

Biliary Stents & Introducers

Description:

- BS- Biliary Stents
- BSST- Biliary Stents Standard PTFE
- BS-DP Biliary Stents Double Pigtail
- Majestick- Biliary Stents Introducer
- Pusher

Configuration:

See brochure

Intended use:

Used for drainage of obstructed bile ducts.

Contraindications:

Those contraindication specific to endoscopic retrograde cholangiopancreatography (ERCP) & endoscopic sphincterotomy (ES)

Complications:

- Duodenal Hemorrhage
- Hematoma
- Septicemia /infection
- Bile peritonitis
- Allergic reaction to contrast or medication
- Stent migration.

Caution:

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

Warning/ Precaution:

- The device should not be left indwelling for more than 90 days. Periodic evaluation is recommended. Not intended for permanent use.
- Attempt to resterilize a single use device may compromise its structural integrity and/or lead to device failure which may result in patient injury or illness.
- Do not use if package is opened or damaged.
- Dispose in accordance with recognized medical practice and under observance of applicable law and regulation.
- Only experienced surgeons should place this device.
- Constant fluoroscopic monitoring is advised.
- Compatibility of channel with the desired stent is required.
- Storage temperature between 5°C to 30°C.

Instruction for Use:

- Inspect the biliary stent for any kink, bends or damage. If any abnormality is detected do not use.
- Place a 0.035" guide wire through the biliary stricture.

For 5F and 7F Stents:

- Gently straighten the stent and slide it over the guidewire and into the scope channel.
- Slide the pusher over the guidewire with small movements; push the stent through the scope channel and into position using the pusher. Maintain the stent and pusher as straight as possible during the deployment.
- Confirm stent position using fluoroscopy. Once the stent is properly positioned, withdraw the guidewire while leaving the pusher in place to prevent stent shifting.
- Reconfirm the position again and then slowly remove the pusher.

For 10F Stent (Using Majestik Biliary Stent Introducer):

- Back load the desired stent on to the guiding catheter and pusher assembly. Advance the whole system over the guidewire and into the accessory channel of endoscope.
- Enter the guiding catheter into the stricture area till at least one marker is above the majority of the stricture.
- Maintaining the position of the guiding catheter advance the stent to the desired position by the pushing catheter.
- Fluoroscopically and endoscopically confirm the appropriate stent placement.
- Retract and remove both the guiding catheter and guidewire into the endoscope while maintaining the position of the pushing catheter.
- Confirm the position of the stent once again and then remove the pushing catheter.

Do not reuse, reprocess & resterilize:

Reuse, Reprocessing & resterilization may compromise the structural integrity, can also create risk of contamination & may not give desired result or create complications, infections which may result in injury, illness or death.

Limited Express Warranty:

The limited express warranty as set forth herein is exclusive and in lieu of all warranties of merchantability and fitness for use, remedies, obligations and liabilities for consequential damages. The products are being sold only for the purpose described herein and such limited express warranty runs only to the original user. In no event shall ALLWIN be liable for any breach of warranty in any amount exceeding the purchase price of the product. ALLWIN reserves the right to make design changes to products without liability to incorporate said changes in ALLWIN products previously designed or sold.

Stent French Size	Minimum Accessory Channel Size
5FR	2mm
7FR	2.8mm
0FR	3.7mm

 Catalogue Number
  Batch Code
  Date of Manufacture
  Use By
  Do not re-use
  Do not Re-Sterilize
  **Rx only**
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 Consult Instruction for use
  Do not use if Packing is damaged
  Caution
  Keep out of sunlight
  Keep Dry
  **STERILE EO**
 Sterilized using ethylene oxide
  **5°C - 30°C** Temperature Limit



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