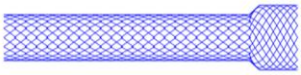
User's Manual

1. Description

The Niti-S Colonic Comfort 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 11 radiopaque markers; 4 in each end and 3 in the center. It has a diameter of 22 and 24 mm and the length ranges from 60 to 120mm.

Niti-S Colonic Comfort Stent	Model Numbers*
	CDTxxyyN-22

*C: Colonic Stent (Endoscopic), D: D-type, T: TTS, N: Single head,
xx: diameter(mm), yy: length(cm), -22: Usable length 220cm

Figure 1. Stent

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

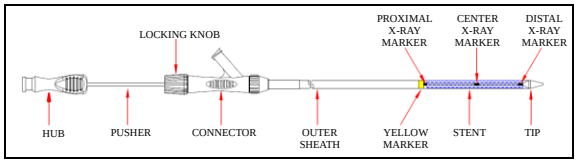


Figure 2. Introducer System (Endoscopic)

- The endoscopic introducer system has a usable length of 220cm

2. Principle of Operation

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

3. Indication for Use

The Niti-S Colonic Comfort Stent is indicated for the palliative treatment of colorectal strictures produced by malignant neoplasms and to relieve large bowel obstruction prior to colectomy in patients with malignant structures.

4. Contraindication

The Niti-S Colonic Comfort Stent is contraindicated for, but not limited to;

- Patient with ascites.
- Placement in polypoid lesions.
- Patient with bleeding disorder.
- Intra-abdominal abscess.
- Patients with coagulopathy.
- Strictures that do not allow passage of a guidewire.
- Any use other than those specifically outlined under indications for use.
- Removal or repositioning of fully deployed uncovered/bare Stents is contraindicated. (See Warnings).
- Suspected or impending perforation.
- Enteral ischemia.
- Recapturing a stent during its deployment is contraindicated.

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.
- Do not attempt to recapture/reload a stent once its deployment is advanced.
- Niti-S Colonic Comfort Stent cannot be recaptured if the connector has been pulled beyond the pusher's marker. Recapturing the stent in tortuous anatomy may damage the device. Recapturing more than twice may also cause damages to the stent wire.

WARNING: The stent is not intended to be removed.

6. Potential complications

Potential complications associated with the use of the Niti-S Colonic Comfort Stent may include, but are not limited to:

Procedural Complications

- Bleeding
- Stent misplacement or inadequate expansion
- Pain
- Death (other than that due to normal disease progression)
- Intestinal Perforation

Post Stent Placement Complications

- Bleeding
- Pain
- Perforation
- Bowel impaction
- Stent misplacement or migration
- Stent occlusion
- Tumor overgrowth
- Tumor ingrowth
- Stent fracture
- Fever
- Foreign body sensation
- Death (other than that due to normal disease progression)
- Sepsis
- Constipation
- Diarrhea
- Infection
- Peritonitis
- Ulceration
- Symptoms of tenesmus or urgency/incontinence

7. Equipment required

- Fluoroscope and/or Endoscope (with a channel size of 3.7 mm or greater)
- 0.035 in/ 0.89 mm guidewire (TTS)
- Introducer sheath appropriately sized for stent and introducer system

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 risks 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.
- 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 use by date.
- The Niti-S Colonic Comfort Stent is supplied sterile. Do not use if the packaging is opened or damaged.
- The Niti-S Colonic Comfort Stent is intended for single use only. Do not resterilize and/or reuse the device.
- Non-clinical testing has demonstrated that the Niti-S Colonic Comfort 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

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 Colonic Comfort 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. (TTS)

A. 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 the introducer.
c) Ensure that the valve of connector connecting the inner sheath and outer sheath is locked by rotation proximal valve end in a clockwise direction to prevent premature stent deployment.
d) Flush the inner lumen of introducer system.

④ Stent Deployment Procedure

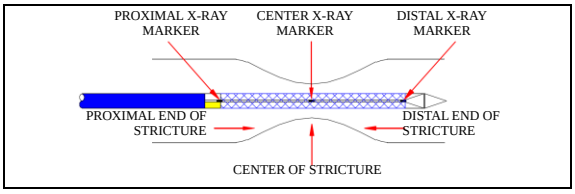


Figure 4

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 to the center of the target stricture exactly.
b) Once the introducer system is in the correct position for deployment, unlock the proximal valve of the 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 connector with the other hand. Gently slide the 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 connector until the stent is fully deployed. (See figure 4, 5)

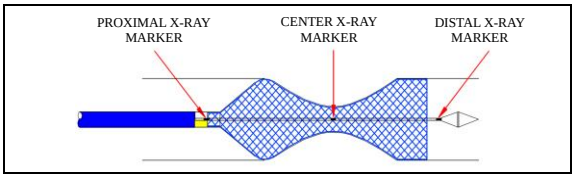


Figure 5

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 the target or stricture.

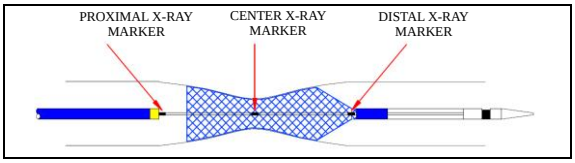


Figure 6

CAUTION Do not push forward or pull backward on the Connector with the stent partially deployed. The Connector must be securely immobilized. Inadvertent movement of the Connector may cause misalignment of the stent and possible damage to the colorectum.

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.)

11. Perform routine post implant procedure

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.

Handling and Storage: Store in a dry and cool place. Keep away from sunlight.

■ **Symbol**

MR	MR conditional
UDI	Unique Device Identifier
REF	Catalog No.
STERILE EO	Sterilized using ethylene oxide
	Use by (Expiration Date)
SN	Serial No.
2	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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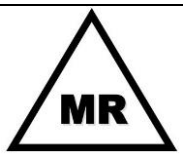
The following information was determined by MRI testing. It is the physician's responsibility to communicate this information to the patient.



MRI Safety Information

A person with the Niti-S Colonic Comfort Stent of Taewoong Medical Co., Ltd. may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	Niti-S Colonic Comfort Stent
Static Magnetic Field Strength (B_0)	1.5T or 3.0T
Maximum Spatial Field Gradient	28 T/m (2,800 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	3.2W/kg
Scan Duration	Under the scan conditions defined, patients with the Taewoong Medical Niti-S Colonic Comfort Stent can be scanned continuously for 60 minutes.
MR Image Artifact	The presence of this implant may produce an image artifact