ARROW®

NEVER SETTLE™

ARROW® Polysite® Pressure Injectable Low Profile Hybrid* Ports

***Lightweight Plastic Body with a Strong Titanium Reservoir**

Indications

- Polysite PI Implantable Infusion Ports are indicated for long-term access to the central venous system and allow for repeated vascular access.
- Polysite PI Implantable Infusion Ports can be used to administer chemotherapy, antibiotics and antiviral drugs, as well as for parenteral nutrition, collection of blood samples and transfusion of blood or blood products.
- Polysite PI Implantable Infusion Ports also can be used for high pressure injection of contrast media during diagnostic studies. The maximum flow rate of power injector equipment used with the pressure injectable port may not exceed 5 mL/sec (300 psi).
- For high pressure injection of contrast media, a high pressure non-coring needle must be used to access the Polysite PI Implanted Port. The manufacturer recommends the use of a PPS PI (Pressure Injectable) Safety Non-Coring Huber Needle.

1 Identification of an ARROW® Polysite® PI Implantable Infusion Port

Always verify the patient has an ARROW Polysite PI Implantable Infusion Port before injecting and ensure it is accessed with a non-coring power injectable infusion set.

The ARROW Polysite PI Implantable Infusion Port can be distinguished from traditional ports through the following means:

- Check patient's chart for Polysite PI Implantable Infusion Port patient record sticker or notation in the patient's chart.
- Using CT Scan, fluoroscopy or chest X-ray, visualize the unique ARROW Polysite PI Implantable Infusion Port Power injectable symbol on the port.
- Request confirmation from the patient by asking them to show you the patient identification card they received when the port was implanted.

AVAILABLE IN 6 Fr. MICRO, 7 Fr. MINI AND 8 Fr. STANDARD SIZES
Not shown at actual size

2 Pressure Injection Instructions

WARNING: Read all package insert warnings, precautions and instructions prior to use. Failure to do so may result in severe patient injury or death. Clinical assessment of patient must be completed to ensure no contraindications exist.

Use sterile technique.

1. Identify the Polysite PI Implantable Port. Ensure that the patient has a Polysite PI Implantable Port. The patient should have a Polysite PI Infusion Port Patient Identification Card, Polysite PI Infusion Port Patient Information Guide or you may be required to identify the Polysite PI Infusion Port using CT Scan, fluoroscopy or chest X-ray. See specific radiopaque identifier as described below.

NOTE: The completed patient identification card should be given to the patient, who should be instructed to carry it at all times.

WARNING: Obtain a visual image to confirm catheter tip position prior to each pressure injection.

NOTE: Lack of port maintenance can lead to occlusion of catheter.

2. Always use high pressure non-coring needles, such as PPS PI™ Safety Huber Needles, which are adapted for use with the Polysite PI Implantable Port System.

CAUTION: Conventional hypodermic needles should not be used, as they can alter the integrity of the septum.

WARNING: Do not reuse high pressure non-coring needles or PPS PI Safety Huber Needles. Deformation of the bevel of the needle can tear or damage the septum of the port. Only use large gauge, high pressure non-coring needles for blood transfusions (19 Ga.) and parenteral nutrition (20 Ga.)

3. Check for port/catheter patency:
   - Attach 10-20 mL syringe filled with sterile normal saline.
   - Aspirate port for adequate blood return.
   - Vigorously flush port.

WARNING: Ensure patency of port prior to pressure injection to reduce the risk of port or catheter failure and/or patient complications.

4. Detach syringe.
5. Attach pressure injection administration set tubing to appropriate PPS PI Safety Huber Needle or other high pressure non-coring needle.

CAUTION: To reduce the risk of port failure and/or catheter tip displacement, do not exceed catheter's maximum recommended flow rate.

6. Position the patient, when possible, with arms vertically above his or her shoulders with palms on the face of the gantry during injection. This position should allow for uninterrupted passage of the injected contrast media through the axillary and subclavian veins.
7. Set the maximum injection machine pressure to 300 psi or the maximum flow rate as seen in table below in order to guarantee the reliability of the system.

Gauge size	22 Ga.	20 Ga.	19 Ga.
Gauge color	Black	Yellow	Cream
Flow rate setting	2 mL/s	5 mL/s	5 mL/s

NOTE: High pressure injection machine pressure limiting settings (safety cut-off) may not prevent over-pressurization of an occluded device.

8. Inject contrast media in accordance with hospital protocol.

CAUTION: Warm contrast media to body temperature prior to pressure injection to minimize the risk of catheter failure.

WARNING: Never inject contrast medium with a viscosity greater than 11.8 CP. Failure to follow these recommendations risks causing failure of the system through excess pressure or obstruction.

9. Instruct the patient to communicate immediately any pain or change in feeling during injection.
10. Disconnect pressure tubing from pressure injector equipment.
11. Attach syringe and flush port using 10-20 mL syringe filled with sterile normal saline.
12. While flushing, remove the non-coring needle by maintaining positive pressure (remove the needle while flushing with heparinized saline simultaneously) to avoid reflux of blood inside the catheter.
13. Discard needle appropriately.
14. Document procedure.

3 Use and Maintenance

Use and maintenance of port/catheter must be done in accordance with hospital/institutional policies, procedures and practice guidelines. All personnel who care for patients with ports must be knowledgeable about effective management to prolong port/catheter dwell time and prevent complications.

Polysite PI series	PART NUMBERS	PORT MATERIAL	CATHETER MATERIAL	CATHETER SIZE (FRENCH)	RESERVOIR VOLUME	CATHETER VOLUMES*
6 Fr. Micro Port	2016 PI 2016 SPI	Titanium/Polyoxymethylene	Polyurethane	6 Fr.	0.2 mL	0.13 mL
7 Fr. Mini Port	3017 PI 3017 SPI	Titanium/Polyoxymethylene	Polyurethane	7 Fr.	0.35 mL	0.17 mL
8 Fr. Standard Port	4018 PI 4018 SPI	Titanium/Polyoxymethylene	Polyurethane	8 Fr.	0.55 mL	0.23 mL

*Volume/10 cm

Determining Port System Volumes for Port Lock Procedures:

To calculate a close approximation of port system volume, you will need to determine the length of the catheter used for each individual patient. (For future reference, it will be helpful to record this information on the patient's chart and/or patient ID card).

Polysite PI Volume = Catheter length:
__ cm x catheter volume/cm + Reservoir volume

General recommendations:

1. Inspect injection site before use.
2. Locate the port by palpation.
3. Observing aseptic technique, prepare injection site for access.
4. Flush the non-coring needle using syringe filled with sterile normal saline.
5. Insert the needle perpendicularly to the skin and advance as far as the base of the port.
6. Check the patency of the device and correct positioning of the needle by obtaining blood reflux via aspiration and by injection of physiological saline without observing resistance to flushing and local extravasation. Resistance to flushing may indicate partial or complete catheter occlusion.

   WARNING: Never try to unblock the device by pressure and never use a syringe smaller than 10 mL to avoid applying excessive pressure within the device. Excessive pressures can damage the catheter or lead to the port disconnection.

   WARNING: Stop injection at the slightest sign of extravasation; follow extravasation protocol.

   CAUTION: Defer chemotherapy when in doubt about the integrity of the port/catheter and further assess its functioning with injections of contrast media and X-ray.

7. Inject or infuse the drug/solution or take the blood sample (before blood sampling, discard appropriate amount in accordance with hospital/institutional policies, procedures, and practice guidelines).
   - Solution and frequency of flushing a venous access port/catheter should be established in hospital/institutional policy.
   - Port/catheter patency is established and maintained by flushing intermittently via syringe with heparinized saline or preservative–free 0.9% sodium chloride.
   - The amount of heparin (proper concentration and volume) should be based on:
     - physician preference
     - hospital/institutional protocol
     - patient's medical condition
     - patient's age
     - laboratory tests

NOTE: Concentrations of heparinized saline (10 to 1000 IU/mL) have been found to be effective.

CAUTION: For children less than two years in age: A maximum concentration of 100 IU/mL sterile heparinized saline should be used.

CAUTION: Assess patient for heparin sensitivity. Heparin-induced thrombocytopenia (HIT) has been reported with use of heparin flush solutions.

NOTE: If the port catheter length is unknown, the following are recommended flushing volumes; (otherwise follow hospital/institutional policies, procedures and practice guidelines.)

FLUSHING VOLUMES	
PROCEDURE	VOLUME (100 U/mL)
When port is not in use	5 mL flush solution every 4 weeks
After each infusion of medication or TPN	10 mL sterile normal saline then (5 mL heparinized saline if using heparine protocol for flushing)
After blood withdrawal	20 mL sterile normal saline then (5 mL heparinized saline if using heparine protocol for flushing)
After high pressure injection of contrast media	10 mL sterile normal saline then (5 mL heparinized saline if using heparine protocol for flushing)

NOTE: Port/catheter priming volumes are printed on product packaging.

8. Flush the device with normal saline after each use.
   - If several medications/solutions must be administered, the SASH or SAS method of flushing will help eliminate occlusions due to incompatible solutions:

   1. Saline 2. Administer drug 3. Saline 4. Heparin (if used)
9. After taking blood samples, flush in accordance with hospital/institutional policies, procedures and practice guidelines.
10. When removing the needle, maintain positive pressure to avoid reflux of blood inside the catheter.

Establishing a "Lock"

If the port remains unused for long periods of time, the "lock" should be changed at least once every four weeks.

Equipment:

- Non-coring needle with connecting line with clamp.
- 10 mL syringe filled with desired flush solution.

CAUTION: Perform hand hygiene:
- Before and immediately after all clinical procedures.
- Before donning and immediately after removal of gloves.

Explain procedure to patient and prepare injection site.

Procedural steps:

1. Aseptically locate and access port with a PPS PI Safety Huber Needle or other non-coring safety needle. Confirm correct positioning of the needle within the port reservoir by aspiration of blood ("flashback"). If there is doubt regarding proper needle placement, perform a radiographic dye procedure to confirm placement.
2. Attach a syringe filled with sterile normal saline or heparinized saline (as applicable) to needle.
3. Inject/infuse required therapy. After therapy is completed, flush the port/catheter in accordance with hospital/institutional policies, procedures and practice guidelines.

   CAUTION: Alcohol should not be used to soak or declot polyurethane catheters because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.
4. When de-accessing port, remove non-coring needle by maintaining positive pressure to avoid reflux of blood inside the catheter. This technique reduces reflux of blood inside the catheter, which decreases the potential for port/catheter occlusion.

   NOTE: Follow established hospital or institutional policy for changing I.V. tubing and accessing cannula.

Always read the instruction insert that accompanies your product.

Teleflex®

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