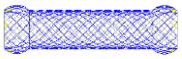
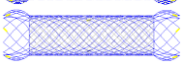
Esophageal TTS Stent

Instructions for Use

1. Description

The Esophageal TTS Stent consists of the implantable metallic stent and introducer system.

The stent is made of Nitinol wire. It is a flexible, fine mesh tubular prosthesis that has 10 radiopaque markers; 4 in each end and 2 in the center. It has a body diameter of **18, 20 and 22mm**, and a total length from **60 to 150mm**. The surface of the body portion of the stent is covered with silicone. The Esophageal TTS Stent is provided in two configurations, either fully covered with silicone or with both heads not covered in silicone (bare).

Type	Shape	Model Numbers*
Full Covered Type		ESTxxyyF
Both Bare Type		ESTxxyyB

*E- Esophageal Stent, S- Silicone Cover, T- TTS
xx-diameter(mm), yy-length(cm), F-Full Covered, B-Both ends bared

Figure 1. Stent

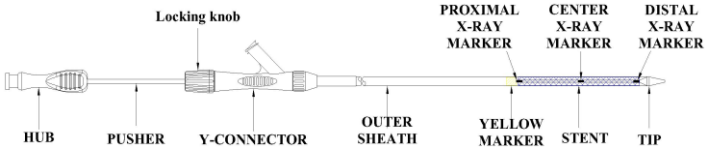


Figure 2. Introducer

The introducer system accepts a 0.035 in(0.89 mm) or 0.038 in(0.97 mm) guidewire. The stent introducer system is passed over the guidewire and through an endoscope into the esophagus. The stent may be positioned appropriately using the X-ray markers for guidance under fluoroscopy.

2. Principle of Operation

The outer sheath is pulled back by immobilizing the hub in one hand, grasping the Y-connector with the other hand, and gently sliding the Y-connector along the pusher towards the hub. Retraction of the outer sheath releases the stent.

3. Indication for Use

The Esophageal TTS Stent is intended for use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors.

4. Contraindication

The Esophageal TTS Stent is contraindicated for:

- Strictures that do not allow passage of a guidewire or the introducer.
- Actively bleeding tumors.

5. 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).

WARNING: The stent is not intended to be removed. Attempts to remove stent after the placement procedure may cause damage to esophageal mucosa.

6. 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

7. Equipment required

- Fluoroscope and/or endoscope
- 0.035 in (0.89 mm) or 0.038 in/ 0.97 mm guidewire

8. 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 **section below.**

9. Instructions in the event of Damage

WARNING: Visually inspect the system for any sign of damage. DO NOT USE if the system has any visible signs of damage. Failure to observe this precaution may result in patient injury.

10. Procedure
The Esophageal TTS Stent may be repositioned immediately after deployment, during the initial placement procedure. (See 12. Instructions for Repositioning of Stents).

WARNING: The stent is not intended to be removed. Attempts to remove stent after the placement procedure may cause damage to esophageal mucosa.

① Examine stricture fluoroscopically

a) Carefully examine both the proximal and distal segment of stricture fluoroscopically.
b) Measure the internal luminal diameter exactly with a fluoroscope.

② Stent Size Determination

a) Measure the length of the target stricture.
b) Select a Stent size that is 20 to 40mm longer than the measured length of the stricture in order to fully cover both ends of lesion.
c) Measure the diameter of the reference stricture - it is necessary to select a Stent which has an unconstrained diameter about 1 to 4mm larger than the largest reference Esophagus diameter to achieve a secure placement.

③ Stent Deployment Preparation

The Esophageal TTS Stent can be placed with the aid of a fluoroscopy and an endoscope. Pass a 0.035 in (0.89 mm) or 0.038 in/ 0.97 guidewire to the level of the stricture.

a) Insert a guidewire across the stricture to where the stent introducer system will be placed over the guide wire.
b) Ensure that the Y connector proximal valve connecting the pusher and outer sheath is locked.
c) Flush the inner lumen of the introducer system.

④ Stent Deployment Procedure

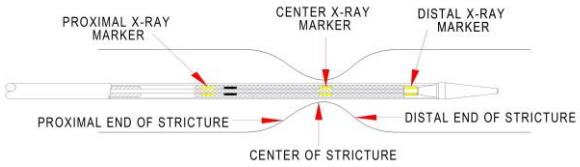


Figure 3

a) Position the introducer system exactly to the center of the target stricture.
b) Once the introducer system is in the correct position for deployment, unlock the proximal valve of the Y-connector by turning counterclockwise more than two times. The stent is now ready for deployment.
c) 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.
d) Continue pulling back on the Y-connector until the stent is fully deployed.

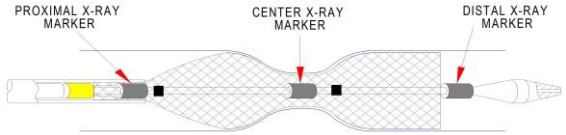


Figure 4

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.

⑤ After Stent Deployment

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

11. Perform routine post implant procedures.

a) Assess the size and structure of the stent lumen. A stent may require up to 1 to 3 days to expand fully.
b) Doctor's experience and discretion determine the appropriate drug regimen for each patient.
c) After implantation, the patient should have a soft diet until otherwise determined by the treating doctor.
d) Observe the patient for development of any complications

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

12. Instructions for Repositioning of Stents (see Warnings)
To reposition a Stent immediately after deployment, use forceps or a snare to grasp the retrieval string and gently adjust to the correct placement. Please note: the stent can only be repositioned proximally.

Reuse Precaution Statement
Contents supplied STERILE (ethylene oxide (EO)). Do not use if sterile barrier is damaged. In the event of damaged packaging, call your Taewoong Medical Co., Ltd. representative. For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and /or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

Storage: Store at room temperature.

Symbol

MR	MR conditional
	Temperature Limitation
REF	Catalog No.
STERILE EO	Sterilized using ethylene oxide
	Use by (Expiration Date)
SN	Serial No.
	Single Use Only
	Manufacturer
	Date of Manufacture
	Do not Resterilize
	Do not Use if Package is Damaged
	Caution
	Consult Instructions for Use
Rx only	Prescription device

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The following information was determined by MRI testing. It is the physician's responsibility to communicate this information to the patient.

MRI Information

MRI Safety Information

A person with the Taewoong Esophageal TTS Stent may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	Esophageal TTS Stent
Static Magnetic Field Strength (B_0)	1.5T or 3.0T
Maximum Spatial Field Gradient	30 T/m or 3000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Volume RF body coil
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (normal operating mode)
Maximum Head SAR	3.2 W/kg (first level control mode)
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF with less than 2 degrees temperature rise
MR Image Artifact	The presence of this implant may produce an image artifact at 30 mm away from the device