Niti-S Esophageal Stent

User's Manual

1. Description

The Niti-S Esophageal 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 and it has 10 radiopaque markers; 4 in each end and 2 in the center. It has a body diameter from 16 to 20mm and a total length from 60 to 150mm.

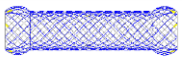
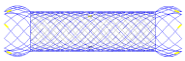
Type		Application
Uncovered		Low possibility of migration
Full Covered-Type		Low possibility of perforation or tumor ingrowth.
Both Bare-Type		Intermediate type between Uncovered type and Full Covered type.

Figure 1. Stent

Full Covered Esophageal Stents may be removed after deployment; (see Warnings).

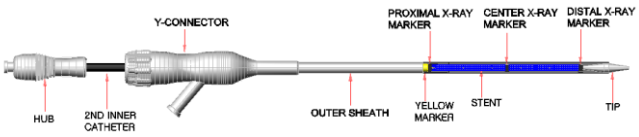


Figure 2. Introducer.

The introducer system accepts a .035 in (0.89 mm) or 0.038 in/ 0.97 mm guidewire. The stent introducer system is passed over the quidewire into the esophagus. The stent is 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 2nd inner catheter towards the hub. Retraction of the outer sheath releases the stent.

3. Indication for Use

Niti-S Esophageal Stent is intended for use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors.

WARANTY

Taewoong Medical Co., LTD. warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond Taewoong's control directly affect the instrument and the results obtained from its use. Taewoong's obligation under this warranty is limited to the repair or replacement of this instrument and Taewoong shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this instrument. Taewoong neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. Taewoong assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, expressed or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.

4. Contraindication

The Niti-S Esophageal Stent is contraindicated for:
- placement in polypoid lesions.
- Strictures that do not allow passage of a guidewire.
- Removal or repositioning of fully deployed uncovered/bare Stents is contraindicated. (see Warnings).
- Any use other than those specifically outlined under indications for use.

5. Warnings

- The device should be used with caution and only after careful consideration in patients with elevated bleeding times, coagulopathies, or in patients with radiation colitis or proctitis.
- 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.
- Full Covered Stent may be repositioned immediately after deployment. (see 12. Instructions for Repositioning of Full Covered Stents).
- Uncovered/bare Stents should not be removed once fully deployed; see Contraindications.

6. Potential complications

Potential complications associated with the use of Esophageal 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 User's Manual 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 Niti-S Stent is supplied sterile. Do not use if any of the packaging is opened or damaged.
- The Niti-S Stent is intended for single use only. Do not resterilize and/or reuse the device.
- MRI Compatible: The Niti-S Stent will not present an additional risk or hazard to a patient in a 1.5 tesla MRI environment or less.

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

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 secure placement.

③ Stent Deployment Preparation

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

a) Under the fluoroscopy guidance, insert a guide wire 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

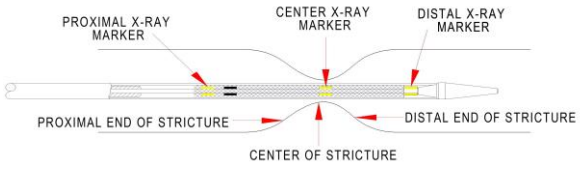


Figure 3

a) Under the fluoroscopy guidance, 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.

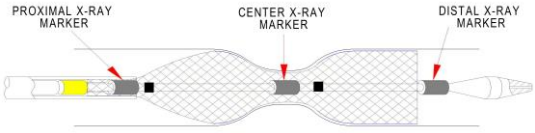


Figure 4

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 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 Full Covered Stents (see Warnings)

To reposition a Full Covered 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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