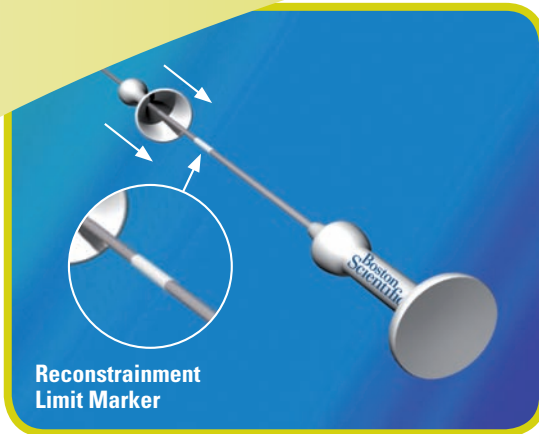


WallFlex™ RX Biliary Stent

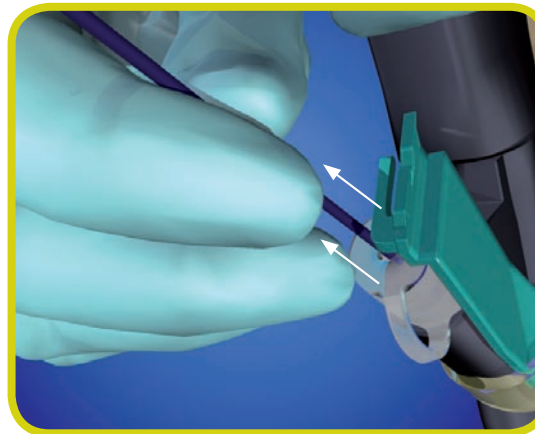
Trans-papillary placement

Boston
Scientific

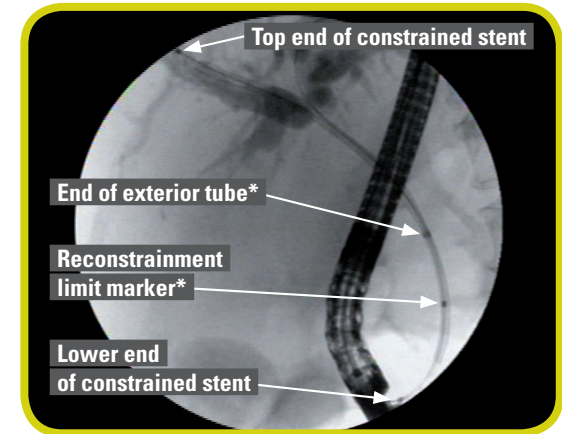
Delivering what's next.™



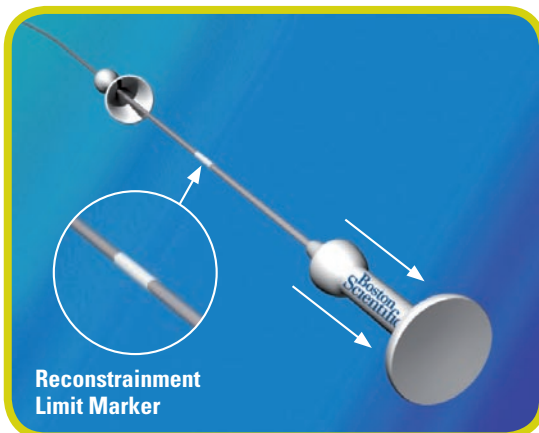
1 Immobilize the proximal handle and start deployment by sliding the distal handle back, towards the proximal handle



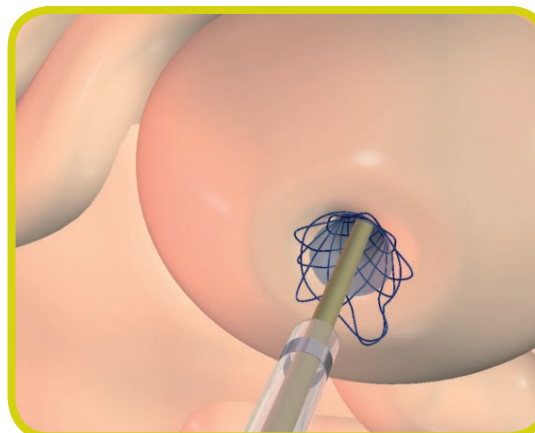
2 Doctor can pull back stent, checking on endoscopic view that position is maintained



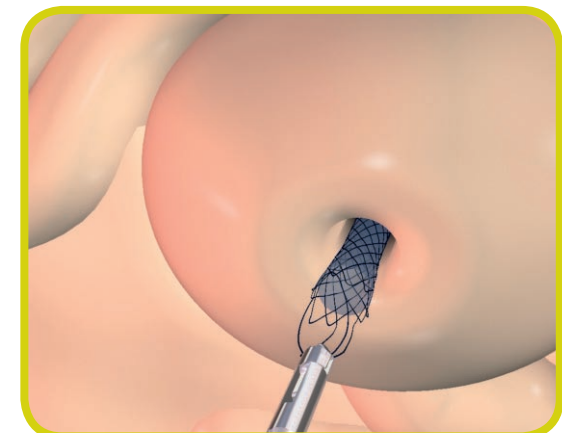
3 Markers indicate extent to which stent can be deployed and still be re-sheathed. When the markers indicated* meet, this is the final opportunity to check stent position



4 Immobilize the distal handle and start reconstraint by sliding the proximal handle backwards, away from the distal handle



5 Final position for transpapillary placement - with end of stent outside papilla



6 To remove if the stent has been misplaced: using forceps, grasp the retrieval loop on the end of the stent. Gently pull the stent back with the scope to remove

Selected Published Evidence - Metal Stents

Is placing a metal stent more clinically effective than plastic ?

This trial showed a survival advantage of 2.5 months for patients receiving a metal stent over those receiving plastic stents ($p < 0.05$). While in rigorous clinical trials intensive follow up is likely to lead to early detection and treatment of stent blockage, in routine clinical practice patient life expectancy can be extended by using a closed cell metal stent.

Schmassmann A. et al. Wallstent™ Versus Plastic Stents in Malignant Biliary Obstruction: Effects of Stent Patency of the First and Second Stent on Patient Compliance and Survival. American Journal of Gastroenterology 1996; 91:654-9

A meta-analysis of randomised controlled trials showed that Self-Expanding Metal Stents (SEMS) significantly increase patient survival when compared to plastic stents ($p = 0.03$). Individual trials have been too small to show this data which has significant clinical implications.

Waschke K.A. et al. Self-expanding metal stents confer a survival advantage in the palliation of distal malignant biliary obstruction, UEGW 2006 Abstract MON-E-397

Metal stent placement is the most effective treatment of inoperable malignant common bile duct stricture.

Kaassis M. et al. Plastic or metal stents for malignant stricture of the common bile duct? Results of a randomized, prospective study. Gastrointest Endosc 2003; 57:178-82

Is placing a metal stent cost-effective ?

Use of plastic stents is preferable for patients surviving less than 4 months, whereas metal stents are more economical for patients with longer survival.

Yeoh et al. Comparative costs of metal versus plastic biliary stent strategies for malignant obstructive jaundice by decision analysis. Gastrointest Endosc 1999; 49:466-71

In patients without hepatic metastases, metal stent placement is cost-effective: a plastic stent should be placed in patients with spread of the tumor to the liver. The high proportion of patients without liver metastases in this study (67.8%) suggests that the indications of SEMS should be expanded.

Kaassis M. et al. Plastic or metal stents for malignant stricture of the common bile duct? Results of a randomized prospective study. Gastrointest Endosc 2003; 57:178-82

Covered or Uncovered metal stent ?

Covered SEMS give superior patency versus uncovered SEMS and deployment is safe and easy. The overall risk-benefit ratio is acceptable in the majority of patients with distal malignant biliary obstruction.

Kahaleh M. Efficacy and complications of covered Wallstents in malignant distal biliary obstruction. Gastrointest Endosc 2005; 61:528-33

This data clearly shows that covered stents overcome the problem of tumour ingrowth and reduce the rate of stent occlusion. Covered stents significantly reduced the need for repeat interventions and may contribute to both higher quality of life and lower overall treatment cost.

Isayama H. et al. A prospective randomized study of "covered" versus "uncovered" diamond stents for the management of distal malignant biliary obstruction. Gut 2004; 53:729-34

This study measured many factors that could contribute to an increased risk of cholecystitis. Analysis showed that an obstruction across the cystic duct by tumour and the presence of gallbladder stone were the only statistically significant risk factors for the development of cholecystitis after metal stent placement.

Suk K.T. et al. Risk factors for cholecystitis after metal stent placement in malignant biliary obstruction. Gastrointest Endosc 2006; 64:522-9

How difficult is stent placement ?

Plastic stent placement is successful in around 90% of cases below the hilum, and around 70% of hilar cases. However metal stenting is successful in around 95% of cases, due to the ease of placement.

Rey J.F. et al. Guidelines of the French Society of Digestive Endoscopy: Biliary Stenting. Endoscopy 2002; 34:169-73

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WallFlex™ Stents
Open
to the
Possibilities™

No warranty is given with regard to removability of this device by endoscopic or other means. Careful consideration must be taken when removing a stent from an intrinsic malignant tumor as the manipulation, repositioning or removal of the stent may result in perforation, bleeding, tissue abrasion or other patient injury. The WallFlex RX Biliary Partially-Covered Stent should not be moved or removed after completion of the initial stent placement procedure.