

Biliary Metal Stents



Please Note: These steps are intended to be for general guidance only. For complete instructions for use, indications, contraindications and warnings, please refer to the product labeling supplied with each device.

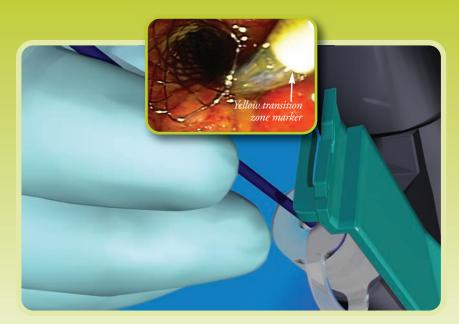
Warning: The safety and effectiveness of the WallFlex Biliary RX Stent for use in the vascular system has not been established.





STARTING STENT DEPLOYMENT - To begin deployment of the stent, immobilize the proximal handle with one hand and slowly slide the smaller distal handle towards the proximal handle with the other hand.

1



ENDOSCOPIC POSITIONING OF STENT - While technician is beginning to deploy the stent, the physician slowly pulls back on stent catheter, monitoring the endoscopic view (and yellow transition zone marker) to maintain correct positioning of stent in the duodenum.

2.



IDENTIFICATION OF FLUOROSCOPIC STENT MARKERS - Fluoroscopic stent markers indicate extent to which stent can be deployed and still be re-sheathed and repositioned during deployment. When the 2nd and 3rd markers meet during deployment (see right fluoro image), this is the final opportunity to check stent position before full deployment.*

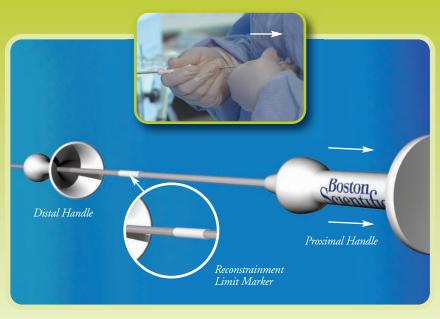
Top end of constrained stent

End of exterior tube

(Marker has reached

reconstrainment

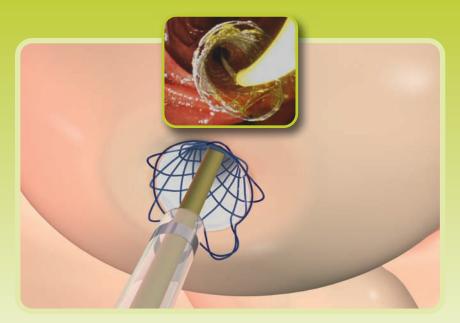
^{*} Warning: A stent cannot be reconstrained after the reconstrainment limit has been exceeded. Warning: Use caution when placing stent near ductal branches to avoid obstruction of duct. Placement of a fully covered biliary stent across a branch duct or major bifurcation may result in complications due to blockage of flow from the branch duct and may prevent endoscopic or transhepatic access for future procedures.



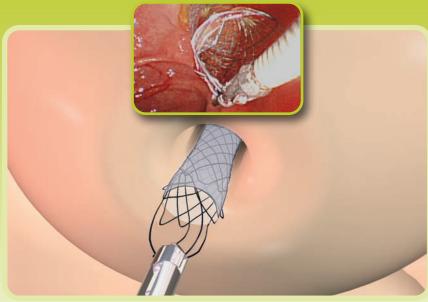
4.

RECONSTRAINING & REPOSITIONING STENT - To reconstrain the stent, immobilize the distal handle with one hand and start reconstrainment by sliding the proximal handle backwards, away from the distal handle. *

^{*} Warning: A stent cannot be reconstrained after the reconstrainment limit has been exceeded.



FULLY DEPLOYED STENT - After re-confirming correction position of stent fluoroscopically and endoscopically at reconstrainment limit marker, continue sliding the distal handle slowly towards the proximal handle until the stent is fully deployed. This image indicates final stent position for transpapillary placement - with the stent outside the papilla.



REMOVING THE STENT* - In the event of incorrect positioning during the initial placement procedure, the stent may be removed using rat tooth forceps to grasp the retrieval loop on the end of the stent.*

^{*} Warning: No warranty is made with regard to removability of this device by endoscopic means or otherwise.

Ordering Information

| Order number | Diameter (mm) | Length (mm) | Covered Length (mm) (PC Only) | Catheter Diameter (F) | Guidewire Diameter | | | |
|---|---------------|-------------|----------------------------------|--------------------------|-----------------------|--|--|--|
| Fully Covered Stents with Permalume® Covering | | | | | | | | |
| M005 7050 0 | 8 | 60 | N/A | 8.5 (2.83mm) | | | | |
| M005 7051 0 | 8 | 80 | | | | | | |
| M005 7052 0 | 10 | 40 | | | .035" | | | |
| M005 7053 0 | 10 | 60 | | | (.89mm) | | | |
| M005 7054 0 | 10 | 80 | | | | | | |

Partially Covered Stents with Permalume Covering

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|--------------------|----|----|----|----------|---------|--|
| M005 7070 0 | 8 | 60 | 48 | | | A V |
| M005 7071 0 | 8 | 80 | 68 | | 3 | ACCOUNT OF |
| M005 7072 0 | 10 | 40 | 28 | 8.5 | .035″ | 0 |
| M005 7073 0 | 10 | 60 | 48 | (2.83mm) | (.89mm) | |
| M005 7074 0 | 10 | 80 | 68 | | | |

Uncovered Stents

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|--------------------|----|-----|-----|-----------------|------------------|
| M005 7060 0 | 8 | 40 | N/A | 8.0 (2.67mm) | .035" (.89mm) |
| M005 7061 0 | 8 | 60 | | | |
| M005 7062 0 | 8 | 80 | | | |
| M005 7063 0 | 8 | 100 | | | |
| M005 7089 0 | 10 | 40 | | | |
| M005 7064 0 | 10 | 60 | | | |
| M005 7065 0 | 10 | 80 | | | |
| M005 7066 0 | 10 | 100 | | | |

Indications, Contraindications, Warnings and Instructions for Use can be found in the product labeling supplied with each device. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Recommended Guidewires

Hydra Jagwire® Guidewire Stiff Shaft .035" (.89mm) - 260cm

M005**5602**1 Straight Dream Tip™ M005**5603**1 Angled Dream Tip

Hydra Jagwire Guidewire Stiff Shaft .035" (.89mm) - 450cm

M005**5606**1 Straight Dream Tip M005**5607**1 Angled Dream Tip



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