RX Biliary System[™]

Boston Scientific

Advancing science for life[™]

> Start

> Benefits of WGC

> RX Biliary System

> RX Compatible Devices

> Managing Costs

> Services& Support

RX Biliary System™ We're in!™

When you control the wire, efficiency comes along for the ride.

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The Benefits of Physician-Controlled Wireguided Cannulation

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Physician-controlled wireguided cannulation (WGC) facilitates deep biliary duct cannulation without the standard contrast-assisted cannulation technique.

Designed to facilitate access and control during endoscopic retrograde cholangiopancreatography (ERCP), the RX Biliary System:

- Puts the physician in control of the guidewire.
- Secures the guidewire to maintain access during exchanges.
- Provides a tactile feel while manipulating the guidewire.

Fluoroscopy image of guidewire placement in common bile duct and pancreatic duct

> Learn more about physician-controlled WGC and Boston Scientific devices by visiting: www.bostonscientific.com/gastro

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The Benefits of Physician-Controlled Wireguided Cannulation





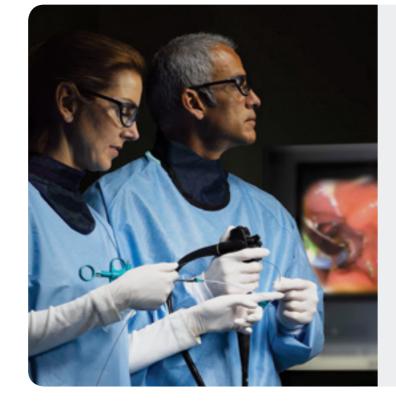
Decreases the amount of fluoroscopy time



Lessens the need for communication and coordination with a nurse or technician



Reduces the amount of time for sedation



- 66 I've been practicing ERCP for 20 plus years so the less fluoro time the better. That's a concern for everybody in the room. The less radiation exposure for staff and patients the better it is. ??
 Oleh Haluszka, M.D., Chief of Gastroenterology Temple University, Philadelphia, Pennsylvania
- **66** RX really does improve your time of cannulation. We used to intubate patients for ERCP. Now the majority of my cases in otherwise healthy patients are done under conscious sedation. You've just reduced an operating-room level procedure to a routine endoscopy. Recovery time is shorter and patients don't complain of a sore throat. **99**

Niraj Jani, M.D., Chief division of Gastroenterology Greater Baltimore Medical, Maryland

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The RX Biliary System

A Locking device has notches for fixation of one or two wires
 B Biopsy port cap designed to reduce air and bile leakage

C Strap secures it below the biopsy port

В (C)

The C-Channel[™] Design allows the guidewire to be *peeled down*, giving the physician control of the guidewire.



RX Locking Device and Biopsy Cap System

Designed to facilitate access and control during ERCP.

Benefits of WGC

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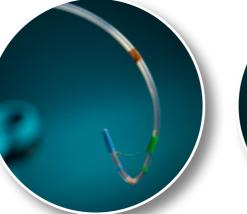
> Managing Costs

Services & Support

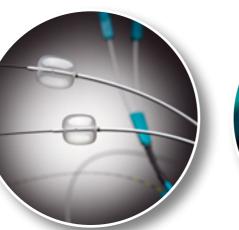


RX Compatible Devices Access, Cannulation, Treatment

The RX Biliary System and complementary devices offer a broad portfolio of products for pancreatico-biliary stone and stricture management.



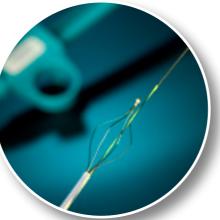
Autotome[™] RX Cannulating Sphincterotome



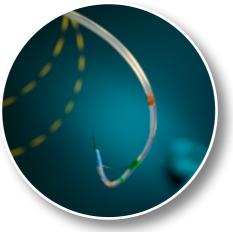
Extractor[™] Pro RX Retrieval Balloon Catheter



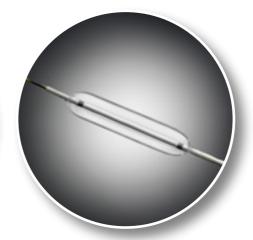
Jagtome[™] RX Cannulating Sphincterotome



Trapezoid™ RX Wireguided Retrieval Basket



Hydratome[™] RX Cannulating Sphincterotome



Hurricane[™] RX Biliary Balloon Dilatation Catheter



Dreamtome[™] RX Cannulating Sphincterotome



RX Cytology Brush Wireguided Cytology Brush

Tap images above for individual product information



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RX Compatible Devices

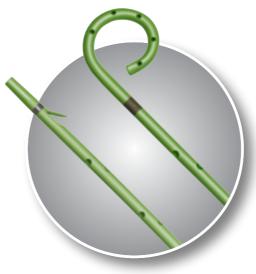
Since its introduction, the RX Biliary System continues to provide utility with the development of new technologies and devices for diagnostic and therapeutic ERCP.



SpyGlass ${}^{\scriptscriptstyle{\mathsf{M}}}$ DS Direct Visualization System

Other Complementary Devices

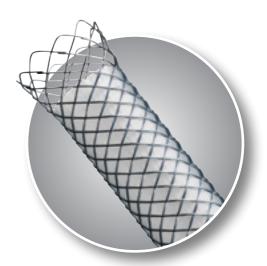
Use in conjunction with .035" and .025" guidewires available in .260cm and 450cm lengths: Dreamwire, Jagwire and Hydra Jagwire High Performance Guidewires



Advanix[™] Pancreatic Stents



Advanix Biliary Stents



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WallFlex[™] RX Biliary Stents

Rapid Refill Continuous Injection System

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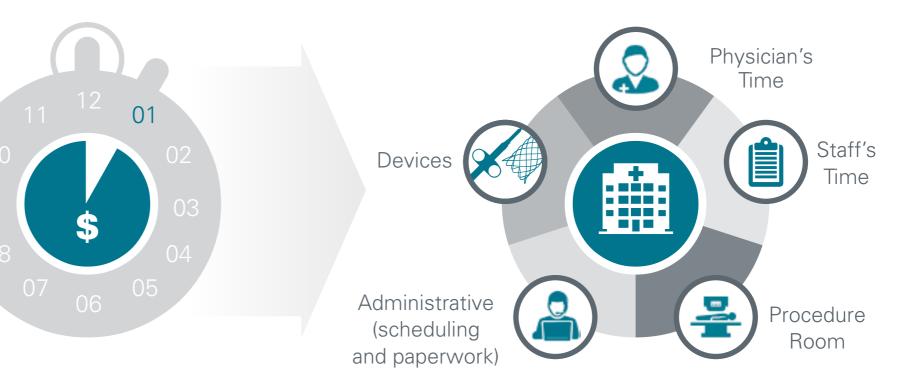


Managing Procedural Efficiencies and Costs



With shorter procedure times, physicians have reported a **reduction in fluoroscopy and sedation** requirements.²

What is the **cost of one hour** of your hospital's procedure time?



1. ASGE 2007, Technology Status Evaluation Report: Short-wire ERCP systems. For biliary indications, the short-wire system yielded a decrease in total procedure time for therapy (from 34 to 27 minutes, P = .002), procedure time after cannulation (from 23 to 18 minutes, P = .006), and a trend toward less fluoroscopy time.

2. RX Biliary System, Still Having an Impact on the Practice of Endoscopy, ACCESS magazine Oct/Nov 2014.



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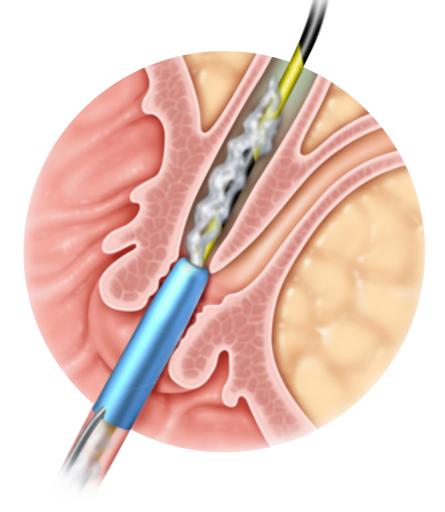
> Managing Costs

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Managing Complications and Costs

- Physician-controlled wireguided cannulation reduces the risk of post-ERCP pancreatitis compared with the standard contrast injection method.¹
- By facilitating physician-controlled wireguided cannulation, the RX Biliary System plays a role in helping manage the potential complications of ERCP.





\$11,054

Hospital Cost The 2011 Medicare average to treat a patient with pancreatitis

- \$7,663 Reimbursement

Average Medicare hospital reimbursement

=\$3,391 Loss

Approximate hospital net loss (ICD-9-CM code: 577.0 acute pancreatitis.)

1. Cennamo et al. Can a Wire-Guided Cannulation Technique Increase Bile Duct Cannulation Rate and Prevent Post-ERCP Pancreatitis?: A Meta-Analysis of Randomized Controlled Trials. The American Journal of Gastroenterology, 2009.



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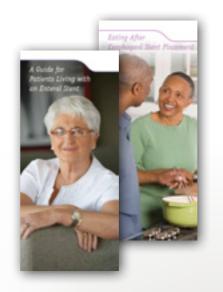
> Services& Support



Services and Support

Boston Scientific offers a broad portfolio of devices for the treatment of gastrointestinal diseases along with services and programs that help impact clinical outcomes and bring efficiencies to managing the endoscopy suite.

- Optimization services for supply chain and workflow processes.
- Reimbursement and coding services, and health policy webinars.
- Patient education materials, health equity and patient management programs.
- Local case support, and clinical staff training through in-services and continuing nursing credit programs.





CLOSEHEGAP Close the Gap is a health equity program created by Boston Scientific that is dedicated to eliminating treatment disparities in communities across the nation at high risk of suffering from gastrointestinal and pulmonary diseases.





Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752-1234 www.bostonscientific.com

Ordering Information 1.888.272.1001

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ENDO-322515-AA July 2015

Warning: The safety and effectiveness of biliary metal stents for use in the vascular system have not been established.

All trademarks are the property of their respective owners.

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

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RX Compatible Devices Access, Cannulation, Treatment

The RX Biliary System and complementary devices offer a broad portfolio of products for pancreatico-biliary stone and stricture management.

Autotome[™] RX Cannulating Sphincterotome

The Autotome RX Cannulating Sphincterotome provides controlled steerability for positioning to facilitate sphincterotomy.* The Autotome RX Cannulating Sphincterotome is available in a range of tapered tip sizes to accommodate varying patient anatomy.

*Autotome RX 39 and Autotome RX 44 Sphincterotomes only.

Extractor[™] Pro RX Retrieval Balloon Catheter Trapezoid[™] RX Wireguided Retrieva Basket

Hurricane[™] RX Biliary Balloon Dilatation Catheter RX Cytology Brush Wireguided Cytology Brush

Tap images han above for individual product information

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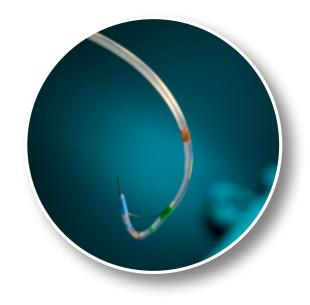
RX Compatible Devices Access, Cannulation, Treatment

The RX Biliary System and complementary devices offer a broad portfolio of products for pancreatico-biliary stone and stricture management.

Jagtome[™] RX Cannulating Sphincterotome

The Jagtome Cannulating Sphincterotome provides controlled steerability for positioning to facilitate sphincterotomy and is preloaded with a Jagwire[™] High Performance Guidewire.*

*Jagtome RX 39 and Autotome RX 44 Sphincterotomes only.



ractor™ Pro RX rieval Balloon Catheter Trapezoid[™] RX Vireguided Retrieval Basket

Hurricane[™] RX Biliary Balloon Dilatation Catheter RX Cytology Brush Wireguided Cytology Brush

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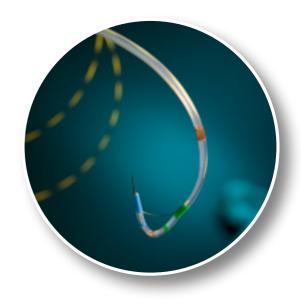
The RX Biliary System and complementary devices offer a broad portfolio of products for pancreatico-biliary stone and stricture management.

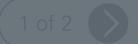
Hydratome[™] RX Cannulating Sphincterotome

The Hydratome RX Cannulating Sphincterotome provides controlled steerability for positioning to facilitate sphincterotomy and is preloaded with a Hydra Jagwire[™] High Performance Guidewire.*

*Hydratome RX 44 Sphincterotomes only.

Trapezoid™ I Wireguided Ret Basket Hurricane[™] RX Biliary Balloon Dilatation Catheter RX Cytology Brush Wireguided Cytology Brush





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Dreamtome[™] RX Cannulating Sphincterotome

The Dreamtome RX Cannulating Sphincterotome provides controlled steerability for positioning to facilitate sphincterotomy and is preloaded with a Dreamwire[™] High Performance Guidewire.



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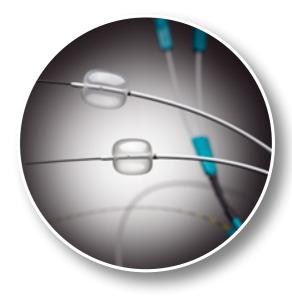
Extractor[™] Pro RX Retrieval Balloon Catheter

The Extractor Pro RX Retrieval Balloon Catheter is indicated for use endoscopically to remove stones from the biliary system, or facilitate injection of contrast of medium while occluding the duct with the balloon.

- The balloon is available in three balloon sizes, each of which can be inflated to two distinct diameters: 9-12mm; 12-15mm and 15-18mm to accommodate anatomical variations.
- A single balloon can be inflated to two distinct sizes if a different diameter is needed without having to exchange devices.
- The squared-shoulder shape of the balloon helps facilitate stone removal.

Extractor[™] Pro RX Retrieval Balloon Catheter Trapezoid[™] RX 'ireguided Retrieval Basket Hurricane[™] RX Biliary Balloon Dilatation Catheter RX Cytology Brush Wireguided Cytology Brush

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RX Compatible Devices

Trapezoid[™] RX Wireguided Retrieval Basket

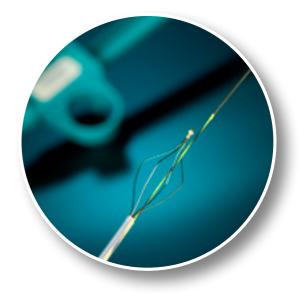
The Trapezoid RX Wireguided Retrieval Basket is indicated for endoscopic crushing and removal of biliary calculi. The Flexi-Stiff[™] Catheter Construction provides a flexible and sturdy catheter designed to bend with biliary anatomy while maintaining pushability. The metal alloy basket is designed to maintain basket symmetry even after difficult stone manipulation.

Maintaining Guidewire Access

- The distal side-port guidewire channel helps facilitate duct access.
- Side port is designed to lead the basket past stones for retrieval.
- Injection with guidewire in place accommodates cholangiography without device exchange.
- The RX Locking Device facilitates multiple sweeps of the duct during stone retrieval by maintaining guidewire position.

Mechanical Crushing Option

The Alliance[™] II Inflation System can be used to crush large stones trapped within the basket with scope in place.



Tip disengages to facilitate basket removal if stone does not break, helping to reduce the risk of basket impaction.

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Hurricane[™] RX Biliary Balloon Dilatation Catheter

The Hurricane RX Biliary Balloon Dilatation Catheter is a double-lumen catheter for endoscopic dilatation of strictures of the biliary tree and the Sphincter of Oddi. The balloon is available in a range of sizes to accommodate patient anatomy and stricture size.

Visualization and Positioning

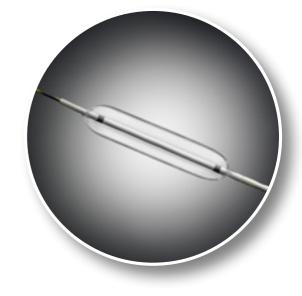
- Two radiopaque markers aid in balloon positioning.
- A dedicated lumen allows for contrast medium injection with a guidewire in place.

Stricture Passage

- The 5.8Fr catheter shaft tapers beneath the balloon to achieve the lowest possible deflated profile.
- A stainless steel stiffening stylet inserted in the proximal portion of the shaft helps augment pushability.
- The RX catheter design allows the guidewire to be locked into place to secure access.

Balloon Inflation - Balloon achieves pressure up to 12ATM

- Long 4cm balloon length is designed to offer stability during stricture dilation.
- Semi-compliant material is designed to adapt to the biliary duct during inflation.
- Balloon is recommended for use the Encore[™] 26 Inflation Device developed for rapid deflation during procedure if necessary.



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RX Cytology Brush Wireguided Cytology Brush

The RX Cytology Brush Wireguided Cytology Brush is a double-lumen wireguided catheter for the collection of cells and the detection of malignant neoplasms in the biliary duct. Device features include:

- Handle has reinforced metal tube for reliable actuation.
- Distal radiopaque marker aids in catheter visualization under fluoroscopy for proper positioning.
- Open channel allows for quick exchange of the guidewire.

Extractor[™] Pro RX Retrieval Balloon Catheter Trapezoid™ RX Wireguided Retrieva Basket

Hurricane[™] RX Biliary Balloon Dilatation Catheter RX Cytology Brush Wireguided Cytology Brush

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