CE
1639

Optimos™ Hook

EC REP

Authorized representative in Europe
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Representante autorizado en Europa
Avrupa yetkili temsilcisi
Autoriseret repræsentant i Europa

Temperature limitation
Limites de température
Temperaturvorgaben
Intervallo termico
Límites de temperatura
Isı sınırlaması
Temperaturgrænser

Consult instructions for use
Consulter les instructions d'utilisation
Gebrauchsanleitung beachten
Consultare le istruzioni per l'uso
Consulte las instrucciones de uso
Kullanım talimatlarına bakın
Konsultér brugsanvisning

Manufacturer
Fabricant
Hersteller
Produttore
Fabricante
Üretici
Fabrikant

REF

Catalogue No.
N° de référence
Katalog-Nr.
N. di catalogo
N° de catálogo
Katalog No.
Referencenummer

STERILE EO

Sterilized using ethylene oxide
Stérilisé à l'aide d'oxyde d'éthylène
Mit Ethylenoxid sterilisiert
Sterilizzato con ossido di etilene
Esterilizado por óxido de etileno
Etilen oksit kullanılarak sterilize edilmiştir
Steriliseret med ethylenoxid

Attention, consult instructions for use
Attention, consulter les instructions d'utilisation
Achtung: Gebrauchsanleitung beachten
Attenzione, consultare le istruzioni per l'uso
Atención, consulte
las instrucciones de uso
Dikkat! Kullanım talimatlarına bakın.
Vær opmærksom, konsultér brugsanvisning

Use by(Expiration Date)
A utiliser avant (date d'expiration)
Verwendbar bis (Verfallsdatum)
Utilizzare entro (data di scadenza)
Utilizar antes de
(fecha de vencimiento)
Son Kullanma Tarihi
Bruges før (udløbsdato)

LOT

Lot No.
Numéro de série
Seriennummer
No. di serie
N° de serie
Lot Number

Do not reuse
Ne pas réutiliser
Nicht wiederverwenden
Non riutilizzare
No reutilizar
Yeniden kullanmayın
Må ikke genbruges

Date of manufacture
Date de fabrication
Datum der Herstellung
Data di produzione
Fecha de fabricación
Üretim Tarihi
Fabrikationsdato

STERILIZE

Do not resterilize
Ne pas stériliser à nouveau
Nur einmal sterilisieren!
Non risterilizzare
No reesterilizar
Yeniden sterilize etmeyin
Må ikke resteriliseres

Do not use if package is damaged
Ne pas utiliser si l'emballage est abîmé
Nicht verwenden, wenn die Verpackung beschädigt ist!
Non utilizzare la confezione se danneggiata
No usar si el paquete está dañado.
Ambalaj hasar görmüşse tekrar kullanmayın
Må ikke bruges, hvis emballagen er beskadiget

TaeWoong MEDICAL

English

User's Manual

1. Description

The Optimos™ Hook body is made of nitinol wire. It facilitates access to the desired part of a stent.

The Optimos™ Hook consists of a hangable hook and sheath.
Hook types are classified by the part of the human body they are applied to.
The sheath is a tube to pull the stent into in its outer sheath. It has a radiopaque marker on the distal end of the outer sheath for radiopacity.

Product Name / Application	Type
Optimos™ Hook / Biliary, Esophageal	Ball

Figure 1. Model

(*Note: The Biliary Optimos™ Hook comes with the hook only.)

A. Hook

B. Sheath

B-1. Inner Sheath

B-2. Outer Sheath

- The Biliary Optimos™ Hook has a usable length of 51cm.
- The Esophageal Optimos™ Hook has a usable length of 76 cm.

Type	Application
Ball	Stent mesh and drawstring

2. Operational Procedure

2.1 Instructions for the Biliary Optimos™ Hook

① Grasp the position of stent that you intend to remove using the fluoroscope.
② Inject the contrast media through the catheter.
③ Insert the guide wire through the catheter.
④ Remove the catheter and insert the 9 Fr Tips sheath following the guide wire. You can remove a stent of 8~10 mm in diameter through the 9 Fr Tips sheath.
⑤ Separate the dilator from the Tips sheath.
⑥ Insert the intended hook type following Tips sheath.
⑦ Capture the drawstring or the proximal wall of the stent using the hook tip.
⑧ Pull the hook and stent together into the Tips sheath.
⑨ Remove the sheath and hook.

2.2 Instructions for the Esophageal Optimos™ Hooks

① Grasp the position of stent that you intend to remove using the fluoroscope.
② Inject the contrast media through the catheter
③ Insert the guide wire through the catheter.
④ Remove the catheter and insert the sheath of the Optimos™ Hook set following the guide wire.
⑤ Separate the inner sheath from the sheath.
⑥ Insert the intended hook type following the outer sheath.
⑦ Capture the drawstring or the proximal mesh of the stent using the hook tip.
⑧ Pull the hook and stent together into the sheath.
⑨ Remove the sheath and hook.

3. Indications for Use

The Optimos™ Hook is intended for removal of a fully covered stent which has been placed in a lumen.

4. Contraindications

Contraindications for the Optimos™ Hook includ, but are not limited to:

- Uncovered/bare stents. (see the warning)
- Excessive tissue hyperplasia and tumor overgrowth in a stent
- Any use other than those specifically outlined under Indications for Use.

5. Precautions

- Read the entire Instructions for Use thoroughly before using this device. It should only be used under the supervision of physicians thoroughly trained in the removal of inserted stents.
- The hook contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity.
- The use of fluoroscopy is recommended.
- The Optimos™ Hook is supplied sterile. Use this device prior to the expiration date (use by date) specified on the package.
- The packaging and the device should be inspected prior to use. Do not use if the hook has been damaged or if any other abnormality is observed.
- The Optimos™ Hook is intended for single use only. Do not resterilize and/or reuse the device.

6. Potential Complications

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

- Injury of the luminal wall (urethral tear)
- Bleeding (hematuria)
- Perforation (fistula)
- Intramural rupture

7. Cautions

- In the case of a failure to grasp the inserted stent, it should be removed by forceps or snare.
- Do not apply excessive force when the stent's distal end is not completely compressed.

8. Warnings

- When the capture position for removing a stent using a hook is unstable, the attempt must be made with extreme care.
- Excessive attempts to remove a stent may result in stent

deformation or patient injury.
- This device should be used with caution and only after careful consideration of the patients.
- Check the expiry date and do not use the device if it is passed.

9. Reuse Precaution Statement
Contents have been sterilized using ethylene oxide (EO) gas.
Do not use if the 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.

10. Storage: Store in a room temperature environment.

⚠ **WARNING:** 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.

⚠ **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.

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

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