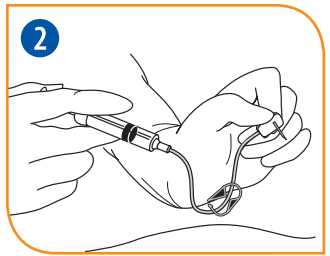
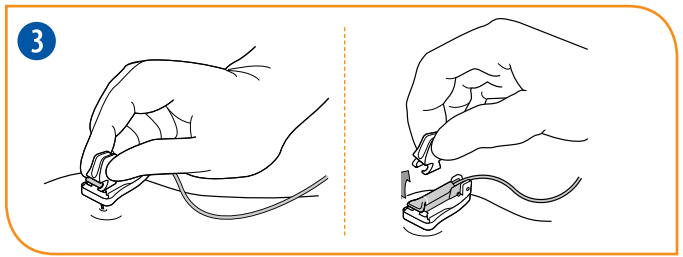
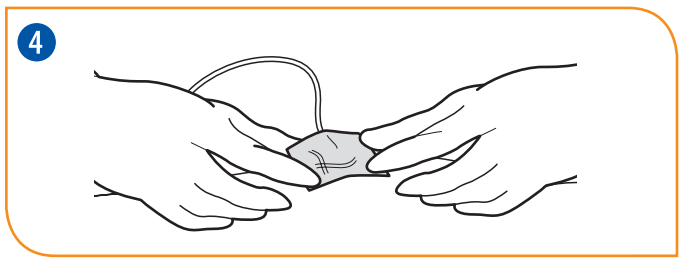
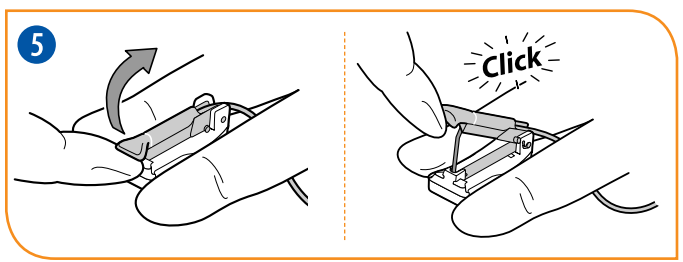








Additional *Instructions for Use* can be printed at
www.smiths-medical.com
U.S. Patent No. 4743231. Other patent(s) pending.

Made in Mexico for:

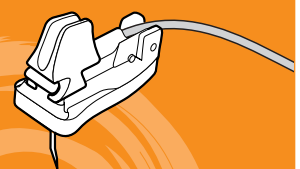
Smiths Medical MD, Inc.
St. Paul, MN 55112 U.S.A.
1 800.426.2448
www.smiths-medical.com

Rx ONLY	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician
REF	Catalog number
LOT	Batch Code
	Use by
LATEX	Latex Free
	Do Not Reuse
	ATTENTION! See instructions for use
TOTM	Tubing contains less than 0.2% DEHP
STERILE EO	Sterilized using ethylene oxide

Deltec

GRIPPER PLUS®
POWER P.A.C.

Instructions for Use



GRIPPER PLUS® POWER P.A.C.
Safety Huber Needle for Power Injection

2007-05
40-5595-01A

smiths medical

GRIPPER PLUS® POWER P.A.C. Safety Huber Needle

This product is indicated for the administration into or withdrawal of fluids from implanted ports. When used with the PORT-A-CATH® POWER P.A.C. implantable venous access system this product is indicated for power injecting contrast media. It is designed to help protect against exposure to bloodborne pathogens caused by accidental needlestick injuries. It does not protect against other routes of bloodborne pathogen transmission. It is recommended that this product be changed in accordance with U.S. Centers for Disease Control (CDC) guidelines for administration sets, local, or country specific guidelines, professional standards of practice, and/or according to your institution's policy. Do not use this product if it appears damaged or if the package has been previously opened or damaged. This product contains a nonvented cap.

WARNINGS:

- This is a single-use product. Tampering with or attempting to re-engage the needle could result in accidental needlestick with a contaminated needle.
- This product does not provide protection against leakage of contaminated fluids.
- Failure to use safety arm correctly (lift safety arm straight back to the lock position until it clicks) when removing needle from portal site could result in the needle tip re-emerging from the base, resulting in accidental needlestick with a contaminated needle. A needlestick with a contaminated needle may cause infectious disease.
- Verify needle length is correct for portal/patient; if too long, needle and/or portal may be damaged at insertion; if too short, needle may not completely pierce portal septum, and medication may be delivered into surrounding tissue and/or needle may be blocked.
- Ensure that there are no occlusions in the catheter prior to using the PORT-A-CATH® POWER P.A.C. for power injection. Failure to identify occlusions may result in catheter damage.
- Stop the injection immediately if local pain, swelling, or signs of extravasation are noted.
- Do not exceed the maximum pressure of 300 psi as this may result in PORT-A-CATH® POWER P.A.C. system failure and/or catheter tip displacement.
- Do not exceed the maximum flow rate as this may result in PORT-A-CATH® POWER P.A.C. system failure and/or catheter tip displacement.

CAUTIONS:

- Do not use needles or other sharps with the luer activated needleless injection site. Use only with administration sets or syringes which have luer connectors. Always use aseptic technique when connecting sets/syringes to the Y-site. Make sure the luer connector is securely attached.
- Follow standard infection control precautions as specified by the CDC (USA) or local equivalent.
- Do not power inject contrast media unless a PORT-A-CATH® POWER P.A.C. system has been verified using the patient identification card, key ring identification card, or implant record in the patient's medical record.

Use aseptic technique. Refer to the illustrations when preparing and using this device.

1. Prepare the portal site for sterile needle insertion ❶.
2. Flush the set ❷.
3. Remove the needle guard. Grasp the GRIPPER PLUS® POWER P.A.C. tab and insert the needle into the portal. **REMOVE THE** GRIPPER PLUS® POWER P.A.C. **TAB** ❸ **and discard it.**
4. Apply a semi-permeable dressing over the GRIPPER PLUS® POWER P.A.C. base, ensuring that a minimum 4 cm area surrounding the base is covered ❹.

When used for power injecting contrast media with the PORT-A-CATH® POWER P.A.C. system:

1. Verify the patient has an implanted PORT-A-CATH® POWER P.A.C. system using the patient identification card, key ring identification card, or implant record in the patient's medical record.
2. Access the PORT-A-CATH® POWER P.A.C. system using aseptic technique according to the instructions above.
3. Attach a 10 ml or larger syringe filled with normal saline.
4. Place the patient in the same position he or she will be in during the power injection.
5. Aspirate for adequate blood return and vigorously flush the system with the full 10 ml of sterile normal saline. Difficulty in withdrawing blood or injecting the saline may indicate catheter blockage or improper needle position.

   NOTE: Do not proceed with power injection until blockage has been cleared or needle position has been corrected.
6. During this saline flush, observe the portal pocket and catheter tract for swelling and inquire or observe whether the patient is experiencing burning pain or discomfort at the portal site. If any of these symptoms are noted and/or swelling of the portal pocket and catheter tract is observed, fluid extravasation into the portal pocket or catheter tract should be suspected.

   WARNING: Ensure that there are no occlusions in the catheter prior to using the PORT-A-CATH® POWER P.A.C. for power injection. Failure to identify occlusions may result in catheter damage.
7. Secure the GRIPPER PLUS® POWER P.A.C. in the portal.
8. Attach the power injection device to the GRIPPER PLUS® POWER P.A.C. and the extension set per the manufacturer's recommendations.
9. Prepare contrast media according to manufacturer's instructions.

   NOTE: Contrast media should be warmed to body temperature before power injecting. Failure to do so may result in PORT-A-CATH® POWER P.A.C. failure.
10. Instruct the patient to notify the clinician immediately if there is any pain or abnormal sensation during the power injection.

    WARNING:
    - *Stop the injection immediately if local pain, swelling, or signs of extravasation are noted.*
    - *Do not exceed the maximum pressure of 300 psi as this may result in PORT-A-CATH® POWER P.A.C. system failure and/or catheter tip displacement.*
    - *Do not exceed the maximum flow rate as this may result in PORT-A-CATH® POWER P.A.C. system failure and/or catheter tip displacement.*
11. Complete the power injection study taking care to not exceed the maximum pressure of 300 psi, or the maximum flow rate of 5 ml/sec. See the chart below for specific flow rates with the GRIPPER PLUS® POWER P.A.C. needle.

GRIPPER PLUS® Gauge Size	19 Gauge	20 Gauge	22 Gauge
Maximum Flow Rate	5 ml/sec	5 ml/sec	3 ml/sec

To remove from portal device: from the back of the GRIPPER PLUS® POWER P.A.C., place fingers on each side of the base. Lift the safety arm straight back to the lock position UNTIL IT CLICKS ❺. Dispose of used needles in a sharps container, in accordance with CDC guidelines (USA) and/or your institution's Bloodborne pathogens program.