Niti-S Biliary Stent

User's Manual

1. Description

The Niti-S Biliary 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 diameter of 8 or 10mm and the length ranges from 40 to 120mm.

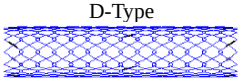
Niti-S Biliary Stent	Application
D-Type 	Low possibility of migration.

Figure 1

The Stent is loaded in introducer system and upon deployment the stent imparts an outward radial force on the luminal surface of the bile duct to establish patency.

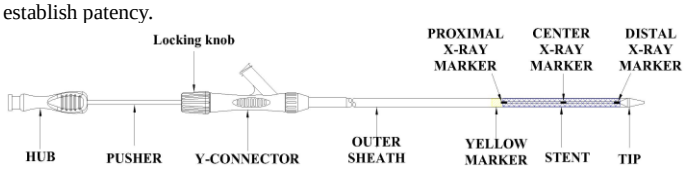


Figure 2.Introducer System (Percutaneous & Endoscopic)

- The percutaneous introducer system has a usable length of 50cm
- The endoscopic introducer system has a usable length of 180cm

Percutaneous Type is recommended
- **When approached percutaneously.**

Endoscopic Type is recommended
- **When approached endoscopically.**

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 Niti-S Biliary Stent is indicated for the palliation of malignant strictures in the biliary tree.

WARRANTY

Taewoong Medical Co., LTD. warrants that reasonable care has been applied within the design and subsequent manufacturing process 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 Biliary Stent is contraindicated;
- Strictures that do not allow passage of a guidewire.
- Patients for whom endoscopic techniques are contraindicated.
- Any use other than those specifically outlined under indications for use.
- Patient with bleeding disorder.
- Patient with ascites.
- Biliary obstruction preventing either endoscopic or percutaneous cholangiography
- Patients with coagulopathy

5. Warnings

- The safety and effectiveness of this device for use in the vascular system has not been established.
- 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.
- Stents cannot be repositioned after complete deployment.
- 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.

6. Potential complications

Potential complications associated with the use of Biliary Stent may include, but are not limited to:

Procedural Complications
- Bleeding
- Stent misplace or inadequate expansion
- Pain
- Death
- Intestinal perforation

Post Stent Placement Complications
- Bleeding
- Pain
- Perforation
- Bowel impaction
- Stent migration
- Stent occlusion
- Stent occlusion due to tumor in-growth through stent
- Stent occlusion due to tumor over-growth around ends of stent
- Tumor Ingrowth
- Peritonitis
- Sludge occlusion
- Fever
- Ulceration
- Foreign body sensation
- Septicemia
- Acute Cholecysitits
- Pancreatitis
- Cholangitis/Cholestasis
- Death (other than that due to normal disease progression)
- Constipation
- Diarrhea
- Infection
- Liver abscess

7. Equipment required

- Percutaneous Placement
  - 0.035" (0.89mm) guidewire at least 180cm long (preferably stiff or extra stiff)
  - Introducer sheath appropriately sized for introducer system
- Endoprosthesis Placement
  - 0.035" (0.89mm) guidewire at least 450cm long (preferably stiff or extra stiff)
  - Endoscope system appropriately sized for instrument channel

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 biliary stent. 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.
- 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 "Expiration Date". Do not use the device beyond the labeled use by date.
- The Niti-S Stent is supplied sterile. Do not use if 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
- **(50cm introducer usable length)**
  Percutaneous transhepatic cholangiography (PTC) should be performed prior to placement of the Niti-S Biliary Stent to characterize the biliary tract morphology and extent of the malignant disease.
- **(180cm introducer usable length)**
  Endoscopic retrograde cholangiopancreatography (ERCP) should be performed prior to placement of the Niti-S Biliary Stent to characterize the biliary tract morphology and extent of the malignant disease.

① Examine stricture endoscopically and fluoroscopically
a) Carefully examine both the proximal and distal segment of stricture endoscopically and/or fluoroscopically.
b) The Internal luminal diameter should be measured exactly with endoscope and/or 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 cover fully both ends of the 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 target diameter, to achieve secure placement.

③ Stent Deployment Preparation
- The Niti-S Stent can be placed with the aid of fluoroscopy, and/or endoscopy.
- Pass a 0.035" (0.89 mm) guidewire to the level of the stricture.

A. Fluoroscopy Procedure
a) Under the fluoroscopy, insert a guide wire across the stricture to where the stent introducer system will be placed over the guide wire
b) Remove the stylet from the distal end of the introducer.
c) Ensure that the valve of Y-connector connecting the inner sheath and outer sheath is locked by rotating the proximal valve end in a clockwise direction to prevent premature stent deployment.
d) Flush the inner lumen of introducer system.

B. Endoscopy Procedure
a) Under the endoscopic guidance, insert an endoscope to the level of the obstruction, then introduce the guide wire through the working channel of the endoscopy. Advance until the guide wire across the target stricture to where the stent introducer system will be placed over the guide wire.
b) Remove the stylet from the distal end of introducer and flush the inner lumen of introducer.
c) Ensure that the valve of Y-connector connecting the inner sheath and outer sheath is locked by rotating proximal valve end in a clockwise direction to prevent premature stent deployment.
d) Flush the inner lumen of introducer system.

④ Stent Deployment Procedure

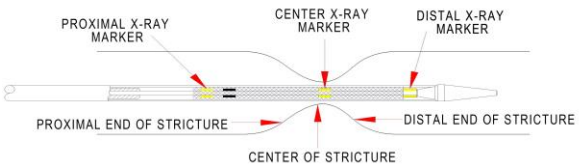


Figure 4

PRECAUTION: Do not twist introducer system or employ a boring motion during the deployment as this may affect positioning and ultimate function of stent.

a) Under the fluoroscope and/or endoscopic 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 the valve more than twice in an anti-clockwise direction.
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) When the center X-ray marker reaches the center of target stricture, continue pulling back on the Y-connector until the stent is fully deployed. (See figure 4, 5)

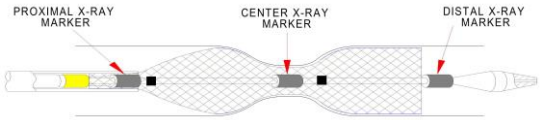


Figure 5

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 bile duct.

⑤ After Stent Deployment
a) Examine the stent fluoroscopically and/or endoscopically to confirm expansion.
b) Carefully remove the introducer system, guidewire and endoscope 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.)
c) Balloon dilatation inside the stent can be performed if doctor desire.

11. Perform routine post implant procedures.
a) Assess the size and stricture of the Stent lumen. A Stent may require up to 1 to 3 days to expand fully.
b) Doctor's experience and discretion can determine the appropriate drug regimen for each patient.
c) After implantation, patient should remain on a soft diet until otherwise determined by the treating doctor.
d) Observe the patient for development of any complications.

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

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.

***Warranty**
Taewoong Medical Co., Inc. warrants that reasonable care has been used in the design and manufacture of this instrument.

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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