Zilver®
Biliary Stent

Suggested Instructions for Use

COOK®
These recommendations are designed to serve only as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgement concerning patient care.

ZILVER® BILIARY STENT

DESIGN FEATURES
The Zilver Biliary Stent is a self-expandable stent made of nitinol. It is a flexible, slotted tube which provides strength and flexibility in the biliary duct upon deployment. Post deployment, the stent imparts an outwardly strong radial force upon the inner lumen of the duct, establishing patency in the designated stent region.

The stent is preloaded in a delivery catheter. Stent deployment is controlled by retraction of the handle while holding the metal cannula stationary.

MRI COMPATIBLE
This term indicates that the device, when used in the MRI environment, is MRI safe and has been demonstrated to neither significantly affect the quality of the diagnostic information nor have its operations affected by a MRI scanner not exceeding 1.5 Tesla.

INDICATIONS FOR USE
The Zilver Biliary Stent is indicated for use in palliation of malignant neoplasms in the biliary tree.

CONTRAINDICATIONS
- Total biliary obstructions and postoperative strictures which cannot be dilated to permit passage of the introducer catheter.
- Stenting of a perforated duct where leakage from the duct could be exacerbated by placement of a stent.
- Patients with bleeding disorders.
- Severe ascites.
WARNINGS AND PRECAUTIONS

- The safety and effectiveness of this device for use in the vascular system have not been established.
- Possible allergic reactions to nitinol should be considered.
- Manipulation of the product requires high resolution fluoroscopic control.
- The stent has not been designed to inhibit tumor ingrowth. Tissue may grow through stents.
- Do not try to remove the stent from the introducer system before use.
- Ensure that the red safety lock is not inadvertently removed until final stent release.
- Deploy the stent over an extra stiff or ultra stiff wire guide.
- Do not attempt to push the handle away from the hub during deployment.
- Do not rotate any part of the system during deployment.
- Do not expose the delivery system to organic solvents (e.g. alcohol).
- Do not use power injection systems with the Zilver Biliary Stent Delivery System.
PRODUCT RECOMMENDATIONS

The product is intended for use by physicians trained and experienced in diagnostic and interventional techniques. Placement of this biliary stent requires advanced skills in interventional biliary procedures. The following instructions will give technical guidance, but do not obviate formal training in the use of the device. Standard techniques for placement of percutaneous transhepatic biliary drainage catheters and metal stents should be employed.

Upon removal from package, inspect the product to ensure no damage has occurred.

Wire Guide Selection

The use of an appropriately-sized wire guide, e.g. a .035 inch extra support is recommended.

Selection of Stent

Measure the length of the target stricture to determine the length of the stent required. Allow for the area proximal and distal to the tumor to be covered with the stent to protect against interference from further tumor ingrowth.

Measure the diameter of the reference lumen (proximal and distal to the stricture) and use the LARGEST reference diameter as your basis for choosing the appropriate stent size.

Stent Size Selection Table

<table>
<thead>
<tr>
<th>Reference Lumen Diameter</th>
<th>Unconstrained Stent Diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.0 – 5.0 mm</td>
<td>6.0 mm</td>
</tr>
<tr>
<td>5.0 – 6.0 mm</td>
<td>7.0 mm</td>
</tr>
<tr>
<td>6.0 – 7.0 mm</td>
<td>8.0 mm</td>
</tr>
<tr>
<td>7.0 – 8.0 mm</td>
<td>9.0 mm</td>
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<tr>
<td>8.0 – 9.0 mm</td>
<td>10.0 mm</td>
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<tr>
<td>9.0 – 11.0 mm</td>
<td>12.0 mm</td>
</tr>
<tr>
<td>11.0 – 13.0 mm</td>
<td>14.0 mm</td>
</tr>
</tbody>
</table>
ZILVER BILIARY STENT AND DELIVERY SYSTEM

Figure 1

a) Handle
b) Hub
c) Safety lock
d) Introducer catheter
e) Introducer tip
f) Side-arm flushing port
g) Metal cannula
h) Radiopaque markers on the delivery system
i) Inner support stylet
j) Gold radiopaque markers

SUGGESTED INSTRUCTIONS FOR USE OF THE ZILVER BILIARY STENT

1. Determine the proper stent size after complete diagnostic evaluation. The stent deployment must be performed under fluoroscopic control.

2. Introduce the wire guide through the access catheter across the distal segment of the target lesion.

3. Remove the access catheter, leaving the wire guide in place.

4. Remove the inner support stylet from the hub of the handle of the stent delivery system.

5. Prior to placing the introducer catheter into the body, use the 1 cc syringe included in the inner package and flush the introducer catheter with saline through the side-arm flushing port.
6. Using fluoroscopic visualization, insert the introducer catheter over the wire guide. Position the catheter so that the two radiopaque marks on the delivery system (h) are at the desired position. The stent is now ready to be deployed. (Figure 2)
DEPLOYMENT OF THE STENT

1. Before deployment it is important to straighten the proximal part of the introducer catheter as much as possible and to keep the handle in a stable position.

2. The stent expansion must be performed under fluoroscopic control.

![Figure 3](image1)

3. Hold the hub (b) on the metal cannula (g) steady. Prior to deploying the stent, remove the red safety lock (c) (Figure 3).

![Figure 4](image2)

Hold the hub end stationary. The stent will be deployed as you pull the handle (a) towards the hub (b). (Figures 4 and 5)
The introducer catheter cannot be re-advanced over the stent during deployment.
4. The stent is fully deployed when the handle (a) reaches the hub (b). (Figure 6)
5. Perform a final cholangiogram to ensure proper placement of the device.

6. Remove the delivery system. **NOTE: If resistance is met during the withdrawal of the delivery system, re-advance the outer sheath to its pre-deployment position. Withdraw the system as one unit.**

7. After stent placement, a temporary external drainage catheter may be placed over the pre-positioned wire guide. This provides access to the stent if an additional treatment is needed.

**MULTIPLE STENT PLACEMENT**

If placement of more than one stent is required in a patient, the following recommendations should be considered:

- In relationship to the lesion site, the distal area of narrowing should be stented first, followed by the proximal locations, i.e. a second stent should be placed proximally to the previously placed stent.
- Stents placed in tandem should slightly overlap.

**PACKAGING**

Supplied sterilized by ethylene oxide gas in peel-open packages. Intended for one-time use. Sterile if package is unopened or undamaged. Do not use the product if there is doubt as to whether the product is sterile.

**CAUTION:** Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

**STORAGE**

Store in a dark, dry, cool place. Avoid extended exposure to light.

**REFERENCES**

These instructions for use are based on experience from physicians and their published literature.

As more data become available, other causal factors may become evident. Refer to your local Cook sales representative for information on available literature.
PATENTS

This product and its use are protected by one or more of the following patents: United States, 4,580,568; 5,380,304; 5,700,253. Other U.S. patents pending. Foreign patents issued and pending.

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