

RX Biliary System™

**Boston
Scientific**
Advancing science for life™

> Start

RX Biliary System™

- > Benefits of WireGuided Cannulation
- > RX Biliary System
- > RX Compatible Devices
- > Managing Costs & Complications
- > Services & Support



RX Biliary System™

We're in!™

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



The Benefits of Physician-Controlled Wireguided Cannulation

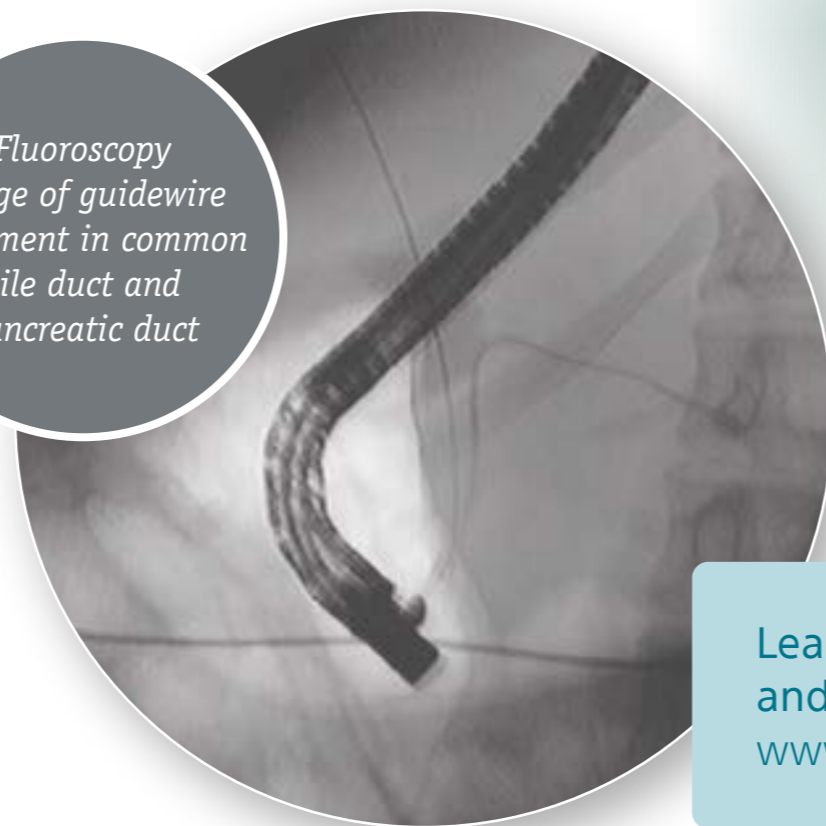


Physician-controlled wireguided cannulation (WGC) facilitates deep biliary duct cannulation without the standard contrast-assisted cannulation technique.

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.eu



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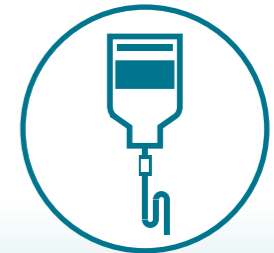
The Benefits of Physician-Controlled Wireguided Cannulation



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



“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

“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.”

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

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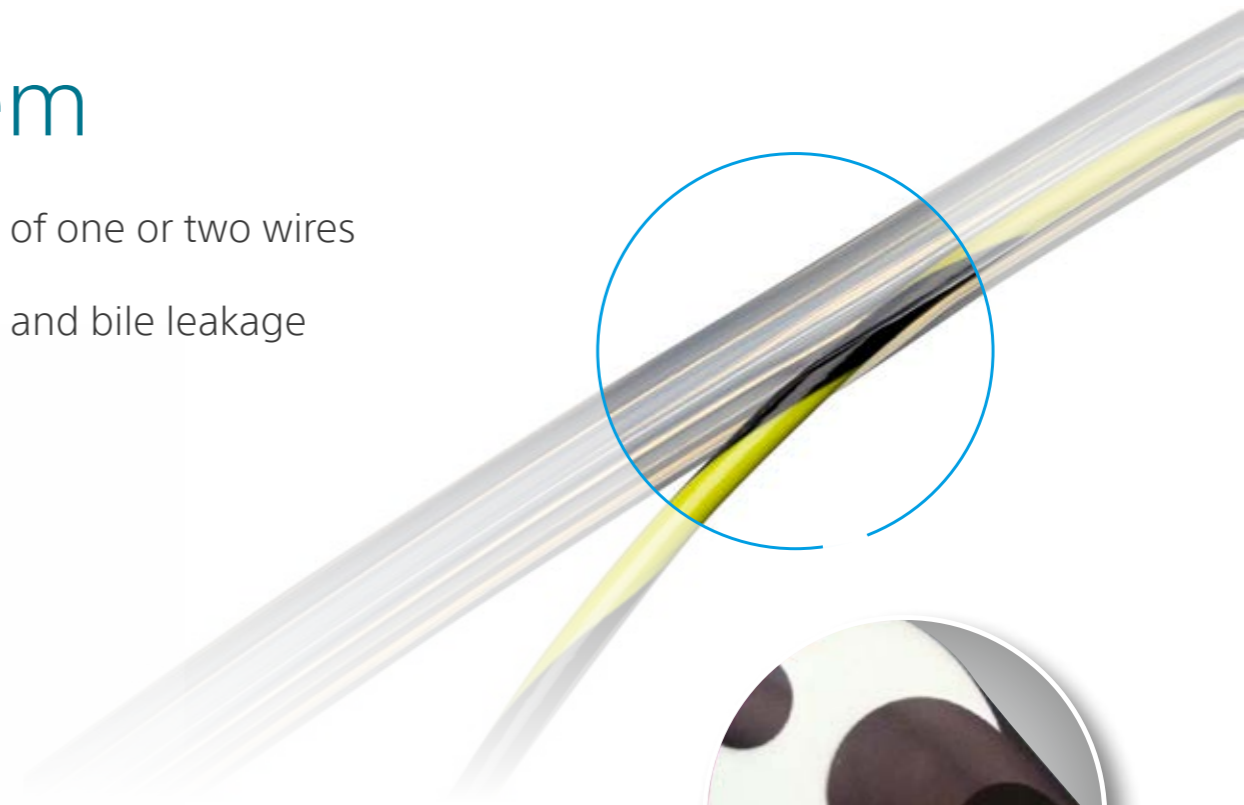
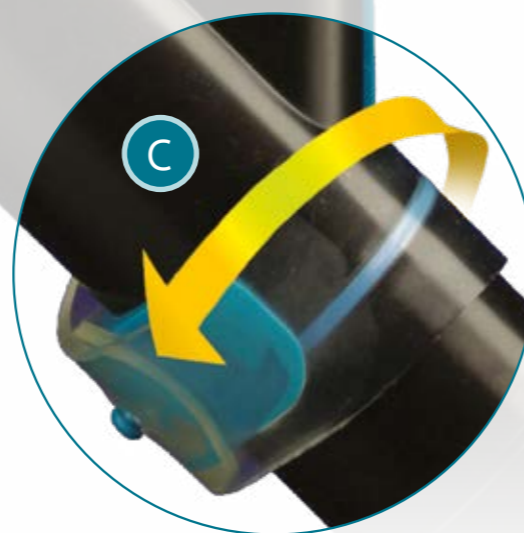
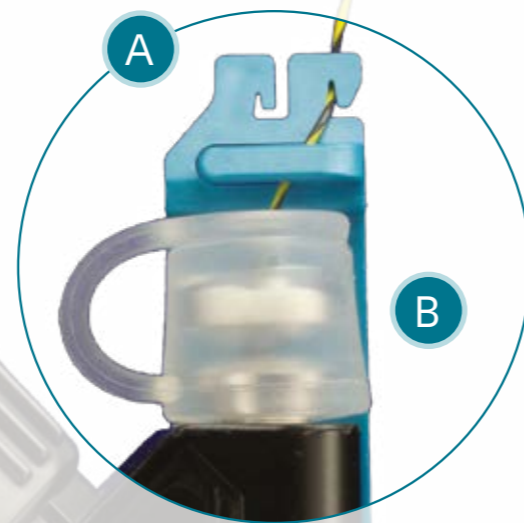
> Managing Costs & Complications

> Services & Support



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



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.

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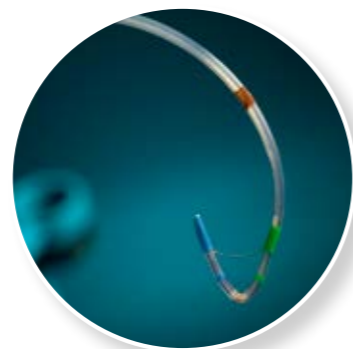
RX Compatible Devices

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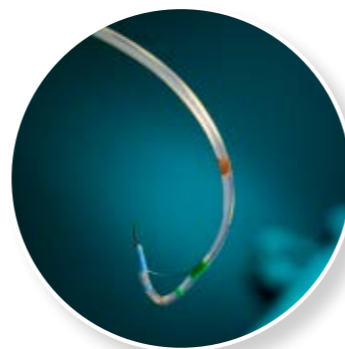


The RX Biliary System and complementary devices offer a broad portfolio of products for pancreatobiliary stone and stricture management.

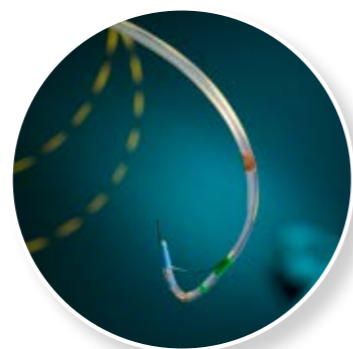
Access



Autotome™ RX
Cannulating
Sphincterotome



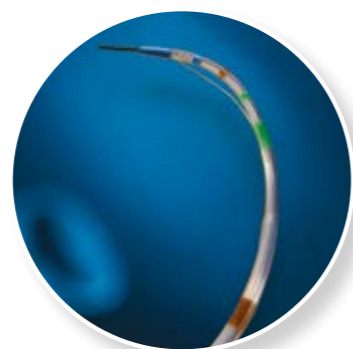
Jagtome™ RX
Cannulating
Sphincterotome



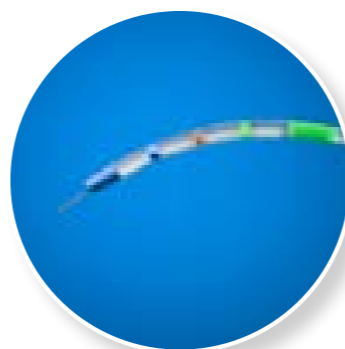
Hydratome™ RX
Cannulating
Sphincterotome



Dreamtome™ RX
Cannulating
Sphincterotome

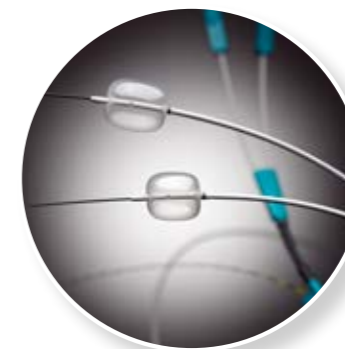


Jagtome™
Revolution RX
Cannulating
Sphincterotome

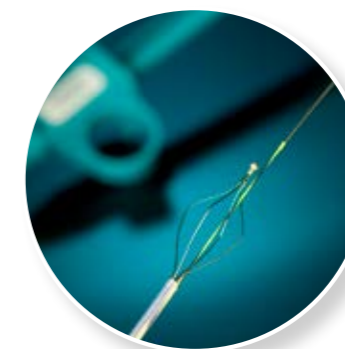


RX Needle-Knife
XL Cannulating
Sphincterotome

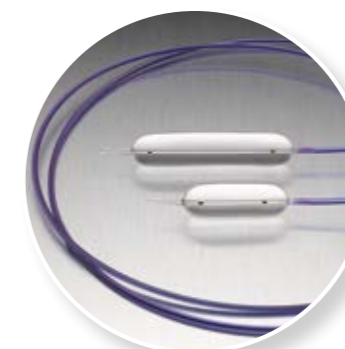
Stone management




Extractor™ Pro RX-S
Retrieval Balloon
Catheter



Trapezoid™ RX
Wireguided Retrieval
Basket



CRE™ RX Biliary
Balloon Dilatation
Catheter

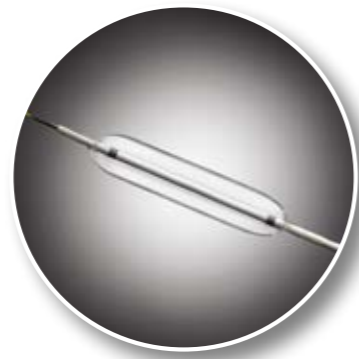
Tap images  above for individual product information



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.

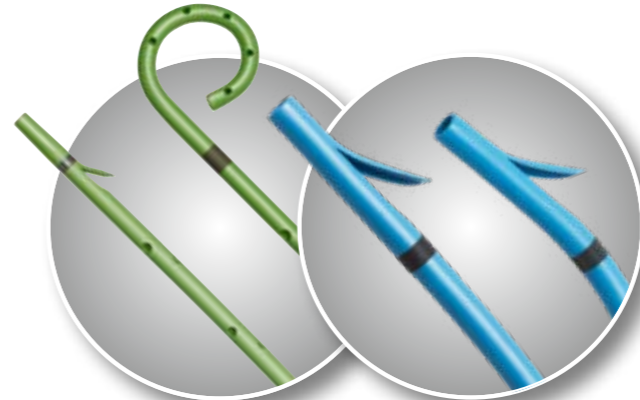
Stricture Management



Hurricane™ RX Biliary Balloon Dilatation Catheter



RX Cytology Brush Wireguided Cytology Brush



Advanix™ Pancreatic & Biliary Stents

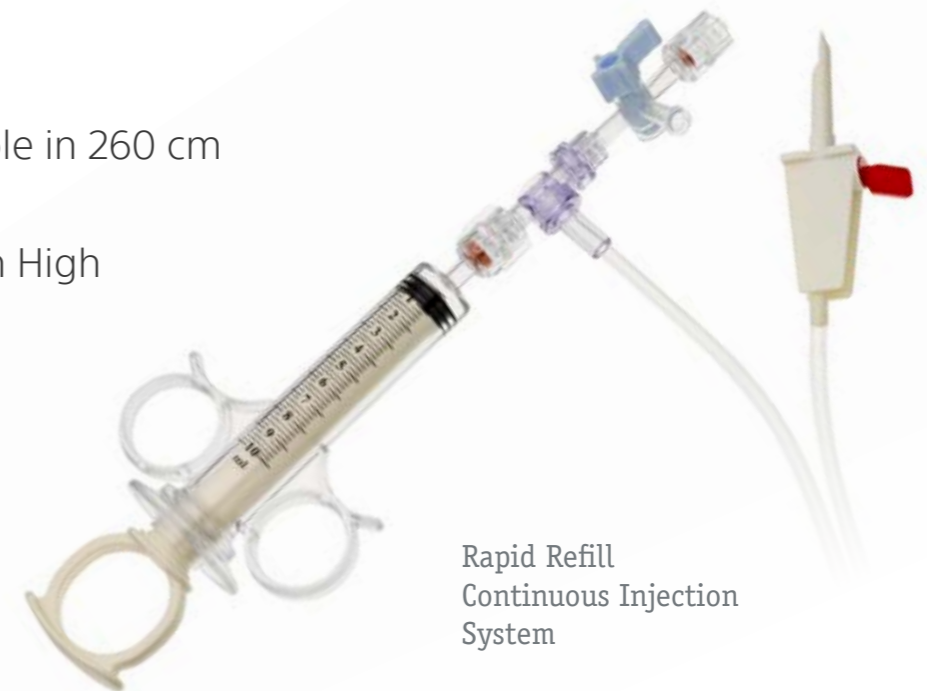


Wallflex™ Biliary RX Stent System

Other Complementary Devices

Use in conjunction with .035" and .025" guidewires available in 260 cm and 450 cm lengths:

Dreamwire, Jagwire, Hydra Jagwire, and Jagwire Revolution High Performance Guidewires



Rapid Refill Continuous Injection System

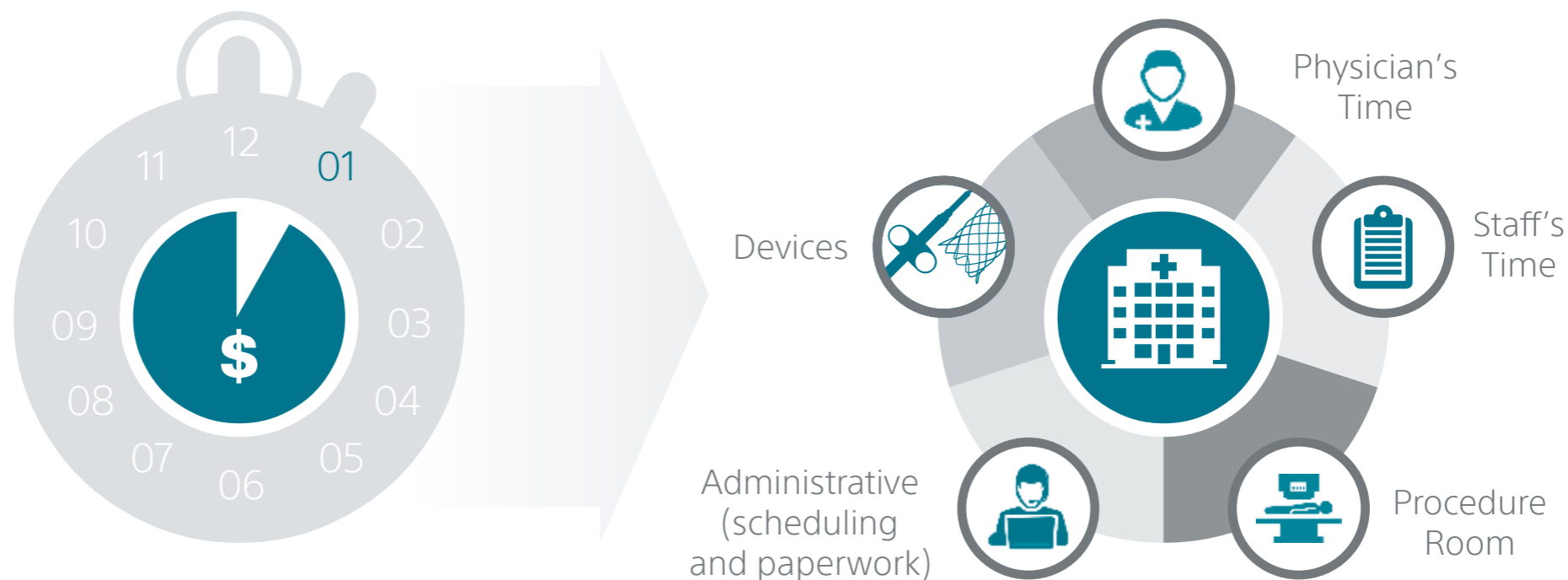


Managing Procedural Efficiencies and Costs



- ✓ The RX Biliary System may help in **reducing procedure time**.¹
- ✓ 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.



Managing the Risk of Post-ERCP Pancreatitis

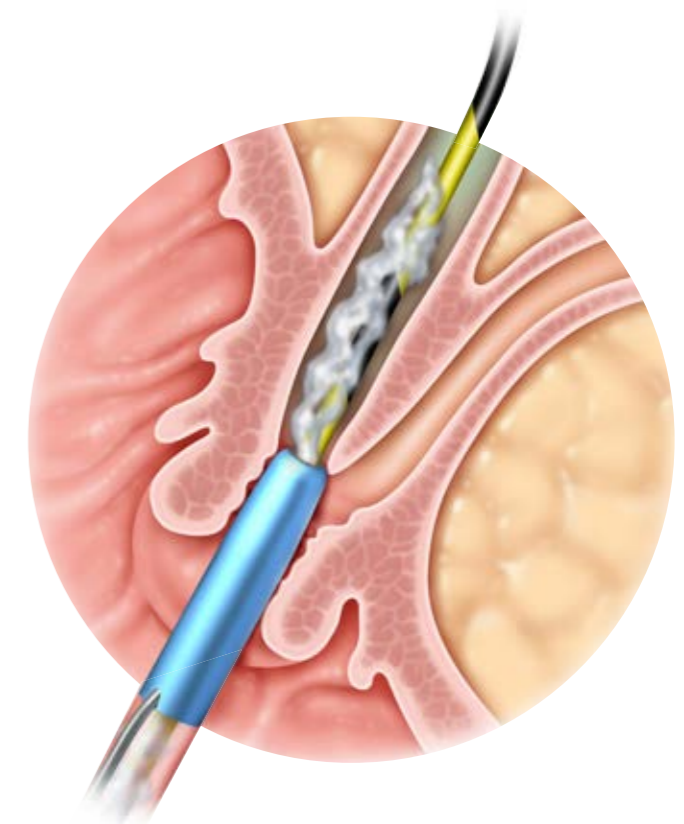
- Post-ERCP Pancreatitis is still the most frequent and severe complication encountered following ERCP with an incidence of 3.5%.¹
- Physician-controlled wireguided cannulation reduces the risk of post-ERCP pancreatitis compared with the standard contrast injection method.²
- By facilitating physician-controlled wireguided cannulation, the RX Biliary System plays a role in helping manage the potential complications of ERCP.
- DirecTip™ Technology of the Autotome™ RX enables the guidewire and contrast to be directed into the duct from the center of the tip, helping the physician inject contrast into the intended duct.*
- In the case of high risk for post-ERCP pancreatitis (PEP), the placement of a 5-Fr prophylactic pancreatic stent should be strongly considered.¹

* Does not apply to the 4.9Fr size.

1. Dumonceau et al. Prophylaxis of post-ERCP pancreatitis: European Society of Gastrointestinal Endoscopy (ESGE) Guideline - updated June 2014. *Endoscopy*. 2014 Sep;46(9):799-815.
2. 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.
3. Buxbaum J et al. Randomized Trial of Endoscopist-Controlled vs. Assistant-Controlled Wire-Guided Cannulation of the Bile Duct. *Am J Gastroenterol*. 2016 Dec;111(12):1841-1847.

“We found a statistically significant lower rate of post-ERCP complications in patients who underwent endoscopist-controlled wire-guided cannulation compared with assistant-controlled wire-guided cannulation”³

	Endoscopist (N=109)	Assistant (N=107)	P value
Endoscopic complications	3 (2.8%)	12 (11.2%)	0.016
Post-ERCP pancreatitis	3 (2.8%)	10 (9.3%)	0.049



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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.

Medical Education

EDUCARE is a comprehensive suite of educational and training programs designed in partnership with expert physicians to support healthcare professionals, enhancing their clinical knowledge and skills.

EDUCARE



CUSTOMISED PROGRAMS

- Trainings at Institute for Advanced Sciences
- Preceptorships
- Webcasts

DIGITAL SOLUTIONS

- Educare Digital Education Platform (Case Studies, Videos, Literature Reviews, Webcast, eLearning Modules)
- ePreceptorship (Live Cases)

LOCAL TRAININGS

- ERCP, EUS and Cholangioscopy
- Nurse Education on ERCP Hemostasis, Dilation and Infection Prevention



Services and Support

Commercial Contracting

We are a dedicated team within Boston Scientific Endoscopy that delivers **commercial solutions** founded on the principals of **partnership, innovation** and **value, evolving** the way we interact and commit with you.



Sharing Goals

We share your passion to tackle the toughest healthcare challenges by working side-by-side with you. We aim to partner with you providing value in each step of the procurement process.



Tailored Offering

We adapt our offering to each specific reality enabling sustainable pathways to improve patient care while preserving budget predictability.



Innovative Solutions

We provide innovative solutions by combining our financial and operational expertise into the changing healthcare ecosystem. Our solutions cover from inventory and service management to contracting and pricing models.

Access innovation through partnership

Commercial Contracting team will partner with you providing sustainable solutions with a broader perspective. Our best in class Contracting Solutions will make innovation available to improve patient care at minimal budget impact, while improving operational efficiencies.

About us

We are present in the key European geographies with a dedicated team of Commercial Contracting managers, Key Account Managers and Sales operations specialists.

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RX Compatible Devices

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

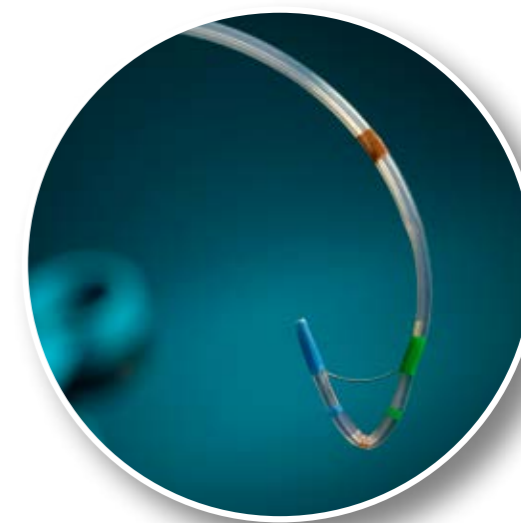
Access

Stone management

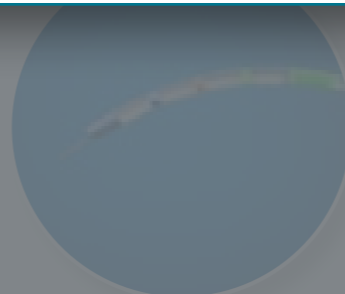
Autotome™ RX Cannulating Sphincterotome

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.



Jagtome™ Revolution RX Cannulating Sphincterotome



RX Needle-Knife XL Cannulating Sphincterotome



CRE™ RX Balloon Dilatation Catheter

RX Biliary System™

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> Managing Costs & Complications

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RX Compatible Devices

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

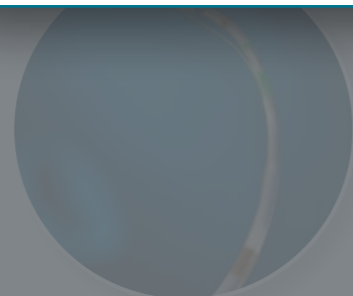
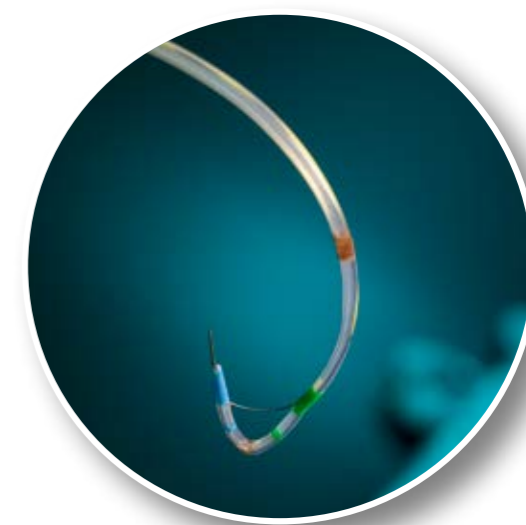
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Stone management

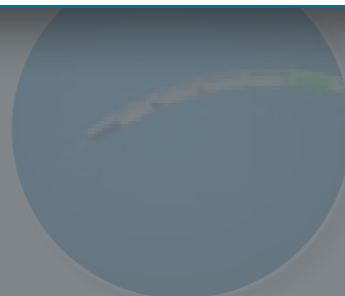
Jagtome™ RX Cannulating Sphincterotome

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

*Jagtome RX 39 and Autotome RX 44 Sphincterotomes only.



Jagtome™ Revolution RX Cannulating Sphincterotome



RX Needle-Knife XL Cannulating Sphincterotome



CRE™ RX Balloon Dilatation Catheter

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RX Compatible Devices

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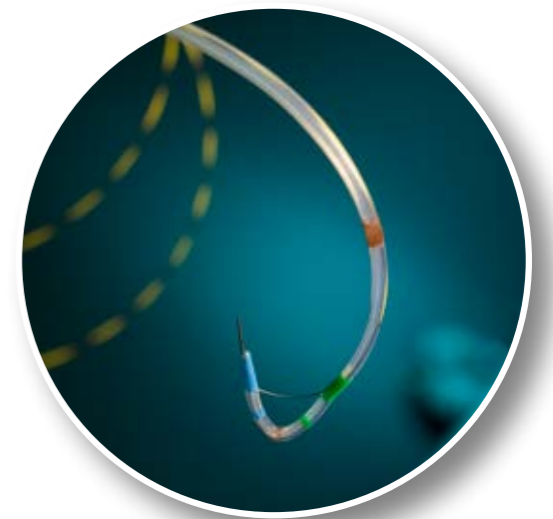
Access

Stone management

Hydratome™ RX Cannulating Sphincterotome

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

*Hydratome RX 44 Sphincterotomes only.



Jagtome™
Revolution RX
Cannulating
Sphincterotome



RX Needle-Knife
XL Cannulating
Sphincterotome



CRE™ RX Balloon
Dilatation Catheter

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RX Compatible Devices

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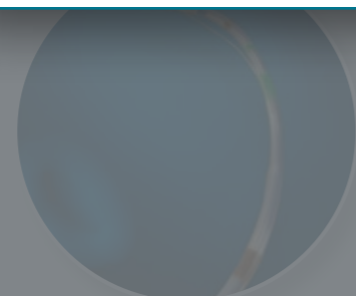
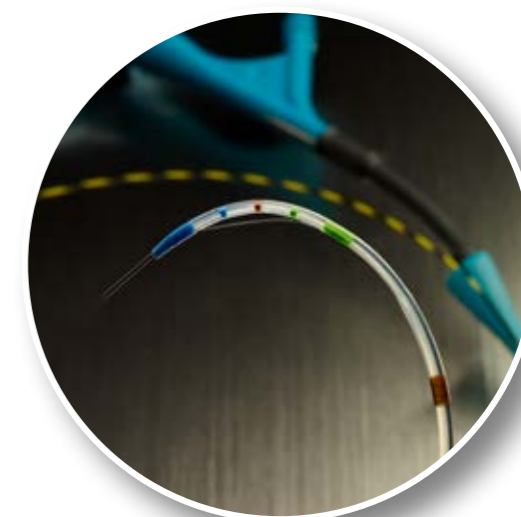
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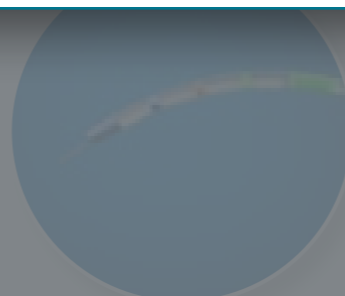
Stone management

Dreamtome™ RX Cannulating Sphincterotome

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



Jagtome™
Revolution RX
Cannulating
Sphincterotome



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RX Compatible Devices

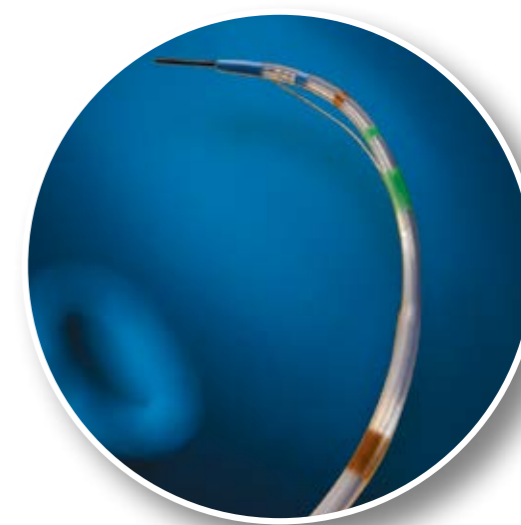
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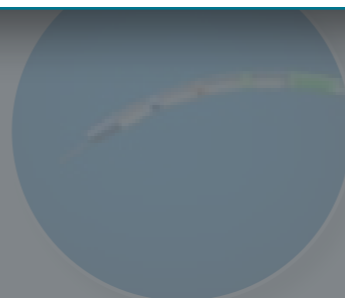
Stone management

Jagtome™ Revolution RX Cannulating Sphincterotome

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



Jagtome™ Revolution RX Cannulating Sphincterotome



RX Needle-Knife XL Cannulating Sphincterotome



CRE™ RX Balloon Dilatation Catheter

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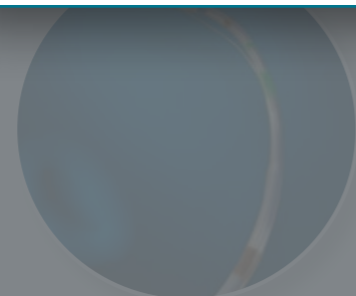
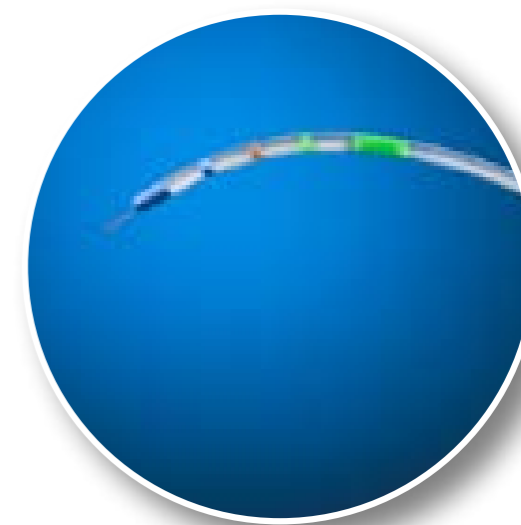
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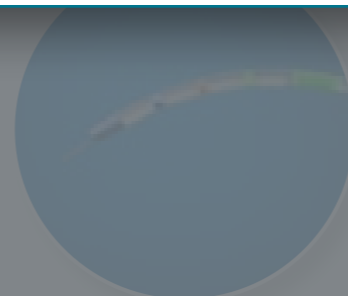
Stone management

RX Needle-Knife Cannulating Sphincterotome

The RX Needle Knife XL Cannulating Sphincterotome is indicated for use in the selective cannulation of the Common Bile Ducts (CBD) and the transendoscopic sphincterotomy of the Papilla of Vater and/or the Sphincter of Oddi. The Sphincterotome can also be used to inject contrast medium.



Jagtome™
Revolution RX
Cannulating
Sphincterotome



RX Needle-Knife
XL Cannulating
Sphincterotome



CRE™ RX Balloon
Dilatation Catheter



RX Compatible Devices



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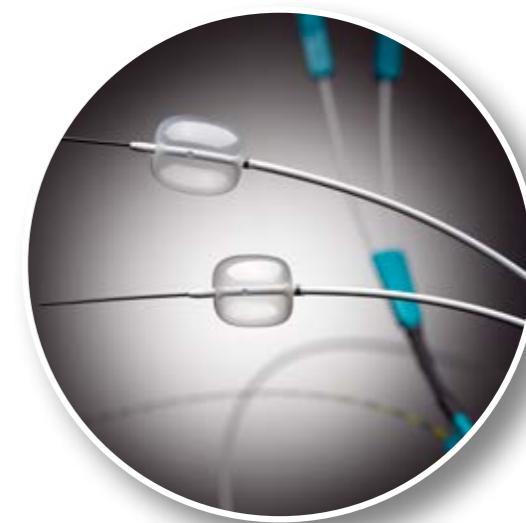
Access

Stone management

Extractor™ Pro RX-S Retrieval Balloon Catheter

The Extractor Pro RX-S 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.
- Increased catheter stiffness with the inserted stiffening stylet designed for improved pushability and kink-resistance.





Trapezoid™ RX Wireguided Retrieval Basket

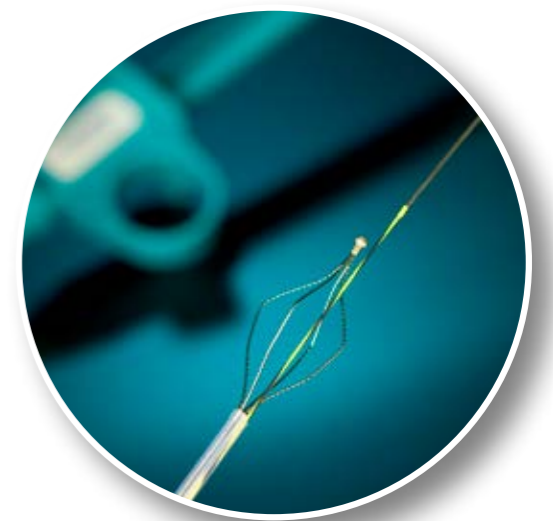
The Trapezoid RX Wireguided Retrieval Basket is indicated for endoscopic crushing and removal of biliary calculi. The Flexi-Stiff™ Catheter Construction provides a flexible and sturdy catheter designed to bend with biliary anatomy while maintaining pushability. The metal alloy basket is designed to maintain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

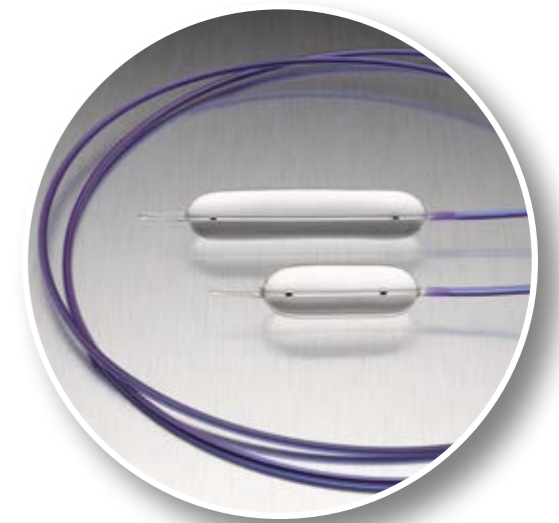


Tip disengages to facilitate basket removal if stone does not break, helping to reduce the risk of basket impaction.



CRE™ RX Biliary Balloon Dilatation Catheter

The CRE™ RX Biliary Balloon Dilatation Catheters are indicated for use in adults for endoscopic dilatation of the Sphincter of Oddi with or without prior sphincterotomy. The CRE RX Biliary Balloon Dilatation Catheters may be used for injection of contrast medium for fluoroscopic visualization of the bile ducts.



New features

- 3 cm Balloon. A shorter length balloon option in addition to 5.5 cm balloon.
- RX Shortwire Compatible. Helps enable physicians to maintain control of guidewire and lock the device. No preloaded guidewire to remove.
- Contrast Injection Port. For convenience and fluoroscopic visualization.

Built on the Foundation of CRE Legacy Design

- Platinum Iridium Radiopaque Markers. Facilitates positioning and enhances visualization under fluoroscopy.
- Pebax™ Balloon Material. Designed to produce three distinct diameters at three separate pressures during in vivo dilation.
- Rounded Balloon Shoulders. Designed to facilitate visualization of dilation through balloon.

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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

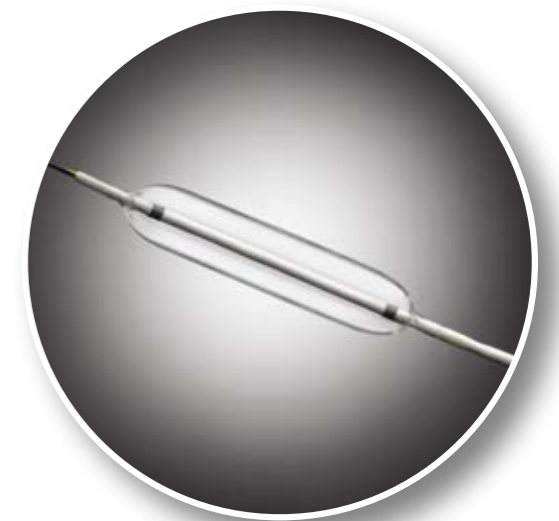
- Two radiopaque markers aid in balloon positioning.
- A dedicated lumen allows for contrast medium injection with a guidewire in place.

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 is designed to augment pushability.
- The RX catheter design allows the guidewire to be locked into place to secure access.

Balloon Inflation

- Available in 2 cm and 4 cm lengths and a range of different diameters (4, 6, 8, 10 mm) to offer stability during stricture dilation in different anatomical variations.
- Balloon is recommended for use the Encore™ 26 Inflation Device developed for rapid deflation during procedure if necessary.



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Access

Stone management

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.



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Revolution RX
Cannulating
Sphincterotome



RX Needle-Knife
XL Cannulating
Sphincterotome



CRE™ RX Balloon
Dilatation Catheter



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