



TECHNICAL PRODUCTS, INC.

TRACHEAL CANNULA
SPEAK-EZ CANNULA®

PRODUCT DESCRIPTION:

The Technical Products tracheal cannula with speaking valve (Speak-EZ Cannula®) or the tracheal cannula without a speaking valve is used to maintain the patency of the tracheostoma. The Speak-EZ Cannula® permits speaking without the need for finger occlusion of the stoma. The valve in the Speak-EZ Cannula® is integral to and is a part of the cannula. The tracheal cannula without the valve simply maintains the patency of the stoma or tracheostomy. It is provided with a plug which must be removed whenever the patient is sleeping.

The devices are available in four diameters, 8mm, 11mm, 13mm and 15mm and in various lengths. They are provided non-sterile.

Both cannulas are made of medical grade silicone elastomer which is biocompatible, smooth, flexible and non-irritating to the stomal area and the tracheal mucosa.

It is recommended that the units be replaced at the end of 90 days of continuous use.

INDICATIONS FOR USE:

- 1. Long or short term maintenance of tracheostomy in Bilateral vocal cord paralysis, Sleep Apnea, Stenosis due to trauma or carcinoma, and radiation therapy, edema or other causal diseases
- 2. To assure an adequate airway following removal of a t-tube or tracheostomy tube
- 3. If assisted respiration is not required, in short term tracheostomies

INSERTION TECHNIQUE:

The cannulas are introduced into the stoma when the surgical wound has healed sufficiently and the tracheostomy tract is established.

A topical anesthesia such as xylocaine spray or gel is applied to the site before introduction of the cannula into the tracheostomy site. The stomal wall thickness is measured by various means (right angled hook or other such instrument). The right angled hook (in some cases a bent pipe cleaner) is inserted into the stoma and then pulled forward to rest against the anterior tracheal wall. The shaft of the hook is then marked with a marking device to indicate the point which represents where the shaft exits the neck. The distance

between the two marks indicates the stomal wall thickness. This is the length the cannula must be in order to seat and seal the stomal orifice correctly. Choose the appropriate size from the Model Chart at the end of this Manual.

The cannula is selected to accommodate the diameter and length of the stoma. The patient extends his neck by lifting his head upward and back. The cannula is then introduced into the tracheostomy site by grasping the inner flanges between the thumb and forefinger and clasping both flanges together so that they can be inserted into the tracheostomy site until they release with the flanges positioned against the anterior tracheal wall.

CAUTION:

When insertion is completed the unit should be checked to insure that the bulb or orientation reference on the outside neck flange is positioned *below* the stent opening in the 6 o'clock position. This insures that the inside flanges are positioned longitudinally against the anterior tracheal wall.

Note: Incorrect orientation could result in the inner flanges partially occluding the airway causing greater resistance to air flow.

- Should the patient have difficulty retaining the device, instruct your patient to contact his physician to rectify the problem.
- Patients who have had long term tracheostomy tubes in place should experience no discomfort in accepting the cannulas.
- First time patients may experience coughing and local discomfort during the first few hours after introduction of the cannulas due to the new sensations and/or local irritations which the patient has not previously experienced. Patience and persistence are required to achieve acceptance and tolerance. Within a few days, patients adapt to the local irritation and use of topical anesthesia is no longer required for insertion or removal of the stent.
- The Speak-EZ Cannula® should be removed when sleeping. If the patient requires or desires a stent when sleeping, the tracheal cannula should be inserted while sleeping.

WARNING:

The Speak-EZ Cannula® and Tracheal Cannula should be replaced with a new device after 90 days of continuous use.

DEVICE CARE AND MAINTENANCE:

It is recommended that these devices be cleaned at least once, preferably twice, daily with a solution of hydrogen peroxide and water.

Do not use harsh chemicals or oil-based detergents as this will damage the device.

Place the device in a bowl or basin and pour in ½ cup water and ½ cup hydrogen peroxide. Use a soft bristle brush (toothbrush), a sponge or swab, or a wireless pipe cleaner to remove any encrustations or foreign particles from the inside of the device. Rinse thoroughly with tap water and allow the device to dry before reinserting the cannula.

When cleaning the Speak-EZ Cannula®, extra care should be used to avoid damage to the valve. Inspect the valve for any defects, cuts, tears, or a missing valve caused by the cleaning procedure. The unit must be discarded and replaced if any of these defects are evident.

CARE OF THE STOMAL SITE:

The patient should follow the physician's instructions carefully regarding the care and cleaning of the tracheostomy site as inflammation or granulation tissue can affect the proper functioning of the cannula.

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

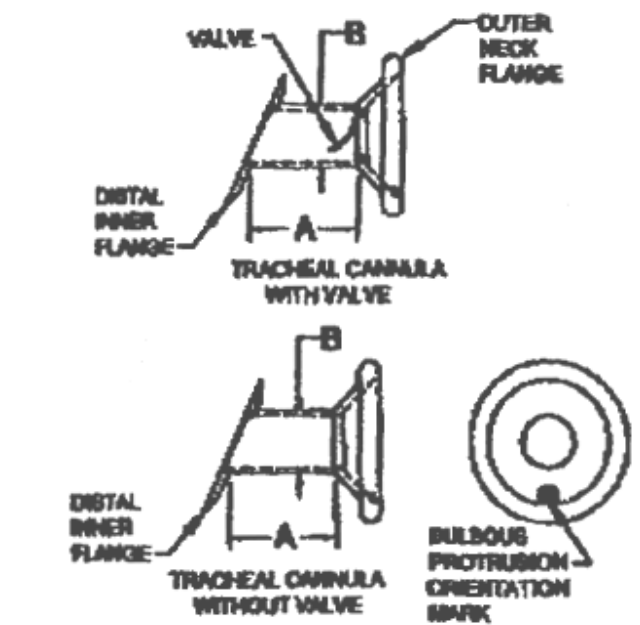
DISCLAIMER OF WARRANTIES:

Technical Products, Inc. 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. Biological differences in individuals can and do affect the performance of devices sometimes causing them to be less than 100% effective. Since Technical Products, Inc. has no control over the conditions under which the device is used, diagnosis of the user, or the method of administration after the device leaves our possession. Technical Products, Inc. warrants neither a good effect or against an ill effect during the use of the device.

Technical Products shall not be liable for any incidental or consequential loss, damage or expense arising directly or indirectly from the use of this device. Technical Products, Inc. will replace any device that we feel was defective at the time of shipment.

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Catalog #	A	B
EZ-0813	13	8
EZ-0815	15	8
EZ-0817	17	8
EZ-0819	19	8
EZ-0821	21	8
EZ-0823	23	8
EZ-1119	19	11
EZ-1122	22	11
EZ-1124	24	11
EZ-1127	27	11
EZ-1130	30	11
EZ-1319	19	13
EZ-1322	22	13
EZ-1324	24	13
EZ-1327	27	13
EZ-1330	30	13
EZ-1519	19	15
EZ-1522	22	15
EZ-1524	24	15

Catalog #	A	B
TC-0813	13	8
TC-0815	15	8
TC-0817	17	8
TC-0819	19	8
TC-0821	21	8
TC-0823	23	8
TC-1119	19	11
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TC-1124	24	11
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TC-1322	22	13
TC-1324	24	13
TC-1327	27	13
TC-1330	30	13
TC-1519	19	15
TC-1522	22	15
TC-1524	24	15