Medical, U.S.A.

**A Plus Medical**

www.aplus-medical.com

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For outside of U.S.A. and Canada

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