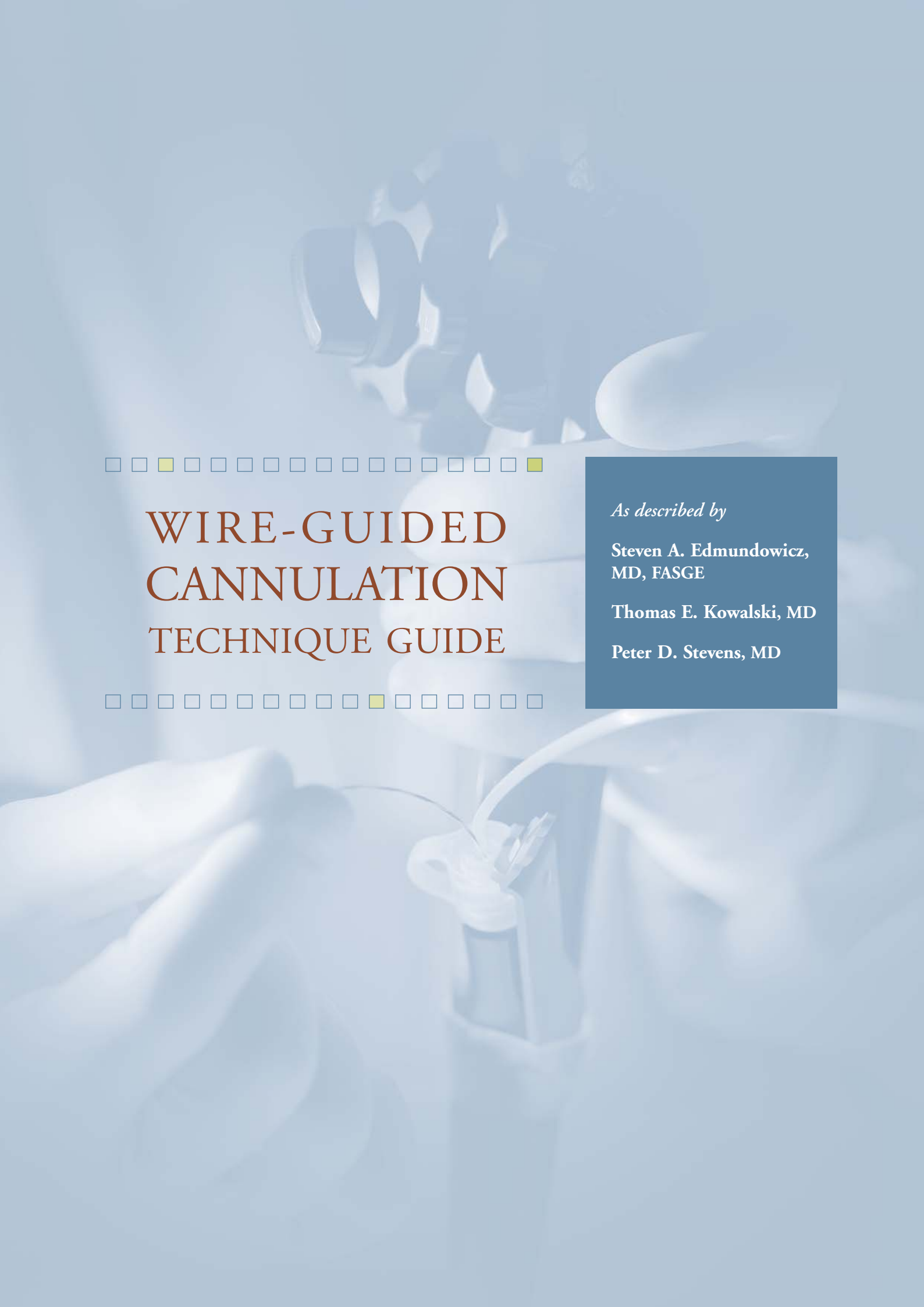

WIRE-GUIDED CANNULATION TECHNIQUE GUIDE

As described by

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Dear Colleagues:

Cannulation is the initial step in all diagnostic and therapeutic Endoscopic Retrograde Cholangiography and Pancreatography (ERCP). It can be a major hurdle for individuals performing this procedure. While reported success rates for cannulation are very high, even experts encounter difficult and sometimes unsuccessful cannulation attempts.

Technologic advancements have modified the tools available to achieve cannulation. Recent developments include systems that allow for a physician controlled cannulation technique. With this technique, Physician Controlled Wire-Guided Cannulation (PCWGC), the physician controls the guidewire and is provided with direct tactile feedback from the wire during cannulation. This affords the operator additional control over the cannulation process that was not possible with previous cannulation techniques, during which the assistant manipulated the guidewire. Additionally, developments in wire technology have allowed the production of coated nitinol core wires with hydrophilic tips that are designed to provide excellent push-ability, precise control, and a less atraumatic "lumen seeking" tip. It is our belief that these features limit ampullary trauma and inadvertent pancreatic duct injections, factors that in theory could reduce the incidence of post procedure pancreatitis. [2, 3, 7]

We feel PCWGC is an important skill that may assist the physician in obtaining cannulation of the desired duct at ERCP. During discussions of this technique at meetings and live courses we have learned there are different PCWGC approaches. This guide is an effort to communicate and share with you the PCWGC approaches we have found most helpful in our practices. It is our hope that by carefully describing the process with step-by-step instructions and tips, you will find it easier to develop your personalised technique for PCWGC to adopt in your practice. Whether you elect to use Physician Controlled Wire-Guided Cannulation in every case or as an option if your initial cannulation technique fails, we have created this guide to assist you and hopefully benefit both you and your patients.

Sincerely,

Steven A. Edmundowicz, MD, FASGE Thomas E. Kowalski, MD Peter D. Stevens, MD

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DEVICE SELECTION

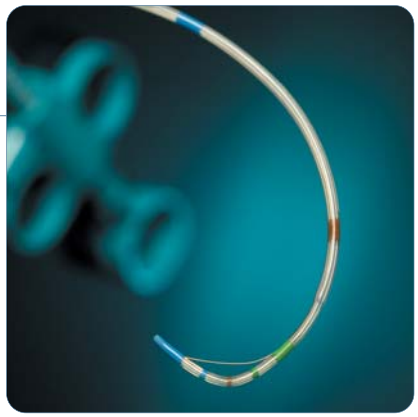
When performing Physician Controlled Wire-Guided Cannulation (PCWGC), a short wire system is utilised. Two key accessories are essential for this technique—the guidewire and the catheter/sphincterotome through which the guidewire is loaded.

Guidewire Selection

When selecting a guidewire, specific characteristics assist in facilitating wire-guided cannulation. It is recommended that a short, straight wire with a nitinol core and good tip flexibility be selected. The tip should be hydrophilic, soft and flexible, but not overly floppy. In most situations, a straight wire tip is preferred, but an angle tip wire may be useful in some situations. A 0.89 mm (0.35 in) wire is generally preferred for push-ability and stability.

Catheter Selection

Although the technique may be performed through a single-lumen catheter, for the majority of cases, it is most efficient to begin cases with a sphincterotome (pre-loaded with a guidewire) that is compatible with a short wire system. When choosing a sphincterotome for cannulation the cutting wire should be short to allow the scope to remain close to the papilla while changing the angulation of the sphincterotome. As such, the 20mm cutting wire may offer more acute angulation of the sphincterotome tip than the 30mm wire by facilitating operation close to the papilla while maintaining device stability. Different tip configurations of the sphincterotome may be useful. A tapered tip sphincterotome design may facilitate accurate positioning of the sphincterotome within the papillary orifice.



The devices represented are a Boston Scientific Hydra Jagwire® Guidewire and a Boston Scientific Autotome™ Sphincterotome.

PROCEDURAL TECHNIQUE

1. A sphincterotome pre-loaded with a guidewire is prepared and passed through the endoscope and below the major papilla.[A] *(Figures 1, 2)*

2. The guidewire is then "peeled" (removed from inside the cannula) from the insertion point, to a point on the sphincterotome just above the operating channel port (to allow manipulation by the physician.) *(Figure 3)*

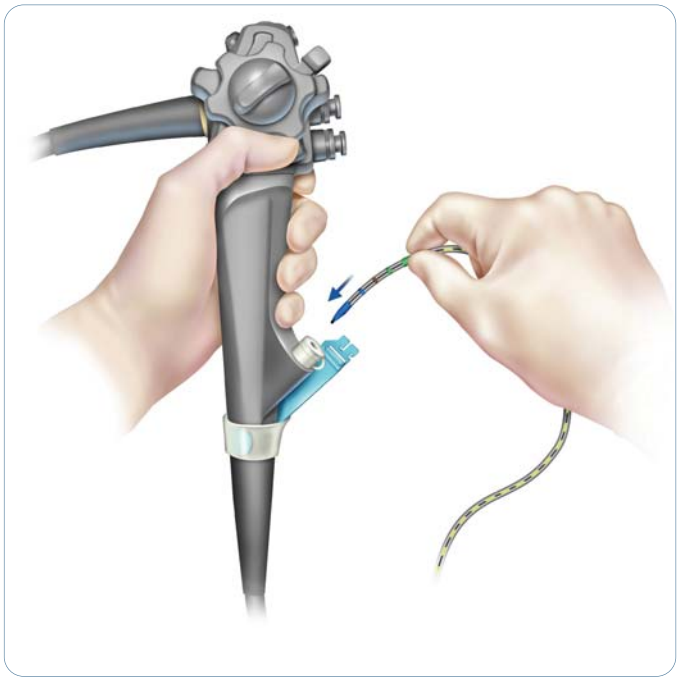


Figure 1 – *Sphincterotome, preloaded with guidewire, is inserted into scope.*

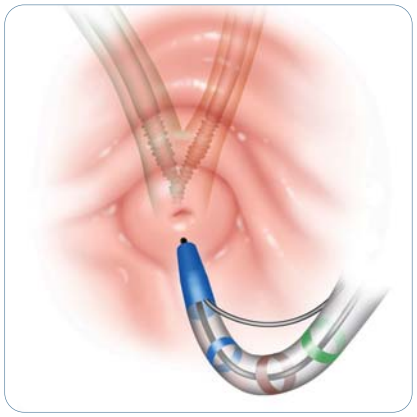


Figure 2 – *Sphincterotome and guidewire are passed into the major papilla.*

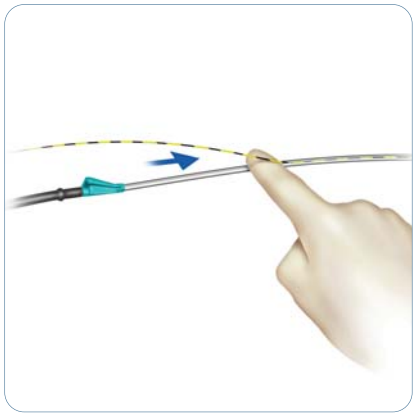


Figure 3 – *Guidewire is "peeled" with forefinger from sphincterotome (other hand holds sphincterotome and wire at device head).*

A ORIENTATION – Orientation to the major papilla is a key component of all cannulation attempts. Wire-guided cannulation requires the operator to place the sphincterotome in the optimum cannulation position for cannulation but uses the wire instead of contrast or the tip of the sphincterotome to actually engage the bile or pancreatic duct.

PROCEDURAL TECHNIQUE (cont.)

3. The guidewire is advanced by the physician to the end of the sphincterotome. The papilla is carefully inspected to determine the orifice and ideal angle of engagement. *(Figure 4)*

4. Once the papillary anatomy is determined, the sphincterotome is flexed until the tip is in alignment with the perceived orientation of the Common Bile Duct [B] (CBD). *(Figure 5)*

5. At this point, depending on physician preference, one of two approaches may be taken to obtain CBD entry with the wire:

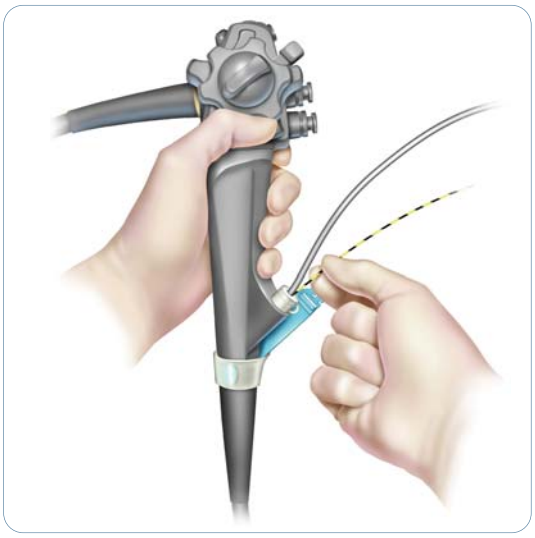
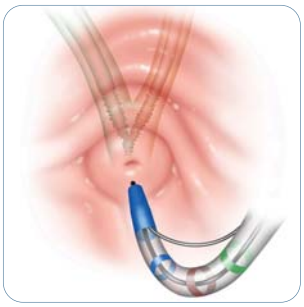
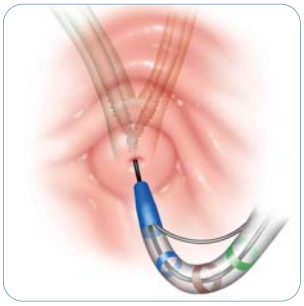


Figure 4 – *Guidewire is advanced by physician.*





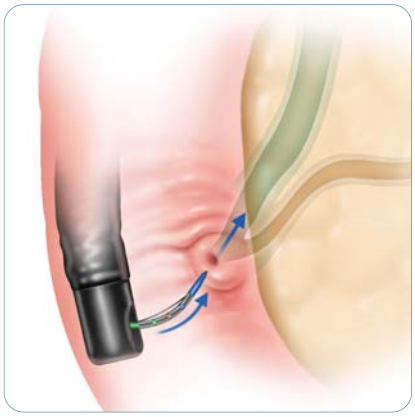


Figure 5 – *Sphincterotome is flexed to align tip with perceived orientation of the CBD.*

B VISUALISING THE ANATOMY – To conceptualise the process of deep cannulation with a wire, it may help to visualise passing the wire through multiple 1-2 mm sections of duct, separated by muscular "rings." As each "ring" is passed, the angle of the wire may need to be reoriented to advance through the next "ring." Occasionally, all the "rings" line up and the wire slides directly into the duct of choice with the initial entry vector. Typically, however, multiple adjustments in wire angle, through scope and elevator positioning and flexing the sphincterotome, are necessary to achieve cannulation.

Technique 1: Sphincterotome Outside the Ampullary Orifice

The guidewire is advanced gently into the papillary orifice and, under fluoroscopic guidance, manipulated into the bile duct. Once the wire advances beyond the papillary orifice, fluoroscopy can be activated and its position in the desired duct confirmed. If prompt and resistance-free passage into the bile duct does not occur, the guidewire is withdrawn and the angle of approach is changed—by manipulating the flex on the sphincterotome or changing the elevator or scope position.[C, D] *(Figures 6, 7, 8)*

Selective cannulation with the wire.

Figure 6 – *Cannulation of CBD with sphincterotome outside ampullary orifice.*

Figure 7 – *Side view*

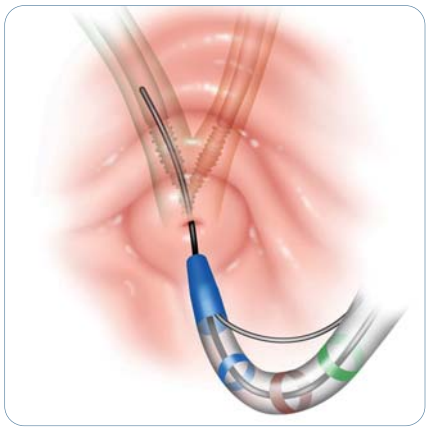


Figure 8 – *En face view*

C APPROACH TO THE AMPULLARY ORIFICE (Technique 1) – When using this technique, the guidewire is advanced out of the sphincterotome so that it extends 2-5 mm beyond the sphincterotome tip toward the papillary orifice. In small motions, the wire is gently moved back and forth to help the operator further realise the vector of the wire in relationship to the major papilla and underlying duct systems. Small adjustments to the scope position and the sphincterotome tip position help to determine the desired angle of entry. The operator analyses the surface of the papilla to the point of entry. At times an orifice is clearly visible, but in other situations it is more difficult to determine. In this case, the surface of the papilla may provide clues for several putative openings. The tip of the wire is used to locate the orifice by gently touching the papilla, feeling and watching for the wire to slip into an orifice. Multiple gentle attempts to enter putative openings are made in succession as the operator changes the point of wire contact on the papilla to precisely target a specific point or to change to a new target. If prompt and resistance free passage into the bile duct does not occur, the guidewire is withdrawn and the angle of approach is changed by manipulating the flex on the sphincterotome or changing the elevator and/or scope position.

D WIRE AS CANNULATION TOOL (Technique 1) – Commonly, the wire tip slips into the common channel at an angle that is not suited for deep cannulation of the common bile duct. Multiple, subtle changes in direction of the wire are required to establish deep cannulation. Using the wire as the cannulation tool in this way allows for additional methods of altering the direction of the wire's tip. The first technique is to use the ampullary orifice as a fulcrum, and to "see-saw" the tip of the wire into a new direction. A second useful technique is to use the wall of the duct to carom the tip of the wire into a new vector. If a gentle bow forms in the wire, the tip of the cannula can be used to rotate the bow and new angles are discovered. At times, more stability is required to for deep cannulation of the CBD, so the endoscopist may "follow" the wire with the sphincterotome into the papilla. Once the tip of the sphincterotome engages the papilla approximately 1-2 mm, the sphincterotome is used as a steer-able conduit for the wire and the cannulation process is then identical to technique 2.

When using these wire cannulation techniques, it is essential to be gentle to avoid trauma to the papilla. One welcomed feature when keeping a short length of wire outside of the papilla, with technique 1, is that the wire itself can absorb excess forward pressure by bowing. Once no "free wire" is visible between the tome and the papilla, bowing is constrained by the duct walls and more force may be applied to the tip of the wire. CAUTION: If only 1 mm or less of the wire is out of the catheter the wire may act like a needle and pierce the epithelium, causing a false tract. This may be prevented by carefully monitoring the force on the wire using the excellent tactile feedback provided by the wire itself.

PROCEDURAL TECHNIQUE (cont.)

Technique 2: Sphincterotome Placed in Ampullary Orifice

Alternatively, the sphincterotome is inserted 1-2 mm into the ampullary orifice. The 1-2 mm limit keeps the tip of the sphincterotome within the common channel instead of pre-committing the wire, most often to the pancreatic duct. In this position, the sphincterotome is used as a conduit to support, angle and guide the wire. Thereafter, the focus is solely on the wire. [E] *(Figures 9, 10, 11)*

Selective cannulation with sphincterotome 1-2 mm inside ampullary orifice.

Figure 9 – *Sphincterotome advanced 1-2 mm inside ampullary orifice.*

Figure 10 – *Side view*

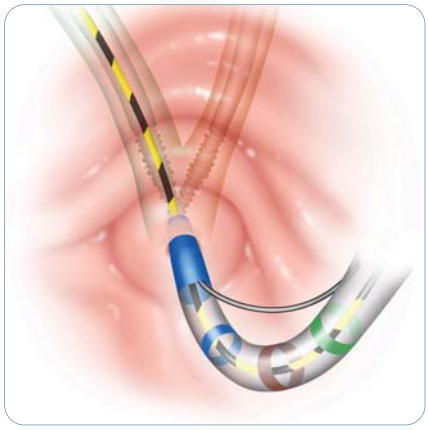


Figure 11 – *En face view*

E TACTILE FEEDBACK AND VISUAL CUES (Technique 2) – During the cannulation process there is excellent tactile feedback between the tip of the wire and the physician's fingers. If there is resistance against the wire, the physician stops advancing, withdraws the wire slightly, changes the orientation of the tip of the sphincterotome and then re-advances the wire, again only 1-3 mm. In this manner, the physician quickly and methodically tests numerous different orientations and angulations of the sphincterotome tip. From a visual standpoint, if the physician sees the sphincterotome moving back towards the duodenal lumen, too much pressure is being applied to the wire and advancement should stop. Fluoroscopy does not aid this technique. Instead, fluoroscopy distracts the physician's concentration from feeling the wire and from the orientation of the sphincterotome tip. The key to this technique is limiting wire movement to very short excursions. The bile duct and pancreatic duct are epithelialized channels that arise from a common channel. To facilitate success with this technique, a sphincterotome orientation that allows the wire to do the work of finding those channels must be achieved. Pushing into the papilla with the sphincterotome or the wire with any substantial force may traumatise the ampulla and kink or increase the angle between the common channel and the bile duct, making cannulation more difficult.

Wire Positioning Tips

USING THE SCOPE FOR POSITIONING

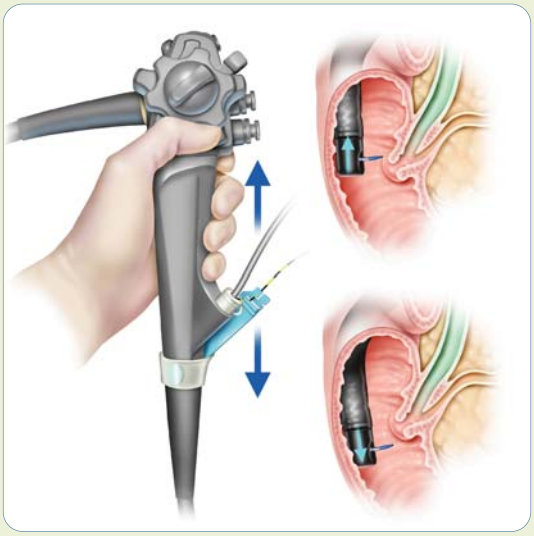


Figure 12 – *Scope is positioned for cannulation just below the papilla. Scope is put in "shortened position" and may be pushed inward and outward to facilitate sphincterotome positioning.*

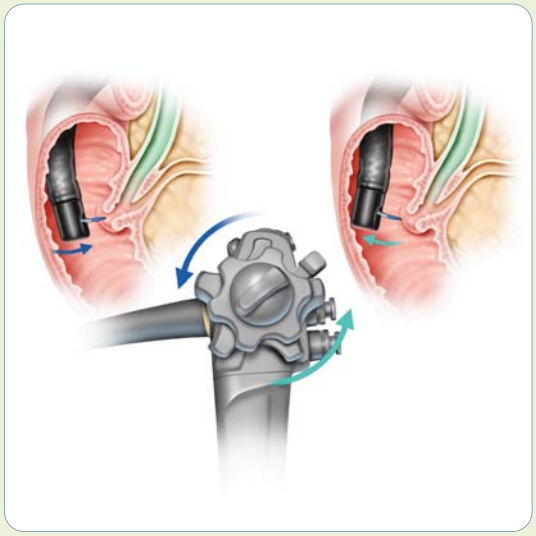


Figure 13 – *Big wheel is rolled in "up" direction (counter-clockwise) to move scope toward ampulla or "down" (clockwise) to move scope away from ampulla. Small wheel facilitates movement to the left or right of papilla.*

USING THE SPHINCTEROTOME FOR POSITIONING

Sphincterotome flex may be used to adjust the position of the sphincterotome.

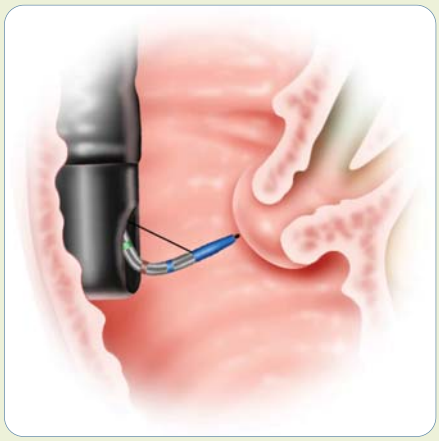


Figure14 – *Side view (technique 1)*

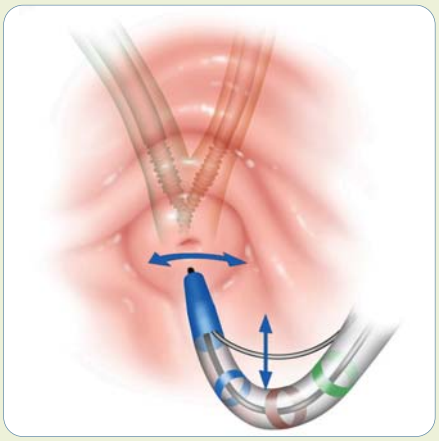


Figure 15 – *En face view (technique 1)*

Figure 16 – *Assistant flexes sphincterotome tip.*

PROCEDURAL TECHNIQUE (cont.)

6. Regardless of which method is used to gain entry into the ampulla, the wire is then advanced 1-3 mm to gently probe the common channel until the tip of the wire finds an epithelialized channel and advances easily. Often the operator experiences tactile feedback from the guidewire that feels like a "give" or "pop" at this point.

7. Once the wire advances freely, fluoroscopy is checked to determine which duct has been entered and then the sphincterotome is advanced over the wire as desired. The guidewire is not forcefully manipulated and if any concern about the location of the guidewire develops the sphincterotome can be gently advanced over the guidewire and a small amount of contrast injected to delineate the anatomy. *(Figure 17)*

8. Once the guidewire is positioned into the desired duct, it is locked in place using the locking device, designed to prevent motion or losing access. The operator may proceed with the diagnostic and therapeutic goals of the procedure. *(Figure 18)*

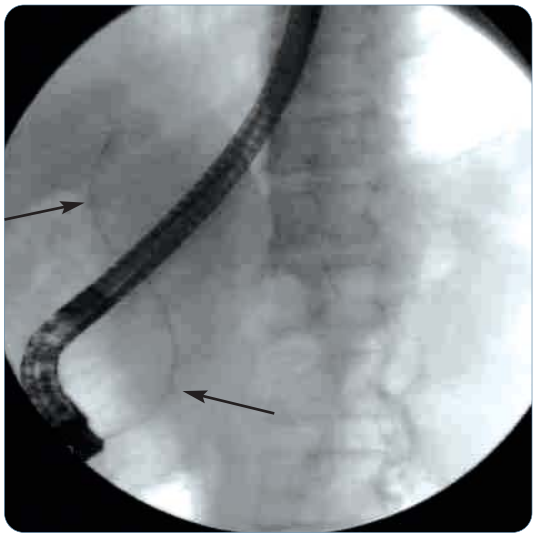


Figure 17 – *Wire position confirmed under fluoroscopy (no contrast).*

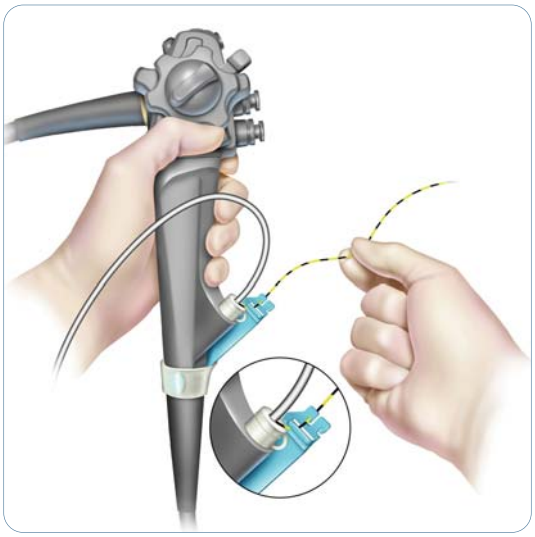


Figure 18 – *Guidewire is locked into place with locking device.*

ALTERNATIVE METHODS

In some cases, technical and anatomical challenges will present or the physician may prefer to have an assistant manipulate the wire. If either of these situations arises, there are two alternative wire-guided cannulation methods to consider.

DOUBLE WIRE METHOD

Alternative method for technical or anatomical challenges

If repeated attempts at cannulation result in continued wire placement in the pancreatic duct, a double wire technique may be used to facilitate bile duct cannulation. With this method, the guidewire is left in the pancreatic duct while a second guidewire is passed to cannulate the CBD. This technique may be especially useful before proceeding with more aggressive cannulation measures such as pancreatic duct stent placement or pre-cut sphincterotomy.

1. If this method is used, the pancreatic wire is advanced deep into the main pancreatic duct, if possible, so that the stiff portion of the wire is within the ampullary segment. Once the wire is advanced to the tail of the pancreas, it is locked in place and the sphincterotome is removed from the duodenoscope.[F] *(Figures 19, 20)*

Figure 19 – *Guidewire is placed in Pancreatic Duct (PD).*

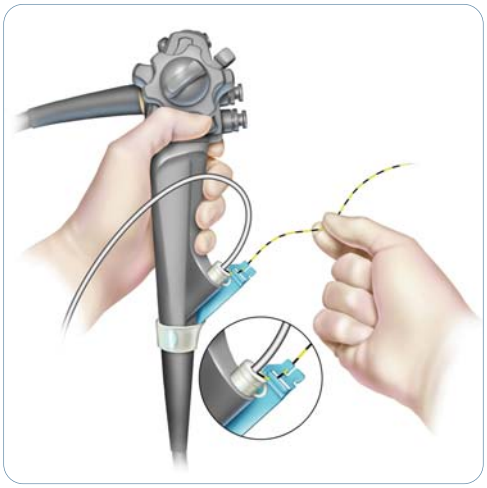


Figure 20 – *Guidewire placed in PD is locked into place with locking device.*

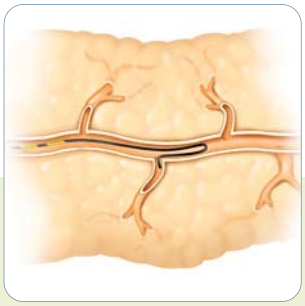


Figure 21 – *Alpha loop in PD to facilitate passage.*

F PANCREATIC WIRE ADVANCEMENT – When advancing the wire in the pancreatic duct care must be taken not to advance a wire in a straight conformation against resistance so as to avoid potential side branch perforation. If there is no resistance, the wire may be advanced to the tail of the pancreas with limited concerns of pancreatic injury. If the tip of the wire enters a side branch, continued gentle advancement may allow the wire to find the path of least resistance by folding on itself and adopting an alpha (or "safety") loop conformation. In the alpha loop conformation the wire is then advanced to the tail, typically without engaging any additional side branches. *(Figure 21)*

DOUBLE WIRE METHOD (cont.)

2. The sphincterotome is then re-loaded with a second short straight wire and advanced to the duodenum. *(Figure 22)*

3. Again, the wire is "peeled" from the insertion point to a point just above the instrument port to allow wire manipulation by the physician. *(Figure 23)*

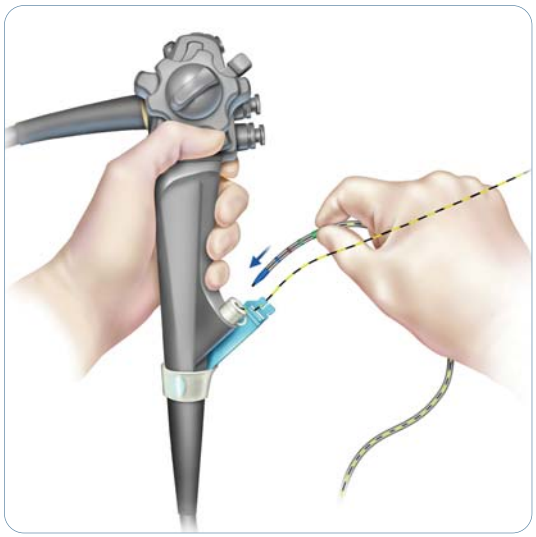


Figure 22 – *Sphincterotome (pre-loaded with a second guidewire) is inserted and passed again to the ampulla. First wire remains locked.*

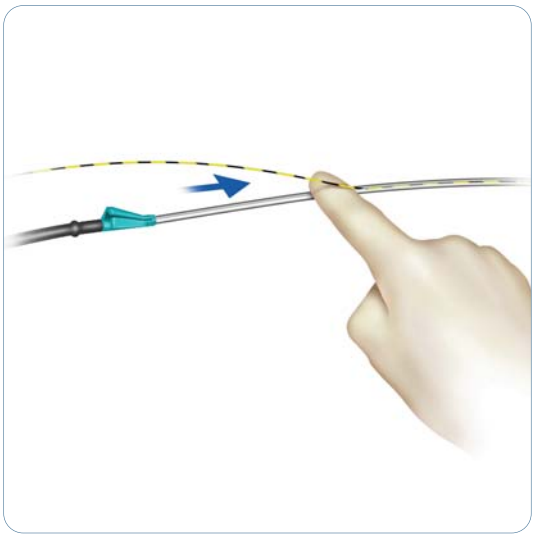


Figure 23 – *Second guidewire is "peeled" with forefinger from sphincterotome for operator manipulation (other hand holds sphincterotome and wire at device head).*

4. The tip of the sphincterotome is manipulated to direct the guidewire slightly above and coming from the right to the left of the pancreatic wire. Using one of the two wire-guided cannulation techniques described in the first section of this guide, the second wire is used to gain access to the bile duct.[G] *(Figures 24, 25, 26, 27)*

5. Upon achievement of CBD cannulation, the second wire is locked into place using the external locking device, and the procedure is continued. Depending on the clinical situation and physician preference, the first wire may be removed, used for additional therapy, or locked into place until the end of the procedure for prophylactic pancreatic stent placement.

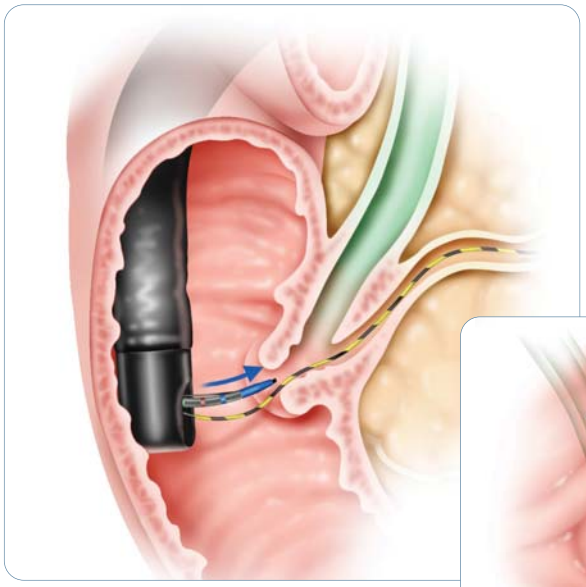


Figure 24 – *Side view (technique 2)*

Guidewire is positioned to perceived CBD orientation. Initial guidewire is still placed in PD.

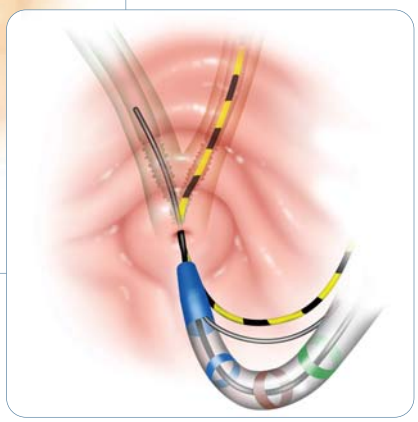


Figure 25 – *En face view (technique 2)*

Figure 26 – *Guidewires placed in CBD and PD. (technique 2)*

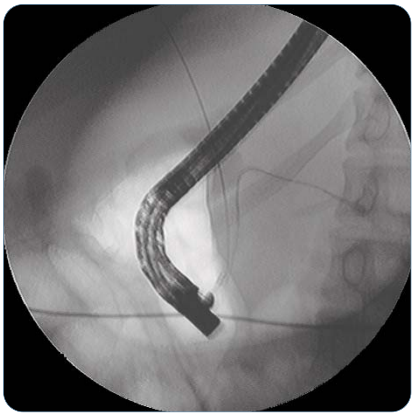


Figure 27 – *Fluoroscopy image of guidewire placement in CBD and PD. (technique 2)*

G PD WIRE INTENDED BENEFIT – The wire in the pancreas lengthens and stabilises the papilla facilitating biliary cannulation. If the intraduodenal biliary segment has a "sigmoid" morphology the pancreatic wire straightens the "S-turn" again facilitating biliary cannulation.

WIRE-GUIDED CANNULATION WITH STAFF ASSISTANCE

Alternative Method – Assistant Maintains Wire Control

While physician control of the guidewire provides immediate feedback and responsiveness during cannulation, some physicians are uncomfortable manipulating the guidewire in addition to the catheter and endoscope. In this setting, the physician and patient may still reap the benefit of wire guided cannulation with the assistant controlling the wire.

1. The sphincterotome is positioned by the physician just below (or in) the papillary orifice. (For details and illustrations, refer to the physician controlled wire-guided cannulation method.)

2. At the physician's direction, the wire is advanced into the desired duct by the assistant. [H]

3. Once the wire passes easily forward the fluoroscopy unit is activated and position confirmed. If it is the desired duct the sphincterotome can be advanced over the wire and contrast injected. The assistant should not advance the wire with excessive force. Once the wire advances 2-3 cm the assistant should hold the wire in place and check the position with fluoroscopy.

4. Once the desired duct is cannulated, the guidewire is locked into place and the procedure continued.

H IMPORTANCE OF COMMUNICATION – Careful and clear communication between the physician and assistant while monitoring the fluoroscopic and video images can lead to successful cannulation of the desired duct. Using this method allows the physician to focus on making small incremental changes in the angulation and direction of the cannulating device, while the assistant can gently probe the orifice with the guidewire.

Resource List

To learn more about wire-guided cannulation, below is a list of published literature on this topic for your reference.

1. Freeman ML, DiSario JA, Nelson DB et al. Risk factors for post-ERCP pancreatitis: a prospective, multicenter study. Gastrointestinal Endoscopy 2001; 54:425-434.

2. Johnson KG, Geenen JE, Johanson JF et al. Evaluation of post-ERCP pancreatitis: potential causes noted during a controlled study of differing contrast media. Gastrointestinal Endoscopy 1997; 46:217-222.

3. Freeman ML and Guda NM. Prevention of post-ERCP pancreatitis: a comprehensive review. Gastrointestinal Endoscopy 2004; 59:845-864

4. Maede S, Hayashi H, Hosokawa O, et al., Prospective randomised pilot trial of selective biliary cannulation using pancreatic guide-wire placement. Endoscopy 2003; 35:721-724.

5. Lella F, Bagnolo F, Columbo E, and Bonassi U. A simple way of avoiding post ERCP pancreatitis. GI Endoscopy 2004; 59:830-834.

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This educational technique guide was developed and produced in cooperation with Steven A. Edmundowicz, MD, FASGE, Thomas E. Kowalski, MD, and Peter D. Stevens, MD. The opinions, recommendations and techniques reflected in this guide are those of these physicians and do not necessarily reflect the opinions and recommendations of Boston Scientific Corporation, its employees or its affiliates.

* Clinical images courtesy of Peter D. Stevens, MD.

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