

Biliary and pancreatic stone extraction devices

The American Society for Gastrointestinal Endoscopy (ASGE) Technology Committee provides reviews of existing, new, or emerging endoscopic technologies that have an impact on the practice of GI endoscopy. Evidence-based methodology is employed by using a MEDLINE literature search to identify pertinent clinical studies on the topic and a MAUDE (Food and Drug Administration Center for Devices and Radiological Health) database search to identify the reported complications of a given technology. Both are supplemented by accessing the “related articles” feature of PubMed and by scrutinizing pertinent references cited by the identified studies. Controlled clinical trials are emphasized, but in many cases data from randomized controlled trials are lacking. In such cases, large case series, preliminary clinical studies, and expert opinions are used. Technical data are gathered from traditional and Web-based publications, proprietary publications, and informal communications with pertinent vendors.

Technology Status Evaluation Reports are drafted by 1 or 2 members of the ASGE Technology Committee, reviewed and edited by the committee as a whole, and approved by the governing board of the ASGE. When financial guidance is indicated, the most recent coding data and list prices at the time of publication are provided. For this review the MEDLINE database was searched through February 2009 for articles related to endoscopy in patients with pancreatic and biliary stones requiring removal, by using the keywords choledocholithiasis, pancreaticolithiasis, stone, and extraction paired with ERCP, endoscopy, and gastrointestinal.

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Biliary and pancreatic duct stones are a major cause of morbidity. Choledocholithiasis, if left untreated, can lead to pain, cholangitis, gallstone pancreatitis, and secondary sclerosing cholangitis. Pancreatic stones, most commonly

seen as a result of chronic pancreatitis, can cause ductal obstruction with its attendant consequences. For patients with choledocholithiasis, the goal of treatment is complete clearance of the biliary tree, most commonly with endoscopic methods. Pancreatic stones also are often removed endoscopically in an attempt to decrease pain and possibly improve pancreatic function.¹

Biliary and pancreatic stone extraction in the context of ERCP uses many different techniques and devices. This document will review the biliary and pancreatic stone extraction devices that are currently commercially available in the United States. A separate Technology Status Evaluation Report is available for pancreaticobiliary lithotripsy devices.²

TECHNOLOGY UNDER REVIEW

The 2 basic types of stone extraction devices are extraction balloon catheters and basket catheters. Both are designed to extract stones in an antegrade fashion through an ampullary orifice previously treated by endoscopic sphincterotomy or less commonly with balloon dilation. There are unique structural and functional aspects to these devices.

Extraction balloons

Extraction balloons are the mainstay of biliary and pancreatic stone removal and have been used for decades.³⁻⁶ In essence, these devices are endoscopic catheters that contain a round balloon near the tip and are available in a variety of sizes (Table 1). Extraction balloon devices contain a single balloon at the tip that usually can be inflated with air to 1, 2, 3, or 4 preset sizes, although by adjustment of the volume of air, balloon sizes between the preset sizes are possible. The sizes specifically refer to the diameter of the inflated balloon and are measured in millimeters.

Modern extraction balloons are typically triple-lumen devices: 1 lumen for air to inflate/deflate the balloon, 1 lumen for a guidewire, and 1 lumen for contrast material injection. Each lumen is independently accessible via a specific port and/or Luer lock on the operational end of the device. Double-lumen extraction balloons are of an older design but are still commercially available and feature 1 lumen for either a guidewire or the injection of contrast material and a second lumen for air to inflate/deflate

TABLE 1. Stone extraction balloons

Manufacturer	Product	Balloon inflated OD (mm)	Catheter length (cm)	Injection site (above/below balloon)	Catheter OD (Fr)	Recommended guidewire	Price (\$)
Triple-lumen balloons							
Boston Scientific (Natick, Mass)	Extractor RX Retrieval	9-12*, 12-15*, and 15-18*		Available above or below	7 taper to 6	0.035	209
	Extractor XL Retrieval	8.5, 11.5, and 15	210	Available above or below	7 taper to 5	0.035	159
	StoneTome Sphincterotome/ Balloon	11.5	200	Above	7 taper to 5.5	0.035	409
Conmed Endoscopic Technologies (Chelmsford, Mass)	Duraglide Stone Removal	8.5, 11.5, and 15	200	Available above or below	7 taper to 5	0.035	176
Cook Endoscopy (Winston-Salem, NC)	D.A.S.H Extraction	8.5-12-15*	200	Above	6	0.025	160
	Tri-Ex Radioopaque	8.5-12-15*	200	Available above or below	7	0.035	160
	Tri-Ex Radioopaque	8.5, 12, and 15	200	Available above or below	7	0.035	171
	Fusion Quatro Extraction	8.5-10-12-15* and 12-15-18-20*	200	Available above or below	6.6	0.035	199
	Fusion Extraction	8.5-12-15*	200	Available above or below	7	0.035	199
Olympus Endoscopy (Center Valley, Penn)	Multi-3 Extraction	8.5-11.5-15*	190	Available above or below	5 (at tip)	0.035	147
	V-System Extraction	8.5-11.5-15*	190	Available above or below	5.5 (at tip)	0.035	186
Double-lumen balloons							
Boston Scientific	Extractor Retrieval	8.5, 11.5, and 15	210	Above	5	0.025	145
Conmed Endoscopic Technologies	Duraglide Stone Retrieval	11.5, and 15	200	Above	7	0.035	145
	Duraglide Tapered Stone Retrieval	8.5, 11.5, and 15	200	Above	7 taper to 5	0.035	145
Cook Endoscopy	Escort II Extraction	8.5-12-15*	200	Above	6.8	0.035	150
	Bouncer Multi-Path Occlusion	15	200	Above	6.6	0.025-0.035†	171
Olympus Endoscopy	Extraction Balloon	11	195	Above	5	0.021	177
	Extraction Balloon	13	350	Above	7	0.035	177
	Extraction Balloon	13	195	Above	7	0.035	177

OD, Outer diameter.

*Indicates variable balloon preset size based on volume of inflation.

†Wire exits catheter below balloon.

the balloon. Double-lumen devices generally do not allow the user to inject contrast material through the device if it is loaded over a guidewire. Some devices come with a built-in Tuohy-Borst adapter to allow contrast material injection and guidewire passage through the same port.

Air is injected through the catheter and into the balloon via the use of specialized syringes that are packaged with each extraction balloon device. Some manufacturers include multiple syringes with the packaging with each syringe, allowing balloon inflation to a specific diameter. These syringes come premarked with standard cubic centimeter markers (to gauge the amount of air in the balloon). Other manufacturers include a single syringe that can be used to inflate the balloon to multiple diameters. These syringes come with cubic centimeter markings but also come with additional markings to indicate the volume of the preset sizes.

Contrast material is injected into the catheter via the use of standard syringes that are filled with contrast dye. Syringes for contrast material (as well as the contrast dye itself) are generally not included in the packaging. Many balloon extraction catheters are designed to work specifically with short-wire or traditional long-wire ERCP systems, and some can be used with either system.⁷

Extraction balloons are available with contrast material ports proximal or distal to the position of the balloon on the catheter. Although extraction balloons with distal injection ports are more commonly used to confirm clearance of a duct during a balloon sweep and allow occlusion ductography, extraction balloons with proximal injection ports can assist in visualizing stones during the process of extraction and help define distal duct anatomy.

One unique stone extraction balloon device is a combination sphincterotome and extraction balloon (Stone-Tome; Boston Scientific, Natick, Mass). This device is a double-lumen sphincterotome that has a built-in, 11.5-mm, extraction balloon. The balloon is available either proximal or distal to the cutting wire.

These devices can be used to perform a variety of functions including occlusion cholangiography/pancreatography but are primarily used to sweep the biliary and pancreatic ducts so as to deliver stones, sludge, and debris out of the ductal system and into the small-bowel lumen.⁸ After a catheter with a balloon diameter similar to the diameter of the duct being treated is chosen, these devices are typically advanced into the desired duct proximal to the stone to be removed. At this point, the balloon is inflated to an appropriate size, and the catheter is withdrawn in the inflated position. The inflated balloon then "sweeps" the stone along the duct, and when the balloon is pulled completely into the small intestine lumen, the stone should be delivered just ahead of the balloon itself. Used in a similar fashion, these devices can assist with extracting foreign bodies (eg, proximally migrated stents) or biliary parasites.

Extraction balloons represent a safe and easy-to-use modality for the removal of the majority of pancreatic

and biliary stones and are in widespread use. Extraction balloons are first-line therapy for stone extraction from the pancreaticobiliary tree. Unlike stone removal baskets, extraction balloons have a very low chance of becoming trapped inside the biliary and/or pancreatic ducts because the balloons can simply be deflated and removed if they become trapped above a stone or stricture. Forceful traction of an extraction balloon may also result in balloon breakage, which also simplifies removal of the device from the ducts.

Stone extraction baskets

Stone extraction baskets have also been in use for decades. Baskets are made from metal wires and are available in a variety of sizes and configurations (Table 2). The wires in stone extraction baskets can be monofilament or braided and are typically made from stainless steel or nitinol. The wires are joined at the most distal end of the basket, often under a small metal cap. A common basket configuration (often referred to as a Dormia basket) involves 4 wires arranged radially at 90° intervals. When the basket is in the open position, it assumes a 3-dimensional shape, the borders defined by the wires, which form 2 perpendicular hexagons. Other available baskets include those with a helical wire configuration, which use more than 4 wires (known as spiral baskets), and baskets with more wires in the distal portion of the basket than the proximal portion of the basket (known as flower baskets). Both spiral baskets and flower baskets are generally used to retrieve smaller stone fragments that might otherwise not be retrieved with Dormia baskets.⁹

The basket itself can be constrained within a metal or a plastic catheter or sheath, which can be advanced through the working channel of the endoscope and into the duct of choice. Baskets that are not designed to crush stones often use plastic catheters. Baskets that crush stones require metal sheaths, because when the basket is closed after a stone has been captured, the basket wires must be forcibly constrained within the metal sheath. Metal lithotripsy catheters may come as part of a stone extraction basket or may be a separate device that is advanced over a plastic inner catheter. Constraining the basket within the metal sheath decreases the volume of space between the wires and results in stone fracture. A plastic sheath would not allow the wires to be constrained with sufficient force for stone fracture and could result in tearing or disruption of the plastic catheter.

Some stone extraction baskets are advanced into the biliary or pancreatic ducts over a guidewire, whereas others are advanced into the appropriate duct via free cannulation. Once in the proper location, the basket is advanced out of the catheter by using the control handle, and as a result is deployed to its operational size in an attempt to capture stones. The open basket is typically advanced gently back and forth under fluoroscopic guidance to facilitate stone entry between the basket wires

TABLE 2. Stone extraction baskets

Manufacturer	Product	Opening width (mm)	Working length (cm)	Minimum channel size (mm)	Price (\$)	Comments
Cook Endoscopy (Winston-Salem, NC)	Fusion Basket	20	200	4.2	376	Lithotripter compatible
	The Web Extraction Basket	15, 20, 25, and 30	220	2.8	194	Compatible with Conquest TTC and Soehendra mechanical lithotripter
	The Web II Extraction Basket	20	200	3.2	194	Soft wire construction. Not for use with mechanical lithotripter
	Memory Basket 5 FR Soft Wire	20	200	2	343	Not for use with mechanical lithotripter, soft multifilament wires
	Memory Basket 7 FR Hard Wire	20, 30	200	2.8	343	Not for use with mechanical lithotripter, hard monofilament basket
	Memory Basket 7 FR Soft Wire	15, 20, 25, and 30	220	2.8	343	Compatible with Conquest TTC and Soehendra lithotripter, multifilament 4-wire basket
	Memory Basket Eight Wire	20	200	2	343	Not for use with mechanical lithotripter
	Mini Basket	5	200	2	290	Not for use with mechanical lithotripter
	Memory Basket Eight Wire	30	200	2	343	Not for use with mechanical lithotripter, spiral basket configuration
Olympus (Center Valley, Penn)	Flower Basket	20	195	2.8	237	Eight-wire construction, for small stone retrieval
	Stiff Wire	22	195	2.8	228	
	Soft Wire	22	195	2.8	228	

into the central compartment. By using the control handle, the endoscopist can close the basket, making the space between the basket wires and thus the central compartment smaller until the stone is securely confined. Stones captured into an open basket can be removed by withdrawing the basket from the duct and pulling the stone out into the small intestine lumen without any attempt to close the basket. Alternatively, if stones slip out of the basket during attempts at withdrawal, the basket can be partially closed to more securely capture the stone prior to removal. If the stone cannot be removed due to its size, configuration, or location (ie, above a stricture), some baskets can be used to forcefully crush stones, a process known as mechanical lithotripsy.¹⁰ Not all stone extraction baskets can function as lithotripters (Table 2). Some baskets can function as lithotripters without any additional hardware, whereas other baskets require additional equipment should lithotripsy become necessary.

CLINICAL EFFICACY

Overall, ERCP is highly effective for the treatment of choledocholithiasis. Despite the long history of use of bal-

loons, there are no published trials comparing different balloons with regard to ease of use and success rates at stone extraction in either the biliary or pancreatic ducts. There are no data to demonstrate the superiority of one extraction balloon device over the others. One small, prospective, randomized study comparing the StoneTome with conventional devices found no difference with regard to stone clearance.¹¹ Individual end-users are left to choose extraction balloon catheters based on price and personal preference for certain catheter features.

Dormia baskets were applied to use in the bile duct soon after their adaptation for use via ERCP, and mechanical lithotripsy was implemented via this route soon after.¹²⁻¹⁴ There is little modern information on the efficacy of stone extraction baskets that allow stone removal without requiring lithotripsy. This likely reflects that most small stones (ie, those less than 1 cm in diameter) can be removed via the use of most available stone extraction baskets in patients who have undergone biliary sphincterotomy.

There is more information on the efficacy of mechanical lithotripters in patients with so-called difficult common bile duct stones. The term *difficult* is generally used to describe stones greater than 1 cm in diameter and/or those

that could not be removed by using balloon extraction catheters or nonlithotripsy stone extraction baskets. In the hands of experienced operators, mechanical lithotripsy can successfully clear the common bile duct in 80% to 90% of patients.¹⁵⁻²² Impacted stones, very large stones (> 25 mm), and stones above biliary strictures are less likely to be successfully removed.^{20,22,23} When these measures fail, alternative lithotripsy techniques such as electrohydraulic or laser lithotripsy and surgery may need to be considered.

SAFETY

Although stone extraction is associated with a significant risk of complications, the majority of complications are related to achieving retrograde pancreaticobiliary access or performing a sphincterotomy. Extraction balloons are considered to be very safe to use during ERCP. Care should be taken not to inflate a balloon in a duct much smaller than the balloon diameter, given the risk of ductal trauma or perforation.²⁴ Overinjection of contrast material above an inflated balloon into the bile or pancreatic ducts can lead to pain during the procedure and, in the case of injection into the pancreatic duct, acute pancreatitis. Extraction balloons have almost no risk of impaction within the biliary or pancreatic ducts. Most balloons, although strong enough to hold air and remove stones, will rupture if excessive mechanical force is applied during attempts at stone removal. The balloon rupture does not lead to clinical sequelae and facilitates catheter removal. With all stone extraction devices, use of excessive force to remove a stone can be associated with trauma to the perampullary region, increasing the risk of bleeding, perforation, or pancreatitis.

In contrast, stone extraction baskets are associated with a greater inherent risk of complications than are extraction balloons. Although this complication is uncommon, stone extraction baskets can become trapped (impacted) in the biliary or pancreatic ducts if they capture a stone that is too large to remove via traction and if the basket/stone complex cannot be separated to allow the basket alone to be removed from the patient. A stone extraction basket that cannot be removed from the biliary or pancreatic ducts while still attached to its catheter represents a medical emergency, and rescue lithotripsy using specialized accessories designed for this occurrence may be required to allow removal of the basket. A variety of endoscopic, radiologic, and surgical techniques have been used to remedy this situation.²⁵⁻³¹ Some modern stone extraction baskets contain built-in safety features to minimize the risk of basket entrapment/impaction. The Trapezoid Basket (Boston Scientific) is specifically designed to break if forcefully closed against severe resistance, allowing the basket to be removed from the patient (albeit without the stone) in the event of a basket impaction. The incidence of basket impactions in the

biliary and/or pancreatic ducts is unknown. Although this remains a rare occurrence, endoscopists must be aware of the inherent risks of extraction basket use. Stone extraction baskets can also fracture and separate from their catheters, becoming lodged in the biliary or pancreatic ducts.

A search of the MAUDE database reveals multiple incidences of basket fracture during attempts at biliary stone extraction. Basket fracture has been reported to occur with essentially all forms of stone extraction baskets. Rarely, attempts at stone extraction by using baskets were associated with a ductal perforation. In most cases of basket fracture, the broken basket and its pieces were endoscopically removed from the patient, although in rare instances surgery was required. Multiple reports of basket impaction also exist, often associated with wire fracture.³²

Mechanical lithotripsy has been studied in a limited manner with regard to safety. Potential complications associated with mechanical lithotripsy of biliary stones include impacted/trapped or broken baskets, basket wire fracture, handle breakage, cholangitis, acute or delayed bleeding, and frank biliary or small-bowel perforation.^{20,33} Some studies have shown a complication rate as high as 20% in patients undergoing mechanical lithotripsy for large common bile duct stones. Data on mechanical lithotripsy for pancreatic duct stones are also limited but suggest that this procedure is performed rarely and carries a markedly increased risk of complications when compared with lithotripsy for biliary stones.^{29,34} Acute pancreatitis and pancreatic leaks can occur in addition to the standard risks of basket entrapment and/or fracture.

FINANCIAL CONSIDERATIONS

In general, extraction balloons are less expensive than stone extraction baskets. Some stone extraction baskets are reusable. Reusable devices tend to be more cost effective.³⁵ Practitioners must also take into account the need for specialized handles for some devices. List prices on available extraction balloons and stone extraction baskets, along with their respective handles, are included in [Tables 1 to 3](#). Relevant CPT* codes for biliary and pancreatic stone extraction are presented in [Table 4](#). If a sphincterotomy is performed to facilitate stone extraction, code 43262 can be combined with code 43264. In limited circumstances, when lithotripsy is performed during stone extraction, codes 43265 and 43264 can be combined. This applies primarily when stone extraction with balloon catheters has been performed but was insufficient to clear the duct, and lithotripsy (with additional device use) was required to

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TABLE 3. Mechanical lithotriptors

Manufacturer	Device	Opening width (mm)	Working length (cm)	Minimum channel size (mm)	Price (\$)	Comments
Boston Scientific (Natick, Mass)	Trapezoid RX Wireguided Retrieval Basket	15, 20, and 30		3.2	349	Emergency release feature to reduce risk of basket entrapment
	Alliance II Handle (Mechanical Lithotripsy)	n/a	n/a	n/a	499	
Cook Endoscopy (Winston-Salem, NC)	Fusion Lithotripsy Compatible Basket	20	208	4.2	376	Compatible with Conquest TTC and Soehendra lithotriptor handles
	Fusion Lithotripsy Compatible Basket	30	208	4.2	376	Compatible with Conquest TTC and Soehendra lithotriptor handles
	Conquest TTC Litotriptor Cable	n/a	170	3.7	167	Metal sheath for mechanical lithotripsy, available in 8.5F or 10F
	Soehendra Lithotriptor Lithotripsy Handle	n/a	n/a	n/a	300	Mechanical lithotriptor handle. Requires use of lithotripsy cable, sold separately
Olympus (Center Valley, Penn)	Lithocrush	22, 26, and 30	195	3.2	454	Requires MAJ-440 reusable handle, double-sheath construction
	Lithocrush	31	195	4.2	454	Requires MAJ-440 reusable handle, double-sheath construction
	Autoclavable Handle	n/a	n/a	n/a	673	Compatible with all Olympus lithotripters, reusable
	Emergency Lithotripor	n/a	n/a	n/a	486	For emergency use only. Replacement coil sheath is an additional \$78

n/a, Not applicable.

TABLE 4. Relevant CPT® codes

43264: ERCP with endoscopic retrograde removal of calculus/calculi from biliary and/or pancreatic ducts.

43265: ERCP with endoscopic retrograde destruction, lithotripsy of calculus/calculi, any method.

When either of the above is performed with sphincterotomy, also use: 43262 ERCP with sphincterotomy/papillotomy

Codes 43262 through 43265 include the work of diagnostic ERCP, and 43260 is not reported separately. Code 43260 includes brushing or washing. If radiological supervision and interpretation is also performed by the physician performing the ERCP, see codes 74328, 74329, and 74330. A separate radiologic interpretation report is typically prepared.

facilitate completion of stone removal. If a balloon catheter is used to remove fragments from lithotripsy, only the 43265 code should be reported. The Center for Medicare Services does not require a -59 modifier on the second code, but some private payers may require a modifier -59 for consideration of payment for the second code.

AREAS FOR FUTURE RESEARCH

Biliary extraction balloons and stone extraction baskets represent mature technologies that have been refined over the last 30 years. Unfortunately, there is a relative paucity of clinical data on specific devices. Prospective, randomized studies designed to compare balloons and baskets to remove stones of various sizes are lacking. There is a clear need for specific studies comparing stone extraction balloons, baskets, mechanical lithotriptors, and the technique of large-diameter balloon dilation after prior sphincterotomy as a means of extracting large stones.^{36,37} Further studies are also needed regarding defining the risks and benefits of mechanical lithotripsy baskets relative to alternative lithotripsy techniques. In addition, the role of endoscopic techniques for pancreatic duct stone extraction relative to the main alternative of surgical therapy requires further study with an emphasis on long-term outcomes.

Stone extraction baskets of increasingly safer design are still needed to reduce the risk of basket impaction and/or fracture. Baskets with built-in safety features such as emergency breakaway points are present in a minority of devices, and development along these lines is warranted. Efforts to reduce the cost and increase the durability and reusability of stone extraction baskets would be worthwhile.

SUMMARY

Stone extraction balloons and baskets are widely available and highly effective tools for the removal of biliary and pancreatic stones. These devices allow removal of stones of many sizes and configurations in the majority of patients. Baskets, especially when used as mechanical lithotripters, still carry a risk of rare but serious complications. Few comparative studies between devices exist, and further studies are warranted, particularly with regard to pancreatic stone extraction.

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