

The RX Biliary System

Still Having an Impact on the Practice of Endoscopy

More than a decade after its launch, the RX (Rapid Exchange) Biliary System™ is still changing the way endoscopic retrograde cholangiopancreatography (ERCP) is practiced worldwide.

Before Boston Scientific introduced the RX Biliary System in 2001, the only ERCP guidewires on the market were long guidewires. An assisting nurse or technician had to control the wire while the physician controlled the ERCP devices, requiring a great deal of communication and coordination. At the same time, the assistant might have to perform multiple tasks — advancing or retracting the guidewire, injecting dye, operating the device, inflating or deflating the balloon, flexing or relaxing the sphincterotome.

Getting it wrong could make cannulation more difficult, create problems advancing the wire to its desired target, cause the team to lose access to the bile or pancreatic ducts. “If you were trying to traverse a difficult stricture you might be pushing too hard and not know it because someone else was manipulating the wire,” says Oleh Haluszka, MD, chief of gastroenterology at Temple University School of Medicine, Philadelphia, Pennsylvania.

PUTTING CONTROL IN THE HANDS OF THE PHYSICIAN

The RX Biliary System, the first short-wire system of its kind, allowed physicians to control the wire. “I learned very quickly the benefits of a short-wire system,” says Josh Forman, MD, therapeutic endoscopist/gastroenterologist at the University of Maryland St. Joseph Medical Center.

“When you had someone else passing the wire it wasn't the same. With the short-wire system, over time you develop a sense of tactile feedback that is incredibly invaluable. Now I couldn't imagine doing this procedure without having my finger on the wire.”

“As the person responsible for the success or failure of the procedure, I want to have as much control in my hands as possible,” says Dr. Haluszka. “I want the feedback of the wire as I'm working in the duct, knowing that it's looping the right way, not going into a side branch. When you control the wire, your brain is giving that message to your hands as opposed to verbalizing it to someone else. There's less uncertainty about how hard to push.”

“I deal with a lot of malignant lesions,” explains Niraj Jani, MD, chief division of gastroenterology at the Greater Baltimore Medical Center, Maryland. “If you're dealing with an obstructive lesion, you want to have a tactile sense of the stricture and ensure that you're not going into a false tract or creating a perforation. With the RX system, you have the tactile sense and can make adjustments if you're having trouble accessing the bile duct. The RX System allows you to assess the situation quickly and change what you need to do.”

RX LOCKING DEVICE KEEPS WIRE IN PLACE

The RX Biliary System locking mechanism used in conjunction with compatible RX devices helped enable physicians to make an exchange without displacing the wire.

“With the older cannulation systems, your biggest responsibility was to never lose the wire,” says Dr. Jani. “In some cases, with one little movement you would lose the wire and have to start the whole case again which can be extremely frustrating in a difficult cannulation case. The RX system gives you benefit of locking the wire in place.”

“The locking mechanism is especially helpful in complicated cases,” says Enrico Souto, MD, assistant professor and director of endoscopy at the University of Miami. “For example, you might need to cannulate both the left and right lobes of the liver. With RX, you can lock the first wire in place and move to the other side without worrying.”

ADVANTAGES FOR PATIENTS AND PHYSICIANS

When the RX Biliary System became available, some physicians immediately recognized its potential to help improve procedural efficiency. But they soon learned that while the system did indeed allow them to reduce the duration of a procedure, it also had other advantages for patients such as reduced fluoroscopy exposure and sedation requirements.



"With the RX system, I use a lot less fluoroscopy than I used to," says Dr. Jani. "I don't shoot a lot of dye because I don't need to — I know where the wire is going. I only inject when I know I'm in the duct and I'm looking for something specific. Even when there is a malignancy, I don't have to fill up the whole biliary system. I put in my stent and I'm done."

Physicians also appreciate reducing their own exposure to fluoroscopy. "I've been practicing ERCP for 20 plus years so the less fluoro time the better," Dr. Haluszka says. "That's a concern for everybody in the room. The less radiation exposure for staff and patients the better it is."

"RX really does improve your time of cannulation," Dr. Jani says. "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."

A SHIFT IN FOCUS TO COST SAVINGS

"It's hard to imagine, but when we first launched the RX system in 2001, the economic pressures we have today didn't exist," says Ryan Hartman, director of marketing, Boston Scientific. "Physicians were focused on the clinical benefits of shorter and successful ERCP procedures."

"But as economy became increasingly important, hospitals began scrutinizing costs. As they evaluated devices on a number of criteria important to them, including their own outcomes data, performance, safety, ease of use, etc., the RX Biliary System has prevailed and proven to be increasingly advantageous."

RX IS EASY TO LEARN, EASY TO TRAIN

Over the years, feedback from physicians has been that the RX Biliary System is easy to learn. "Working with a shorter wire and the RX system makes ERCP so much easier on physicians and on our technicians," Dr. Forman says. "They learn so much more quickly and while they help handle the wire, they never have to push. That really decreases the anxiety level in the room."

Jennifer Maranki, MD, assistant professor at Temple University School of Medicine, says that the RX System also makes it easy for a supervising physician to train fellows. "Instead of worrying about the long exchange, you can dedicate more time to teaching them about scope position and other aspects of the procedure that are related to the devices being used," she says.

CONTINUED INNOVATION

Widespread adoption of the RX Biliary System has profoundly changed how ERCP is performed. "I've been using the RX system since it came out and it's become a more full complement of devices over time," Dr. Haluszka says. "That really lends itself to my type of practice, which is geared towards therapeutic procedures."

"Boston Scientific continues to refine its products to improve and grow," Dr. Jani says. "They've branched into other areas that really help us with tissue acquisition. I do a large number of endoscopic ultrasounds and Boston Scientific is constantly looking to improve their EUS needles."

BOSTON SCIENTIFIC AS A VALUED PARTNER

"One thing that really stands out for me about Boston Scientific is its level of customer support," Dr. Forman says. "When we're using new equipment or a technician is relatively new and needs training, we need help from our reps and they do an amazing job being there for us."

"What separates Boston Scientific from other companies is that the sales representatives are constantly doing in-service training and educational conferences throughout the year for the nurses and technicians," Dr. Jani says. "Their approach is much more academic. They don't just bring in a product — they provide the clinical data and evidence to support their devices."

Adoption Outside the U.S.

Physicians outside the U.S. also recognize the benefits of the RX biliary System. To date, the RX locking device and RX compatible devices are in use in over 45 countries, including China, Brazil and many countries throughout Europe.

"The system gives me control of the guidewire without having to communicate specific instructions to my assistant. Having control of the wire has increased my cannulation success rate," explains Dr. Teresa Staiano of the Institute of Ospitalieri, Cremona, Italy.

"Using the locking device I can perform multiple exchanges and withdrawal of devices with a reduced risk of losing the guidewire. Maintaining access and controlling the exchange of devices is critical for therapeutic ERCP."

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Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Information for the use only in countries with applicable health authority product registrations.

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