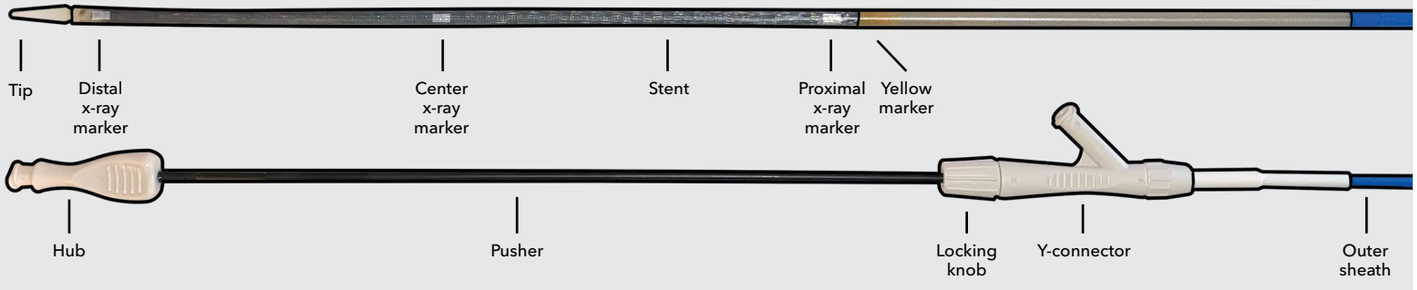
QUICK REFERENCE GUIDE

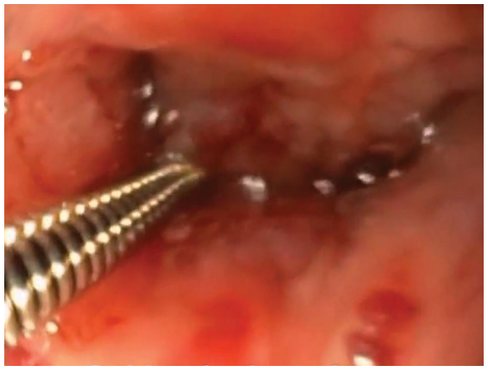
Taewoong NiTi-S™

# TTS Esophageal Stent

## Features

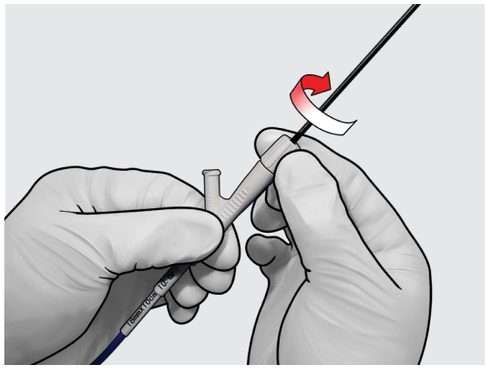



## Step 1



Pass a 0.035 inch (0.89 mm) or 0.038 inch (0.97 mm) wire guide to the level of the stricture. Insert a wire guide across the stricture to where the stent introducer system will be placed over the wire guide.

## Step 2



Ensure that the Y-connector's proximal valve, connecting the pusher and outer sheath, is locked.

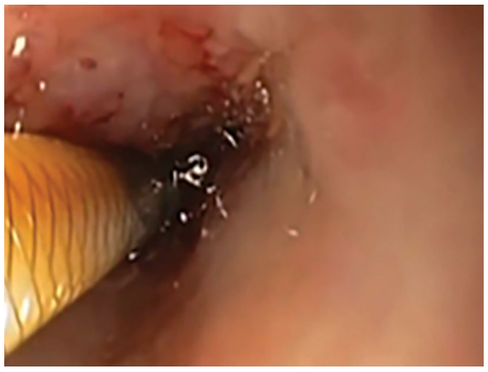
## Step 3

Flush the inner lumen of the introducer system.

COOK MEDICAL

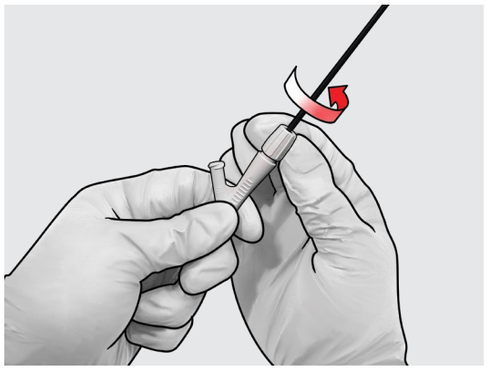
Only available in the US.

## Step 4



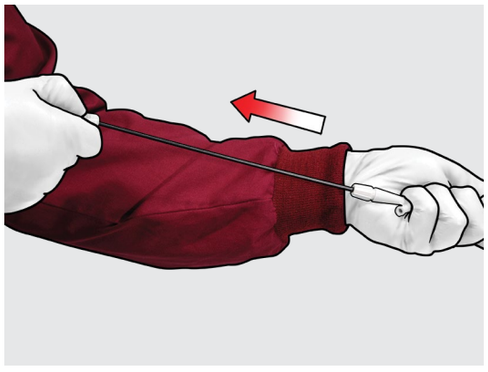
Position the introducer system exactly in the center of the target stricture.

## Step 5



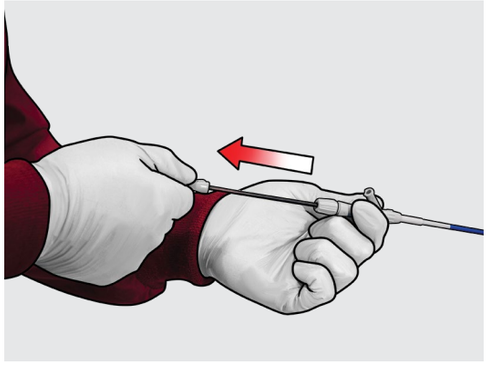
Once the introducer system is in the correct position for deployment, unlock the proximal valve of the Y-connector by turning counter-clockwise more than two times. The stent is now ready for deployment.

## Step 6



To begin stent deployment, immobilize the hub in one hand and grasp the Y-connector with the other hand. Gently slide the Y-connector back along the pusher towards the hub.

## Step 7

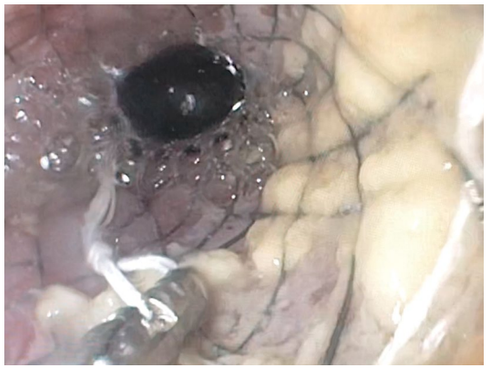


Continue pulling back on the Y-connector until the stent is fully deployed.
**Caution:** Do not push forward or pull backward on the hub with the stent partially deployed. The hub must be securely immobilized. Inadvertent movement of the hub may cause misalignment of the stent and possible damage to the esophagus.

## Step 8

Examine the stent fluoroscopically or endoscopically to confirm expansion. Carefully remove the introducer system and the wire guide from the patient. If excessive resistance is felt during removal, wait 3 to 5 minutes to allow further stent expansion. (Place the inner sheath back into the outer sheath, as in the original state, prior to removal.)

## Step 9



To reposition a stent immediately after deployment, use forceps or a snare to grasp the retrieval string and gently adjust it to the correct placement. **Note:** The stent can only be repositioned proximally.

**Refer to the current Instructions for Use for detailed information regarding use, contraindications, associated risks, etc.**

**Clinical images in steps 1, 4, and 8 courtesy of Dr. Giorgio Battaglia, Istituto Oncologico Veneto Padova, Italy.**

**Clinical image in step 9 courtesy of Dr. Matthew Kutner, Hackensack University Medical Center, Hackensack, US.**

**Esophageal TTS Stent**

**CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner).**

**INDICATION FOR USE:** The Esophageal TTS Stent is intended for use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors and occlusion of concurrent esophageal fistulas.

**CONTRAINDICATION:** The Esophageal TTS Stent is contraindicated for: • Strictures that do not allow passage of a guidewire or the introducer. • Actively bleeding tumors.

**WARNINGS:** The device should be used with caution and only after careful consideration in patients with elevated bleeding times or coagulopathies. • Chemoradiation therapy or radiotherapy alone may lead to tumor shrinkage and subsequent stent migration. • The stent contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity. • Do not expose the introducer system to organic solvent (e.g. Alcohol) • Do not use with Ethiodol or Lipiodol contrast media. • The Esophageal TTS Stent may only be repositioned immediately after deployment, during the initial placement procedure. (See 12. Instructions for Repositioning of Stents **in the complete Instructions for Use**). **WARNING: The stent is not intended to be removed. Attempts to remove stent after the placement procedure may cause damage to esophageal mucosa.**

**PRECAUTIONS:** Read the entire Instructions For Use thoroughly before using this device. It should only be used by or under the supervision of physicians thoroughly trained in the placement of stents. A thorough understanding of the techniques, principles, clinical applications and risk associated with this procedure is necessary before using the device. • Care should be taken when removing the introducer system and guidewire immediately after stent deployment since this may result in stent dislodgement if the stent has not been adequately deployed. • Care should be taken when performing dilation after the Stent has been deployed as this may result in perforation, bleeding, Stent dislodgement or Stent migration. • The packaging and the device should be inspected prior to use. • Do not attempt to reload deployed stents onto the introducer system. • Use of fluoroscopy is recommended to ensure correct placement of the device. • Check the expiration date "Use by". Do not use the device beyond the labeled use by date. • The Esophageal TTS Stent is supplied sterile. Do not use if any of the packaging is opened or damaged. • The Esophageal TTS Stent is intended for single use only. Do not resterilize and/or reuse the device. • Non-clinical testing has demonstrated that the Esophageal TTS stent is MR Conditional. Please refer to the MR Imaging Information **in the complete Instructions for Use**.

**POTENTIAL COMPLICATIONS:** Potential complications associated with the use of Esophageal TTS Stent may include, but are not limited to: Procedural Complications • Bleeding • Stent misplace or inadequate expansion • Pain • Death • Aspiration Post Stent Placement Complications • Bleeding • Pain • Reflux • Perforation • Stent migration • Food bolus impaction (lavage and debridement may be necessary on a periodic basis) • Stent occlusion due to tumor in-growth through stent • Stent occlusion due to tumor over-growth around ends of stent • Fever • Ulceration • Foreign body sensation • Septicemia or Sepsis • Death (other than that due to normal disease progression) • Esophagitis • Infection • Dysphagia • Esophagobronchial fistula • Acute angulations • Aspirations • Pneumonias • Haematemesis • Airway Compressions

**See Instructions for Use for full product information.**

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