

Hood Stoma Stent System

Patents Applied

Single patient use only

These instructions are applicable only to the Hood Stoma Stent System and should be read carefully before using the product.

Description

Stoma Stent

The Hood Stoma Stent is a self-retaining device used to maintain patency of a tracheostoma. The Stoma Stents are smooth, flexible, and non-irritating to the skin and tracheal mucosa.

Hood recommends that this product be changed every 90 days.

This product has been designed to be expelled with vigorous coughing or sneezing.

Hood Speaking Valve

The Hood Speaking Valve is a one-way valve that can be used as an accessory to the Stoma Stent. It is designed to allow the patient to speak without physically occluding the stoma.

Like the Stoma Stent, Hood recommends that the Speaking Valve be changed every 90 days. If the valve makes any unwanted sound, replace the valve.

The Speaking Valves are available to complement the Hood Stoma Stents, size 8, 11, 13, and 15mm O. D. The Stoma Stent plug can be easily detached and replaced with the correct Speaking Valve.

WARNING

This device is not intended for uses other than manufacturer's specifications. The Speaking Valve is not to be used when sleeping or resting, or with an inflated cuff unless both inner and outer cannulas of tracheostomy tube are fenestrated. It is not intended for patients experiencing difficulty breathing.

If the flap on the valve is protruding for any reason, do not pull on the flap to remove the Speaking Valve from the stoma stent. Gently push the flap back in and remove if needed by grasping and removing the body of the speaking valve.

Hood Weaning Kit

The Hood Weaning Kit consists of two plugs with holes of differing diameters. Once it has been determined that a patient can be relieved of a tracheostomy, this kit is useful in helping wean a difficult patient from the tracheostomy. This is accomplished by reducing the allowable volume of air through the stoma in a controlled fashion, the patient is forced to use the upper respiratory tract.

Hood Stoma Gauge

The Hood Stoma Gauge can be used to determine the precise depth of the stoma in order to aid the physician in providing a comfortable fit for Hood's self-retaining Stoma Stents.

Indications

Principal indications for Stoma Stent use are:

1. Maintenance of long-term or permanent tracheostomy in:
 - a. Sleep Apnea
 - b. Bilateral vocal cord paralysis
 - c. Laryngeal (glottic) insufficiency or stenosis due to trauma, carcinoma, radiation therapy, edema, and other diseases
2. Short-term tracheostomy when assisted respiration is not required.
3. Following removal of cannula or T-Tube until adequate airway is assured or as an alternative to a T-Tube in appropriate cases.

Procedures for Insertion

Hood Stoma Stent

Altering of the inner flange by physician only.

The stent may be introduced once the surgical wound has sufficiently healed and the tracheostomy tract is established. At the initial introduction of the stent, topical anesthesia of the tracheal mucous membrane is suggested. This is achieved with xylocaine spray or gel. The distance between the surface of the skin, at the level of the

tracheostomy site, to the anterior tracheal wall is measured superiorly and inferiorly with a Hood Stoma Gauge. The neck is extended and the appropriate stent is introduced by guiding the lower flange down towards the distal trachea, inducing the upper flange to follow through into position, or by claspng both flanges together, leading them through the stoma until they extend into position. It is important to note that if the flanges are clasped or compressed using any kind of forcep, the jaws must be blunt. The patient and/or a family member are then trained to manage the stent by themselves. Half an hour is usually required. Patience and persistence may be necessary to achieve acceptance and tolerance (Fig. 1).

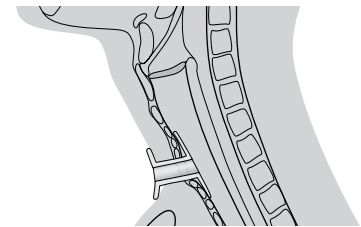


Fig. 1
Diagram showing Stoma Stent in position. Altering of the inner flange by physician only.

Coughing and local discomfort may be encountered during the first few hours while the patient adapts to new sensations. Patients adapt to the local irritation within a few days, after which time they do not require topical anesthesia for insertion or removal of the stent.

Fiberoptic endoscopic monitoring may be indicated. Partial trimming of the inner flanges by the treating surgeon may be required in selected cases. Patients capable of breathing through their mouth should plug the stent. The Hood Speaking Valve may replace the plug, in those with restricted inspiratory phase.¹

Hood Speaking Valve

When required, the stoma stent plug can easily be detached (Fig. 2) and replaced with the correct Speaking Valve (Fig. 3)

Fig. 2
To **insert** the Speaking Valve gently twist and push the Speaking Valve into the Stoma Stent until the hub is flush against the neck flange of the Stoma Stent.

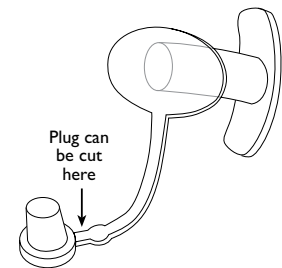
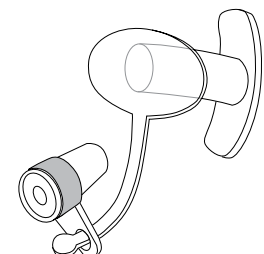


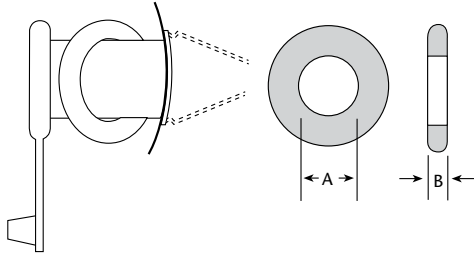
Fig. 3
To **remove** the Speaking Valve, gently twist and pull it out of the Stoma Stent.



Hood Stoma Stent Ring Spacer

The Hood Stoma Stent Ring Spacer is used to shorten the length of the Stoma Stent in increments of 1-2mm without having to physically alter the Stoma Stent. The rings are designed to complement the 8mm, 11mm, and 13mm Stoma Stents (Fig. 4).

Fig. 4



Homecare and Maintenance

Cleaning instructions: Stoma Stents, Speaking Valves, and Weaning Kit

The Stoma Stent should be removed and cleaned once or twice daily. Inspect the Stent carefully to insure there are no tears or holes. If a tear or hole is visible, replace the Stoma Stent immediately.

Take care not to cut or tear the Stoma Stent. If damaged, replace the Stent immediately.

If a flange tears and cannot be found, notify your physician.

It is suggested that patients have two devices for cleaning and reusing at home. In this way, they can remove one, immediately insert the clean, extra device and clean the used device.

It is important to clean the device with the solution recommended and according to the instructions provided here. Solutions used in cleaning are limited to hydrogen peroxide and tap water (sterile water is preferred). **No harsh chemicals or detergents should be used in cleaning. A soft, non-abrasive brush and/or pipe cleaner should be used to remove encrustations when cleaning. An abrasive brush may damage the device. Smoking with the Stoma Stent in place is contraindicated.**

Care should be taken when cleaning the Speaking Valve. Clean with hydrogen peroxide using a very soft brush, taking special care not to damage the flap. Rinse thoroughly with clean water.

Supplies:

- Basin or shallow pan
- 1/2 cup hydrogen peroxide
- 1 cup tap water or sterile water
- Soft, non-abrasive brush
- Soft, clean, wash cloth
- Ziplock bag for storage

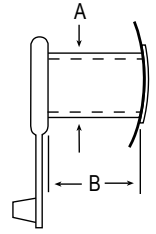
Place the device in the basin, pour 1/2 cup of hydrogen peroxide and 1/2 cup water in the basin, submerging the device. Gently remove crusts and cleanse using the nonabrasive brush. Thoroughly rinse off the device with water. Dry with the soft, wash cloth. Place in a clean Ziplock bag and store ready for use for your next change.

The Hood Stoma Stent and Speaking Valve should be replaced after 3 months of use.

Stoma Stent Ordering Information

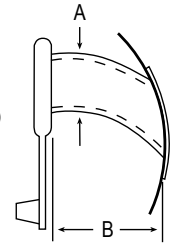
Straight Stoma

Code No.	A O.D. (mm)	A I.D. (mm)	B Length (mm)
SS-0811	8	5.5	11
SS-0813	8	5.5	13
SS-0815	8	5.5	15
SS-0817	8	5.5	17
SS-0819	8	5.5	19
SS-0821	8	5.5	21
SS-0823	8	5.5	23
SS-1111	11	7.5	11
SS-1113	11	7.5	13
SS-1115	11	7.5	15
SS-1119	11	7.5	19
SS-1122	11	7.5	22
SS-1124	11	7.5	24
SS-1127	11	7.5	27
SS-0411	11	7.5	1 of each length 19, 22, 24, 27
SS-1319	13	10	19
SS-1322	13	10	22
SS-1324	13	10	24
SS-0213	13	10	1 of each length 22, 24
SS-1530	15	11.5	30
SS-1540	15	11.5	40
SS-1550	15	11.5	50



Curved Stoma

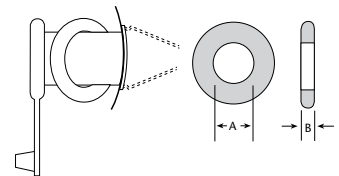
Code No.	A O.D. (mm)	A I.D. (mm)	B Length (mm)
CS-1113	11	7.5	13
CS-1119	11	7.5	19
CS-1122	11	7.5	22
CS-1124	11	7.5	24
CS-1127	11	7.5	27
CS-0411	11	7.5	1 of each length 19, 22, 24, 27
CS-1319	13	10	19
CS-1322	13	10	22
CS-1324	13	10	24
CS-0213	13	10	1 of each length 22, 24



* Shaded areas indicates sizes that are ordered in a set.
Longer lengths available upon request.

Hood Stoma Stent Ring Spacer

Code No.	A (mm)	B (mm)
SSR-081	8	1
SSR-082	8	2
SSR-111	11	1
SSR-112	11	2
SSR-131	13	1
SSR-132	13	2



Hood Weaning Kit

Code No.
WK-6000

Stoma Stent Accessories

Eliachar Speaking Valve

Code No.	Size
LRV-4008-S	Fits 8mm O.D. Stoma Stent
LRV-4011-S	Fits 11mm O.D. Stoma Stent
LRV-4013-S	Fits 13mm O.D. Stoma Stent
LRV-4015-S	Fits 15mm O.D. Stoma Stent

Hood Stoma Gauge (SINGLE USE ONLY)

Code No.	
SG-10	
SG-10-Set	Set of 6

Only the Speaking Valves have been treated with

Ultra-smooth *Plus*[®]

Ultra-smooth Plus[®] surface treatment. This proprietary technology modifies the surface properties of silicone. Ultra-smooth Plus[®] treated silicone is thromboresistant, resistant to biofilm germination, bacterial and fungal growth, and has less surface friction.

DISCLAIMER OF WARRANTIES:

Hood Laboratories warrants that reasonable care has been used in the manufacture of this device. This warranty is exclusive and in lieu of all other warranties, whether expressed, implied, written or oral, including, but not limited to, any implied warranties of merchantability or fitness. As a result of biological differences in individuals, no product is 100% effective under all circumstances. Because of this fact and since we have no control over the conditions under which the device is used, diagnosis of the patient, methods of administration or its handling after the device leaves our possession, Hood Laboratories does not warrant either a good effect or against an ill effect following its use. Hood Laboratories shall not be liable for any incidental or consequential loss, damage or expense arising directly or indirectly from the use of the device. Hood Laboratories will replace any device that we feel was defective at the time of shipment. No representative of Hood Laboratories may change any of the foregoing or assume any additional liability or responsibility in connection with this device. Any serious incident that has occurred in relationship to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

CAUTION: Federal Law restricts this device to sale by or on the order of the physician.

Further information may be obtained and orders can be placed by calling (800)942-5227 or through our 24-hour fax (781)826-3899.

References

1. Eliachar I, McDonnell, M, Nguyen D. New Stoma Stent Applicable in Long-Term Tracheostomy, Otolaryngology Head Neck Surg 1990:103:913-7.
2. Eliachar I, Stegmayer RJ, Levine HL, Sivak ED, Mehta AC, Tucker HM. Planning and management of long-standing tracheostomy, Otolaryngology Head Neck Surg 1987:97:385-90.
3. Sparker AW, Robbins KT, Nevlud GN, Watkins CN, Jahrsdoefer RA. A prospective evaluation of speaking tracheostomy tubes for ventilated dependent patients. Laryngoscope 1987:97:82-92.
4. FG, Strauss M, Houck JR, Roger JC, Kales A. Further clinical experience with the silicone tracheal cannula in obstructive sleep apnea. Otolaryngology Head Neck Surg 1987:97:313-8.



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