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ARROW®

Arrowg+ard Blue® Percutaneous Sheath Introducer Product

Rx only

Arrowg+ard Blue® Antimicrobial Catheter Technology Information

Arrowg+ard® Antimicrobial Surface:

The Arrow® antimicrobial sheath consists of a polyurethane sheath plus an exterior antimicrobial surface treatment. Substantial antimicrobial activity associated with this antimicrobial surface on catheters and/or sheaths has been demonstrated in the following ways:

- Significant antimicrobial activity associated with the Arrowg+ard antimicrobial surface has been demonstrated using zone of inhibition bioassays against the following organisms:
  - *Escherichia coli*
  - *Pseudomonas aeruginosa*
  - *Staphylococcus epidermidis*
  - *Staphylococcus aureus*
  - *Klebsiella pneumoniae*
  - *Candida albicans*
- Contact inhibition of microbial growth on the surface has been demonstrated against organisms commonly associated with nosocomial infections; e.g. *Staphylococcus epidermidis and Staphylococcus aureus*.
- Antimicrobial activity on the surface of the Arrowg+ard catheter during handling and placement has been demonstrated *in situ* in limited animal studies.
- The Arrowg+ard catheter has demonstrated a significant decrease in the rate of bacterial colonization along the catheter in limited animal studies.
- A prospective, randomized clinical trial of 403 catheter insertions in adult patients in a medical-surgical ICU showed that the antimicrobial catheters were 50% less likely to be colonized than control catheters (p=0.003) and 80% less likely to produce catheter-related bacteremia (p=0.02).
- Arrow antimicrobial catheters retained antibacterial activity with zones of inhibition of 4 to 10 mm against *Staphylococcus aureus* and *Escherichia coli* after 10 days of implantation in rats.
- Complete data were obtained for 403 catheters (195 control catheters and 208 antimicrobial catheters) in 158 patients. Control catheters removed from patients who were receiving systemic antibiotic therapy occasionally showed low-level surface activity that was unrelated to the length of time the catheters had been in place (mean zone of inhibition ± SD, 1.7 mm ± 2.8 mm); in contrast, antimicrobial catheters uniformly showed residual surface activity (mean zone of inhibition, 5.4 ± 2.2 mm; P<0.002), which declined after prolonged periods *in situ*. Antimicrobial activity was seen with antimicrobial catheters that had been in place for as long as 15 days.
- Arrow antimicrobial catheters produced large zones of inhibition *in vitro* (range 10 to 18 mm) against the following microbes:
  - *Methicillin-resistant Staphylococcus aureus*
  - *Gentamicin/methicillin-resistant Staphylococcus aureus*
  - *Staphylococcus aureus*
  - *Staphylococcus epidermidis*
  - *Escherichia coli*
  - *Pseudomonas aeruginosa*
  - *Klebsiella pneumoniae*
  - *Candida albicans*
- After 7 days of implantation the catheters retained 6-7 mm zones of inhibition against *Staphylococcus aureus*.
- Antibacterial activity was retained against *Staphylococcus epidermidis* (10^6 bacterial concentration) from subcutaneous segments of Arrowg+ard antimicrobial surface catheters for at least 120 hours and some up to 520 hours after insertion of the catheters into cardiac surgical patients (both double- and triple-lumen catheters). The zone of inhibition size varied in 7 Fr. triple-lumen catheters from 2.5 to 10 mm at 500 hours.

If the total amount of silver sulfadiazine and chlorhexidine contained in the antimicrobial surface sheath was released from the sheath as a single dose, the blood levels of silver, sulfadiazine, and chlorhexidine that would be found would be less than the blood levels found after clinical usage of these compounds in established safe dosages as administered via mucous membranes and skin.

The potential exposure of patients to the two agents, silver sulfadiazine and chlorhexidine, on the antimicrobial surface is significantly less than that encountered when these compounds are used on burn wounds, on cutaneous wounds, or as mucosal irrigants.

No adverse effects of a toxicologic nature have been associated with the clinical use of this antimicrobial surface in spite of the fact that catheters have been placed in patients sensitive to sulfonamides but who were unaware of their sensitivity. However, the Arrowg+ard antimicrobial surface has been reported to cause severe anaphylactic reactions in a limited number of patients in Japan and the UK (first case reported May 1996). Refer to the Contraindications section for additional information.

Indications for Use:

The Arrowg+ard percutaneous sheath introducer permits venous access and catheter introduction to the central circulation.

The Arrowg+ard antimicrobial surface is intended to help provide protection against sheath-related infections. It is not intended to be used as a treatment for existing infections nor as a substitute for a tunneled catheter in those patients requiring long-term therapy. One clinical study indicates that the antimicrobial properties of the catheter may not be effective when it is used to administer TPN.

Contraindications:

The Arrowg+ard Blue antimicrobial sheath introducer is contraindicated for patients with known hypersensitivity to chlorhexidine, silver sulfadiazine, and/or sulfa drugs.

Clinical Benefits to be Expected:

The ability to access into the circulation and infuse large fluid volumes rapidly into a patient for treatment of shock or trauma, as examples.

The ability to introduce single or multi-lumen central venous catheters, other treatment devices, or exploratory/diagnostic devices, reducing the number of needle sticks and vascular access locations to the patient.

Provide protection against catheter-related bloodstream infections.

Special Patient Populations:

Controlled studies of this product have not been conducted in pregnant women, pediatric or neonatal patients, and patients with known sulfonamide hypersensitivity, erythema multiforme, Stevens-Johnson syndrome and glucose-6-phosphate dehydrogenase deficiency. Benefits of use of this catheter should be weighed against any possible risk.

Hypersensitivity Potential:

Hypersensitivity reactions are a concern with antimicrobial catheters in that they can be very serious and even life-threatening. Since antimicrobial catheters were introduced into the market, there have been reports of hypersensitivity occurrences. This may affect your patient population, especially if your patient is of Japanese origin.

Warning:

1. **Remove device immediately if adverse reactions occur after device placement. Chlorhexidine containing compounds have been used as topical disinfectants since the mid-1970's. An effective antimicrobial agent, chlorhexidine found use in many antiseptic skin creams, mouth rinses, cosmetic products, medical devices and disinfectants used to prepare the skin for a surgical procedure.**

   NOTE: Perform sensitivity testing to confirm allergy to device antimicrobial agents, if adverse reaction occurs.

⚠ *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 potential entrapment of the guidewire by any implanted device in circulatory system. It is recommended that if patient has a circulatory system implant, insertion procedure be done under direct visualization to reduce risk of guidewire entrapment.**
4. **Do not use excessive force when introducing guidewire or sheath/dilator assembly as this can lead to vessel perforation, bleeding, or component damage.**
5. **Passage of guidewire into the right heart can cause dysrhythmias, right bundle branch block, and a perforation of vessel, atrial or ventricular wall.**
6. **Do not apply excessive force in placing or removing guidewire, dilator, or sheath. Excessive force can cause component damage or breakage. If damage is suspected or withdrawal cannot be easily accomplished, radiographic visualization should be obtained and further consultation requested.**
7. **Using devices not indicated for pressure injection for such applications can result in inter-lumen crossover or rupture with potential for injury.**
8. **Do not secure, staple and/or suture directly to outside diameter of device body or extension lines to reduce risk of cutting or damaging the device or impeding device flow. Secure only at indicated stabilization locations.**
9. **Air embolism can occur if air is allowed to enter a vascular access device or vein. Do not leave open needles or uncapped, unclamped devices in central venous puncture site. Use only securely tightened Luer-Lock connections with any vascular access device to guard against inadvertent disconnection.**
10. **Use of subclavian vein insertion site may be associated with subclavian stenosis.**
11. **Clinicians must be aware of complications/undesirable side-effects associated with this device including, but not limited to:**
    - vessel wall perforation
    - pleural and mediastinal injuries
    - air embolism
    - sheath embolism
    - thoracic duct laceration
    - bacteremia
    - septicemia
    - thrombosis
    - inadvertent arterial puncture
    - nerve damage/injury
    - hematoma
    - hemorrhage
    - dysrhythmias
    - hemothorax
    - occlusion
    - pneumothorax
    - anaphylactic reaction
    - cardiac tamponade
    - catheter embolism
    - fibrin sheath formation
    - exit site infection
    - vessel erosion
    - catheter tip malposition
    - anaphylaxis
    - hemothorax
    - extravasation

Precautions:

1. **Do not alter the device, 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.**
4. **Some disinfectants used at device insertion site contain solvents which can weaken the device material. Alcohol, acetone, and polyethylene glycol can weaken the structure of polyurethane materials. These agents may also weaken the adhesive bond between stabilization device and skin.**
   - **Do not use acetone on device surface.**
   - **Do not use alcohol to soak device surface or allow alcohol to dwell in a device lumen to restore patency or as an infection prevention measure.**
   - **Do not use polyethylene glycol containing ointments at insertion site.**
   - **Take care when infusing drugs with a high concentration of alcohol.**
   - **Allow insertion site to dry completely prior to applying dressing.**
5. **Indwelling devices should be routinely inspected for desired flow rate, security of dressing, correct position, and for secure Luer-Lock connection.**
6. **For blood sampling, temporarily shut off remaining port(s) through which solutions are being infused.**
7. **Promptly remove any intravascular catheter that is no longer essential. Should this device be used for intermittent venous access, maintain distal lumen sideport patency according to institutional policies, procedures, and practice guidelines.**

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.

Prep Puncture Site:

1. Position patient as appropriate for insertion site.
   - Subclavian or Jugular approach: Place patient in slight Trendelenburg position as tolerated to reduce risk of air embolism and enhance venous filling.
   - Femoral approach: Place patient in supine position.
2. Prepare clean skin with an appropriate antiseptic agent.
3. Drape puncture site.

4. Administer local anesthetic per institutional policies and procedures.
5. Dispose of needle.

SharpsAway® II Locking Disposal Cup (where provided):

The SharpsAway II Locking Disposal Cup is used for disposal of needles (15 Ga. - 30 Ga.).

- Using one-handed technique, firmly push needles into disposal cup holes (refer to Figure 1).

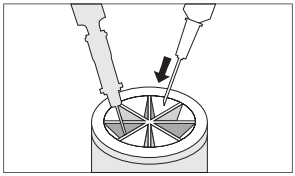

Figure 1

- Once placed into disposal cup, needles will be automatically secured in place so that they cannot be reused.

⚠ **Precaution: Do not attempt to remove needles that have been placed into SharpsAway II Locking Disposal Cup. These needles are secured in place. Damage may occur to needles if they are forced out of disposal cup.**

- Where provided, a foam SharpsAway® system may be utilized by pushing needles into foam after use.

⚠ **Precaution: Do not re-use needles after they have been placed into the foam SharpsAway system. Particulate matter may adhere to needle tip.**

6. Prepare flow-directed catheter according to manufacturer's instructions. Wet balloon with flush solution to facilitate passage through catheter contamination shield.

⚠ **Precaution: Do not inflate balloon of flow-directed catheter prior to insertion through catheter contamination shield to reduce the risk of balloon damage.**

7. Apply Contamination Shield:

   a. If using a catheter contamination shield with Tuohy-Borst adapter (where provided), insert tip of desired catheter through Tuohy-Borst adapter end of catheter contamination shield. Advance catheter through tubing and hub at other end (refer to Figure 2).

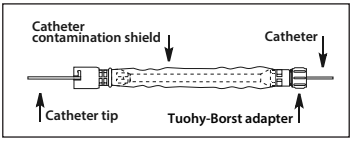

Figure 2

   b. If using a catheter contamination shield with TwistLock™ adapter (where provided), ensure double TwistLock of catheter contamination shield is fully opened (refer to Figure 3).

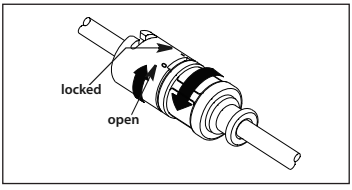

Figure 3

- Insert tip of desired catheter through proximal end of catheter contamination shield. Advance catheter through tubing and hub at other end (refer to Figure 4).

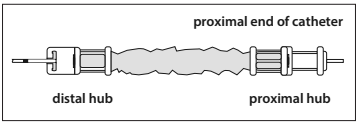

Figure 4

8. Slide entire catheter contamination shield to proximal end of catheter.
9. If flow directed catheter is used, inflate and deflate balloon with syringe to ensure integrity.

⚠ **Precaution: Do not exceed balloon catheter manufacturer's recommended volume.**

   Place catheter and catheter contamination shield on sterile field awaiting final placement.

10. Insert entire length of dilator through hemostasis valve into sheath pressing hub of dilator firmly into hub of hemostasis valve assembly. Place assembly on sterile field awaiting final sheath placement.

Gain Initial Venous Access:

Echogenic Needle (where provided):

An echogenic needle is used to allow access to the vascular system for the introduction of a guidewire to facilitate catheter placement. The needle tip is enhanced for approximately 1 cm for clinician to identify exact needle tip location when puncturing the vessel under ultrasound.

Protected Needle/Safety Needle (where provided):

A protected needle/safety needle should be used in accordance with manufacturer's instructions for use.

Arrow® Raulerson Syringe (where provided):

Arrow Raulerson Syringe is used in conjunction with Arrow Advancer for guidewire insertion.

11. Insert introducer needle or catheter/needle with attached syringe or Arrow Raulerson Syringe (where provided) into vein and aspirate.

⚠ **Warning: Do not leave open needles or uncapped, unclamped devices in central venous puncture site. Air embolism can occur if air is allowed to enter a central venous access device or vein.**

⚠ **Precaution: Do not reinsert needle into introducer catheter (where provided) to reduce risk of catheter embolus.**

Verify Venous Access:

Utilize one of the following techniques to verify venous access because of the potential for inadvertent arterial placement:

- Central Venous Waveform:
  - Insert fluid primed blunt tip pressure transduction probe into rear of plunger and through valves of Arrow Raulerson Syringe and observe for central venous pressure waveform.
    - ◊ Remove transduction probe if using Arrow Raulerson Syringe.
- Pulsatile Flow (if hemodynamic monitoring equipment is not available):
  - Use transduction probe to open syringe valving system of Arrow Raulerson Syringe and observe for pulsatile flow.
  - Disconnect syringe from needle and observe for pulsatile flow.

⚠ **Warning: Pulsatile flow is usually an indicator of inadvertent arterial puncture.**

⚠ **Precaution: Do not rely on blood aspirate color to indicate venous access.**

Insert Guidewire:

Guidewire:

Kits/Sets are available with a variety of guidewires. Guidewires are provided in different diameters, lengths and tip configurations for specific insertion techniques. Become familiar with the guidewire(s) to be used with the specific technique before beginning the actual insertion procedure.

Arrow Advancer (where provided):

Arrow Advancer is used to straighten "J" Tip of guidewire for introduction of the guidewire into Arrow Raulerson Syringe or a needle.

- Using thumb, retract "J" (refer to Figure 5).

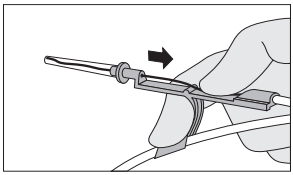

Figure 5

- Place tip of Arrow Advancer – with "J" retracted – into the hole in rear of Arrow Raulerson Syringe plunger or introducer needle.

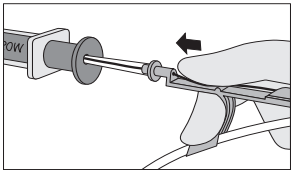

Figure 6

12. Straighten "J" tip of guidewire using straightening tube or Arrow Advancer as described. Advance guidewire into Arrow Raulerson Syringe approximately 10 cm until it passes through syringe valves or into introducer needle (or catheter).
    - Advancement of guidewire may require a gentle twisting motion.
    - If using Arrow Advancer, raise thumb and pull Arrow Advancer approximately 4 - 8 cm away from Arrow Raulerson Syringe or introducer needle. Lower thumb onto Arrow Advancer and while maintaining a firm grip on guidewire, push assembly into syringe barrel to further advance guidewire (refer to Figure 6). Continue until guidewire reaches desired depth.
13. Use centimeter markings (where provided) on guidewire as a reference to assist in determining how much guidewire has been inserted.

NOTE: When guidewire is used in conjunction with Arrow Raulerson Syringe (fully aspirated) and a 2-1/2" (6.35 cm) introducer needle, the following positioning references can be made:

- ***20 cm mark (two bands) entering back of plunger = guidewire tip at end of needle***
- ***32 cm mark (three bands) entering back of plunger = guidewire tip approximately 10 cm beyond end of needle***

⚠ **Precaution: Maintain firm grip on guidewire at all times. Keep sufficient guidewire length exposed for handling purposes. A non-controlled guidewire can lead to wire embolus.**

⚠ **Warning: Do not aspirate Arrow Raulerson Syringe while guidewire is in place; air may enter syringe through rear valve.**

⚠ **Precaution: Do not reinfuse blood to reduce risk of blood leakage from rear (cap) of syringe.**

⚠ **Warning: Do not withdraw guidewire against needle bevel to reduce risk of possible severing or damaging of guidewire.**

14. Remove introducer needle and Arrow Raulerson Syringe (or catheter) while holding guidewire in place.
15. Use centimeter markings on guidewire to adjust indwelling length according to desired depth of indwelling device placement.
16. Enlarge cutaneous puncture site with cutting edge of scalpel positioned away from the guidewire.

⚠ **Warning: Do not cut guidewire to alter length.**

⚠ **Warning: Do not cut guidewire with scalpel.**

- **Position cutting edge of scalpel away from guidewire.**
- **Engage safety and/or locking feature of scalpel (where provided) when not in use to reduce the risk of sharps injury.**

17. Use tissue dilator to enlarge tissue tract to the vein as required. Follow the angle of the guidewire slowly through the skin.

⚠ **Warning: Do not leave tissue dilator in place as an indwelling catheter. Leaving tissue dilator in place puts patient at risk for possible vessel wall perforation.**

Advance Device:

18. Thread tapered tip of dilator/sheath/valve assembly over guidewire. Sufficient guidewire length must remain exposed at hub end of device to maintain a firm grip on guidewire.
19. Grasping near skin, advance assembly with slight twisting motion to a depth sufficient to enter vessel. Dilator may be partially withdrawn to facilitate advancement of sheath through tortuous vessel.

⚠ **Precaution: Do not withdraw dilator until the sheath is well within the vessel to reduce the risk of damage to sheath tip.**

20. Advance sheath assembly off dilator into vessel, again grasping near skin and using slight twisting motion.
21. To check for proper sheath placement within the vessel, remove side port end cap and attach syringe for aspiration. Hold sheath assembly in place and withdraw guidewire and dilator sufficiently to allow venous blood flow to be aspirated into side port.

⚠ **Precaution: Maintain firm grip on guidewire at all times**

22. Holding sheath assembly in place, remove guidewire and dilator as a unit. Place sterile-gloved finger over hemostasis valve.

⚠ **Warning: To reduce the risk of possible vessel wall perforation, do not leave dilator in place as an indwelling catheter.**

⚠ **Warning: Although the incidence of guidewire failure is extremely low, practitioner should be aware of the potential for breakage if undue force is applied to the wire.**

Flush and connect side port to appropriate line as necessary.

23. Feed catheter through sheath assembly into vessel. Advance catheter to desired position.

⚠ **Warning: Hemostasis valve must be occluded at all times to reduce the risk of air embolism, contamination or hemorrhage. In the absence of an indwelling central catheter use the Arrow obturator to occlude hemostasis valve.**

24. Hold catheter in place and reposition catheter contamination shield so that distal hub is approximately five inches (12.7 cm) from hemostasis valve.
25. Hold proximal hub of catheter contamination shield in place. Disengage distal hub from inner feed tube by pulling forward. Advance distal hub forward toward hemostasis valve assembly. Hold assembly in place.
26. Press distal hub of catheter contamination shield over assembly cap. Twist to lock (refer to Figure 7).

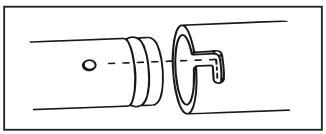

Figure 7

- Orient slot in hub with locking pin on assembly cap.
- Slide hub forward over cap and twist.

27. While maintaining catheter position lock the catheter in place:

    a. If using a catheter contamination shield with a Tuohy-Borst adapter, grasp catheter through front portion of catheter contamination shield and hold in place while repositioning Tuohy-Borst adapter end as desired.

⚠ **Precaution: Do not reposition Tuohy-Borst adapter end on insertion catheter once moved to this final position.**

- Tighten Tuohy-Borst adapter by pressing down on cap and simultaneously turning clockwise to secure hub to catheter. Gently pull catheter to verify securement.

⚠ **Precaution: Do not overtighten Tuohy-Borst adapter to reduce the risk of lumen constriction or insertion catheter damage.**

- Tuohy-Borst adapter end of catheter contamination shield should be secured with sterile tape to inhibit catheter movement (refer to Figure 8).

⚠ **Precaution: Do not apply tape to the transparent sheathing on the shield to reduce the risk of tearing material.**

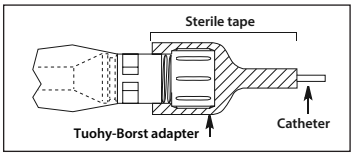

Figure 8

b. If using a catheter contamination shield with a TwistLock adapter, twist the upper half of the distal hub in clockwise direction to lock catheter in place. Reposition proximal end of catheter shield as desired. Twist upper and lower halves in opposite directions to lock in place. Test the adapter by gently tugging on the catheter to ensure a secure grip on the catheter (refer to Figure 9).

⚠ **Precaution: Do not reposition proximal hub once locked in final position.**

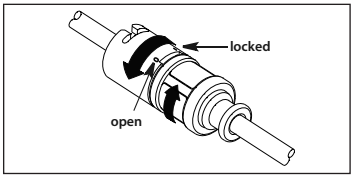

Figure 9

Secure Device:

28. Use suture tab to secure sheath and/or anchor with a purse string suture around the sheath suture ring.

⚠ **Precaution: Do not secure directly to the outside diameter of the sheath to reduce the risk of cutting or damaging the sheath or impeding flow.**

29. Ensure insertion site is dry before applying dressing per manufacturer's instructions.

⚠ **Precaution: Maintain the insertion site with regular, meticulous redressing using aseptic technique.**

30. Document procedure per institutional policies and procedures.

Care and Maintenance:

Dressing:

Dress according to institutional policies, procedures, and practice guidelines. Change immediately if the integrity becomes compromised e.g. dressing becomes damp, soiled, loosened or no longer occlusive.

Catheter Patency:

Maintain device patency according to institutional policies, procedures and practice guidelines. All personnel who care for patients with central venous devices must be knowledgeable about effective management to prolong device's dwell time and prevent injury.

Catheter Removal from Sheath Procedure:

1. Position patient as clinically indicated to reduce risk of potential air embolus.
2. Unlock catheter contamination shield from sheath and withdraw catheter from sheath. Temporarily cover valve opening with sterile-gloved finger until obturator is inserted. Apply obturator cap.

⚠ **Warning: Hemostasis valve must be occluded at all times to reduce the risk of air embolism, contamination or hemorrhage**

Sheath Removal Procedure:

1. Position patient as clinically indicated to reduce risk of potential air embolus.
2. Remove dressing.

⚠ **Precaution: To reduce the risk of cutting device, do not use scissors to remove dressing.**

3. Remove securement from device, if applicable.

⚠ **Precaution: Be careful not to cut the device.**

4. Ask patient to take a breath and hold it if removing jugular or subclavian insertion.
5. Remove device (and catheter, if applicable) slowly, pulling it parallel to the skin.
6. Apply direct pressure to site until hemostasis is achieved followed by an ointment based occlusive dressing.

⚠ **Warning: Residual catheter track remains an air entry point until site is epithelialized. Occlusive dressing should remain in place for at least 24 hours or until site appears epithelialized.**

7. Document removal procedure including confirmation that entire device has been removed per institutional policies and procedures.

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	Store below 25°C (77°F). Avoid excessive heat above 40°C (104°F)	Catalogue number	Lot number	Use by
								
Manufacturer	Date of manufacture	Electronic instructions for use	Unique device identifier					

"Rx only" is used within this labeling to communicate the following statement as presented in the FDA CFR: Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

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