

ARROW

Percutaneous Sheath Introducer Product with ARROW^gard™ Antimicrobial Surface

Safety and Efficacy Considerations:

The product is designed for single use only. Do not resterilize or reuse. Do not alter the sheath or any other kit/set component during insertion, use, or removal.

Procedure must be performed by trained personnel well versed in anatomical landmarks, safe technique and potential complications.

Warning: Prior to use read all package insert warnings, precautions and instructions. Failure to do so may result in severe patient injury.

ARROW^gard™ 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 ARROW^gard™ 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*²²
- 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*²².
- Antimicrobial activity on the surface of the ARROW^gard™ catheter during handling and placement has been demonstrated *in situ* in limited animal studies.
- The ARROW^gard™ 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)²⁰.
- 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 rats²².
- 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 \pm SD, 1.7 \pm 2.8 mm); in contrast, antimicrobial catheters uniformly showed residual surface activity (mean zone of inhibition, 5.4 \pm 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 days²⁰.
- Arrow antimicrobial catheters produced large zones on 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*¹¹.

- Antibacterial activity was retained against *Staphylococcus epidermidis* (10^6 bacterial concentration) from subcutaneous segments of ARROW^gardTM 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 hours³.

If the total amount of silver sulfadiazine and chlorhexidine contained in the antimicrobial surface 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 sensitivity⁹. However, hypersensitive reactions to chlorhexidine have been reported (May 1996) in Japanese patients (data on file, Arrow International, Inc.).

Indications for Use:

The ARROW^gardTM percutaneous sheath introducer permits venous access and catheter introduction to the central circulation.

The ARROW^gardTM 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 is it indicated for long-term use.

Contraindications:

The ARROW^gardTM antimicrobial sheath introducer is contraindicated for patients with known hypersensitivity to chlorhexidine, silver sulfadiazine, and/or sulfa drugs. The ARROW^gardTM antimicrobial surface has been reported to cause hypersensitive reactions in Japanese patients.

The literature indicates that individuals of Japanese extraction are known to have had immediate hypersensitive reactions following topical chlorhexidine administration^{10,13,17,18,24,25,29,31}. If adverse reactions occur after sheath placement, remove immediately.

Special Patient Populations:

Since controlled studies of the antimicrobial surface in pregnant women²³ and patients with known sulfonamide hypersensitivity such as erythema multiforme and Stevens-Johnson syndrome⁹ have not been conducted, benefits of this antimicrobial surface should be weighed against any possible risk.

Warnings and Precautions:*

1. **Warning: Practitioners must be aware of complications associated with percutaneous sheath introduction including vessel wall perforation²⁸, pleural and mediastinal injuries^{1,19}, air embolism^{6,12,16,21}, sheath embolism, thoracic duct laceration², bacteremia, septicemia, thrombosis⁴, inadvertent arterial puncture⁷, nerve damage, hematoma formation, hemorrhage⁵, and dysrhythmias.**
2. **Warning: Do not apply excessive force in removing guide wire, dilator or sheath. If withdrawal cannot be easily accomplished, a chest x-ray should be obtained and further consultation requested.**
3. **Warning: The practitioner must be aware of potential air embolism problems associated with leaving open needles, sheaths, or catheters in venous puncture sites or as a consequence of inadvertent disconnects. To lessen the risk of disconnects, only securely tightened Luer-Lock connections should be used with this device. Follow hospital protocol for all sheath and side port maintenance to guard against air embolism.**
4. **Warning: Hemostasis valve must be occluded at all times to minimize the risk of air embolism or hemorrhage. If catheter introduction is delayed, or catheter is removed, temporarily cover valve opening with sterile-gloved finger until catheter or obturator is inserted. Use Arrow obturator,**

either included with this product or sold separately, as dummy catheter with hemostasis valve/side port assembly and sheath. This will ensure that leakage does not occur and inner seal is protected from contamination²¹.

5. **Warning:** Care should be exercised in passing spring-wire guide. Use of excessive length of the guide wire into the right heart can cause dysrhythmias, right bundle branch block⁸, and vessel wall, atrial or ventricular perforation.
6. **Warning:** Due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens, health care workers should routinely use universal blood and body-fluid precautions in the care of all patients.
7. **Precaution:** Do not suture directly to the outside diameter of the sheath to minimize the risk of cutting or damaging the sheath or impeding sheath flow.
8. **Precaution:** Indwelling sheaths should be routinely inspected for desired flow rate, security of dressing, correct position and for proper Luer-Lock connection.
9. **Precaution:** Maintain the insertion site with regular meticulous redressing using aseptic technique.
10. **Precaution:** Alcohol and acetone can weaken the structure of polyurethane material. Therefore, care should be taken when instilling drugs containing alcohol or when using high concentration of alcohol or acetone when performing routine insertion site care and maintenance. Alcohol should not be utilized to de clot polyurethane sheaths.
11. **Precaution:** Do not inflate balloon of flow-directed catheter prior to insertion through catheter contamination shield to minimize the risk of balloon damage.

Carefully read all warnings and precautions throughout procedure instructions.

**A Suggested Procedure:
Use sterile technique.**

1. **Precaution:** Place patient in slight Trendelenburg position as tolerated to reduce the

risk of air embolism. If femoral approach is used, place patient in supine position.

2. Prep area of anticipated venipuncture.
3. Drape puncture site as required.
4. Perform skin wheal using desired needle. In kits where provided, a SharpsAway[®] disposal cup is used for the disposal of needles. Push needles into foam after use. Discard entire cup at completion of procedure. **Precaution: Do not reuse needles after they have been placed into the disposal cup. Particulate matter may adhere to needle tip.**
5. Insert tip of desired catheter through rubber seal end of catheter contamination shield. Advance catheter through tubing and hub at other end.

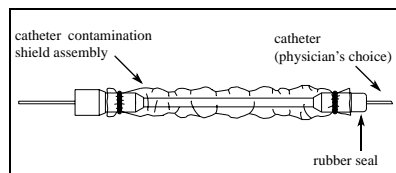


Fig. 1

6. Slide entire catheter contamination shield to proximal end of catheter.
7. 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 sheath placement.
8. Insert entire length of dilator through hemostasis valve into sheath pressing hub of dilator firmly into hub of hemostasis valve/side port assembly. Place assembly on sterile field awaiting final sheath placement.
9. In kits where provided, use a 22 Ga. needle and syringe to locate central vein.
10. Insert introducer catheter/needle assembly with attached syringe into vein beside locator needle and aspirate. Remove locator needle. Withdraw needle and attached syringe from introducer catheter. If no free flow of venous blood is observed after needle is removed, attach syringe to the catheter and aspirate until good

venous blood flow is established. **Precaution:** The color of the blood aspirated is not always a reliable indicator of venous access¹⁴. Do not reinsert needle into introducer catheter.

Alternate Technique:

Introducer needle may be used in the standard manner as alternative to catheter/needle assembly.

11. Because of the potential for inadvertent arterial placement, verify venous access via a wave form obtained by a calibrated pressure transducer (refer to Fig. 2).

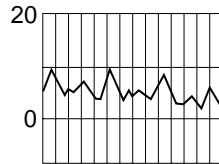


Fig. 2

If a pressure transducer is not available, check for pulsatile flow. Pulsatile flow is usually an indicator of inadvertent arterial puncture.

12. Insert desired tip of spring-wire guide through the introducer needle or catheter into vein. If the "J" tip is used, prepare for insertion by sliding the plastic tube over the "J" to straighten. Advance the spring-wire guide in the routine fashion to the desired depth. Advancement of "J" tip may require a gentle rotating motion. **Warning: Do not cut spring-wire guide to alter length. Do not withdraw spring-wire guide against needle bevel to minimize the risk of possible severing or damaging of spring-wire guide.**
13. Hold spring-wire guide in place and remove introducer needle or catheter. **Precaution: Maintain firm grip on spring-wire guide at all times.**
14. Enlarge cutaneous puncture site with cutting edge of scalpel positioned away from the spring-wire guide. **Precaution: Do not cut guide wire.**
15. Thread tapered tip of dilator/sheath/valve assembly over spring-wire guide. 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 minimize the risk of damage to sheath tip.**
16. Advance sheath/valve assembly off dilator into vessel, again grasping near skin and using slight twisting motion.
17. To check for proper sheath placement within the vessel, remove side port end cap and attach syringe for aspiration. Hold sheath/valve assembly in place and withdraw spring-wire guide and dilator sufficiently to allow venous blood flow to be aspirated into side port. **Precaution: Maintain firm grip on spring-wire guide at all times.**
18. Holding sheath/valve assembly in place, remove guide wire and dilator as a unit. Place sterile-gloved finger over hemostasis valve. **Warning: To minimize the risk of possible vessel wall perforation do not leave vessel dilator in place as an indwelling catheter. Warning: Although the incidence of spring-wire guide 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.
19. Feed catheter through sheath/valve assembly into vessel. Advance catheter to desired position. **Warning: Hemostasis valve must be occluded at all times to minimize the risk of air embolism or hemorrhage. If catheter introduction is delayed, temporarily cover valve opening with sterile-gloved finger until obturator is inserted. Use Arrow obturator, either included with this product or sold separately, as dummy catheter with hemostasis valve/side port assembly and sheath. This will ensure that leakage does not occur and inner seal is protected from contamination²¹.**
20. Hold catheter in place and reposition catheter contamination shield so that distal hub is approximately five inches (12.7 cm) from

hemostasis valve/side port assembly (refer to Fig. 3).

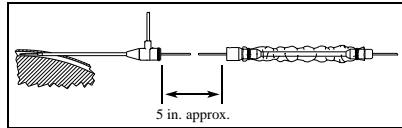


Fig. 3

21. Hold rear hub (seal end) of catheter contamination shield in place. Disengage distal hub from inner feed tube by pulling forward. Advance distal hub forward toward hemostasis valve/side port assembly. Hold assembly in place (refer to Fig. 4).

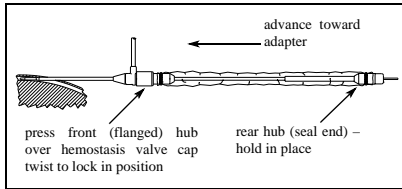


Fig. 4

22. Press distal hub of catheter contamination shield over assembly cap. Twist to lock (refer to Fig. 5).

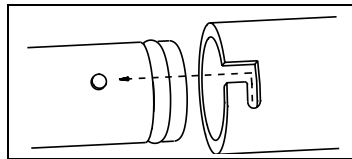


Fig. 5

- Orient slot in hub with locking pin on assembly cap.
 - Slide hub forward over cap and twist.
23. Grasp catheter through front portion of catheter contamination shield and hold in place while repositioning rubber seal end as desired (refer to Fig. 6). **Precaution: Do not reposition rubber seal end once moved into final position.**

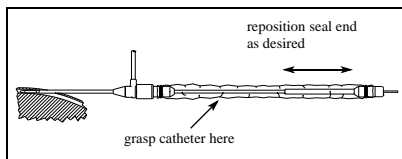


Fig. 6

24. Rubber seal end of catheter contamination shield should be secured with sterile tape to inhibit catheter movement (refer to Fig. 7). **Precaution: Do not apply tape to the transparent sheathing between the O-rings to minimize the risk of tearing material.**

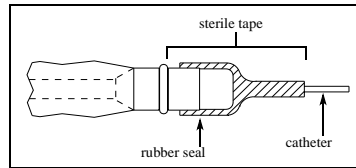


Fig. 7

25. Use suture tab to secure sheath and/or anchor with a purse string suture around the sheath suture ring. **Precaution: Do not suture directly to the outside diameter of the sheath to minimize the risk of cutting or damaging the sheath or impeding flow.**
26. Dress puncture site per hospital protocol. **Precaution: Maintain the insertion site with regular, meticulous redressing using aseptic technique.**
27. Record the insertion procedure on the patient's chart.

Catheter Removal Procedure:

1. **Precaution: Place the patient in a supine position.**
2. Remove dressing, if applicable. **Precaution: To minimize the risk of cutting the sheath, do not use scissors to remove the dressing.**
3. Withdraw catheter from sheath. **Warning: Hemostasis valve must be occluded at all times to minimize the risk of air embolism or hemorrhage.** Temporarily cover valve opening with sterile-gloved finger until catheter or obturator is inserted.

Sheath Removal Procedure:

1. **Precaution: Place the patient in a supine position.**
2. Remove dressing, if applicable. **Precaution: To minimize the risk of cutting the sheath, do not use scissors to remove the dressing.**
3. If applicable, remove sutures from sheath. **Precaution: Be careful not to cut the sheath.**

4. Withdraw device from sheath. Cover hemostasis valve with sterile-gloved finger. **Warning: Hemostasis valve must be occluded at all times to minimize the risk of air embolism or hemorrhage.**
5. **Warning: Exposure of the central vein to atmospheric pressure may result in entry of air into the central venous system.** Remove sheath slowly, pulling it parallel to the skin. As sheath exits the site, apply pressure with a dressing impermeable to air, e.g. vaseline gauze. Because the residual sheath track remains an air entry point until completely sealed, the occlusive dressing should remain in place for at least 24-72 hours dependent upon the amount of time the sheath was indwelling^{15,26,27,30}.
6. Upon removal of the sheath, inspect it to make sure that the entire length has been withdrawn.
7. Verify that the sheath was intact upon removal.
8. Document removal procedure.

References:

1. Albertson TE, Fisher CJ, Vera Z. Accidental mediastinal entry via left internal jugular vein cannulation. *Intensive Care Med.* 1985;11:154-157.
2. Arditis J, Giala M, Anagnostidou A. Accidental puncture of the right lymphatic duct during pulmonary artery catheterization. *Acta Anaesthesiol Scand.* 1988;32:67-68.
3. Bach A, Achmidt H, Bottinger B, et al. Retention of antibacterial activity and bacterial colonization of antiseptic-bonded central venous catheters. *J Antimicrobial Chemotherapy.* 1996;37:315-322.
4. Benumof JL. Thrombosis after pulmonary-artery catheterization via the internal jugular vein. *NEJM.* 1982;306:1487. Letter.
5. Benya RV. Fibrin sheath formation surrounding a pulmonary artery catheter sheath: eversion of the sleeve during catheter removal. *Crit Care Med.* 1990;18:345. Letter.
6. Bristow A, Batjer H, Chow V, Rosenstein J. Air embolism via a pulmonary artery catheter introducer. *Anesthesiology.* 1985;63:340-341. Letter.
7. Brzowski BK, Mills JL, Beckett WC. Iatrogenic subclavian artery pseudoaneurysms: case reports. *J Trauma.* 1990;30:616-618.
8. Eissa NT, Kvetan V. Guide wire as a cause of complete heart block in patients with preexisting left bundle branch block. *Anesthesiology.* 1990;73:772-774.
9. Farber T. ARROW^gardTM antiseptic surface - toxicology review. Monograph. Published by Arrow International, Inc. April 1992.
10. Fukui A, Ohsumi A, Takaori M. A case of anaphylactic shock induced by chlorhexidine gluconate. *J Japan Society for Clin Anesthesia.* 1989;9:356-360.
11. Greenfeld JI, Sampath L, Popilskis SJ, Brunner SR, Stylianos S, Modak S. Decreased bacterial adherence and biofilm formation on chlorhexidine and silver sulfadiazine-impregnated central venous catheters implanted in swine. *Crit Care Med.* 1995;23:894-900.
12. Hartung EJ, Ender J, Sgouropoulou S, Bierl R, Engelhardt W, Engemann R. Severe air embolism caused by a pulmonary artery introducer sheath. *Anesthesiology.* 1994;80:1402. Letter.
13. Harukuni I, Ishizawa Y, Nishikawa T, Takeshima R, Dohi S, Naito H. Anaphylactic shock with ventricular fibrillation induced by chlorhexidine. *Japanese J of Anesthesiology.* 1992;41:455-459.
14. Jobs DR, Schwartz AJ, Greenhow DE, Stephenson LW, Ellison N. Safer jugular vein cannulation: recognition of arterial punctures and preferential use of the external jugular route. *Anesthesiology.* 1983;59:353-355.
15. Kashuk JL, Penn I. Air embolism after central venous catheterization. *Surg Gynecol Obstet.* September 1984;159:249-252.
16. Kondo K, O'Reily LP, Chiota J. Air embolism associated with an introducer for pulmonary arterial catheters. *Anesth Analg.* 1984;63:871-872.
17. Kubo H, Akiyama Y, Honda K, Nakajo N. Anaphylaxis following oral irrigation with chlorhexidine gluconate. *J Japanese Dental Society of Anesthesiology.* 1985;13:659-663.
18. Layton GT, Stanworth DR, Amos HE. The incidence of IgE and IgG antibodies to chlo-

- rhexidine. *Clinical and Experimental Allergy*. 1989;19:307-314.
19. Macksood MJ, Setter M. Hydrothorax and hydromediastinum after use of an indwelling percutaneous catheter introducer. *Crit Care Med*. 1983;11:957-958.
20. Maki DG, Wheeler SJ, Stolz SM, Mermel LA. Prevention of central venous catheter-related bloodstream infection by use of an antiseptic-impregnated catheter. *Ann Int Med*. August 15, 1997;127:257-266.
21. Mihm FG, Rosenthal MH. Pulmonary artery catheterization. In: Benumof JL, ed. *Clinical Procedures in Anesthesia and Intensive Care*. Philadelphia, PA: JB Lippincott; 1992. p. 419.
22. Modak SM, Sampath L. Development and evaluation of a new polyurethane central venous antiseptic catheter: reducing central venous catheter infections. *Infections in Medicine*. June 1992;23-29.
23. Modak SM. (Written communication, June 1991).
24. Okano M, Nomura M, Hata S, et al. Anaphylactic symptoms due to chlorhexidine gluconate. *Arch Dermatol*. 1989;125:50-52.
25. Okano M, Nomura M, Okada N, Sato K, Tashiro M. Four cases presenting anaphylactic reactions due to topical application of Hibitane[®]. *Skin Research*. 1983;25:587-592.
26. Paskin DL, Hoffman WS, Tuddenham WJ. A new complication of subclavian vein catheterization. *Ann Surg*. March 1974;179:266-268.
27. Phifer TJ, Bridges M, Conrad SA. The residual central venous catheter track – an occult source of lethal air embolism: case report. *J Trauma*. 1991;31:1558-1560.
28. Roy RC. Possible hazards from catheter sheath introducers. *Crit Care Med*. 1984;12:616. Letter.
29. Takeda K, Inoue K, Matsuya T, et al. An allergic shock possibly induced by the chlorhexidine: report of a case. *J Osaka Univ Dent Soc*. 1985;30:221-225.
30. Thielen JB, Nyquist J. Subclavian catheter removal. *J Intravenous Nurs*. March/April 1991;14:114-118.
31. Tsuneto S, Watanabe A., Koyama K, Nakayama K, Saito H, Saito K. Anaphylax shock induced by chlorhexidine mixed in the vial of lidocaine. *Japan Society Clin Anesthesia*. 1987;7:272-277.
- Arrow International, Inc. recommends that the user be acquainted with the reference literature.
- *If you have any questions or would like additional reference information, please contact Arrow International, Inc.



K-09804-107A (8/97)

ARROW

INTERNATIONAL

2400 Bernville Road

Reading, PA 19605

1-800-523-8446

1-610-378-0131

8 a.m. - 8 p.m. EST

