

Amplified Suggested Procedure Using The Arrow Guidewire Technique for Peritoneal Lavage

Rx only.

Introduction:

Peritoneal lavage is based on the simple concept that the presence of intraperitoneal blood indicated intraperitoneal injury. This procedure can be rapidly and accurately performed in the emergency room as a diagnostic tool in the assessment of seriously injured patients with blunt abdominal trauma. This Arrow® kit utilizes a "J" tipped guidewire for catheter placement obviating the older complication-prone trocar technique.

A volume of approximately one liter of normal saline or Ringer's lactate is instilled into the peritoneal cavity then recovered and analyzed for blood content.

The physician using the Arrow® Peritoneal Lavage Kit is provided with everything needed to diagnose intraperitoneal bleeding with increased safety, reliability, and convenience. A 20 Ga. short bevel introducer needle is the largest sharp object to enter the peritoneum. The very soft "J" tip of the guidewire minimizes the potential for complications.

Indications for Use:

For evaluation of bleeding in the abdominal cavity or ruptured organ.

Contraindications:

Patients with an acute abdomen requiring immediate surgery or penetrating abdominal trauma.

⚠️ General Warnings and Precautions

Warnings:

1. Sterile, Single use: Do not reuse, reprocess or resterilize. Reuse of device creates a potential risk of serious injury and/or infection which may lead to death. Reprocessing of medical devices intended for single use only may result in degraded performance or a loss of functionality.
2. Read all package insert warnings, precautions and instructions prior to use. Failure to do so may result in severe patient injury or death.
3. Clinicians must be aware of complications associated with peritoneal lavage including, but not limited to injury to organs and/or vessels by needle or catheter, infection, cutaneous bleeding and/or hematoma.

Precautions:

1. Do not alter the catheter, guidewire or any other kit/set component during insertion, use or removal.
2. Procedure must be performed by trained personnel well versed in anatomical landmarks, safe technique and potential complications.
3. Use standard precautions and follow institutional policies for all procedures including safe disposal of devices.

Kits/Sets may not contain all accessory components detailed in these instructions for use. Become familiar with instructions for individual component(s) before beginning the procedure.

A Suggested Procedure: Use sterile technique.

1. Place patient in supine position making sure that the patient has voided or urinary catheter is in place. Insert nasogastric tube to decompress stomach.
2. The preferred site for catheter insertion is the midline, midway between the umbilicus and symphysis pubis. Avoid insertion through or immediately adjacent to a previous abdominal incision.

3. Remove prep swabsticks and prep shaved skin in area of puncture site.
4. Remove wrapped tray from outer package and open to create sterile field and expose kit components for use.
5. Place fenestrated drape over puncture site.
6. Use 18 Ga. T.W. needle to aspirate anesthetic into 5 mL syringe.
7. Perform skin wheal using 25 Ga. or 22 Ga. needle.
8. Make 3 mm skin incision using #11 blade scalpel.

Note: Do not proceed until skin and subcutaneous hemostasis is observed.

9. Insert catheter/needle assembly through incision into peritoneum aiming toward the pelvic hollow.

Note: 18 Ga. T.W. needle (without catheter) can be alternately used to puncture peritoneum and pass wire guide if desired. If desired, the catheter/needle assembly can be connected to I.V. tubing and bottle/bag of saline or Ringer's lactate solution.

The penetration into the peritoneum will usually be recognized by a distinct "pop" and confirmed by a free flow of solution. Advance tip of catheter an additional 2-3mm into peritoneal cavity. Remove introducer needle (refer to Figure 1).

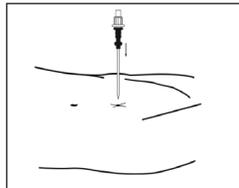


Figure 1

- ⚠️ Precaution: If needle is used instead of introducer catheter, do not withdraw guidewire against needle bevel to avoid possible severing of guidewire.

- ⚠️ Precaution: Do not reinsert needle into catheter.

10. Insert desired end of guidewire through 16 Ga. catheter into peritoneal cavity. If "J" tip is used, prepare for insertion by sliding plastic tube over "J" to straighten it. Advance guidewire into peritoneum to required depth.

Note: If wire does not initially advance with ease, catheter most likely has not been placed properly within peritoneal cavity (refer to Figure 2).

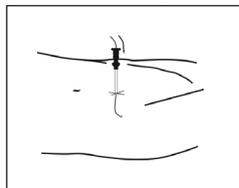


Figure 2

11. Remove introducer catheter and thread tip of 8 Fr. catheter over guidewire (be certain that sufficient wire guide length remains exposed at hub end of catheter to maintain firm grip on wire guide). Grasping near skin, advance catheter to required depth in peritoneal cavity (refer to Figure 3).

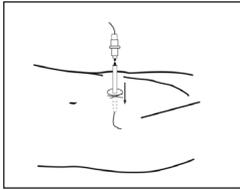


Figure 3

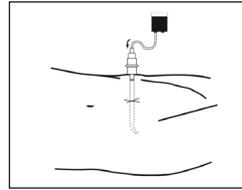


Figure 5

- ⚠ **Precaution: Maintain firm grip on guidewire at all times.**
- 12. Hold catheter at required depth and remove guidewire. Aspirate using 5 mL syringe.
- ⚠ **Precaution: Potential for guidewire breakage. Although the incidence of guidewire failure is extremely low, physicians should be aware of the potential for breakage if undue force is applied to the wire.**

The Arrow catheter included in this product has been designed to freely pass over the guidewire; if resistance is encountered when attempting to remove the guidewire after catheter placement, the guidewire may be kinked about the tip of the catheter (refer to Figure 4). In this circumstance, pulling back on the guidewire may result in undue force being applied resulting in guidewire breakage. If resistance is encountered, withdraw the catheter relative to the guidewire about 2-3 cm and attempt to remove the guidewire; if resistance is again encountered, remove the guidewire and catheter simultaneously.



Figure 4

- 13. If aspiration is non-diagnostic, connect I.V. tubing to catheter and bottle/bag of saline or Ringer's lactate (20 mL/kg up to 1000 mL).
- 14. Run solution into peritoneal cavity. Gently manipulate patient as required to insure proper intermixing of fluid. Suggested time to allow for intermixing is 10 minutes (refer to Figure 5).

- 15. Lower bottle/bag and I.V. tubing to floor level so that lavage fluid can drain freely by gravity due to siphoning effect.
- Note: If no fluid return occurs, reinsert guidewire and again check for fluid return after wire guide removal. If fluid return still does not occur, flush catheter with saline solution. If fluid return still does not occur, exchange old catheter with new utilizing wire guide (refer to Figure 6).*

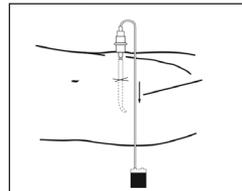


Figure 6

- 16. Analyze fluid for red blood cells or other material as indicated using standard hospital technique.
- 17. After lavage has been accomplished, remove catheter and dress puncture site as required.

For reference literature concerning patient assessment, clinician education, insertion technique, and potential complications associated with this procedure, consult standard textbooks, medical literature, and Arrow International LLC website: www.teleflex.com

A pdf copy of this IFU is located at www.teleflex.com/IFU

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Symbol Glossary: Symbols are in compliance with ISO 15223-1. Some symbols may not apply to this product. Refer to product labeling for symbols that apply specifically to this product.

								
Caution	Medical device	Consult instructions for use	Contains a medicinal substance	Do not reuse	Do not resterilize	Sterilized by ethylene oxide	Single sterile barrier system with protective packaging inside	
								
Single sterile barrier system	Keep away from sunlight	Keep dry	Do not use if package is damaged	Not made with natural rubber latex	Catalogue number	Lot number	Use by	Manufacturer
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Date of manufacture								

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