HILZO stents

**HILZO™ Esophageal Stent**
User Manual

**HILZO™ Özofagus Stenti**
Kullanım Kılavuzu

**HILZO™ Øsofageal Stent**
Brugermanual

**Stent Esofágico HILZO™**
Manual de usuario

**Stent Esofágico HILZO™**
Manual do Utilizador

**ХИЛЗО™ Эзофагеальный Стент**
Инструкция по эксплуатации

**Stent œsophagien HILZO™**
Manuel d'utilisation

**Stent Esofageo HILZO™**
Istruzioni d'Uso

**HILZO™ Esophageal Stent**
Návod k použití

**HILZO™ Esophageal Stent**
Användarmanual

**HILZO™ Esophageal Stent**
Brukerhåndbok

BCM

# ENGLISH

## SYMBOLS

CE 2195

CE mark is a mandatory conformity marking for certain products sold within the European Economic Area(EEA)

EC REP

Authorized representative in the European Community


Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

Indicates a medical device that should not be used if the package has been damaged or opened.

Indicates the date after which the medical device is not to be used.


Indicates the country where the medical device was manufactured.

REF

Indicates the manufacturer's catalogue number so that the medical device can be identified.

Indicates a medical device that needs protection from light sources.

STERILE EO

Indicates a medical device that has been sterilized using ethylene oxide.


Indicates a medical device that is not to be resterilized.

Indicates the need for the user to consult the instructions for use for important cautionary information.


Indicates the temperature limits to which the medical device can be safely exposed

Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.

LOT

Indicates the manufacturer's batch code so that the batch or lot can be identified.

SN

Indicates the manufacturer's serial number so that a specific medical device can be identified.


MR conditional

## MRI Information


**Magnetic Resonance Conditional**

Non-clinical testing has demonstrated that HILZO™ Esophageal Stent is MR Conditional.
A patient using the device can be scanned safety under following conditions:

- Static magnetic field of 1.5T MRI, 3.0T MRI only
- Maximum spatial gradient magnetic field of 720 Gauss/cm(extrapolated) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg

***RF Heating***

HILZO™ Esophageal Stent rises maximum 1.7°C for 15 min of scanning as defined above.

***Artifact Information***

Under T1 SE and GRE pulse sequence, HILZO™ Esophageal Stent extended maximum 8mm artifact size compared to its original shape.

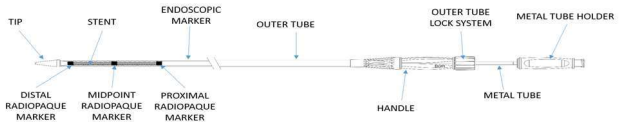
| **Pulse sequence** | **T1 SE** | **T1-SE** | **GRE** | **GRE** |
|---|---|---|---|---|
| **Image plane** | Parallel | Perpendicular | Parallel | Perpendicular |
| **Signal void size** | 253mm$^2$ | 15mm$^2$ | 1,172mm$^2$ | 145mm$^2$ |

## 1. Description

The HILZO™ Esophageal Stent system consists of a delivery system preloaded with a self-expanding esophageal metal stent. The stent is made of Nitinol wire knitted in a tubular mesh configuration. This design configuration makes a stent flexible and self-expandable. The stent has 6 radiopaque markers.

The stent is mounted on an inner catheter and is constrained by an outer tube. The outer tube is pulled back by immobilizing the metal tube holder with one hand, grasping the handle with the other hand, and gently sliding the handle along the metal tube (2nd inner catheter) towards the metal tube holder. With a retraction of the outer sheath, the stent is released. When the Stent is deployed, the stent self-expands and imparts an outward radial force on the luminal surface of the esophageal to establish patency.

**Figure 2. HILZO™ Esophageal Delivery System**




For esophageal stenting, two different approaches are utilized: OTW (Over-The-Wire) and TTS (Through-The-endoscope) approach.
HILZO™ Stent system has two different delivery systems depending on the approach.

**Table 2.** Delivery system Type

| Delivery system type | Usable Length | Approach |
|---|---|---|
| OTW (Over-The-Wire) | 70cm | The stent delivery system is passed over the guidewire into the esophagus |
| TTS (Through-The-Scope) | 180cm | The stent delivery system is inserted into the esophagus through an endoscope |

## 2. Indication for Use

The HILZO™ Esophageal Stent is intended for maintaining esophageal luminal patency in esophageal stricture caused by intrinsic and/or extrinsic malignant tumors, occlusion of concurrent esophageal fistulas, refractory benign esophageal strictures.

## WARRANTY

BCM 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 BCM's control directly affect the instrument and the results obtained from its use. BCM's obligation under this warranty is limited to the replacement of this instrument and BCM shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this instrument. BCM neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. BCM 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.

## ⚠Contraindication

The HILZO™ Esophageal Stent is contraindicated for, but is not limited to:

- Placement in polypoid lesions
- Patient with bleeding disorder
- Strictures that do not allow passage of a guidewire
- Any use other than those specifically outlined under indications for use.
- Suspected or impending perforation
- Strictures that cannot be dilated enough to pass the endoscope or the delivery system
- Placement of the proximal end of the stent within 2 cm of the cricopharyngeal muscle

## ⚠Warnings

- The device should be used with caution and only after careful consideration in patients with elevated bleeding times, coagulopathies, significant preexisting pulmonary or cardiac disease.
- Chemoradiation therapy or radiotherapy alone may lead to tumor shrinkage and subsequent stent migration and/or fracture.

- The stent contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity.
- Do not expose the delivery system to organic solvent (e.g. Alcohol)
- Do not use with Ethiodol or Lipiodol contrast media.
- HILZO™ Covered Stents can be removed where the treating doctor's clinical assessment of the stented stricture indicates the Stent can be safely removed. Caution should be exercised in deciding to and when removing the Stent.
- HILZO™ Covered Stent cannot be removed when there is tumor in-growth/over-growth/ occlusion of the Stent lumen.
- Uncovered/bare Stents should not be removed once fully deployed; see Contraindications.
- 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.

⚠ **Potential complications**

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

- Bleeding
- Pain
- Perforation
- Stent misplacement or migration
- Stent occlusion
- Stent occlusion due to tumor in-growth through Stent
- Stent occlusion due to tumor over-growth around ends of Stent
- Tumor in-growth
- Fever
- Foreign body sensation
- Death (other than that due to normal disease progression)
- Sepsis
- Intestingal obstruction secondary to migrationHaematemesis
- Airway Compressions
- Reflux
- Food bolus impaction
- Esophagitis
- Recurrent Dysphagia
- Fistula formation
- Ulcerations
- Aspiration
- Edema
- Nausea
- Mediastinitis
- Anemia
- Spondylodiscitis
- Leakage
- Pressure necrosis
- Vocal cord palsy

Please be aware that potential adverse effects may arise even with the proper use of medical devices. Accordingly, this device should only be used by persons qualified in the procedures for which it is indicated.

**3. Required equipment**

- Fluoroscope and/or endoscope with minimum 3.7mm working channel
- 0.035" (0.89 mm) Guidewire

**4. 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 delivery 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 into the delivery 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 use by date.
- The HILZO™ Stent is supplied sterile. Do not use if the packaging is opened or damaged.
- The HILZO™ Stent is intended for single use only. Do not resterilize and/or reuse the device.

• Be careful not to contaminate the product during package open.
• Excessive force or manipulation should not be used to position or deploy the stent. This may cause inadvertent damage to the device and/or endoscope.

**5. Pre-Procedure Note**
• Carefully remove the delivery system from the packaging.
• Visually inspect the device for damage or defects.

**6. Procedure**
① Examine stricture endoscopically and fluoroscopically
a) Carefully examine both the proximal and distal segment of the stricture endoscopically and/or fluoroscopically.
b) The Internal luminal diameter should be measured exactly with an endoscope and/or a fluoroscope.
② Stent Size selection
a) Measure the length of the target stricture.
b) Select a stent size that is 20mm longer than the measured length of the stricture in order to cover fully both ends of the lesion.
c) Check stent size and specification on label.
③ Stent Deployment Preparation
- The HLZO™ Esophageal Stent can be placed with the aid of fluoroscopy and/or endoscopy.
- Pass guidewire to the level of the stricture.
a) Under fluoroscopic/endpscopic guidance, insert a guide wire across the stricture to where the stent delivery system will be placed over the guide wire.
b) Ensure that the outer tube lock system is locked to prevent premature stent deployment. The outer tube lock system is locked by rotation in a clockwise direction.
④ Stent Deployment Procedure

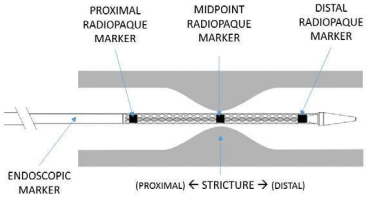



**Figure 3**

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

a) Under fluoroscopic and/or endoscopic guidance, position the delivery system to the center of the target stricture exactly.
b) Once the delivery system is in the correct position for deployment, unlock the outer tube lock system by turning it more than twice in an anti-clockwise direction.
c) To begin stent deployment, immobilize the metal tube holder with one hand and grasp the handle with the other hand. Gently slide the handle back along the metal tube towards the metal tube holder.
d) When the center X-ray marker reaches the center of target stricture, continue pulling back the handle until the stent is fully deployed. (See figure 3, 4)

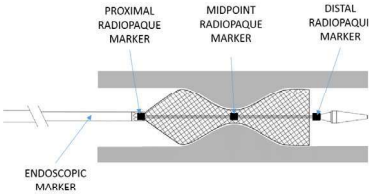



**Figure 4**

⚠ **CAUTION:** Do not push forward or pull backward the metal tube holder with the stent partially deployed. The metal tube holder must be securely immobilized. Inadvertent movement of the metal tube holder may cause misalignment of the stent and possible damage to the esophagus.

⑤ After Stent Deployment
a) Examine the stent fluoroscopically and/or endoscopically to confirm expansion.

b) Carefully remove the delivery system, guidewire and endoscope from the patient. If excessive resistance is felt during removal, wait 3~5 minutes to allow further stent expansion

**7. 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 complication.

**8. Instructions for removal of HILZO™ Covered Stents (see Warnings)**

Visually examine the Stent for any tumor in-growth/over-growth into the Stent lumen or whether the Stent is occluded. If the Stent lumen is clear, carefully remove using a forcep and/or snare. Grasp the proximal end of the Stent then carefully retrieve the Stent. If the Stent cannot be easily withdrawn, do not remove the Stent.

To reposition a HILZO™ Covered Stent immediately after deployment, use forceps or a snare to grasp the end of the stent and gently adjust to the correct placement.
Please note: the stent can only be repositioned and/or removed 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 BCM 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 of 1-30°C**

**Period of validity: Three years**

**Disposal Requirements:** After use, dispose product and packaging in accordance with hospital, administrative and/or local government policy for biohazardous medical waste.