

INDICATIONS:

Sil.Flex Stoma 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.
- 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 Stoma Pad before placement.
- Periodically check for correct position of the Sil.Flex Stoma Pad.
- Do not use oil, grease or any hydrocarbon-based substance on any part of the Sil.Flex Stoma Pad.
- The Sil.Flex Stoma Pad is a Single Patient Use product and is not intended for reprocessing and use on another patient.
- To obtain best performance from the Sil.Flex Stoma Pad, use within 2 years from the week listed in the lot code (YYWW).

INSTRUCTIONS FOR USE:

1. Inspect package for damage. Discard product if package is damaged or package seal has been broken.
2. Remove the Sil.Flex Stoma Pad from the package and inspect for damage. Discard if product is ripped or torn.
3. The top (portion to be placed towards the tracheostomy tube neck flange) of the Sil.Flex Stoma Pad may be identified by its flat surface and printed information.

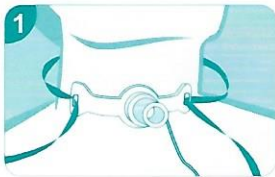
This side towards flange



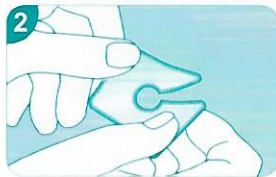
This side towards neck



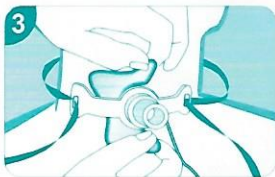
4. To place the Sil.Flex Stoma Pad:



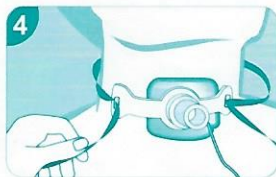
1. Loosen tracheostomy strap and inspect stoma site. Clean as required.



2. Open Sil.Flex Stoma Pad. The concave (curved) side should be oriented toward the patient's neck.



3. Carefully insert the Sil.Flex Stoma Pad between neck flange and neck.



4. Tighten tracheostomy strap and inspect tube position and proper placement of the Sil.Flex Stoma Pad.

5. In accordance with institution policy, or as instructed, periodically check the Sil.Flex Stoma Pad for proper placement and clean as required.
6. The Sil.Flex Stoma Pad should be discarded after a maximum 2 week use, or should tracheostomy care dictate more frequent changes.

CLEANING:

Care should be taken while cleaning to avoid damage.

The pad may be cleaned with:

1. A mild non hydrocarbon based detergent or;
 2. A diluted hydrogen peroxide solution (equal amounts of 3% hydrogen peroxide and sterile distilled water) or;
 3. A 70% isopropyl alcohol prep pad
- The pad should be washed gently with a soft brush, prep pad or with hand.
 - After cleaning with either a detergent or diluted hydrogen peroxide solution, rinse the pad with sterile water and dry before placement on a patient.
 - Always inspect the pad for damage after cleaning and rinsing. If present, discard.

SANITIZATION:

- Clean the Sil.Flex Stoma Pad as instructed above.
- Sanitization may be obtained with the use of either:
 - A 3% USP hydrogen peroxide solution; or
 - A 65% ethyl alcohol gel without out fragrance or other additives; or
 - Cold disinfection solution approved for used on medical equipment

To sanitize:

1. Clean and rinse the pad as instructed above.
 - a. 3% USP Hydrogen Peroxide solution:
 - i. Submerge the pad in the solution for 30 minutes.
 - ii. Thoroughly rinse the pad with sterile water.
 - iii. Dry with a sterile sponge or allow to air dry before reuse.
 - b. 60% ethyl alcohol gel
 - i. Apply the gel to the pad ensuring that the pad is thoroughly coated.
 - ii. Allow to air dry before reuse.
 - c. Cold disinfection solution –follow disinfection solution manufacture procedure.
2. Always inspect the pad for damage after sanitization. If present, discard.

ORDERING INFORMATION:

Product Code	Size	A Length (mm)	B Edge (mm)	C Center (mm)	D Width (mm)	Tube Size (mm)
SP00	0	35	3.0	1.5	30	≤ 9.0
SP01	1	35	5.0	3.0	30	≤ 9.0
SP02	2	45	5.0	3.0	38	≥ 9.0
SP03	3	45	8.5	7.0	38	≥ 9.0
SP04	4	52	12.0	10	45	≥ 9.0



Note: The color of the pad may vary depending on the storage condition. This is normal and will not affect the function of the pad.