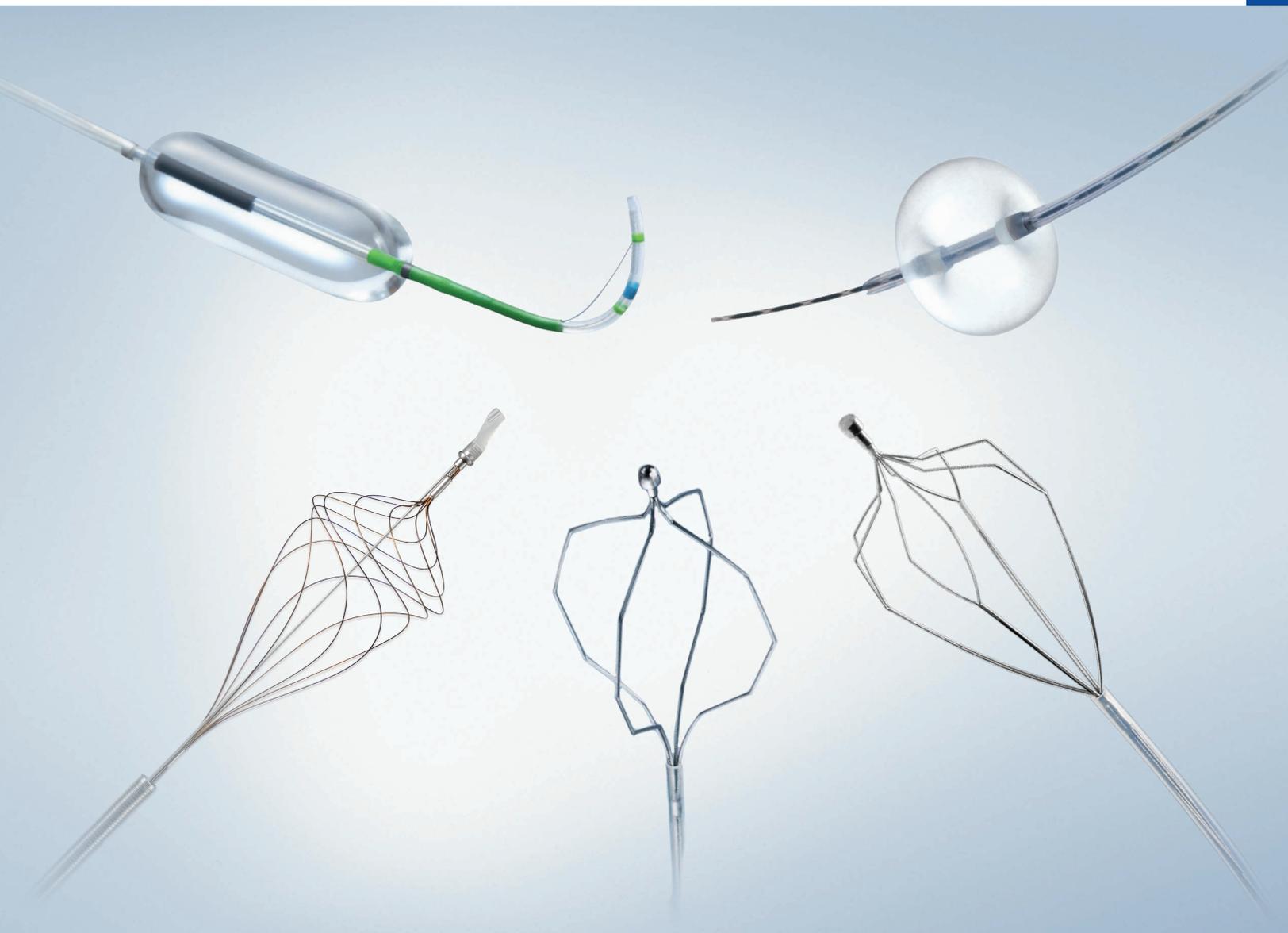


# Stone Management

Strategy and Optimum Device Selection for Stone Treatment



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## Doctors' Profile



### Takao Itoi, MD

**Chair and Professor of Department of Gastroenterology and Hepatology, Tokyo Medical University**

- |   |   |
|---|---|
| 1991 Tokyo Medical University, Awarded the bachelor's degree  | 2015 Visiting Professor of Department of Gastroenterology and Hepatology, Tokyo Medical and Dental University |
| 1991 Resident of Tokyo Medical University   | 2016 Visiting Professor (part-time) of Department of Gastroenterology and Hepatology, Keio University         |
| 1993 Research Fellow of 1st Department of Pathology, Niigata University                             | 2016 Chair and Professor of Department of Gastroenterology and Hepatology, Tokyo Medical University           |
| 2010 Associate Professor of Department of Gastroenterology and Hepatology, Tokyo Medical University |   |
| 2010 Visiting Professor, Nanjing University School of Medicine                                      |   |



### Shomei Ryozaawa, MD

**Professor and Chairman, Department of Gastroenterology, Saitama Medical University International Medical Center**

- |   |  |
|---|--|
| 1991 Awarded M.D. of Yamaguchi University School of Medicine  | 2007 Associate Professor in Department of Gastroenterology and Hepatology, Yamaguchi University Hospital             |
| 1991 Resident in Internal Medicine, Yamaguchi University Hospital   | 2010 Visiting Professor, Nanjing University School of Medicine   |
| 1994 Research Fellow of 1st Department of Pathology, Niigata University (Prof. Hidenobu Watanabe)                       | 2011 Associate Professor in Digestive Disease Center, Showa University Northern Yokohama Hospital                    |
| 1997 Awarded Ph.D. of Yamaguchi University Graduate School of Medicine  | 2013 Professor and Chairman, Department of Gastroenterology, Saitama Medical University International Medical Center |
| 2000 Trainee in Department of Interdisciplinary Endoscopy, University Hospital, Hamburg-Eppendorf (Prof. Nib Soehendra) | 2014 Director, Endoscopy Center, Saitama Medical University International Medical Center                             |
| 2001 Medical Staff in Department of Gastroenterology and Hepatology, Kokura Memorial Hospital, Fukuoka                  |  |
| 2003 Assistant Professor in Department of Gastroenterology and Hepatology, Yamaguchi University Hospital                |  |



### Hiroyuki Isayama, MD

**Professor, Department of Gastroenterology, Graduate School of Medicine, Juntendo University**

- |   |   |
|---|---|
| 1992 Jikei University School of Medicine awarded M.D.   | 2013 Part-time Lecturer, School of Medicine, Wakayama Medical University  |
| 1992 Japanese Red Cross Medical Center, Resident of Internal Medicine   | 2013 Associate Professor, Department of Gastroenterology, Graduate School of Medicine, University of Tokyo        |
| 1994 Japanese Red Cross Medical Center, Senior Resident of Gastroenterology   | 2013 Deputy Section Chief, Department of Gastroenterology, Graduate School of Medicine, University of Tokyo       |
| 1997 University of Tokyo Hospital, 2nd Dept. of Internal Medicine   | 2017 Senior Associate Professor, Department of Gastroenterology, Graduate School of Medicine, Juntendo University |
| 1999 Mitsui Memorial Hospital, Dept. of Gastroenterology  | 2017 Special instructor, Department of Gastroenterology, Okinawa Prefectural Hospitals                            |
| 2001 University of Tokyo Hospital, Dept. of Gastroenterology  | 2017 Professor, Department of Gastroenterology, Graduate School of Medicine, Juntendo University                  |
| 2002 Post-graduate school, University of Tokyo, awarded Ph.D.   |   |
| 2004 Assistant Professor, Department of Gastroenterology, Graduate School of Medicine, the University of Tokyo  |   |
| 2012 Associate Professor, Department of Gastroenterology, Training Program for Oncology Professionals, Graduate School of Medicine, University of Tokyo |   |



### Akio Katanuma, MD

**Director, Center for Gastroenterology Teine-Keijinkai Hospital**

- |   |  |
|---|--|
| 1991 Sapporo Medical University awarded M.D.                                      | 2017 Visiting Professor of Department of Gastroenterology and Hepatology, Tokyo Medical University |
| 1991 Department of Gastroenterology and Hepatology, Sapporo Medical University    | 2018 Director, Center for Gastroenterology Teine Keijinkai Hospital                                |
| 1992 Department of Gastroenterology and Hepatology, Muroran City General Hospital |  |
| 1994 Department of Hematology, Teine Keijinkai Hospital                           |  |
| 1997 Center for Gastroenterology Teine Keijinkai Hospital                         |  |
| 2015 Deputy Director, Center of Gastroenterology Teine Keijinkai Hospital         |  |



### Ichiro Yasuda, MD

**Director and Professor, Third Dept. of Internal Medicine, University of Toyama**

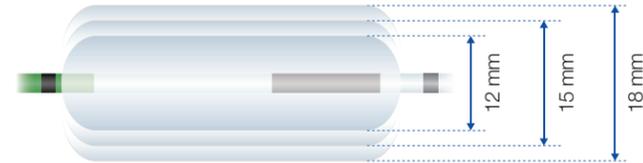
- |  |   |
|--|---|
| 1990 Awarded M.D. of Gifu University, Japan  | 2004 Assistant Professor, Div. of Endoscopy, Gifu University Hospital, Japan                        |
| 1991 Resident, Department of Gastroenterology, Gifu Municipal Hospital   | 2005 Clinical Lecturer, First Dept. of Internal Medicine, Gifu University Hospital, Japan           |
| 1992 Clinical Fellow, Dept. of Internal Medicine, Fujita Health Hospital, Japan (Prof. Saburo Nakazawa)                | 2006 Concurrent Lecturer, First Dept. of Internal Medicine, Gifu University Hospital, Japan         |
| 1993 Medical Staff, Department of Gastroenterology, Gifu Municipal Hospital, Japan                                     | 2008 Lecturer, First Dept. of Internal Medicine, Gifu University Hospital, Japan                    |
| 1998 Medical Staff, First Dept. of Internal Medicine, Gifu University Hospital, Japan                                  | 2012 Associate Professor, First Dept. of Internal Medicine, Gifu University Hospital, Japan         |
| 2002 Trainee in Department of Interdisciplinary Endoscopy, University Hospital Hamburg-Eppendorf (Prof. Nib Soehendra) | 2014 Director and Professor, Department of Gastroenterology, Teikyo University Mizonokuchi Hospital |
| 2003 Medical Staff, First Dept. of Internal Medicine, Gifu University Hospital, Japan                                  | 2018 Director and Professor, Third Department of Internal Medicine, University of Toyama, Japan     |

# Large Balloon with EST

## Takao's Strategy – StoneMasterV



**Takao Itoi, MD**  
Chair and Professor of Department of Gastroenterology and Hepatology, Tokyo Medical University



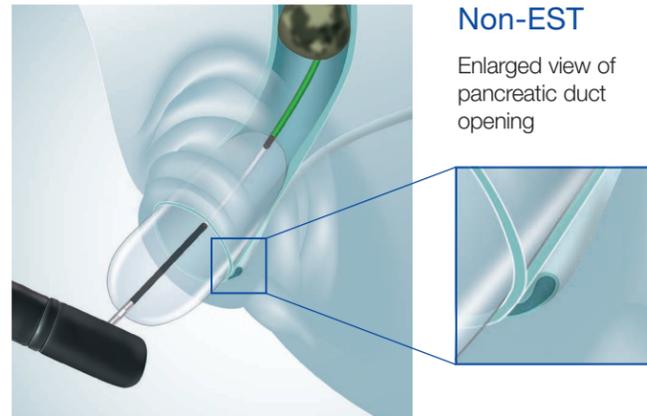
Balloon diameter (mm)	12 mm	15 mm	18 mm
Dilation pressure (atm)	0.5	2.0	3.5

increased risk of complications. If this is the case, then going by the maxim, “the bigger, the better”, would make perfect sense. Using a larger balloon that doesn't have to be maximally dilated may lead to safer EPLBD procedures than increasing the pressure of a small-diameter balloon to the maximum.

### EST: The Gateway to Papillary Treatment

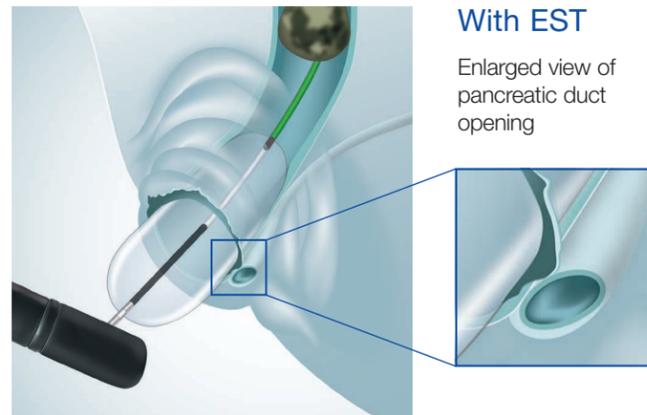
At Tokyo Medical University, we regard EST as the first-line treatment for patients suffering from common bile duct stones. Where necessary, papillary treatment can be facilitated by endoscopic techniques such as mechanical lithotripsy (ML) and EPLBD, which is used for the removal of large stones. At our hospital, we apply EST to virtually all cases, with the width of the incision in the medium range (as far as the encircling fold).

EPLBD is usually indicated for patients with large stones or stacked stones with dilated bile ducts. Basically, EPLBD is applied as an additional treatment when it is determined during papillary treatment that stones cannot be removed with EST alone.



#### Non-EST

Enlarged view of pancreatic duct opening



#### With EST

Enlarged view of pancreatic duct opening

### Indications for EPLBD

#### Eligibility Criterion

- Large stone (> Minimum dia. 13-15 mm)
- Stacked stones (>10 mm, 3 pcs. or more)
- Bile duct dilated fully until the lower bile duct)

#### Exclusion Criterion

- Abnormal coagulation (including use of anticoagulant)
- Acute pancreatitis
- Bacteremia
- Bile duct stricture case

### Advantages of Using EPLBD with EST as the Primary Treatment Method

For patients with intact papillae capable of undergoing EPLBD with EST, the advantages are many (low invasion, low cost, etc.). Once MRCP and CT scans have confirmed that the patient is a suitable candidate, we will normally go ahead and perform treatment using EPLBD with EST. The biggest advantage of EPLBD with EST is that it reduces the mechanical compression of the pancreatic duct opening normally caused by the balloon pressure applied to the bile duct when EST is performed. This can be particularly beneficial as we believe it can help reduce the risk of pancreatitis.

### Benefits of the Low-pressure Setting on the StoneMasterV

The best way to perform EPLBD is to dilate the duct at low pressure. This helps minimize the loads on and risks to the duodenal papilla and bile duct. In our opinion, the low-pressure setting of the StoneMasterV is best suited for this purpose. When using StoneMasterV previously, we have always found dilation to be more than adequate and have never experienced any problems when performing a procedure. We also believe that low-pressure dilation even with a large-size 18 mm-diameter balloon can support safer EPLBD procedures.

### Effective Use of Convenient “C-hook” Tool

The coexistence of the knife and balloon functions sometimes makes the inflator and knife control section bulky during dilation. In this case, we recommend securing the knife control section to the scope using the C-hook. The C-hook can also be useful with Olympus products other than StoneMasterV, especially in situations where not enough assistants are available.



Fixing the knife control section using the C-hook allows the assistant to focus on the inflator control.

### Selection of Balloon Size in EPLBD

Our policy when selecting a balloon size is to select a balloon with a maximum dilation diameter one step larger than the expected bile duct diameter. This means that in EPLBD using the separate type we typically select a balloon with a diameter between 15 and 18 mm. The reason we select a balloon slightly larger than the target bile duct is that this allows us to dilate the duct without reaching the maximum dilation pressure of the balloon, making possible safe dilation under low pressure. Even if the selected balloon does not reach the bile duct diameter, it is still possible to take advantage of the “dilating margin”, which enables additional dilation. We have also found that having some margin can reduce the load to the papilla and better facilitate stone removal than when using a balloon that fits exactly. Further to this, we believe that selecting the maximum dilation diameter of the balloon does not lead to any

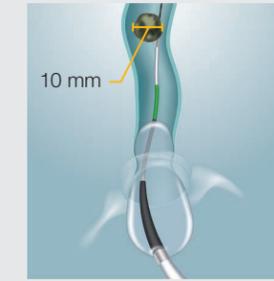
### EPLBD (Dilating margin)



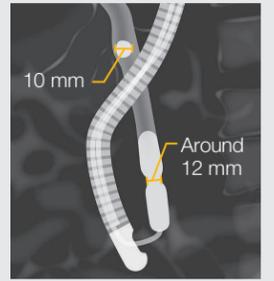
Endoscopic image



Endoscopic image



Endoscopic illustration



Endoscopic illustration

Treatment of the papillary sphincter does not require dilation greater than the stone size. Instead, low pressure can be safely used by controlling the dilation at the minimum necessary level. The StoneMasterV has a maximum dilation diameter of 18 mm, but we believe that a diameter of 12 to 15 mm is sufficient with stones no larger than 12 mm.

### Safe Use of EST Knife Inside the Bile Duct

Because the StoneMasterV has been designed to allow the operator to proceed directly to EPLBD after EST, some doctors have expressed concern about the potential risks associated with insertion of the knife into the bile duct. We are confident that this design in no way compromises safety; rather, we believe that deep insertion of the device with wire-guided cannulation actually makes dilation safer because the balloon is stabilized near the papilla and cause no significant position deviation during EPLBD.

# Mechanical Lithotripter

## Shomei's Strategy – LithoCrushV



**Shomei Ryozaawa, MD**  
 Professor and Chairman, Department of  
 Gastroenterology, Saitama Medical University  
 International Medical Center

### Minimize Incision

EST is always the first choice. We keep the incision area for EST at the requisite minimum level (high frequency setting: ESG-100 pulse cut slow 30 W). We apply EPBD when EST appears too risky – for example, patients with coagulopathies, patients taking oral antithrombotic drugs, patients with an extremely small papilla, patients with periampullary diverticulum and patients with surgically altered anatomy.

In general, however, EST is indicated for almost all cases. EPLBD is indicated for large and multiple stones with bile duct dilatation that are difficult to treat by EST and EPBD alone. We normally perform EST before EPLBD. The precut technique are used after conventional methods of biliary cannulation and the pancreatic guidewire-assisted technique have failed.

### Device Selection Criterion

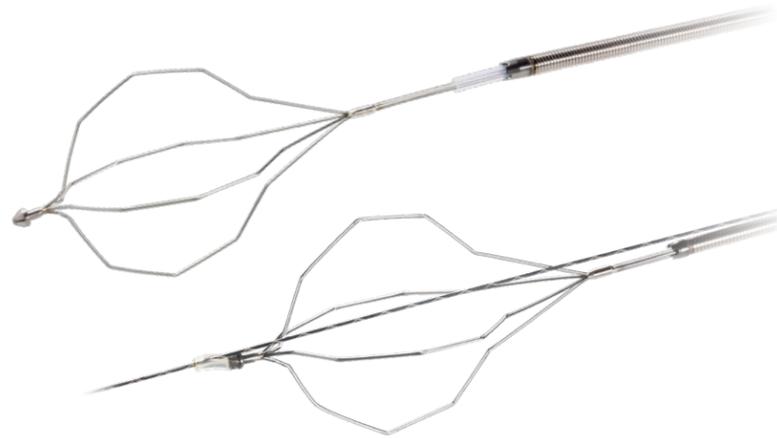
The basket is our preferred choice when dealing with stones. We use the 8-wire spiral basket for small stones under 5 mm and sludge, the 8-wire FlowerBasketV for stones from 5 to 8 mm, the 4-wire TetraCatchV for stones from 8 to 10 mm, and the lithotripsy basket (LithoCrushV) for stones over 10 mm.

In situations where the basket catheter has difficulty grasping the stones – with small stones, intrahepatic stones, or a pocket-shaped distal bile duct, for example – we use the retrieval balloon catheter.

### Cases Where Lithotripsy has Been Used

The best way to perform EPLBD is to dilate the duct at low pressure. This helps minimize the loads on and risks to the duodenal papilla and bile duct. In our opinion, the low-pressure setting of the StoneMasterV is best suited for this purpose.

When using StoneMasterV previously, we have always found dilation to be more than adequate and have never experienced any problems when performing a procedure. We also believe that low-pressure dilation even with a large-size 18 mm-diameter balloon can support safer EPLBD procedures.



Retrieval/Lithotripsy Device Selection Criterion	
<b>Retrieval</b>	
< 5 mm, sludge	→ 8-wire basket
5 mm – 8 mm	→ FlowerBasketV
8 mm – 10 mm	→ TetraCatchV
<b>Lithotripsy</b>	
> 10 mm	→ LithoCrushV
	→ Wire-guided (BML-V442QR-30)
	→ Hard wire (BML-V242QR-30)

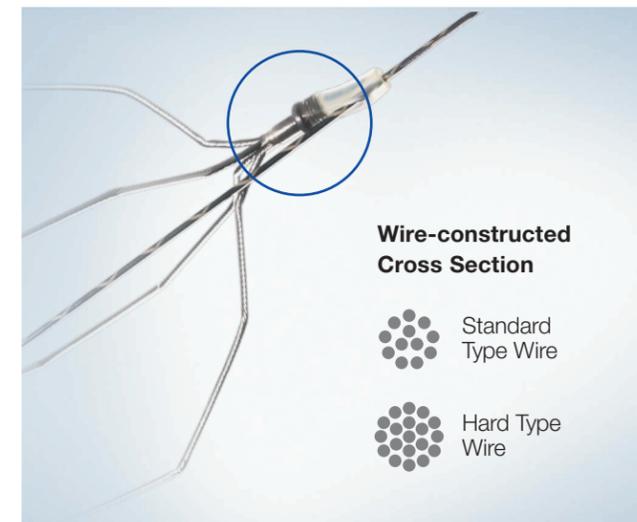
### Using the LithoCrushV

The first choice is the wire-guided type (BML-V442QR-30), which is the easiest to use and offers excellent access. Before introduction of the wire-guided type, it was very difficult to guide the retrieval basket to the bile duct. While the guidewire and basket are installed in parallel on some wire-guided models, they are coaxial on the LithoCrushV, which makes insertion remarkably easy.

In cases where CT imaging shows that the stone may be difficult to grasp, we use the hard-wire type (BML-V242QR-30), which has more coils than the standard type.

Because the extra coils provide excellent expansion force, switching to the hard-wire type may make retrieval possible in cases where it is difficult to grasp the stones during a procedure.

The LithoCrush line also includes two standard wire type models with a sheath slide mechanism.



### Stone Retrieval Technique

The standard retrieval technique is to expand the basket above the stones, then shaking the basket a little at a time to grasp the stones (see endoscopic and radiological images to right).

The LithoCrushV also incorporates a “basket rotation function”, which can be used when the standard method does not appear to be working. Even during use of the wire-guided type, the rotation facility can be used by withdrawing the guidewire.

Occasionally, it may be difficult to grasp stones in the hepatic portal region or intrahepatic bile duct. In this case, withdrawing the guidewire before approach may facilitate extraction.

### Preventing Basket Deformation

Many doctors believe that it is not necessary to close (tighten) the basket fully. We share that belief. If the stones have been crushed before the basket has fully closed, there is no reason to tighten the basket any further. This also seems to help prevent deformation of the basket (see diagram to right).

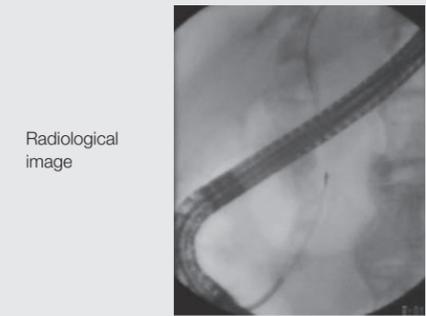
### BML-V442QR-30 (Wire-guided hard type)



Endoscopic image

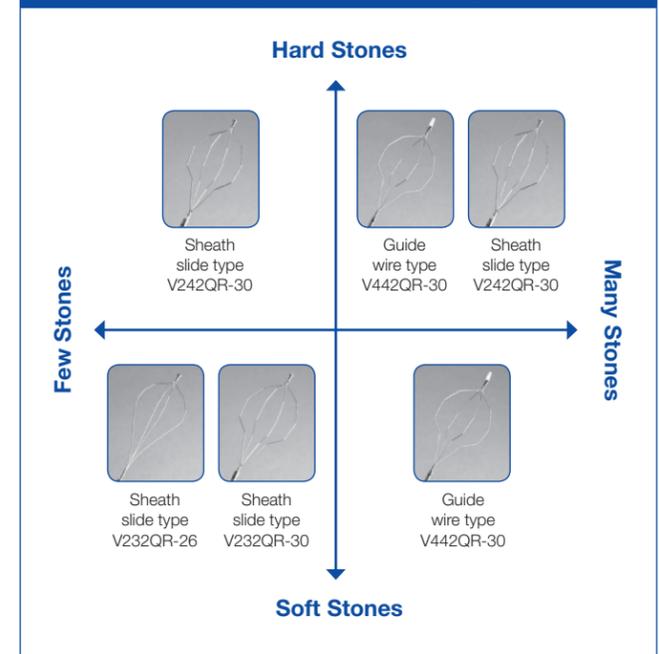


Endoscopic image



Radiological image

### Using the Lithotripsy Basket According to Case



# Retrieval Balloon

## Hiroyuki's Strategy – Multi-3V Plus



**Hiroyuki Isayama, MD**  
 Professor, Department of Gastroenterology,  
 Graduate School of Medicine,  
 Juntendo University



### EST Small Incision + EPBD is the Basic Policy

Our basic policy in dealing with stones is to perform the EST small incision + balloon dilation. We use the EPBD balloon for stones from 8 to 10 mm, and perform EPLBD, if possible, with stones of 12 mm or more. EPBD only is used with patients taking an oral antithrombotic, patients with abnormal blood coagulation due to hepatic diseases, patients subject to hepatic ablation, patients with benign biliary hilar stricture, etc. This is because eliminating the papillary functions with the EST brings about the risk of hepatic abscesses in the regions exposed to radio waves or areas without drainage. We also attempt EPBD in cases where EST is difficult and/or risky – for example, with patients with postoperative reconstructed gastrointestinal anatomy.

### Advantages of Small Incision + Balloon Dilation

One of the main advantages of the EST small incision and additional balloon dilation technique is that no special skills are required so they can easily be performed by even non-expert endoscopist. We also believe that stone removal is easier with this technique than with EST alone or EPBD alone because it can open up the papilla sufficiently. We see it as a technique that boasts many advantages, including a low probability of complications such as perforation, bleeding and pancreatitis. Overall, the simplicity of the technique combined with a lower risk of mistakes makes this an excellent choice for papillary treatment with high safety and low risk – factors which,

we believe, are critical to success. When we perform EPLBD, we usually add EST as well. However, even without EST, both efficacy and safety are first class, so we are comfortable performing EPLBD even with cases where EST is difficult.

If the diameter of a stone is larger than the dilated diameter of the EPLBD, we select the lithotripsy basket considering the risk of impaction. We recommend that retrieval without crushing the stone should be tried first. Only crush the stone if it is too difficult to retrieve it otherwise.

### Choosing a Stone Extraction Device

The first criterion for selection is whether there is a possibility that it will be necessary to crush the stone. If there is not, select the balloon. If the stone is big enough that there is a risk of impaction, select the lithotripsy basket.

When we used to perform EPBD almost exclusively, the insufficient opening of the papilla made it necessary to select a basket that could catch and remove the stones. This was also the same when only EST was performed. However, with the introduction of small incision + balloon dilation technique, opening the papilla was no longer a problem, so the strategy has changed because extraction using a balloon is easy. Stone extraction using a balloon is simple, and that is one of the main advantages of this technique.

We believe that the basket is most effective in those cases where there is a pocket at the lower end of the bile duct. In these cases, or when there is a small papillary opening, it is necessary to catch the stones securely with a basket for extraction. The most important thing to remember is that the stone extraction device should be selected according to the degree of opening of the papilla.

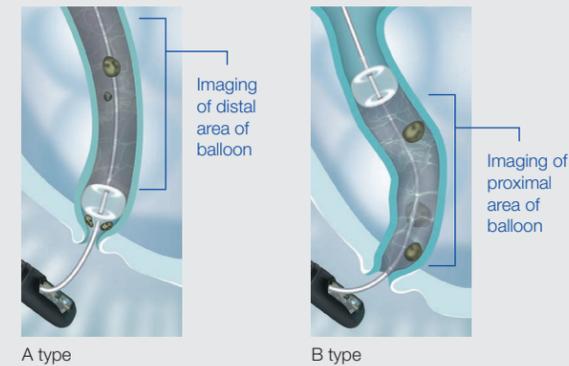
### Selecting a Balloon

There are a surprisingly large number of balloon types classified for very specific applications, including the position of the injection port, the position of guide wire passage, and the size of the balloon. When choosing between the standard (over-the-wire) type and distal wire-guided type, we generally use the distal wire-guided type because of its high degree of usability. We find the standard type effective in cases where pushability is required – for example, when the stones are pushed through the HGS route or when the enteroscope forceps channel is narrow when treating a patient with postoperative reconstructed gastrointestinal anatomy.

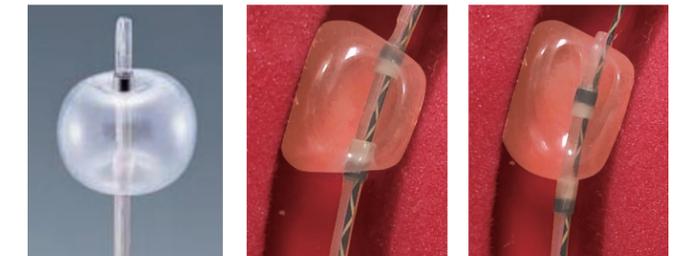
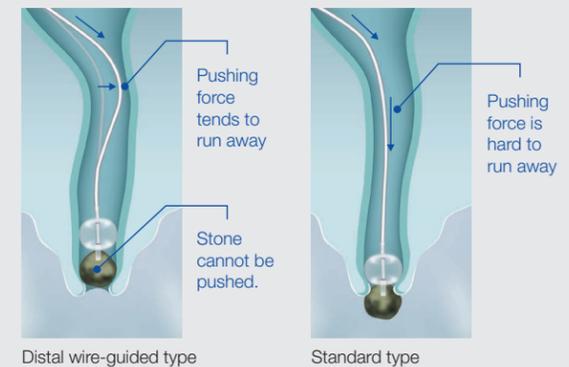
We also choose the standard type if the operator is a trainee, as well as providing support for the procedure. For the injection port, our favorite choice is the type with an opening on the distal end (A-type). This type makes it easy to check for residual stones and to prevent small stones from slipping through the sides of the balloon. This may occur when the pressure in the region on the intrahepatic side of the balloon becomes negative during extraction. This can be avoided by setting the pressure on the intrahepatic side to positive using the A-type port.

bile duct to push the stone out with negative pressure. Olympus balloons are equipped with radiopaque bands at the distal and proximal ends of balloon. This is an advantage because they facilitate confirmation of the position where the dilation begins. Ideally the balloon's shape should extend laterally rather than longitudinally. Longitudinal extension may cause interference with stones, while the lateral extension facilitates scraping out the stones. From this perspective, the laterally extending design of the Multi-3V Plus is ideal. It can also be recommended highly because very little deviation or deformation of the balloon is caused by friction inside the bile duct.

### Imaging Bile Duct with ERCP



### Pushing Intra-hepatic Stone with HGS

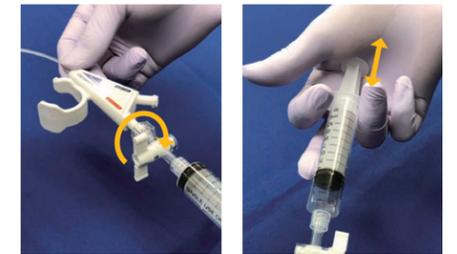


Appearance of balloon      Absence of balloon deformation

### A Tip on Deflation

Deflation adjustment on the Multi-3V Plus is relatively easy. When fine deflation control is necessary, it is often recommended to turn the stopcock by one turn per step, but we recommend the method of supporting the syringe with a palm (palm technique).

One of the advantages of this technique is that controlling deflation with the syringe lets the operator sense when the balloon is contacting the wall, making it easier to know when optimum dilation size has been achieved.

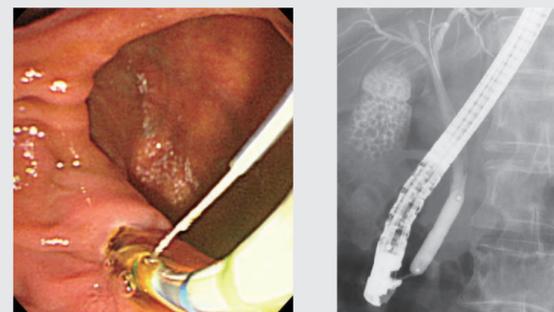


Stopcock technique      Palm technique

### Coexistence of Approaching Performance and Operability

There are basically not many cases of use but, if the guidewire slips out after several approaches, we feel that the bile duct approach using the balloon can be continued because Multi-3V Plus maintains the high cannulation performance. We believe that the variation of catheter diameters on the distal and proximal ends makes it possible to provide both the high approaching performance and operability.

### EST + EPBD



Endoscopic image of EST      Radiological image of EPBD

# Retrieval Balloon

## Akio's Strategy – FlowerBasketV/TetraCatchV



**Akio Katanuma, MD**  
 Director, Center for Gastroenterology  
 Teine-Keijinkai Hospital

### When to Switch from EST to EPLBD

Whenever possible, we select EST for the papillary treatment. The extent of incision is basically the medium incision (until the encircling fold). EPLBD is being used more often now than in the past and, provided that the selection criterion is met, we believe it can be performed successfully by prioritizing the success of lithotomy and the time taken for the procedure. In our opinion, EST is fundamental for performing EPLBD. As with ordinary EST, we use a medium incision width.

### Selection of Stone Retrieval Device

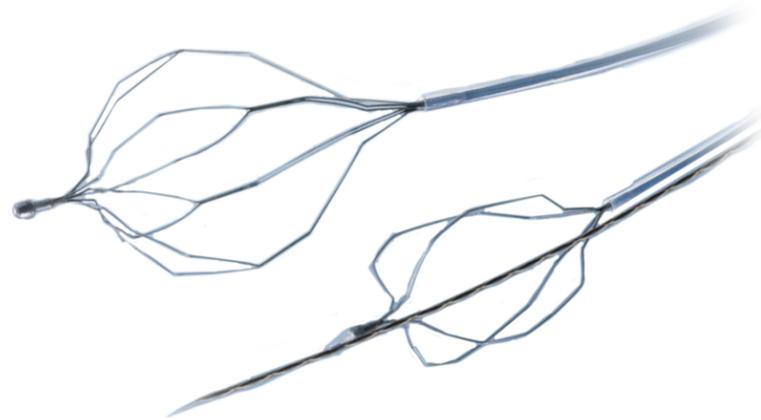
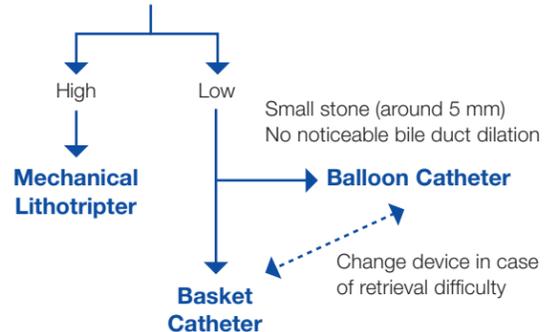
Although there are several preconditions, we believe that the device to be used depends on the size, number and properties of stones, as well as the bile duct diameter. If the risk of impaction is expected to be high, then the lithotripsy basket should be selected. I personally select a basket most frequently, and am also of the opinion that the basket can still be selected even if the stone is not so large and seems easy to remove. Normally, we select a basket in cases with relatively high difficulty levels where catching performance is in question – for example, with a dilated bile duct.

What is important is to select the optimum device by considering all the different factors in each case. When it is difficult to decide which is the best option, choose your favorite device and procedure.

### Selection of Stone Retrieval Device

#### Risk of Impaction

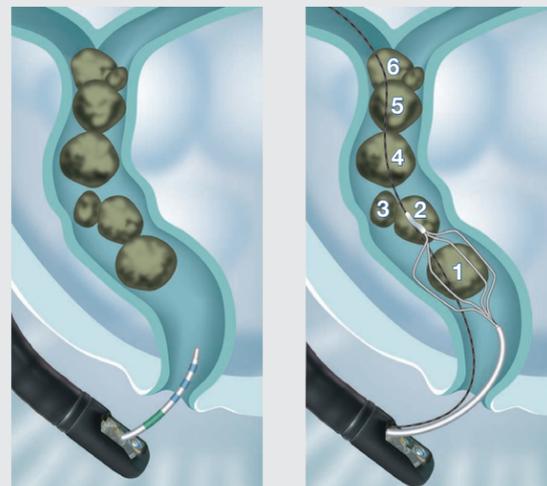
- Large stone
- Stacked stone
- Narrow intra-pancreatic bile duct



### Caution When Using a Basket

We retrieve stacked stones by grasping them a little at a time using a basket. Though this is a textbook story, care should be taken against impaction by retrieving the stones in order from the papilla side. With stacked stones, expand the basket slowly on the side of the stone to be retrieved. If the basket is expanded forcefully, there is a risk of displacing stones or grasping undesired stones. It is therefore important to work closely with the assistants.

### Image of a Stone Being Grasped



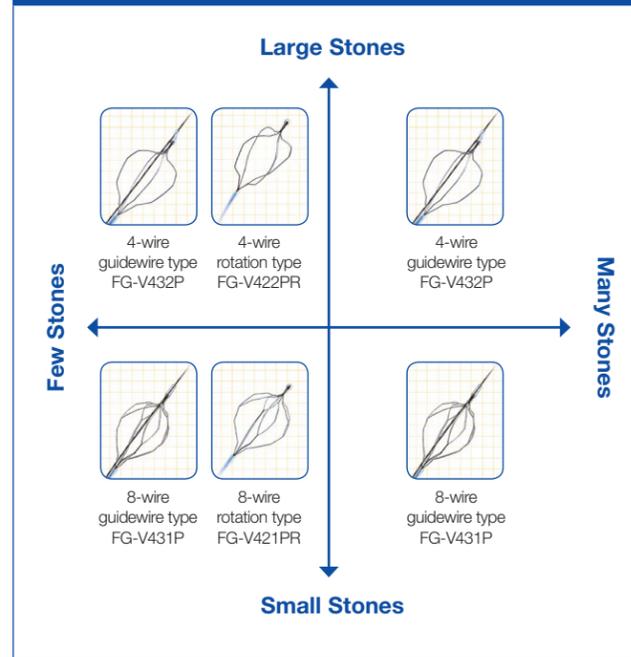
Begin retrieval from the stone at the bottom. Slowly open the basket so as not to push the stone at the top into a deeper area. The key is to withdraw the sheath toward the proximal end at the same time as opening the basket.

### Choosing a Basket

Olympus provides baskets that can be selected according to each case. Our first choice is generally the TetraCatchV (FG-V432P). This is a guide wire type and the main reasons for choosing it are its excellent approachability thanks to the wire-guided design and the low impaction risk thanks to the simple basket shape.

For most ordinary-size stones, the TetraCatchV is more than fit to purpose. However, when dealing with smaller stones that tend to slip off the TetraCatchV, we believe that the FlowerBasketV is an effective alternative.

### The Most Suitable Retrieval Basket According to Case



### Coping with Difficult Cases

When stones are hard to remove with ordinary methods – for example, in cases with a dilated bile duct or with a pocket on the lower bile duct, it may be worth considering the use of the rotation facility.

At some hospitals, the stones are scraped off by opening the basket in the region from the lower bile duct to the papilla and making use of the expansion force of the basket itself. The design of the Tetra (4-wire) makes it suitable for this type of retrieval using expansive force.

### Guidewire Type 4-wire

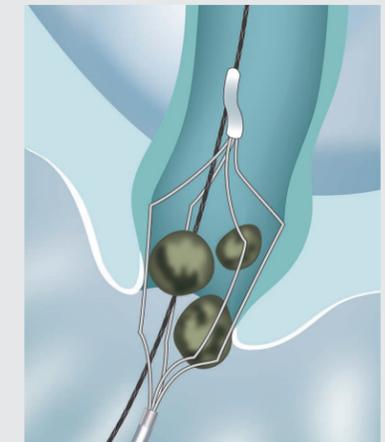


Endoscopic image



Radiological image

### Making Use of Basket's Expansive Force by Scraping off Stones



### High Basic Performance

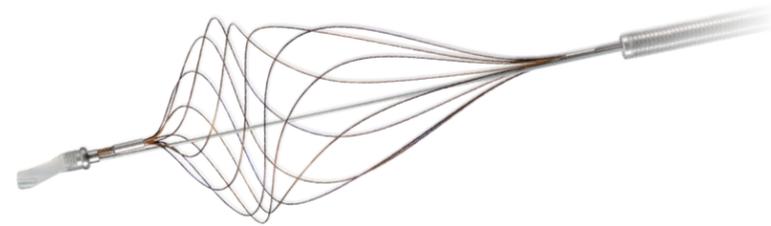
Olympus baskets are designed to offer superior basic performance in a number of critical areas. One of these is sheath elasticity. The “pliability” of the flexible sheath must be finely balanced to ensure possible smooth insertion under the wire-guided procedure without causing axial deviation. Olympus has achieved just the right level of elasticity to ensure the highest level of performance. This feature proves especially valuable when repeated approaches are necessary, as proper “pliability” can reduce procedure time and minimize operator stress.

# New Retrieval Basket

## Ichiro's Strategy – VorticCatchV



Ichiro Yasuda, MD  
 Director and Professor,  
 Third Department of Internal Medicine,  
 University of Toyama



### Controlling the Incision Length According to Stone Size

We generally perform EST before removing bile duct stones. The incision length is determined according to the stone size. In cases with large or stacked stones that are hard to remove with EST alone, EPLBD is performed more preferably than before. Considering the advantages such as the reduction of procedure time and complications, we expect that EPLBD will be more widely used in the future. As with ordinary EST, we use a medium incision width.

### When to Use a Lithotripsy Basket

We believe that increased use of EPLBD has led to a decrease in the need to use lithotripsy baskets. For instance with a stone size of 10-14 mm (up to scope diameter on X-ray), the lithotripsy basket is used following the EPLBD. At that time, we first attempt to retrieve the stone without crushing it.

### Device Selection According to Stone Size and Condition of Biliary Orifice after Papillary Treatment

The decision on device selection should be based on the sizes of the stone and the bile duct opening after papillary treatment. The basket has a higher grasping performance and the force to pull out the stones than the balloon, so it is our first choice in cases where the papilla has been treated with EST alone. We believe that it is particularly effective when the stone and the bile duct opening are similar sizes.

The balloon, on the other hand, is the preferred method for retrieval of stacked stones after EPLBD and of multiple stones. In case with stacked stones, basket impaction in the papilla can occur if the basket grasped a stone in the upstream position first.

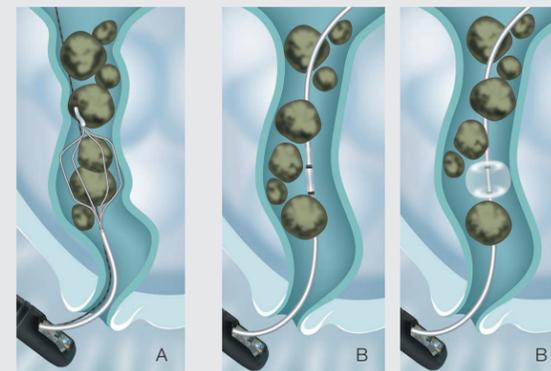
Therefore, it is necessary to retrieve the stones in order from the downstream position in such cases. However, it is sometimes difficult to retrieve the stacked stones beginning at the lowest stone. We believe that the balloon is more effective than the basket in such cases because it is possible by inflating the balloon between stones.

### Case in Which the Basket is Effective



When the incision width and stone width are identical (or similar), the basket is suitable for extraction because of the strong pulling force.

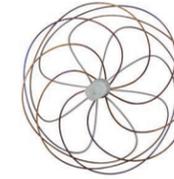
### Case in Which the Balloon is Effective (Stacked stones after EPLBD)



- Even when only the stone at the bottom is to be grasped, the basket is hard to fine-adjust so several stones tend to be grasped.
- The balloon can be dilated relatively easily between stones so it is also effective with stacked stones.

### Cases in Which VorticCatchV is Effective

We believe that this device is effective for small stones in general. It is particularly effective in cases where a pocket has formed at the lower end of the bile duct.



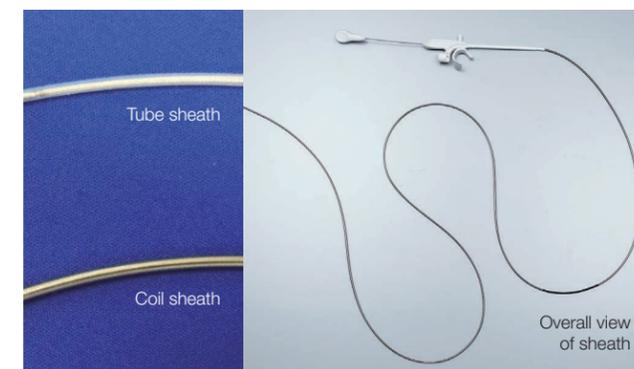
(Image shows top view of VorticCatchV.)

### Effective Range

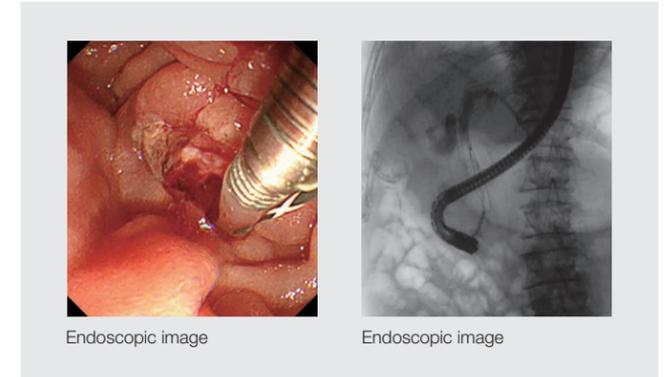
We believe that stones that can be retrieved with a balloon can be retrieved just as effectively with VorticCatchV. Namely, it can deal with any stone with a size of about 8 mm or less. In addition, even with the biliary sludge cases that used to be hard to remove with a balloon, a basket may be effective because its structure means that it stays in close contact with the entire circumferences of bile duct.

### Usefulness of Nitinol Basket and Coil Sheath

Baskets made from Nitinol – a material featuring high endurance and shape memory – offer excellent durability, while their unique shape has proven to ease retrieval. With previous baskets, the shape used to be deformed after two or three retrievals. The VorticCatchV, on the other hand, appears to maintain its shape even after repeating 10 or more retrievals. As the basket expands reliably even in narrow bile ducts, it provides excellent stone grasping capability.



The sheath is a coil sheath with high durability. With traditional tube sheaths, the proximal section of the sheath tended to be shrunk by repeated basket opening/closing operations. The adoption of the coil sheath is expected to minimize these problems. It is often thought that the coil sheath makes it hard to approach the papilla because of the reduced flexibility. However, the coil sheath used with VorticCatchV has higher flexibility than previous coil sheaths so the approach to the papilla is easier.



### Caution When Using VorticCatchV

Because the VorticCatchV employs a coil sheath, impaction of the basket can be avoided by connecting the MAJ-441 handle as shown above. However, as this function is an optional means for escaping from impaction, it should not be used in the same way as with a lithotripsy device. It is best to use it in the same way as a traditional basket.

