Indications for Use Statement

510(k) Number (if known): K081311

Device Name: PowerPort™ Implanted Port with Groshong™ Catheter

Indications for Use:

The PowerPort™ implanted port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medication, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples. When used with a PowerLoc™ safety infusion set, the PowerPort™ device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s.

Prescription Use ✓ (Part 21 CFR §801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR §801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anthony D. Watson
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081311

PowerPort™ Implanted Port with Groshong™ Catheter

Special 510(k) Premarket Notification

TABLE OF CONTENTS

SCREENING CHECKLIST FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

See Related Information

510(k) Number: _____

The cover letter clearly identifies the type of 510(k) submission as **(Check the appropriate box)**:

☑ Special 510(k) - Do Sections 1 and 2
☐ Abbreviated 510(k) - Do Sections 1, 3 and 4
☐ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	Sec. 3	
Table of Contents.	Pg. 1	
Truthful and Accurate Statement.	Sec. 5	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	Sec. 6	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	Sec. 6	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	Att. 4 & 5	
Statement of Indications for Use that is on a separate page in the premarket submission.	Sec. 4	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.	Sec. 10	
510(k) Summary or 510(k) Statement.	Sec. 6	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	Sec. 9 & Att. 1	
Identification of legally marketed predicate device. *	Sec. 8	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	Sec. 11	
Class III Certification and Summary. **	N/A	

Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	N/A	
510(k) Kit Certification ***	Att. 2	

* - May not be applicable for Special 510(k)s.
** - Required for Class III devices, only.
*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.	Sec. 8	
A description of the modified device and a comparison to the sponsor's predicate device.	Sec. 10	
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.	Sec. 10	
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.	Sec. 11.3	
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.	Sec. 11.5	
c. A Declaration of Conformity with design controls that includes the following statements:	Sec. 7	
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.	Sec. 7	
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.	Sec. 7	

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, **SEE Required Elements for a Declaration of Conformity to a Recognized Standard,** which is posted with the 510(k) boilers on the **H drive.**]		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) Sterilization process		
ii) Validation method of sterilization process		
iii) SAL		
iv) Packaging		
v) Specify pyrogen free		
vi) ETO residues		
vii) Radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening _____Yes _____No

Reviewer:_____

Concurrence by Review Branch:_____

Date:_____

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at:
http://www.fda.gov/cdrh/modact/leastburdensome.html

Uploaded on March 3, 2004

Section 1

Medical Device User Fee Cover Sheet (Form FDA-3601)

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4)
Write the Payment Identification number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

BARD ACCESS SYSTEMS
605 NORTH 5600 WEST
Salt Lake City UT 84123
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
870385835

2. CONTACT NAME
Susan Scott

2.1 E-MAIL ADDRESS
susan.scott@crbard.com

2.2 TELEPHONE NUMBER (include Area code)
801-595-0700 5484

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
801-595-5425

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4)
16-Jan-2008

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Section 2

CDRH Premarket Review Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: May 31, 2007.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
May 8, 2008	(b)(4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission ☐ Premarket Report ☐ Modular Submission ☐ Amendment ☐ Report ☐ Report Amendment ☐ Licensing Agreement	☐ Regular (180 day) ☐ Special ☐ Panel Track (PMA Only) ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA &HDE Supplement ☐ Other	☐ Original PDP ☐ Notice of Completion ☐ Amendment to PDP	☒ Original Submission: ☐ Traditional ☒ Special ☐ Abbreviated (Complete section I, Page 5) ☐ Additional Information ☐ Third Party	☐ Pre-510(K) Meeting ☐ Pre-IDE Meeting ☐ Pre-PMA Meeting ☐ Pre-PDP Meeting ☐ Day 100 Meeting ☐ Agreement Meeting ☐ Determination Meeting ☐ Other *(specify):*

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission ☐ Amendment ☐ Supplement	☐ Original Submission ☐ Amendment ☐ Supplement ☐ Report ☐ Report Amendment	☐ Original Submission ☐ Additional Information	☐ Original Submission ☐ Additional Information	☐ 513(g) ☐ Other *(describe submission):*

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
C. R. Bard Inc.	1720496		
Division Name *(if applicable)*	Phone Number *(including area code)*		
Bard Access Systems	(801) 595-0700 x5484		
Street Address	FAX Number *(including area code)*		
605 N 5600 W	(801) 595-5425		
City	State / Province	ZIP/Postal Code	Country
Salt Lake City	UT	84116	U.S.A.
Contact Name			
JiHyun Kim			
Contact Title	Contact E-mail Address		
Regulatory Affairs Manager	jihyun.kim@crbard.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
N/A			
Division Name *(if applicable)*	Phone Number *(including area code)*		
	( )		
Street Address	FAX Number *(including area code)*		
	( )		
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site
- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*
- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment
- ☐ Response to FDA correspondence:
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address
- ☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION – IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access
- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final
- ☐ Repose to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing
- ☐ Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology
- ☒ Other Reason *(specify)*:

Expanding PowerPort™ implanted port family by adding valved Groshong™ catheter. (Groshong™ valved catheter currently used with BardPort® implanted ports (non-power injection) and sold as power injectable Groshong™ PICC catheter kits.)

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	80 LJT	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K060812	Titanium PowerPort™ Implanted Port	Bard Access Systems, Inc. (wholly owned subsidiary of C. R. Bard)
2	(b)(4)		
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Subcutaneous, Implanted, Intravascular Infusion Port & Catheter

	Trade or Proprietary or Model Name for This Device	Model Number
1	PowerPort™ Implanted Port with Groshong™ Catheter	multiple
2		
3		
4		
5		

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K060812	2 3 (b)(4)		4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
80 LJT	CFR § 880.5965	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

General Hospital

Indications *(from labeling)*

The PowerPort™ Implanted Port is indicated for patient therapies requiring repeated access to the vascular systems. The port system can be used for infusion of medication, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples. When used with a PowerLoc™ Safety Infusion Set, the PowerPort™ device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	FDA Establishment Registration Number (b)(4)	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name C. R. Bard, Inc.		Establishment Registration Number (b)(4)	

(b)(4)

(b)(4)

☒ Original ☐ Add ☐ Delete	FDA Establishment Registration Number (b)(4)	☐ Manufacturer ☐ Contract Manufacturer	☒ Contract Sterilizer ☐ Repackager / Relabeler

(b)(4)

☒ Original ☐ Add ☐ Delete	FDA Establishment Registration Number 3006260740	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name C. R. Bard, Inc.		Establishment Registration Number 3006260740		
Division Name *(if applicable)* Bard Access Systems (wholly owned subsidiary of C. R. Bard		Phone Number *(including area code)* (801) 595-7000		
Street Address 605 N 5600 W		FAX Number *(including area code)* (801) 595-5425		
City Salt Lake City		State / Province UT	ZIP/Postal Code 84116	Country U.S.A.
Contact Name Ramon Ricart	Contact Title V. P. Quality Systems	Contact E-mail Address Ramon.ricart@crbard.com		

SECTION I	UTILIZATION OF STANDARDS			
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.				
	Standards No.	Standards Organization	Standards Title	Version	Date
1		FDA	Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters		03/16/1995
	Standards No.	Standards Organization	Standards Title	Version	Date
2		FDA	Guidance on 510(k) Submissions for Implanted Infusion Ports		10/01/1990
	Standards No.	Standards Organization	Standards Title	Version	Date
3	10555-1: 1997	BS/EN/ISO	Sterile, Single-Use Intravascular Catheters. Part 1: General Requirements		1997
	Standards No.	Standards Organization	Standards Title	Version	Date
4	10555-1: 1995	ISO	Sterile, Single-Use Intravascular Catheters. Part 1: General Requirements, Amendement 1: 1999, Amendement 2: 2004		2006
	Standards No.	Standards Organization	Standards Title	Version	Date
5	10555-3: 1996	ISO	Sterile, Single-Use Intravascular Catheters. Part 3: Central Venous Catheters		1998
	Standards No.	Standards Organization	Standards Title	Version	Date
6	10993-1: 2003	AAMI/ANSI/ISO	"Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" and the FDA Modified ISO 10993 Test Profile		2003
	Standards No.	Standards Organization	Standards Title	Version	Date
7	11135:1994	AAMI/ANSI/ISO	Medical Devices -- Validation and Routine Control of Ethylene Oxide Sterilization		1994
	Standards No.	Standards Organization	Standards Title	Version	Date
8	14971:2007	ISO	*Medical Devices – Application of risk management to medical devices* (General)		2007

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

Section 3

510(k) Cover Letter

BARD
ACCESS SYSTEMS

May 8, 2008

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Re: **Special 510(k): Device Modification**
PowerPort™ Implanted Port with Groshong™ Catheter
80 LJT – Subcutaneous, Implanted, Intravascular Infusion Port & Catheter
21 CFR § 880.5965 – Class II
General Hospital

Dear Madam/Sir:

In accordance with section 510(k) of the Federal Food, Drug and Cosmetic Act and pursuant to 21 CFR §807.81, Bard Access Systems, of C.R. Bard, Inc. hereby submits this premarket notification of intent to introduce into interstate commerce the PowerPort™ implanted port with Groshong™ catheter. Enclosed is one hard copy and one compact disk copy of the 510(k) notification for FDA review.

The "Special 510(k): Device Modification" pathway has been selected since the subject device represents a modification to Bard Access Systems' predicate PowerPort™ Implanted Titanium Port [K060812], **(b)(4)** **(b)(4)** Neither the fundamental, scientific technology, nor the intended use of the product are being altered with this modification.

The introduction of the subject PowerPort™ Implanted Port with Groshong™ catheter will expand Bard's current PowerPort™ family of power-injectable implanted port products. As with Bard's current PowerPort™ family of products, the subject device can be used with any non-coring infusion set for routine vascular access, but must be combined with a Bard PowerLoc™ safety infusion set for power injection of contrast media.

The terms "substantially equivalent", "similar", and related terms and descriptions in this notification are defined terms or words of art defined by the Food and Drug Administration as those words are used in the Federal Food, Drug and Cosmetic Act as amended and the regulations promulgated there under and are not to be construed or interpreted for any other purpose.

It is the understanding of C.R. Bard, Inc. that written notification will be received from FDA if this device is subject to §522 of the Federal Food, Drug and Cosmetic Act, *i.e.*, Postmarket Surveillance.

C.R. Bard. Inc. requests that the FDA keep and maintain confidential both the existence and the contents of this Premarket Notification in accordance with 21 CFR §807.95(b). C.R. Bard, Inc. also requests that the FDA keep and maintain confidential the contents of this letter.

If you have any questions or require any additional information related to this notification, please contact me at your convenience through any of the contact information listed below. I hereby authorize the FDA to communicate with me regarding this submission via fax and/or e-mail. Thank you in advance for your consideration of our application.

Sincerely,

(b)(6)

Ji Hyun Kim
Regulatory Affairs Manager
Bard Access Systems
605 North 5600 West
Salt Lake City, UT 84116

Tel: (801) 595-0700 x7105
Fax: (801) 595-5425
jihyun.kim@crbard.com

Section 4

Indications for Use Statement

Indications for Use Statement

510(k) Number (if known): _____

Device Name: PowerPort™ Implanted Port with Groshong™ Catheter

Indications for Use:

The PowerPort™ implanted port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medication, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples. When used with a PowerLoc™ safety infusion set, the PowerPort™ device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s.

Prescription Use ✓ (Part 21 CFR §801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR §801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5

Truthful & Accuracy Statement

Truthful & Accuracy Statement

Pursuant to 21 CFR §807.87(k), I hereby certify that, in my capacity as Vice President of Regulatory Affairs at Bard Access Systems, Inc., I believe, to the best of my knowledge, that all data and information submitted in this "Special 510(k): Device Modification" premarket notification application are truthful and accurate and that no material fact having a significant bearing on the subject product has been omitted.

(b)(6)

RICK GAYKOWSKI

May 8, 2008

Date

Section 6

510(k) Summary of Safety & Effectiveness

510(k) Summary

(b)(4)

(b)(4)

Section 7

Declaration of Conformity

Declaration of Conformity

I certify, in my capacity as Vice President, Research and Development of Bard Access Systems that I believe, to the best of my knowledge, that all relevant and applicable verification and validation activities were performed by the designated individual(s) as required by the risk analysis, and the results demonstrated that the predetermined performance acceptance criteria were met.

(b)(6)

5/09/2008

KELLY POWERS
Vice President, Research & Development
Bard Access Systems

Date

I certify, in my capacity as Vice President, Quality Assurance of Bard Access Systems that I believe, to the best of my knowledge, that the manufacturing facilities listed below are in conformance with the design controls procedure requirements as specified in 21 CFR § 820.30 and the records are available for review.

Bard Access System
605 North 5600 West
Salt Lake City, UT
84116

(b)(4)

RAMON RICART
Vice President, Quality Systems
Bard Access Systems

Date

Declaration of Conformity

I certify, in my capacity as Vice President, Research and Development of Bard Access Systems that I believe, to the best of my knowledge, that all relevant and applicable verification and validation activities were performed by the designated individual(s) as required by the risk analysis, and the results demonstrated that the predetermined performance acceptance criteria were met.

(b)(6)

5/09/2008

KELLY POWERS
Vice President, Research & Development
Bard Access Systems

Date

I certify, in my capacity as Vice President, Quality Assurance of Bard Access Systems that I believe, to the best of my knowledge, that the manufacturing facilities listed below are in conformance with the design controls procedure requirements as specified in 21 CFR § 820.30 and the records are available for review.

Bard Access System
605 North 5600 West
Salt Lake City, UT
84116

(b)(4)

(b)(6)

RAMON RICART
Vice President, Quality Systems
Bard Access Systems

Date

Section 8

General Overview

8.1 General Overview

The purpose of this Premarket Notification is to obtain market clearance of the PowerPort™ implanted port with Groshong® catheter. This application clearly demonstrates that the subject device is substantially equivalent to Bard Access System's currently marketed predicates PowerPort™ Implanted Titanium Port (b)(4)

(b)(4)

C.R. Bard, Inc. has been manufacturing and distributing totally implanted port/catheter devices since 1986. Implanted ports are used when long term vascular access is desirable. Many patients who receive a port often require contrast enhanced computed tomography (CECT) to monitor the progress of their disease with the preferred method for contrast media administration being power injection. Often, deterioration of the patient's peripheral vasculature makes placement of a peripheral IV or PICC for CECT very difficult and painful. For these patients, being able to administer contrast media through their port is beneficial.

On July 14, 2006, Bard Access Systems (BAS) received clearance for the market's first power-injectable implanted port [K060812].

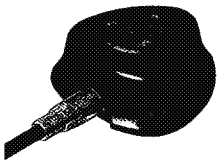
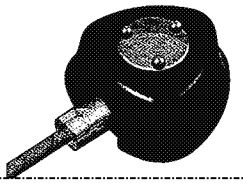
The BAS family of PowerPort™ implanted port/catheter devices is cleared for routine vascular access as well as for power injection of contrast media. For routine vascular access, a PowerPort™ port/catheter device can be accessed with any 19 Ga or smaller non-coring needle. However, for power injection procedures, a PowerPort™ port/catheter device must be accessed with a PowerLoc™ safety infusion set (PowerLoc SIS) to create a power injectable system. **No changes have been made to the PowerLoc™ safety infusion set design or materials as previously cleared in K060812.**

(b)(4)

(b)(4)

8.2 Abbreviations Used in this 510(k) Submission

Note: For brevity, the subject and predicate device names will be abbreviated as follows:

Device	Abbreviation	Full Name
Subject 	**PPort w/ Groshong**	Titanium PowerPort™ Implanted Port with Groshong™ Catheter
Primary Predicate 	**Ti PowerPort™**	PowerPort™ Implanted Titanium Port with 8 Fr ChronoFlex® Polyurethane Catheter K060812

(b)(4)

Section 9

Device Description and Comparison

Device Description

The subject device has the same fundamental, scientific technology and is indicated for the same use and patient population as all current devices in the BAS family of PowerPort™ implanted ports. The description of the subject PPort w/ Groshong device is as follows:

Similarities

PowerPort™ / PowerLoc™ System Description

(b)(4)

Subject Port Body Description

7. The subject port body is triangular in shape to aid in identification and septum

(b)(4)

8. The subject titanium port material includes an anodization that give a purple color (b)(4)

9. The septum of the subject port has three (3) palpation bumps to identify the device as

(b)(4)

Subject Catheter Description

(b)(4)

Subject Cathlock Description

(b)(4)

9.1 Modifications Addressed in the "Special 510(k): Device Modification" Premarket Notification

This submission covers the following modifications to the predicate devices:

Differences

(b)(4)

For a comparison of the subject and predicate devices, refer to Table 10-1 in Section 10.
For subject and predicate device drawings, refer to Attachment 1.
For copies of subject and predicate labeling, refer to Attachments 4 and 5.

9.2 Principles of Operation

No new operating principles have been introduced with the subject device. The subject PPort w/ Groshong device relies on the same basic, fundamental scientific technology as the predicate Ti PowerPort™ (b)(4)

(b)(4)

9.3 Instructions for Use (IFU) and Labeling

(b)(4)

(b)(4)

Attachment 4 contains copies of all kit labeling including IFU and unit labels. Attachment 5 contains ancillary labeling: the Patient Discharge Kit (provided external to each kit); and in-service education guides for Nurses and CT Technicians.

9.4 Process Summary

(b)(4)

9.5 Sterilization Process

(b)(4)

9.6 Sterile Packaging Description

(b)(4)

(b)(4)

9.7 Regulatory Status of Device Materials

(b)(4)

(b)(4)

9.8 Biocompatibility

(b)(4)

(b)(4) No new biocompatibility testing was performed.

(b)(4)

9.9 Stability

(b)(4)

(b)(4) verification testing of the (b)(4) subject port with catheter was performed (b)(4)
The tests with conditioning and acceptance criteria are listed in the Design Control Activity Summary Table (Tests #1-18 of Table 11-4).

(b)(4)

9.10 Kit Component Identification and Certification

All kit components are legally marketed devices and are used with other similar BAS kits currently on the market. Refer to Attachment 3 for kit component identification and certification.

9.12 History of Change

(b)(4)

Section 10

Substantial Equivalence Discussion

10.1 Similarities to the Predicate Ti PowerPort™ and BardPort w/Groshong Devices:

The subject PPort w/ Groshong device (comprised of a titanium implanted port (b)(4) Groshong solid blue silicone catheter (tipped and valved) attached with a cathlock (compression fitting)) is similar to the previously cleared predicates **Ti PowerPort™ and (b)(4) (K060812, (b)(4)** in the following aspects:

- Same intended use
- Same indications for use
- Same operating principle
- Same basic, fundamental scientific technology
- Same port body and septum design
- (b)(4)
- Same biocompatibility requirements
- (b)(4)

See Table 10-1 for a comparison of the subject and predicate devices.

Table 10.1: PowerPort™ Implanted Port with Groshong Device Comparison

Attribute:	Predicate Port Device: PowerPort™ Implanted Titanium Port (K060812)		Subject Device: PowerPort™ Implanted Port with Groshong® Catheter
Classification	Class II, 80 LJT, 21 CFR §880.5965 Subcutaneous, Implanted, Intravascular Infusion Port & Catheter		Class II, 80 LJT, 21 CFR §880.5965 Subcutaneous, Implanted, Intravascular Infusion Port & Catheter
Duration of Use	Long term (>30 days)		Long term (>30 days)
Intended Use (per IFU)	The **PowerPort™** Implanted Port is a totally implantable vascular access device designed to provide long-term, repeated access to the vascular system.		The **PowerPort™** Implanted Port is a totally implantable vascular access device designed to provide long-term, repeated access to the vascular system.
Indications for Use (per IFU)	The PowerPort™ Implanted Port is indicated for patient therapies requiring repeated access to the vascular system. The port device can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products and for the withdrawal of blood samples. When used with the PowerLoc™ Safety Infusion Set, the PowerPort™ device is indicated for power injection of contrast media. For power injection of contrast media, the recommended infusion rate is 5 ml/s.	(b)(4)	The **PowerPort™ Implanted Port** is indicated for patient therapies requiring repeated access to the vascular system. The port device can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products and for the withdrawal of blood samples. When used with the PowerLoc™ Safety Infusion Set, the PowerPort™ device is indicated for power injection of contrast media. For power injection of contrast media, the recommended infusion rate is 5 ml/s.
Device Dimensions	Catheter: (b)(4)		Catheter: (b)(4)

K091292

Table 10.1: PowerPort™ Implanted Port with Groshong Device Comparison

Attribute:	Predicate Port Device: PowerPort™ Implanted Titanium Port (K060812)	Subject Device: PowerPort™ Implanted Port with Groshong® Catheter
	Titanium Port:	Titanium Port:
Insertion Site Means of Insertion Tunnel Required Tip Placement Location	(b)(4)	(b)(4)
Device Description	Catheter: (b)(4) Port Body: 6. triangular titanium port with anodized surface (creating purple color). (b)(4) 8. one piece silicone septum with 3 raised bumps (b)(4)	Catheter: 1. **Silicone** 2. **closed tip, valved** (b)(4) Port Body: 6. triangular titanium port with anodized surface (creating purple color). (b)(4) 8. one piece silicone septum with 3 raised bumps (b)(4)

(b)(4)

(b)(4)

Table 10.1: PowerPort™ Implanted Port with Groshong Device Comparison

Attribute:	Predicate Port Device: PowerPort™ Implanted Titanium Port (K060812)	(b)(4)	Subject Device: PowerPort™ Implanted Port with Groshong® Catheter
	Connection: (b)(4) cathlock is compression fit over catheter/stem connection		Connection: (b)(4) cathlock is compression fit over catheter/stem connection

Special 510(k) Decision Tree

The decision tree included in "*The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications"* was used to determine that a Special 510(k) could be submitted for the subject device.

Answers to the questions in the decision tree led to the conclusion that the modifications are eligible for consideration as a Special 510(k) since:

- The device represents a modification to Bard Access Systems' own predicate devices – (b)(4) (b)(4)
- The modifications are appropriate for reliance on results from the design control process.
- Design validation was completed. The design validation confirmed that all design inputs and user needs are met.
- Conformance with performance acceptance criteria was assured.

Statements follow the flow chart included as "*Appendix 1, The New 510(k) Paradigm"*, in "*The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications"*, dated March 20, 1998 (See Attachment 3).

10.2 510(k) Substantial Equivalence Decision Tree

New device is compared to Marketed Device?

Yes. All procedural devices and components applicable to this 510(k) notification are compared to legally marketed predicates.

Does the new device have the same indication statement and intended use as the predicate?

Yes.

Does the new device have the same technological characteristic, e.g. design, materials, etc.?

No, not in all regards. The principles of operation and fundamental design are the same as the primary predicate device. None of the noted "differences" have any significant effect on the safety and effectiveness of the subject product, or precludes its substantial equivalence to any significant degree.

Could the new characteristics affect safety or effectiveness?

Yes, the design changes could affect safety or effectiveness.

Do the new characteristics raise new types of safety and effectiveness question?

No, there are no new types of safety and effectiveness questions. To assure that risks posed by the subject device are acceptable, a risk management process, including failure modes and effects analysis (FMEA), was conducted for the subject device in accordance with a BAS internal protocol which is based on *ISO 14971:2007, "Medical Devices – Application of risk management to medical devices (General)"*.

Do accepted scientific methods exist for assessing effects of the new characteristics?

Yes. The following documents were used to evaluate the device performance:

- *Guidance on 510(k) Submissions for Implanted Infusion Ports,* dated October 1990
- *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters,* dated 3/16/95
- BS/EN/ISO 10555-1: 1997, *Sterile, single-use intravascular catheters, Part 1. General requirements.*
- ISO 10555-1: 1995, *Sterile, single-use intravascular catheters, Part 1. General requirements, Amendment 1: 1999*
- BS/EN/ISO 10555-3: 1997, *Sterile, single-use intravascular catheters, Part 3. Central venous catheters*
- AAMI/ANSI/ISO 11135: 1994, *Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization*
- AAMI/ANSI/ISO 10993-1: 2003, *Biological Evaluation of medical Devices Part 1: Evaluation and Testing,* and the FDA Modified ISO 10993 Test Profile
- ISO 14971:2007, *Medical devices – Application of risk management to medical devices (general)*

Design validation was performed to confirm that design inputs and customer needs are met. Per the current risk assessment, there are no hazards or failure modes that rely solely on design validation for controls.

Biocompatibility requirements of ISO 10993 *Biological Evaluation of Medical Devices Part-1: Evaluation and Testing* and the FDA Modified ISO 10993 Test Profile were met for long term implanted devices that exhibit tissue contact (port and catheter), indirect blood contact (port) and direct blood contact (catheter). All materials used in the manufacture of the subject device were previously cleared for similar applications by Bard Access Systems.

Are performance data available to assess effects of new characteristics?

Yes. Verification testing was performed according to protocols based on the above referenced guidance document recommendations and additional standards.

Performance data demonstrate equivalence?

Yes. Performance data gathered in design verification met predetermined acceptance criteria and thus demonstrated that the subject PPort w/ Groshong device is substantially equivalent to the predicate Ti PowerPort (b)(4) **devices** The risks associated with use of the new device were found acceptable when evaluated through the risk management process including FMEA.

Conclusion

The subject PowerPort™ implanted port with Groshong® catheter met all predetermined performance and acceptance criteria of design verification evaluations and the testing performed. Based on the FDA's decision tree, the subject device is substantially equivalent to the primary and secondary predicate devices listed below:

- K060812, PowerPort™ Implanted Titanium Port cleared July 14, 2006

(b)(4)

Section 11

Design Control Activities

11.1 Declaration of Conformity

The "Declaration of Conformity with Design Controls" can be found in Section 7.

11.2 Design Inputs and User Needs

No new user needs have been identified. (b)(4)

(b)(4)

(b)(4) Therefore, new design inputs are limited to establishing safety and efficacy of the subject device.

11.3 Risk Analysis

To assure that risks presented by the subject design are acceptable, a risk management program, including a failure modes and effects analysis (FMEA) of the subject device, was conducted in accordance with (b)(4) ISO 14971: 2007, *Medical Devices – Application of Risk Management to Medical Devices.* (b)(4)

(b)(4)

(b)(4) there were no new types of safety or effectiveness questions raised with the analysis of the subject PPort w/ Groshong device.

11.4 Summary of Design Validation Activities

(b)(4)

11.5 Summary of Design Verification Activities

As identified in the FMEA, design verification tests were designed and performed to demonstrate that the subject device met predetermined performance specifications and to assure that there were no unacceptable increased risks associated with the modifications to the predicate design. Functional tests were performed on sterilized, finished devices or their equivalents.

To determine that the new device does not increase risks associated with its use to unacceptable levels, the standard battery of tests to establish reasonable safety and effectiveness of implanted ports and catheters was performed. The battery of tests included tests in conformance with recommendations and standard identified in the following documents:

- *Guidance on 510(k) Submissions for Implanted Infusion Ports,* dated October 1990
- *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters,* dated 3/16/95
- BS/EN/ISO 10555-1: 1997, *Sterile, single-use intravascular catheters, Part 1. General requirements.*
- ISO 10555-1: 1995, *Sterile, single-use intravascular catheters, Part 1. General requirements, Amendment 1: 1999*
- BS/EN/ISO 10555-3: 1997, *Sterile, single-use intravascular catheters, Part 3. Central venous catheters*
- AAMI/ANSI/ISO 11135: 1994, *Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization*
- AAMI/ANSI/ISO 10993-1: 2003, *Biological Evaluation of medical Devices Part 1: Evaluation and Testing,* and the FDA Modified ISO 10993 Test Profile
- ISO 14971:2007, *Medical devices – Application of risk management to medical devices (general)*

11.6 Establishing Performance Acceptance Criteria

(b)(4)

(b)(4)

11.7 Port & Catheter Guidance and ISO Standard Testing

Testing was performed per the following FDA guidance documents:

(i) *Guidance on 510(k) Submissions for Implanted Infusion Ports,* dated October 1990

(ii) *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters,* dated 3/16/95

Note: No standards or guidances exist for power injection through port devices.

(b)(4)

The subject PPort w/ Groshong® device **met all predetermined design verification acceptance criteria** for tests listed below.

(b)(4)

(b)(4)

11.8 Design Control Activities Summary Tables

Following are tabular summaries of design control activities relevant to the subject device. Table 11-3 presents design control activities which identifies specific information on the device modifications, all risks which result from these changes, verification activities. The verification activities are then further defined in Table 11-4 with specific acceptance criteria and results of verification. The "Declaration of Conformity with Design Controls" statement is located in Section 7.

The subject PPort with Groshong™ catheter met all predetermined acceptance criteria for design verification and validation as specified by applicable standards, test protocols and/or customer inputs and does not introduce unacceptable increased risks associated with the design modifications.

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

11.9 Conclusion

The subject PowerPort™ Implanted Port with Groshong® catheter met all predetermined performance and acceptance criteria of design verification evaluations and the testing performed. Based on the FDA's decision tree, the subject device is substantially equivalent to the primary and secondary predicate devices listed below:

PowerPort™ Implanted Titanium Port [K060812, cleared July 14, 2006]

(b)(4)

Attachments

Attachment 1
Device Drawings – Subject & Predicates

(b)(4)

(b)(4)

(b)(4)

Attachment 2
Kit Component Certification Table

Kit Component Certification
Titanium PowerPort™ Port with 8.0 Fr Groshong Catheter

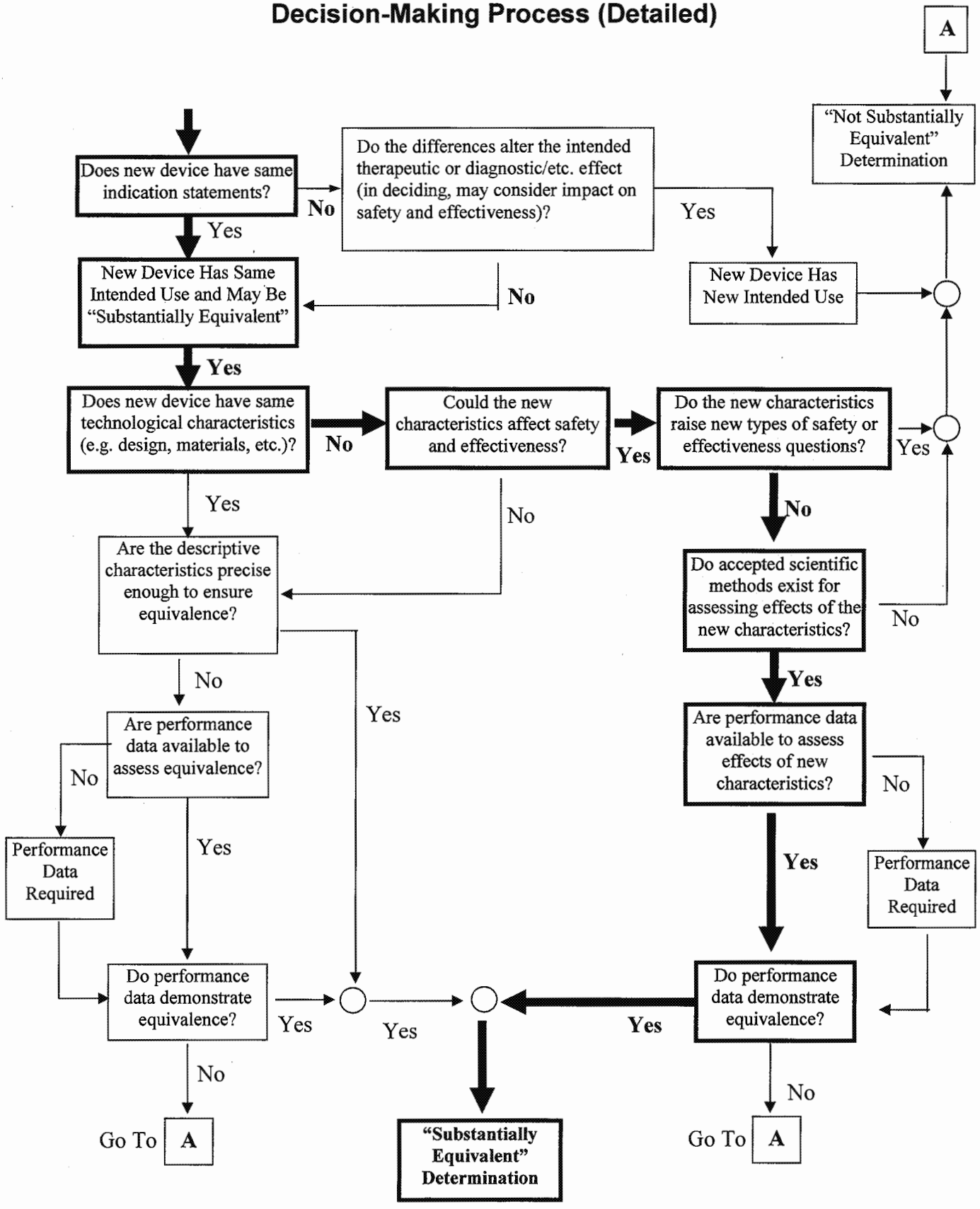
(b)(4)

8998

(b)(4)

Attachment 3
FDA Flow Chart

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



Attachment 4
Kit Labeling – Subject & Predicate

Sterile Package Labeling:

- PowerPort™ Tyvek Lid
- PowerPort™ Unit Label
- PowerPort™ Implant Record
- PowerPort™ IFU
- PowerPort™ IFU Inserts (subject only)
- PowerLoc Safety Infusion Set Label
- Groshong Label for Patient Discharge (subject only)

Note: labeling images are not to scale

Bard Access Systems

Peel Here

Single Use - **Do not resterilize.**

Refer to enclosed instructions prior to use.

Sterile, non-pyrogenic unless package is damaged or opened. Sterilized by ethylene oxide.
Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Bard Access Systems, Inc.
Salt Lake City, Utah 84116
1-800-545-0890
www.bardaccess.com

0710575
0509R

BARD

Labeling Subject Device

0716231 0712R

Groshong* Catheter with

PowerPort*

IMPLANTABLE PORT

FEEL THE NEW* STANDARD OF CARE

BARD

Access Systems

REF Reorder Number

PowerPort* Implanted Port with Suture Plugs
with Attachable 8 Fr. Groshong* Single-Lumen Venous Catheter

Contents:

1 Each - Titanium Port
- Base fits within Diameter 32 mm, Internal Volume 0.6 ml

1 Each - Radiopaque Silicone Catheter, 8 Fr.
- 45 cm Length, 1.5 mm I.D., Depth Markings every cm
- 0.9 ml Volume (0.2 ml per 10 cm of Length)
- Avg. Gravity Flow Rate > 500 ml/hr with 19 Ga. Needle
- Max Power Injection Rate = 5 ml/s with 19 Ga. PowerLoc* SIS

2 Each - Catheter Lock

1 Each - Guidewire "J" tip with Straightener 0.89 mm (0.035 in) x 45 cm length
1 Each - Introducer with Vessel Dilator, PTFE, 8 Fr. x 15 cm (6 in)
1 Each - Needle, Introducer, 18 Ga. x 7 cm (2.75 in.)
2 Each - Needle, Non-Coring, 22 Ga. (1 Straight, 1 Right Angle)
1 Each - Syringe
1 Each - PowerLoc* Safety Infusion Set, (SIS), 20 Ga.
1 Each - Tunneler
1 Each - Vein Pick

* Bard, PowerPort, PowerLoc, the color purple, Feel The New Standard of Care and Groshong are trademarks and/or registered trademarks of C. R. Bard, Inc. or an affiliate.
U.S. patents pending.

MR This product and package do not contain natural rubber latex

CT 300 psi Max

DEHP DEHP Free

+H303170806000

+$$100822APPRVD05

Use By: 2007- 10

LOT Lot No.: 22APPRVD

Assembled in Mexico
0715437 0804R
0001 Rev 0

Groshong* Catheter with PowerPort® IMPLANTABLE PORT FEEL THE NEW* STANDARD OF CARE

Titanium Implanted Port with Suture Plugs

8 Fr. French Size — Groshong* CV Catheter

Reorder Number **1778000**

BARD

Groshong* Catheter with PowerPort® IMPLANTABLE PORT FEEL THE NEW* STANDARD OF CARE

REF 1778000

LOT Lot No.: 22APPRVD

BARD

Patient ID

Groshong* Catheter with PowerPort® IMPLANTABLE PORT FEEL THE NEW* STANDARD OF CARE

REF 1778000

LOT Lot No.: 22APPRVD

BARD

Implant Record

Groshong* Catheter with PowerPort® IMPLANTABLE PORT FEEL THE NEW* STANDARD OF CARE

REF 1778000

LOT Lot No.: 22APPRVD

BARD

Implant Record

Groshong* Catheter with PowerPort® IMPLANTABLE PORT FEEL THE NEW* STANDARD OF CARE

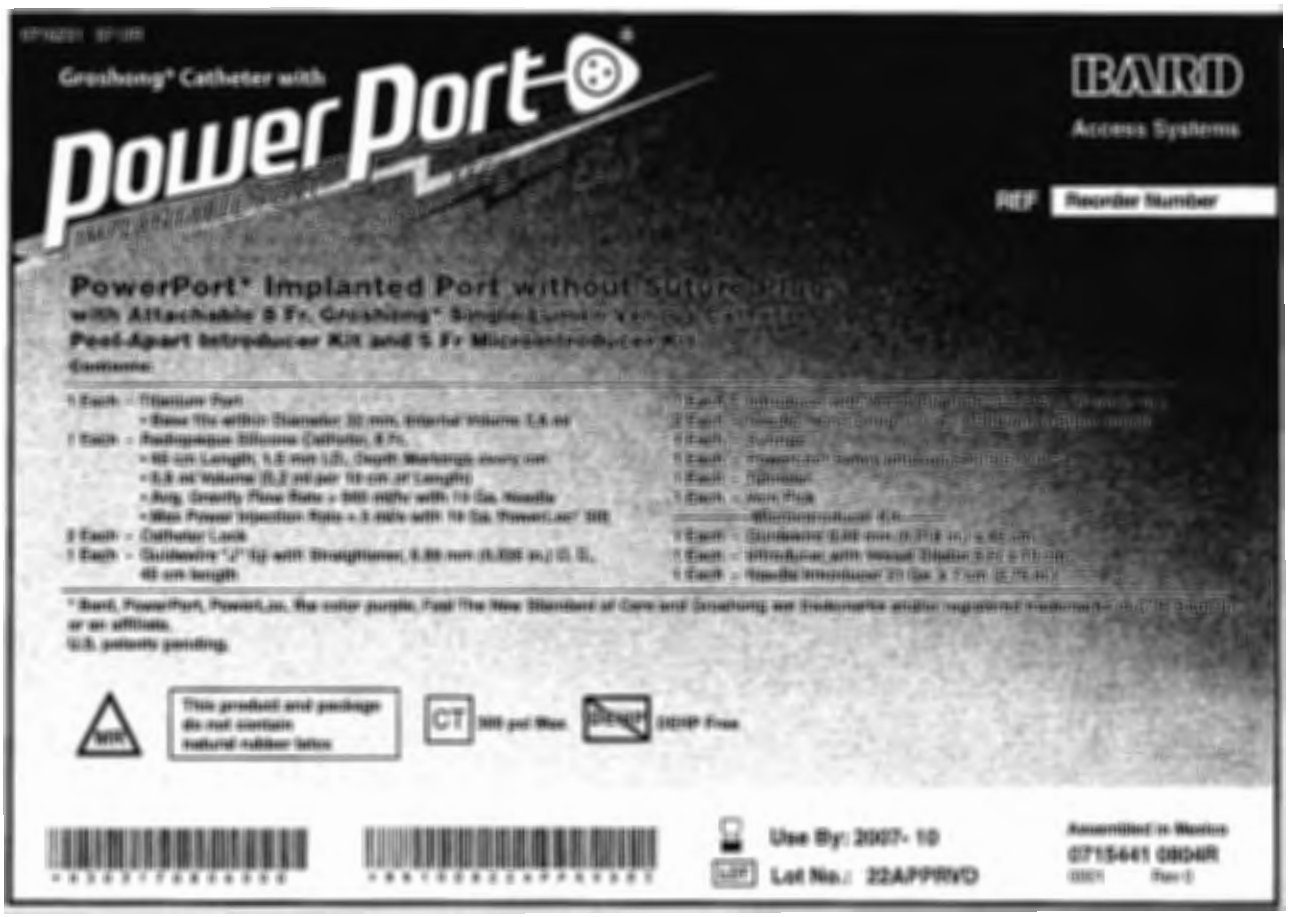
REF 1778000

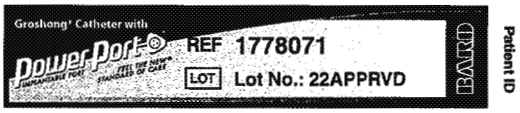
LOT Lot No.: 22APPRVD

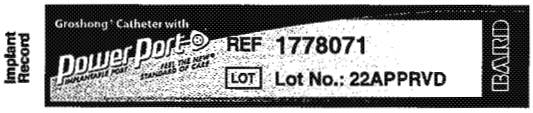
BARD

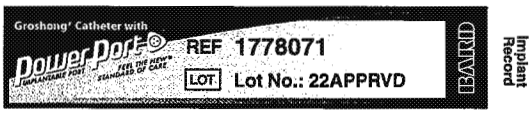
Implant Record

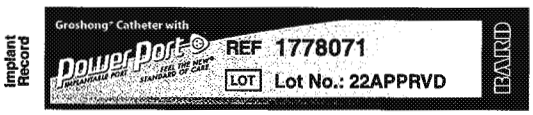
Labeling Subject Device



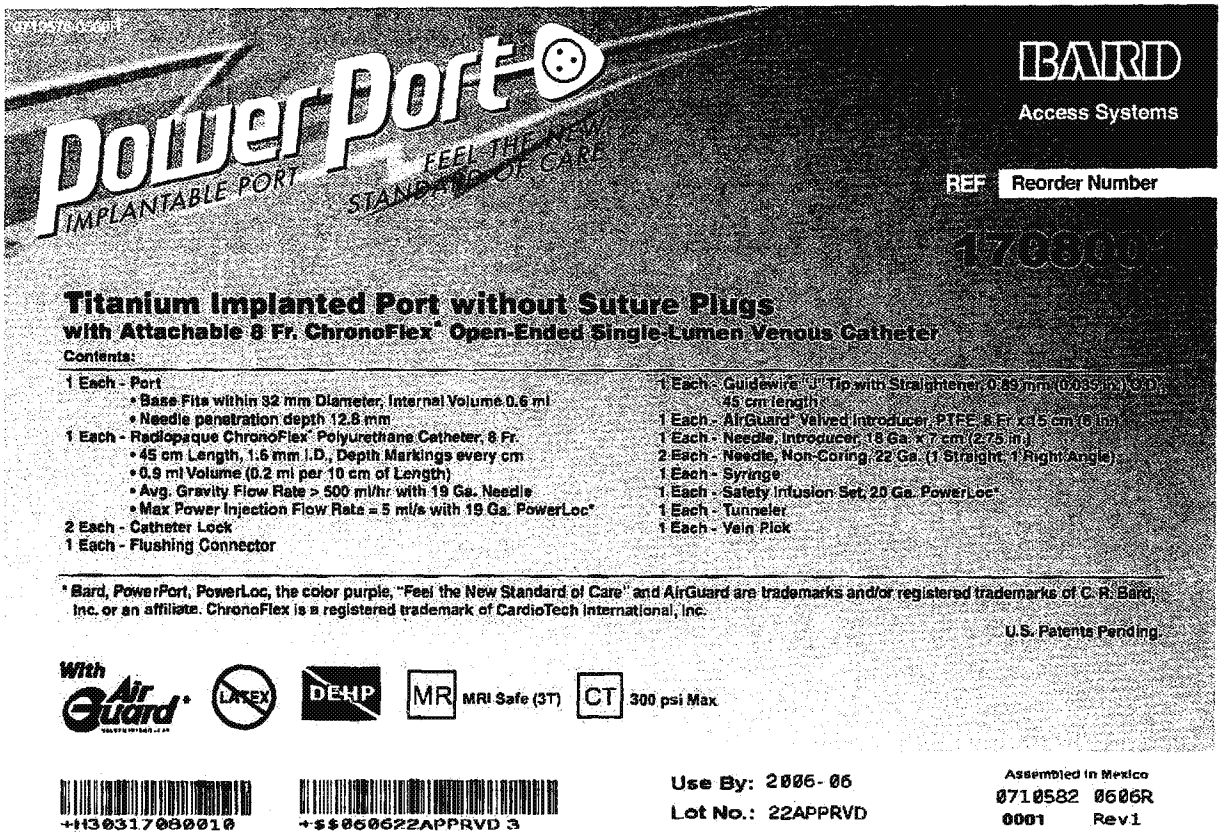


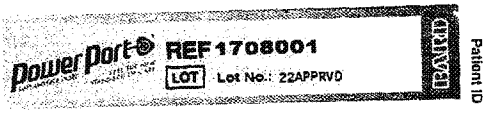


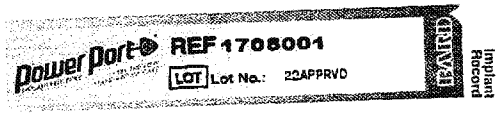


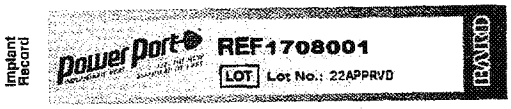


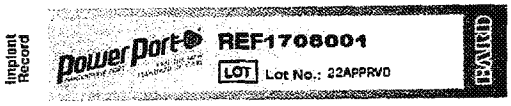
Labeling Predicate Device











Labeling Predicate Device

(b)(4)

(b)(4)

Subject
Implant Record

Groshong® Catheter with

Power Port®

Implant Record / O.R. File

Please indicate Port Placement

Patient's Name _____

Product Code _____

Implant Site _____

Implanting Physician _____

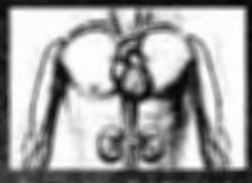
Implant Date _____

Place product identification sticker from the cuff label here.

Groshong® Catheter with

Power Port®

Implant Record / O.R. File



Please indicate Port Placement

Patient's Name _____

Product Code _____

Implant Site _____

Implanting Physician _____

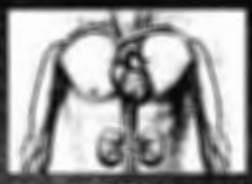
Implant Date _____

Place product identification sticker from the cuff label here.

Groshong® Catheter with

Power Port®

Implant Record / O.R. File



Please indicate Port Placement

Patient's Name _____

Product Code _____

Implant Site _____

Implanting Physician _____

Implant Date _____

Place product identification sticker from the cuff label here.

Predicate Devices

BARD Access Systems

PowerPort* IMPLANTABLE PORT FEEL THE NEW* STANDARD OF CARE

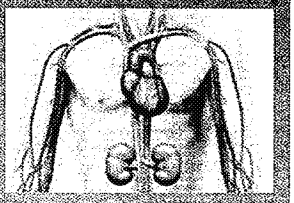
Implant Record / C.R. File

Caution: Use only non-coring needles for access and only a PowerLoc* Safety Infusion Set for power injection.

All Bard Ports are MRI safe (3T).

Before power injecting, palpate the PowerPort* to confirm the presence of three bumps on the septum and three sides on the port.

* Bard, PowerPort, PowerLoc, the color purple, and "Feel the New Standard of Care" and are trademarks and/or registered trademarks of C. R. Bard, Inc. or an affiliate.



Please Indicate Port Placement

Bard Access Systems, Inc.
Salt Lake City, UT 84116 USA / 801.595.0700 / 800.545.0890 / www.bardaccess.com

Patient's Name _____
Product Code _____
Implant Site _____
Implanting Physician _____
Implant Date _____

Place product identification sticker from the unit label here

0713272 060SR

BARD Access Systems

PowerPort* IMPLANTABLE PORT FEEL THE NEW* STANDARD OF CARE

Implant Record / Patient Chart

Caution: Use only non-coring needles for access and only a PowerLoc* Safety Infusion Set for power injection.

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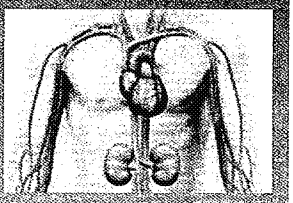

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BARD Access Systems

PowerPort* IMPLANTABLE PORT FEEL THE NEW* STANDARD OF CARE

Implant Record

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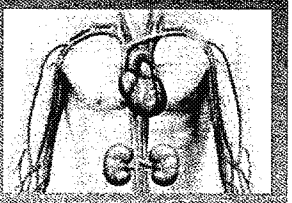

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Salt Lake City, UT 84116 USA / 801.595.0700 / 800.545.0890 / www.bardaccess.com

Patient's Name _____
Product Code _____
Implant Site _____
Implanting Physician _____
Implant Date _____

Place product identification sticker from the unit label here

0713272 060SR

Subject
Instructions for Use

References

1. Jacobs, D. M. et. al., "Anatomical and Morphological Evaluation of Pacemaker Lead Compression. PACE. 1993 Mar; 16(1):434-444
2. Magney, J. E. et. al., "Anatomical Mechanisms Explaining Damage to Pacemaker Leads, Defibrillator Leads, and Failure of Central Venous Catheters Adjacent to the Sternoclavicular Joint". PACE. 1993 Mar; 16(1):445-457
3. Hinke, D.H.; Zandt-Stastny, D.A.; Goodman, L.R.; et al. Pinch-off syndrome: A complication of implantable subclavian venous access devices. Radiology 177: 353-356, 1990.
4. Ingle, Rebecca; Nace, Corinne. "Venous Access Devices: Catheter Pinch-off and Fracture." 1993, Bard Access Systems, Inc.
5. Camp-Sorrell, Dawn. "Access Device Guidelines." 2nd Ed. Oncology Nursing Society, 2004.

Note: The PowerPort* system testing included at least 36 power injection cycles with a PowerLoc* Safety Infusion Set and 11.8 cP viscosity contrast solution.

Further Reading

- See PowerPort* Implanted Port Nursing Guide and/or PowerPort* Implanted Port CT Guide for more details
- Bard Access Systems is proud to offer *"Your* Port Access Advantage"* patient education module for helping patients select their best access option.
- www.powerportadvantage.com

See Bard Access Systems Sales Representative for more information about any of these products.
An issued or revision date for these instructions is included for the user's information. In the event two years have elapsed between this date and product use, the user should contact Bard Access Systems, Inc. to see if additional product information is available.

Revised date: January 2008

CT Contrast Enhanced Computed Tomography Information

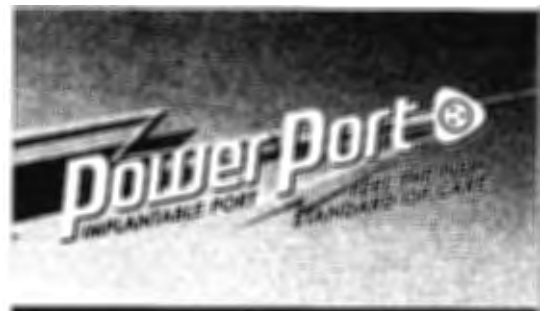
MR Conditional
See MRI Information Insert

This product and package does not contain natural rubber latex.

DEHP This device does not contain DEHP

Bard Access Systems, Inc.
Salt Lake City, UT 84116 USA 801-595-0700
Clinical Information Hotline: 800-443-3385
Ordering Information: 800-545-0890
www.bardaccess.com
www.portadvantage.com
www.powerportadvantage.com

0715912 / 0803R



Implanted Port System

Instructions for Use

BARD

Access Systems

DEHP MR CT 300 psi max

Dear Physician,

Thank you for giving this patient a PowerPort* device. This port not only facilitates infusions, but also allows for the power injection of contrast media for CECT scans. As older technology ports could not withstand power injections, some clinicians may not yet be familiar with a PowerPort* device, and may not recognize that one can receive contrast injections through this port. To avoid unnecessary needlesticks for this patient, we request your help informing other clinicians of the added utility of this port. To help other clinicians identify this patient as a patient with a PowerPort* implantable port, please inform the patient that they have received a PowerPort* device and ensure they receive the Patient Discharge Packet that was packaged with the PowerPort* implanted port packaging.

Thank you,
Bard Access Systems

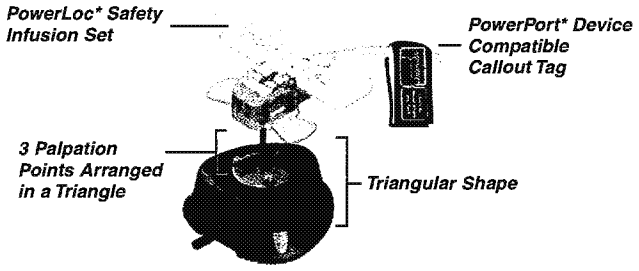
CT Contrast Enhanced Computed Tomography Information

New Important Information:

- This device is contraindicated for catheter insertion in the subclavian vein medial to the border of the first rib, an area which is associated with higher rates of pinch-off.[1,2]
- **For power injecting contrast media, a PowerLoc* Safety Infusion Set (SIS) must always be used to access the PowerPort* implanted port.**
- Contrast media should be warmed to body temperature prior to power injection.
  Warning: Failure to warm contrast media to body temperature prior to power injection may result in port system failure.
- If possible, the patient should receive power injection with arms vertically above the shoulder with the palms of the hands on the face of the gantry during injection. This allows for uninterrupted passage of injected contrast through the axillary and subclavian veins at the thoracic outlet.
- Check for patency, via aspiration, then vigorously flush the PowerPort* device with a syringe and sterile normal saline prior to and immediately following the completion of power injection studies. This will ensure the patency of the PowerPort* implanted port and prevent damage to the port system. Resistance to flushing may indicate partial or complete catheter occlusion. Do not proceed with power injection study until occlusion has been cleared. **Warning:** Failure to ensure patency of the catheter prior to power injection studies may result in port system failure.
- For implanted ports with Groshong* catheters, heparin lock procedures are not necessary. Sterile normal saline may be used for locking Groshong* catheters.
- Do not exceed a 300 psi pressure limit setting, or the maximum flow rate setting shown below, on the power injection machine if power injecting through the PowerPort* device:

PowerLoc* SIS Gauge Size	19 Ga.	20 Ga.	22 Ga.
PowerLoc* SIS Gauge Color*	Cream	Yellow	Black
Maximum Flow Rate Setting	5 ml/s	5 ml/s	2 ml/s

Warning: Do not power inject through a port system that exhibits signs of clavicle-first rib compression or pinch-off, as it may result in port system failure.
Warning: Power injector machine pressure limiting feature may not prevent over pressurization of an occluded catheter.
Warning: Exceeding the maximum flow rate may result in port system failure and/or catheter tip displacement.
Warning: If local pain, swelling or signs of extravasation are noted, the injection should be stopped immediately.
Warning: PowerPort* Implanted Port indication for power injection of contrast media implies the port's ability to withstand the procedure, but does not imply appropriateness of the procedure for a particular patient nor for a particular infusion set. A suitably trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure and for evaluating the suitability of any infusion set used to access the port.



Description

The PowerPort* implanted port is an implantable access device designed to provide repeated access to the vascular system. Port access is performed by percutaneous needle insertion using a non-coring needle. **Power injection is performed using a PowerLoc* Safety Infusion Set only.** The PowerPort* device consists of two primary components: an injection port with a self-sealing silicone septum and a radiopaque catheter. PowerPort* implanted ports can be identified subcutaneously by feeling the top of the septum which includes three palpation points arranged in a triangle and by palpating the sides of the port, which is also triangular. **All materials are biocompatible, can be used with virtually all injectable solutions and can be safely used with CECT. For implanted ports with Groshong* catheters, the Groshong* catheter valve helps provide security against blood reflux and air embolism into the port/catheter system. The Groshong* catheter may be flushed with normal saline and does not require heparin to maintain patency.**

Indications For Use

The PowerPort* implanted port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples.

When used with a PowerLoc* Safety Infusion Set, the PowerPort* device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s.

Contraindications, Warnings, and Precautions

Contraindications

This device is contraindicated for catheter insertion in the subclavian vein medial to the border of the first rib, an area which is associated with higher rates of pinch-off[1,2]

The device is also contraindicated:

- When the presence of device related infection, bacteremia, or septicemia is known or suspected.
- When the patient's body size is insufficient for the size of the implanted device.
- When the patient is known or is suspected to be allergic to materials contained in the device.
- If severe chronic obstructive lung disease exists.
- If the prospective insertion site has been previously irradiated.
- If the prospective placement site has previously suffered episodes of venous thrombosis or vascular surgical procedures.
- If local tissue factors will prevent proper device stabilization and/or access.

Warnings

I. During Placement:

- Intended for Single Patient Use. DO NOT REUSE. Bard Access Systems, Inc. products are single use devices and should never be reimplanted. Any device that has been contaminated by blood should not be reused or resterilized.
- After use, this product may be a potential biohazard. Handle and discard in accordance with accepted medical practice and applicable local, state and federal laws and regulations.
- During placement through a non-AirGuard* peel-away introducer sheath, hold thumb over exposed opening of sheath to prevent air aspiration. The risk of air aspiration is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver.
- Do not suture catheter to port, port stem, or surrounding tissue. Any damage or constriction of catheter may compromise power injection performance and catheter integrity.
- Avoid vessel perforation.
- Do not power inject through a port system that exhibits signs of clavicle-first rib compression or pinch-off as it may result in port system failure.

II. During Port Access:

- DO NOT USE A SYRINGE SMALLER THAN 10ml. Flushing occluded catheters with small syringes can create excessive pressures within the port system.
- **PowerPort* ports are only power injectable when accessed with a PowerLoc* Safety Infusion Set.**
- Failure to warm contrast media to body temperature prior to power injection may result in port system failure.
- Failure to ensure patency of the catheter prior to power injection studies may result in port system failure.
- Power injector machine pressure limiting feature may not prevent over pressurization of an occluded catheter.
- Exceeding the maximum flow rate may result in port system failure and/or catheter tip displacement.
- PowerPort* device indication for power injection of contrast media implies the Port's ability to withstand the procedure, but does not imply appropriateness of the procedure for a particular patient nor for a particular infusion set. A suitably trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure and for evaluating the suitability of any infusion set used to access the port.
- Do not exceed a 300 psi pressure limit setting, or the maximum flow rate setting on the power injection machine, if power injecting through the PowerPort* device.

Signs of Pinch-off

Clinical:
- Difficulty with blood withdrawal
- Resistance to infusion of fluids
- Patient position changes required for infusion of fluids or blood withdrawal

Radiologic:
- Grade 1 or 2 distortion on chest X-ray. Pinch-off should be evaluated for degree of severity prior to explantation. Patients indicating any degree of catheter distortion at the clavicle/first rib area should be followed diligently. There are grades of pinch-off that should be recognized with appropriate chest x-ray as follows: [3,4]

Grade	Severity	Recommended Action
Grade 0	No distortion	No action.
Grade 1	Distortion present **without** luminal narrowing	Chest x-ray should be taken every one to three months to monitor progression of pinch off to grade 2 distortion. Shoulder positioning during chest x-rays should be noted as it can contribute to changes in distortion grades.
Grade 2	Distortion present **with** luminal narrowing	Removal of the catheter should be considered.
Grade 3	Catheter transection or fracture	Prompt removal of the catheter.

Precautions

- Carefully read and follow all instructions prior to use.
- Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- Only qualified healthcare practitioners should insert, manipulate and remove these devices.
- Avoid inadvertent puncture of the skin or fascia with the tip of the tunneler.
- If the guidewire must be withdrawn while the needle is inserted, remove both the needle and wire as a unit to help prevent the needle from damaging or shearing the guidewire.
- Use only non-coring needles with the port.
- Prior to advancing the catheter lock, ensure that the catheter is properly positioned. A catheter not advanced to the proper region may not seat securely and lead to dislodgment and extravasation. The catheter must be straight with no sign of kinking. A slight pull on the catheter is sufficient to straighten it. Advancing the catheter lock over a kinked catheter may damage the catheter.
- Follow Universal Precautions when inserting and maintaining the catheter.
- Follow all contraindications, warnings, precautions and instructions for all infusates as specified by their manufacturers.
- Precautions are intended to help avoid catheter damage and/or patient injury.

I. Prior to Placement:
- Examine package carefully before opening to confirm its integrity and that the expiration date has not passed. The device is supplied in a double sterile package and is non-pyrogenic. Do not use if package is damaged, opened or the expiration date has passed. Sterilized by ethylene oxide. Do not resterilize.
- Inspect kit for presence of all components.
- Check patient's records, and ask patient, whether they have any known allergies to chemicals or materials that will be used during the placement procedure.
- Fill (prime) the device with sterile heparinized saline or normal saline solution to help avoid air embolism. Remember that some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients must not have their port primed with heparinized saline.
- When using an introducer kit, verify that the catheter fits easily through the introducer sheath.

II. During Placement:
- Do not allow accidental device contact with sharp instruments. Mechanical damage may occur. Use only smooth edged, atraumatic clamps or forceps.
- Take care not to perforate, tear, or fracture the catheter during placement. After assembling catheter to port, check assembly for leaks or damage.
- Do not use the catheter if there is any evidence of mechanical damage or leaking.
- Do not bend catheter at sharp angles during implantation. This can compromise catheter patency.
- Carefully follow the connection technique given in these instructions to ensure proper catheter connection and to avoid catheter damage.
- Do not use sutures to secure catheter to the port stem as it could collapse or damage the catheter.
- When using peel-apart introducers:
  - Carefully insert the introducer and catheter to avoid inadvertent penetration to vital structures in the thorax.
  - Avoid blood vessel damage by maintaining a catheter or dilator as internal support when using a peel-apart introducer.
  - Avoid sheath damage by simultaneously advancing the sheath and dilator as a single unit using a rotational motion.

Possible Complications

The use of a subcutaneous port provides an important means of venous access for critically ill patients. However, the potential exists for serious complications, including the following:

- Air Embolism
- Bleeding
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Catheter or Port Erosion Through the Skin
- Catheter Embolism
- Catheter Occlusion
- Catheter Occlusion, Damage or Breakage due to Compression between the Clavicle and First Rib
- Catheter or port related Sepsis
- Device Rotation or Extrusion
- Endocarditis
- Extravasation
- Fibrin Sheath Formation
- Hematoma
- Hemothroax
- Hydrothorax
- Intolerance Reaction to Implanted Device
- Inflammation, Necrosis, or Scarring of Skin Over Implant Area
- Laceration of Vessels or Viscus
- Perforation of Vessels or Viscus
- Pneumothorax
- Spontaneous Catheter Tip Malposition or Retraction
- Thoracic Duct Injury
- Thromboembolism
- Vascular Thrombosis
- Vessel Erosion
- Risks Normally Associated with Local or General Anesthesia, Surgery, and Post-Operative Recovery

These and other complications are well documented in medical literature and should be carefully considered before placing the port.

Implantation Instructions

Please read through complete implantation instructions before implanting port, noting "Contraindications, Warnings, and Precautions" and "Possible Complications" sections of this manual before beginning procedure.

Preventing Pinch-Off

The risk of pinch-off syndrome can be avoided by inserting the catheter via the internal jugular vein (IJ). Subclavian insertion of the catheter medial to the border of the first rib may cause catheter pinch-off, which in turn results in occlusion causing port system failure during power injection.

If you choose to insert the catheter into the subclavian vein, it should be inserted lateral to the border of the first rib or at the junction with the axillary vein because such insertion will avoid compression of the catheter, which can cause damage and even severance of the catheter. The use of image guidance upon insertion is strongly recommended. A radiographic confirmation of catheter insertion should be made to ensure that the catheter is not being pinched.

Implantation Preparation

1. Select implantation procedure to be used.
2. Select the site for port placement.
   Note: Port pocket site selection should allow for port placement in an anatomic area that provides good port stability, does not interfere with patient mobility, does not create pressure points, has not previously been irradiated, does not show signs of infection, and does not interfere with clothing. Consider the amount of cutaneous tissue over the port septum, as excessive tissue will make access difficult. Conversely, too thin a tissue layer over the port may lead to tissue erosion. A tissue thickness of 0.5 cm to 2 cm is appropriate.
3. Complete patient implant record, including length of catheter implanted, product reorder number and lot number.
4. Perform adequate anesthesia.
5. Create sterile field and open tray.
6. Surgically prep and drape the implantation site.

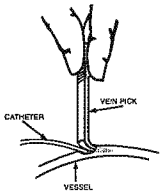
7a. **For Attachable Catheters:** Flush open-ended catheters with sterile heparinized saline, through flush connector and clamp the catheter closed several centimeters from the distal (port) end.
   Note: Clamp catheter segments that will be cut off prior to attachment.

7b. **For Pre-Attached Catheters:** Use a non-coring needle to flush the port and catheter system with sterile heparinized saline.

7c. **For Groshong® catheters:** Flush catheter with sterile normal saline through the pre-loaded stylet connector.

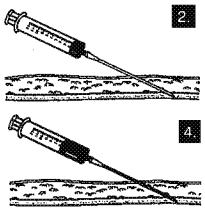
Caution: Remember that some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients must not have their port primed with heparinized saline.

Cut-Down Procedure



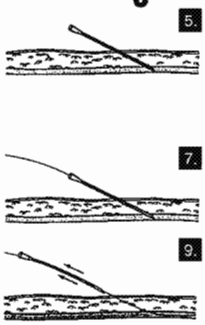
1. Place patient in the Trendelenburg position with head turned away from the intended venipuncture site. Use a cut-down incision to expose the entry vein of choice.
2. Perform vessel incision after vessel is isolated and stabilized to prevent bleeding and air aspiration.
3. If using a vein pick, insert its tapered end through the incision and advance it into the vessel. Then slide the catheter tip into the grooved underside of the pick.
4. Advance the catheter tip into the vessel.
5. Withdraw the vein pick, if used.
6. Advance the catheter into the vessel to the desired infusion site. **Note:** Catheters should be positioned with the catheter tip at the junction of the superior vena cava and the right atrium. Verify correct catheter tip position, using fluoroscopy, or appropriate technology. **Warning:** Do not suture catheter to port, port stem, or surrounding tissue. Any damage or constriction of catheter may compromise power injection performance and catheter integrity.

Percutaneous Procedure:



1. Place patient in the Trendelenburg position with head turned away from the intended venipuncture site.
2. Locate desired vessel using a small gauge needle attached to a syringe. Refer to the "Warnings" section covering catheter Pinch-off, if inserting the catheter via the subclavian vein.
3. Attach introducer needle to the syringe and insert into vessel alongside the small gauge needle. Remove small gauge needle.
4. Aspirate gently as the insertion is made. If the artery is entered, withdraw the needle and apply manual pressure for several minutes. If the pleural space is entered, withdraw the needle and evaluate patient for possible pneumothorax.
5. When the vein has been entered, remove the syringe leaving the needle in place. **Warning:** Place a finger over the hub of the needle to minimize blood loss and the risk of air aspiration. The risk of air aspiration is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver.

6. If using a micropuncture set, insert the flexible end of the micropuncture guidewire into the needle. Advance the guidewire as far as appropriate. Verify correct positioning, using fluoroscopy or ultrasound. Gently withdraw and remove the needle, while holding the micropuncture guidewire in position. **Caution:** If the guidewire must be withdrawn while the needle is inserted, remove both needle and wire as a unit to prevent the needle from damaging or shearing the guidewire. Advance the small sheath and dilator together as a unit over the micropuncture guidewire, using a slight rotational motion. Withdraw the dilator and guidewire, leaving the microintroducer sheath in place. **Warning:** Place a thumb over the opening of the sheath to minimize blood loss and risk of air embolism.
7. Straighten "J " tip of standard guidewire with tip straightener and insert tapered end of tip straightener into the needle (or microintroducer sheath if using a micropuncture set).
8. Remove the tip straightener and advance the standard guidewire into the superior vena cava. Advance the guidewire as far as appropriate for the procedure. Verify correct positioning, using fluoroscopy, or appropriate technology.
9. Gently withdraw and remove needle (or microintroducer sheath if using micropuncture set). **Caution:** If the guidewire must be withdrawn while the needle is inserted, remove both the needle and wire as a unit to help prevent the needle from damaging or shearing the guidewire.



Peel-Apart Sheath Introducer Instructions

1. Advance the vessel dilator and sheath introducer as a unit over the exposed wire using a rotational motion. Advance it into the vein as a unit, leaving at least 2 cm of sheath exposed. **Note:** Placement may be facilitated by making a small incision to ease introduction of vessel dilator and sheath introducer. **Warning:** Avoid vessel perforation.
2. Release the locking mechanism and gently withdraw the vessel dilator and "J" wire, leaving the sheath in place.
3. **Warning:** For non-AirGuard* introducers, hold thumb over exposed opening of sheath to prevent air aspiration. The risk of air aspiration is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver.
4. Insert catheter into the sheath. Advance the catheter through the sheath into the vessel to the desired infusion site. Catheters should be positioned with the catheter tip at the junction of the superior vena cava and the right atrium.
5. Verify correct catheter tip position using fluoroscopy, or appropriate technology.
6. Grasp the two handles of the peel-apart sheath and pull outward and upward at the same time. Peel the sheath away from the catheter completely. Make sure the catheter is not dislodged from vessel.

Catheter Tunneling Procedure

1. Create a subcutaneous pocket using blunt dissection.
   Note: Do a trial placement to verify that the pocket is large enough to accommodate the port and that the port does not lie beneath the incision.

Attachable Catheters

Create a subcutaneous tunnel from the venous site to the port pocket site using tunneler or long forceps per the following:

a. Make a small incision at the venous entry site.
b. Insert tip of tunneler into the small incision.
c. Form tunnel by advancing tip of tunneler from the venous entry site to the port pocket site. **Caution:** Avoid inadvertent puncture of the skin or fascia with the tip of the tunneler.
d. Remove catheter lock from the catheter. For implanted ports with Groshong* catheters, remove the catheter lock and stiffener stylet from the catheter. **Caution:** Never use a catheter lock that appears cracked or otherwise damaged.
e. Attach end of catheter onto the tunneler barb with a twisting motion. **Note:** Barb threads must be completely covered by the catheter to adequately secure the catheter as it is pulled through the tunnel. A suture may be tied around the catheter between the tunneler body and the large barb to hold it more securely.
f. Pull the tunneler through to the port pocket site while gently holding the catheter. **Note:** The catheter must not be forced.
g. Place catheter lock back onto catheter, ensuring the black radiopaque ring or strain relief sleeve faces distally (toward the end of the catheter that will be placed centrally).
h. Cut the catheter to the proper length at a 90° angle, allowing sufficient slack for body movement and port connection. Check catheter for any damage. If any damage is noted, cut damaged section off before connecting catheter to port.

Pre-Attached Catheters

Create subcutaneous tunnel from the port pocket site to the venous entrance site per the following:

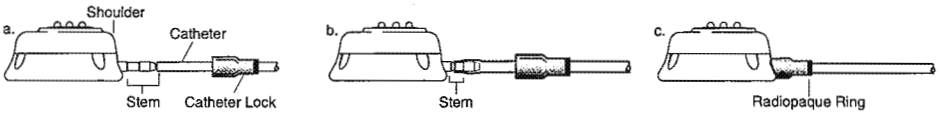
a. Form tunnel by advancing the tip of the tunneler from the port pocket site to the venous entry site. **Caution:** Avoid inadvertent puncture of the skin or fascia with the tip of the tunneler.
b. Connect the catheter tip onto the end of the tunneler.
c. Pull the tunneler through to the venous entry site while gently holding the catheter. Note: The catheter must not be forced.
d. Cut off the end of the catheter attached to the tunneler.
e. Estimate the catheter length required for the tip placement at the junction of the superior vena cava and right atrium by placing the catheter on the chest along the venous path to the right atrium. Cut catheter to length at a 90° angle.

Connect Catheter to Port for attachable catheters

1. Flush all air from the port body using a 10 ml syringe with a non-coring needle filled with sterile heparinized saline (100 USP U/ml) or normal saline. Insert the needle through the septum and inject the fluid while pointing the stem up. **Caution:** Remember that some patients may be hypersensitive to heparin and these patients must not have their port flushed with heparinized saline.
2. Cleanse all system components with irrigation solution.

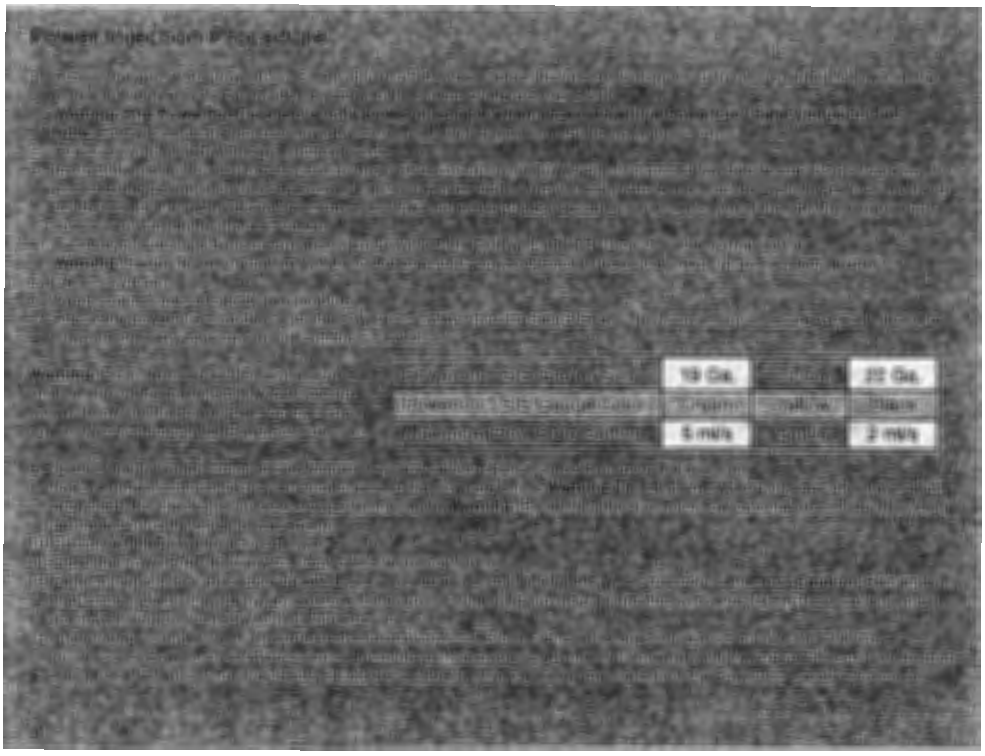
Caution: Prior to advancing the catheter lock, ensure that the catheter is properly positioned. A catheter not advanced to the proper region may not seat securely and lead to dislodgment and extravasation. The catheter must be straight with no sign of kinking. A slight pull on the catheter is sufficient to straighten it. Advancing the catheter lock over a kinked catheter may damage the catheter. Do not hold the catheter or cathlock with any instruments that could potentially damage either piece (e.g., hemostats).

3. Connect catheter to port:
   a. Align port stem with catheter. **Note:** If the catheter and lock are connected and then disconnected, the catheter end must be re-trimmed to ensure a secure re-connection.
   b. Advance catheter over port stem to midway point. **Note:** Advancing catheter too far along port stem could lead to "mushrooming" of tubing when the catheter lock is advanced. Should this occur, it is advisable to stop advancing the catheter lock, pull the catheter back along the stem away from the port, and re-assemble the connection.
   c. Advance catheter lock straight until flush with port. **Note:** When using the catheter lock be sure the end containing a colored radiopaque ring is distal to the port. Catheter lock should be sufficient to secure catheter to port. Bard Access Systems does not recommend suturing around the catheter as doing so could compress, kink, or damage catheter.



Position Port and Close Incision Site

1. Place the port in the subcutaneous pocket away from the incision line. This will reduce the risk of port migration and the possibility of it flipping over. Secure the port to the underlying fascia using non-absorbable, monofilament sutures. Leave sufficient slack in the catheter to permit slight movement, and verify that the catheter is not kinked.
2. After suturing the port in the pocket, flush the wound with an appropriate antibiotic solution.
3. Conduct flow studies on the catheter using a non-coring needle and 10 ml syringe to confirm that the flow is not obstructed, that no leak exists, and that the catheter is correctly positioned.
4. Aspirate to confirm the ability to draw blood.
5. Flush and lock the port system as described under heparin lock procedure for open-ended catheters or saline lock procedures for implanted ports with Groshong® catheters.
   Caution: Remember that some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients must not have their port locked with heparinized saline.
6. After therapy completion, flush port per institutional protocol. Close clamp while injecting last 0.5 ml of flush solution.
7. Close the incision site, so that the port does not lie beneath the incision.
8. Apply dressing according to hospital practice.



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 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.) For PowerPort* implanted port catheters, multiply the catheter length in cm by 0.02, then add 0.6ml for the port reservoir:

Port System Volume = Catheter length: _____ cm x 0.02 ml/cm + 0.6 ml = _____ ml volume.

Heparin Lock Procedure for Open-Ended Catheters

To help prevent clot formation and catheter blockage, implanted ports with open-ended catheters should be filled with sterile heparinized saline after each use. If the port remains unused for long periods of time, the heparin lock should be changed at least once every four weeks.

Caution: Remember that some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients must not have their port locked with heparinized saline.

If the port catheter length is not known, the following are recommended flushing volumes for open-ended catheters, or follow institutional protocol.

FLUSHING VOLUMES, Open-Ended Catheters

PROCEDURE	VOLUME (100 U/ml)
When port not in use	5 ml heparinized saline every 4 weeks
After each infusion of medication or TPN	10 ml sterile normal saline then 5 ml heparinized saline
After blood withdrawal	20 ml sterile normal saline then 5 ml heparinized saline
After power injection of contrast media	10 ml sterile normal saline then 5 ml heparinized saline

Equipment:

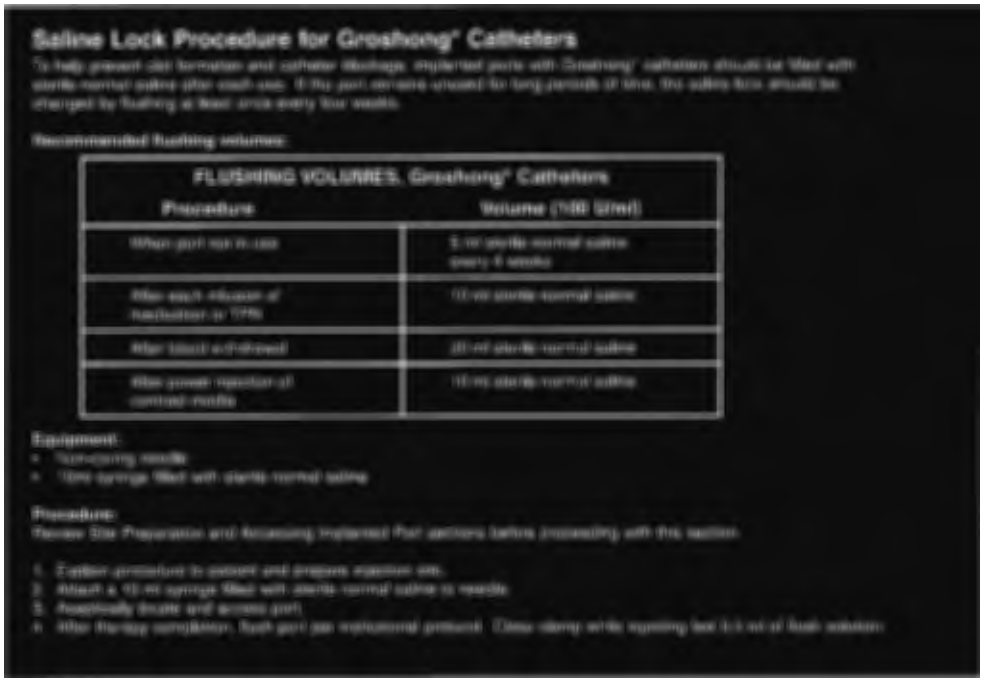
- Non-coring needle
- 10 ml syringe filled with sterile saline
- 10 ml syringe filled with 5 ml heparinized saline (100 U/ml)

Note: Other concentrations of heparinized saline (10 to 1000 U/ml) have been found to be effective. Determination of proper concentration and volume should be based on patient's medical condition, laboratory tests, and prior experience.

Procedure:

1. Explain procedure to patient and prepare injection site.
2. Attach a 10 ml syringe filled with sterile normal saline to needle.
3. Aseptically locate and access port.
4. After therapy completion, flush port per institutional protocol, then repeat with 5 ml 100 U/ml heparinized saline, or with volume calculated above. Close clamp while injecting last 0.5 ml of flush solution.

Note: Alcohol should not be used to soak or declot polyurethane catheters because alcohol is known to degrade the polyurethane catheters over time with repeated and prolonged exposure.



Bard Access Systems

MRI Information Insert

Non-clinical testing has demonstrated the device is MR Conditional. It can be scanned safely under:

- static magnetic field of 3 Tesla or less
- spatial gradient field of 330 Gauss/cm or less
- maximum specific absorption rate (SAR) of 6 W/kg for 30 minutes of scanning.

In non-clinical testing, the device produced a temperature rise of less than 0.5 °C at a maximum specific absorption rate (SAR) of 6 W/kg for 30 minutes of MR scanning in a 3T Siemens Trio with software version VA25.

For Minimal Image artifact

- MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

Bard Access Systems, Inc.
Salt Lake City, UT 84116 USA 801-595-0700
Clinical Information Hotline: 800-443-3385
Ordering Information: 800-545-0890
www.bardaccess.com
www.portadvantage.com
www.powerportadvantage.com

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Power Injection Information for PowerPort* System

Catheter and Size++	Maximum Indicated CT Flow Rate[a]	Operating Pressure in the Port Reservoir[b]	Average Port-Catheter Static Burst Pressure[c]	Range of Port-Catheter Static Burst Pressures[c]
6 Fr. SL ChronoFlex* Polyurethane Catheter	5 ml/s	72 psi	143 psi	136-152 psi
8 Fr. SL ChronoFlex* Polyurethane Catheter	5 ml/s	43 psi	126 psi	107-145 psi
8 Fr. SL Groshong* Catheter	5 ml/s	45 psi	101 psi	74-126 psi
9.6 Fr. SL Silicone Catheter	5 ml/s	34 psi	107 psi	86-114 psi

Note: CT injector pressure limit should be set at a maximum of 300 psi. Flow rates less than 5 ml/s and/or lower viscosity contrast will generate lower pressures in the port and catheter.

[a] Represents flow capability of port and catheter assembly for power injection of contrast media.

[b] Internal port pressure during maximum indicated CT flow rate using contrast media with 11.8 centipoise (cP) viscosity.

[c] Worst case static burst pressure of the port-catheter assembly.

++ See catalog for family range of ports offered with each catheter size.

* Bard, PowerPort, Groshong and the color purple are trademarks and/or registered trademarks of C. R. Bard, Inc. or an affiliate. ChronoFlex is a registered trademark of CardioTech International, Inc. or an affiliate.

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Salt Lake City, UT 84116 USA 801-595-0700
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Ordering Information: 800-545-0890
www.bardaccess.com
www.portadvantage.com
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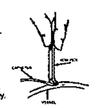
0715911 0804R

If you choose to insert the catheter into the subclavian vein, it should be inserted lateral to the border of the first rib or at the junction with the axillary vein because such insertion will avoid compression of the catheter, which can cause damage and even severance of the catheter. The use of image guidance upon insertion is strongly recommended. A radiographic confirmation of catheter insertion should be made to ensure that the catheter is not being pinched.

Implantation Preparation

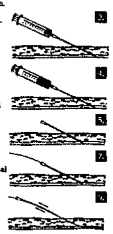
1. Select implantation procedure to be used.
2. Select the site for port placement.
   Note: Port pocket site selection should allow for port placement in an anatomic area that provides good port stability, does not interfere with patient mobility, does not create pressure points, has not previously been irradiated, does not show signs of infection, and does not interfere with clothing. Consider the amount of cutaneous tissue over the port septum, as excessive tissue will make access difficult. Conversely, too thin a tissue layer over the port may lead to tissue erosion. A tissue thickness of 0.5 cm to 2 cm is appropriate.
3. Complete patient implant record, including product reorder number and lot number.
4. Perform adequate anesthesia.
5. Create sterile field and open tray.
6. Surgically prep and drape the implantation site.
7. For Attachable Catheters. Using flush connector, flush open-ended catheters with heparinized saline and clamp the catheter closed several centimeters from the distal (port) end. Remember that some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients must not have their port primed with heparinized saline.
   Note: Clamp catheter segments that will be cut off prior to attachment.

Cut-Down Procedure



1. Place patient in the Trendelenburg position with head turned away from the intended venipuncture site. Use a cut-down incision to expose the entry vein of choice.
2. Perform vessel incision after vessel is isolated and stabilized to prevent bleeding and air aspiration.
3. If using a vein pick, insert its tapered end through the incision and advance it into the vessel. Then slide the catheter tip into the grooved underside of the pick.
4. Advance the catheter tip into the vessel.
5. Withdraw the vein pick, if used.
6. Advance the catheter into the vessel to the desired infusion site.
   Note: Catheters should be positioned with the catheter tip at the junction of the superior vena cava and the right atrium. Verify correct catheter tip position, using fluoroscopy, or appropriate technology. Do not occlude or cut catheter when using sutures to secure catheter.

Percutaneous Procedure:



1. Place patient in the Trendelenburg position with head turned away from the intended venipuncture site.
2. Locate desired vessel using a small gauge needle attached to a syringe.
   Refer to the "Warnings" section covering catheter Pinch-off, if inserting the catheter via the subclavian vein.
3. Attach introducer needle to the syringe and insert into vessel alongside the small gauge needle. Remove small gauge needle.
4. Aspirate gently as the insertion is made. If the artery is entered, withdraw the needle and apply manual pressure for several minutes. If the pleural space is entered, withdraw the needle and evaluate patient for possible pneumothorax.
5. When the vein has been entered, remove the syringe leaving the needle in place. Warning: Place a finger over the hub of the needle to minimize blood loss and the risk of air aspiration. The risk of air aspiration is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver.
6. If using a micropuncture set, insert the flexible end of the micropuncture guidewire into the needle. Advance the guidewire as far as appropriate. Verify correct positioning, using fluoroscopy or ultrasound. Gently withdraw and remove the needle, while holding the micropuncture guidewire in position. Caution: If the guidewire must be withdrawn while the needle is inserted, remove both needle and wire as a unit to prevent the needle from damaging or shearing the guidewire. Advance the small sheath and dilator together as a unit over the micropuncture guidewire, using a slight rotational motion. Withdraw the dilator and guidewire, leaving the microintroducer sheath in place. Warning: Place a thumb over the opening of the sheath to minimize blood loss and risk of air embolism.
7. Straighten "J" tip of standard guidewire with tip straightener and insert tapered end of tip straightener into the needle (or microintroducer sheath if using a micropuncture set).
8. Remove the tip straightener and advance the standard guidewire into the superior vena cava. Advance the guidewire as far as appropriate for the procedure. Verify correct positioning, using fluoroscopy, or appropriate technology.
9. Gently withdraw and remove needle (or microintroducer sheath if using micropuncture set).
   Caution: If the guidewire must be withdrawn while the needle is inserted, remove both the needle and wire as a unit to help prevent the needle from damaging or shearing the guidewire.

Peel-Apart Sheath Introducer Instructions

1. Advance the vessel dilator and sheath introducer as a unit over the exposed wire using a rotational motion. Advance it into the vein as a unit, leaving at least 2 cm of sheath exposed. Note: Placement may be facilitated by making a small incision to ease introduction of vessel dilator and sheath introducer. Warning: Avoid vessel perforation.
2. Release the locking mechanism and gently withdraw the vessel dilator and "J" wire, leaving the sheath in place.
3. Warning: Hold thumb over exposed opening of sheath to prevent air aspiration. The risk of air aspiration is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver.
4. Insert catheter into the sheath. Advance the catheter through the sheath into the vessel to the desired infusion site. Catheters should be positioned with the catheter tip at the junction of the superior vena cava and the right atrium.
5. Verify correct catheter tip position using fluoroscopy, or appropriate technology.
6. Grasp the two handles of the peel-apart sheath and pull outward and upward at the same time.
7. Peel the sheath away from the catheter completely. Make sure the catheter is not dislodged from vessel.

Catheter Tunneling Procedure

1. Create a subcutaneous pocket using blunt dissection.
   Note: Do a trial placement to verify that the pocket is large enough to accommodate the port and that the port does not lie beneath the incision.

Attachable Catheters

Create a subcutaneous tunnel from the venous site to the port pocket site using tunneler or long forceps per the following:

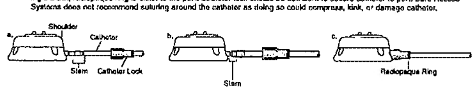
a. Make a small incision at the venous entry site.
b. Insert tip of tunneler into the small incision.
c. Form tunnel by advancing tip of tunneler from the venous entry site to the port pocket site.
   Caution: Avoid inadvertent puncture of the skin or fascia with the tip of the tunneler.
d. Remove catheter lock from the catheter. Caution: Never use a catheter lock that appears cracked or otherwise damaged.
e. Attach end of catheter onto the tunneler barb with a twisting motion. Note: Barb threads must be completely covered by the catheter to adequately secure the catheter as it is pulled through the tunnel. A suture may be tied around the catheter between the tunneler body and the large barb to hold it more securely.
f. Pull the tunneler through to the port pocket site while gently holding the catheter. Note: The catheter must not be forced.
g. Place catheter lock back onto catheter, ensuring the black radiopaque ring or strain relief sleeve faces distally (toward the end of the catheter that will be placed centrally).
h. Cut the catheter to the proper length at a 90° angle, allowing sufficient slack for body movement and port connection. Check catheter for any damage. If any damage is noted, cut damaged section off before connecting catheter to port.

Connect Catheter to Port

1. Flush all air from the port body using a 10 ml syringe with a non-coring needle filled with heparinized saline (100 USP U/ml). Insert the needle through the septum and inject the fluid while pointing the stem up. Caution: Remember that some patients may be hypersensitive to heparin and these patients must not have their port flushed with heparinized saline.
2. Cleanse all system components with irrigation solution.
3. Connect catheter to port:

Caution: Prior to advancing the catheter lock, ensure that the catheter is properly positioned. A catheter not advanced to the proper region may not seat securely and lead to dislodgment and extravasation. The catheter must be straight with no sign of kinking. A slight pull on the catheter is sufficient to straighten it. Advancing the catheter lock over a kinked catheter may damage the catheter. Do not hold the catheter or cathlock with any instruments that could potentially damage either piece (e.g., hemostats).

a. Align port stem with catheter. Note: If the catheter and lock are connected and then disconnected, the catheter end must be re-trimmed to ensure a secure re-connection.
b. Advance catheter over port stem to midway point. Note: Advancing catheter too far along port stem could lead to "mushrooming" of tubing when the catheter lock is advanced. Should this occur, it is advisable to stop advancing the catheter lock, pull the catheter back along the stem away from the port, and re-assemble the connection.
c. Advance catheter lock straight until flush with port. Note: When using a "clearlock" catheter lock be sure the end containing a black, radiopaque ring is distal to the port. Catheter lock should be sufficient to secure catheter to port. Bard Access Systems does not recommend suturing around the catheter as doing so could compress, kink, or damage catheter.



Position Port and Close Incision Site

1. Place the port in the subcutaneous pocket away from the incision line. This will reduce the risk of port migration and the possibility of it flipping over. Secure the port to the underlying fascia using non-absorbable, monofilament sutures. Leave sufficient slack in the catheter to permit slight movement, and verify that the catheter is not kinked.
2. After suturing the port in the pocket, flush the wound with an appropriate antibiotic solution.
3. Conduct flow studies on the catheter using a non-coring needle and 10 ml syringe to confirm that the flow is not obstructed, that no leak exists, and that the catheter is correctly positioned.
4. Aspirate to confirm the ability to draw blood.
5. Flush and heparin lock the port system as described under heparin lock procedure. Caution: Remember that some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients must not have their port locked with heparinized saline.
6. Aftertherapy completion, flush port per institutional protocol. Close clamp while injecting last 0.5 ml of flush solution.
7. Close the incision site, so that the port does not lie beneath the incision.
8. Apply dressing according to hospital practice.

Heparin Lock Procedure

To help prevent clot formation and catheter blockage, implanted ports with open-ended catheters should be filled with sterile heparinized saline after each use. If the port remains unused for long periods of time, the heparin lock should be changed at least once every four weeks.
Caution: Remember that some patients may be hypersensitive to heparin and these patients must not have their port locked with heparinized saline.

Determining Port Volumes

For PowerPort* devices, you will need to determine the length of catheter used for each individual patient. For 8 Fr. polyurethane catheters, multiply the catheter length in cm by 0.02 ml, then add 0.6 ml for the port reservoir:

Catheter length: ________ cm x 0.02 ml/cm + 0.6 ml = ___________ ml volume.

For future reference it will be helpful to record this information on the patient's chart and/or patient ID card.

Recommended flushing volumes:

FLUSHING VOLUMES

PROCEDURE	VOLUME (100 U/ml)
When port not in use	5 ml heparinized saline every 4 weeks
After each infusion of medication or TPN	10 ml sterile normal saline then 5 ml heparinized saline
After blood withdrawal	20 ml sterile normal saline then 5 ml heparinized saline
After power injection of contrast media	10 ml sterile normal saline then 5 ml heparinized saline

Equipment:

- Non-coring needle
- 10 ml syringe filled with sterile saline
- 10 ml syringe filled with 5 ml heparinized saline (100 U/ml)

Note: Other concentrations of heparinized saline (10 to 1000 U/ml) have been found to be effective. Determination of proper concentration and volume should be based on patient's medical condition, laboratory tests, and prior experience.

Procedure:

1. Explain procedure to patient and prepare injection site.
2. Attach a 10 ml syringe filled with sterile normal saline to needle.
3. Aseptically locate and access port.
4. Flush the system, then repeat with 5 ml 100 U/ml heparinized saline.
5. Aftertherapy completion, flush port per institutional protocol. Close clamp while injecting last 0.5 ml of flush solution. Alcohol should not be used to soak or declot polyurethane catheters because alcohol is known to degrade the polyurethane catheters over time with repeated and prolonged exposure.

References

1. Jacobs, D. M. et. al., "Anatomical and Morphological Evaluation of Pacemaker Lead Compression. PACE. 1993 Mar; 16(1):434-444
2. Magney, J. E. et. al., "Anatomical Mechanisms Explaining Damage to Pacemaker Leads, Defibrillator Leads, and Failure of Central Venous Catheters Adjacent to the Sternoclavicular Joint". PACE. 1993 Mar; 16(1):445-457
3. Hinke, D.H.; Zandt-Stastny, D.A.; Goodman, L.R.; et al. Pinch-off syndrome: A complication of implantable subclavian venous access devices. Radiology 177: 353-356, 1990.
4. Ingle, Rebecca; Nace, Corinne. "Venous Access Devices: Catheter Pinch-off and Fracture." 1993, Bard Access Systems, Inc.
5. Camp-Sorrell, Dawn. "Access Device Guidelines." 2nd Ed. Oncology Nursing Society, 2004.

Note: The PowerPort* system testing included at least 36 power injection cycles with a PowerLoc* Safety Infusion Set and 11.8 cP viscosity contrast solution.

Further Reading

- See PowerPort* Implanted Port Nursing Guide and/or PowerPort* Implanted Port CT Guide for more details
- Bard Access Systems is proud to offer "Your Port Access Advantage"* patient education module for helping patients select their best access option.

See Bard Access Systems Sales Representative for more information about any of these products.

An issued or revision date for these instructions is included for the user's information. In the event two years have elapsed between this date and product use, the user should contact Bard Access Systems, Inc. to see if additional product information is available.

Revised date: December 2006

CT Contrast Enhanced Computed Tomography Information

Bard Access Systems, Inc.
Salt Lake City, UT 84116 USA 801-595-0700
Clinical Information Hotline: 800-443-3385
Ordering Information: 800-545-0890
www.bardaccess.com
www.portadvantage.com
www.powerportadvantage.com

0714765 / 0612R Rev 0

Implanted Port
with Open-Ended Catheter

Instructions for Use

BARD
Access Systems

MR CT

00051

Predicate Devices

Dear Physician,

Thank you for giving this patient a PowerPort* device. This port not only facilitates infusions, but also allows for the power injection of contrast media for CECT scans. As older technology ports could not withstand power injections, some clinicians may not yet be familiar with a PowerPort* device, and may not recognize that one can receive contrast injections through this port. To avoid unnecessary needle-sticks for this patient, we request your help informing other clinicians of the added utility of this port. To help other clinicians identify this patient as a patient with a PowerPort* implantable port, please inform the patient that they have received a PowerPort* device and ensure they receive the Patient Discharge Packet that was packaged with the PowerPort* implanted port packaging.

Thank you,
Bard Access Systems' Port Team

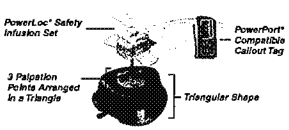
Contrast Enhanced Computed Tomography Information

New Important Information:

- This device is contraindicated for catheter insertion in the subclavian vein medial to the border of the first rib, an area which is associated with higher rates of pinch-off.[1,2]
- **For power injecting contrast media, a PowerLoc* Infusion Set must always be used to access the PowerPort* implanted port.**
- Contrast media should be warmed to body temperature prior to power injection.
  Warning: Failure to warm contrast media to body temperature prior to power injection may result in port system failure.
- If possible, the patient should receive power injection with arms vertically above the shoulder with the palms of the hands on the face of the gantry during injection. This allows for uninterrupted passage of injected contrast through the axillary and subclavian veins at the thoracic outlet.
- Check for patency, via aspiration, then vigorously flush the PowerPort* device with a syringe and sterile normal saline prior to and immediately following the completion of power injection studies. This will ensure the patency of the PowerPort* implanted port and prevent damage to the port system. Resistance to flushing may indicate partial or complete catheter occlusion. Do not proceed with power injection study until occlusion has been cleared. **Warning:** Failure to ensure patency of the catheter prior to power injection studies may result in port system failure.
- Do not exceed a 300 psi pressure limit setting, or the maximum flow rate setting shown below, on the power injection machine if power injecting through the PowerPort* device:

PowerLoc* Gauge Size	19 Ga.	20 Ga.	22 Ga.
PowerLoc* Wing Color	Cream	Yellow	Black
Maximum Flow Rate Setting	5 ml/s	5 ml/s	2 ml/s

Warning: Do not power inject through a port system that exhibits signs of clavicle-first rib compression or pinch-off, as it may result in port system failure.
Warning: Power Injector machine pressure limiting feature may not prevent over pressurization of an occluded catheter.
Warning: Exceeding the maximum flow rate may result in port system failure and/or catheter tip displacement.
Warning: If local pain, swelling or signs of extravasation are noted, the injection should be stopped immediately.
Warning: PowerPort* Implanted Port indication for power injection of contrast media implies the port's ability to withstand the procedure, but does not imply appropriateness of the procedure for a particular patient nor for a particular infusion set. A suitably trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure and for evaluating the suitability of any infusion set used to access the port.



Power Injection Procedure

1. Access the port with a PowerLoc* Safety Infusion Set. Make certain that needle tip is inserted fully within the port.
   Warning: The PowerPort* system is only power injectable when accessed with a PowerLoc* Safety Infusion Set.
   Note: Follow institutional protocol to verify correct catheter tip position prior to power injection.
2. Attach a syringe filled with sterile normal saline.
3. Instruct the patient to assume the position they will be in during the power injection procedure, before checking for patency. If possible, the patient should receive power injection with his or her arm vertically above the shoulder with the palm of the hand on the face of the gantry during injection. This allows for uninterrupted passage of injected contrast through the axillary and subclavian veins at the thoracic outlet.
4. Aspirate for adequate blood return and vigorously flush the port with at least 10 ml of sterile normal saline.
   Warning: Failure to ensure patency of the catheter prior to power injection studies may result in port system failure.
5. Detach syringe.
6. Warm contrast media to body temperature.
7. Attach the power injection device to the PowerLoc* Infusion Set ensuring connection is secure. Check indicated flow rate of safety infusion set and confirm CT settings.

PowerLoc* Gauge Size	19 Ga.	20 Ga.	22 Ga.
PowerLoc* Wing Color	Cream	Yellow	Black
Maximum Flow Rate Setting	5 ml/s	5 ml/s	2 ml/s

8. Instruct the patient to communicate immediately any pain or change in feeling during the injection.
9. Inject warmed contrast, taking care not to exceed the flow rate limits. **Warning:** If local pain, swelling or signs of extravasation are noted, the injection should be stopped immediately. **Warning:** Exceeding the maximum flow rate may result in port system failure and/or catheter tip displacement.
10. Disconnect the power injection device.
11. Flush the PowerPort* device with 10 ml of sterile normal saline.
12. Perform heparin lock procedure. Remember that some patients may be hyper-sensitive to heparin or suffer heparin induced thrombocytopenia (HIT). These patients must not have their port primed with heparinized saline.
13. After therapy completion, flush port per institutional protocol. Close clamp while injecting last 0.5 ml of flush solution.
14. Pull PowerLoc's safety infusion sets top wings away from the lower wings until you feel a "click" at which time the needle should be captured within PowerLoc's safety mechanism.

Warning: Do not exceed a 300 psi pressure limit setting, or the maximum flow rate setting shown below, on the power injection machine if power injecting through the PowerPort* device:

Power Injection Information for PowerPort* System

Catheter and Size	Maximum Indicated CT Flow Rate[a]	Average Pressure in the Port Reservoir[b]	Average Port-Catheter Static Burst Pressure[c]	Range of Port-Catheter Static Burst Pressures[c]
8 Fr. SL Purple ChronoFlex® Polyurethane Catheter	5 ml/s	42 psi	140 psi	135-145 psi
8 Fr. SL White ChronoFlex® Polyurethane Catheter	5 ml/s	43 psi	126 psi	107-145 psi

Note: CT injector pressure should be set at a maximum of 300 psi. Flow rates less than 5 ml/s and/or lower viscosity contrast will generate lower pressures in the port and catheter.
[a] Represents flow capability of port and catheter assembly for power injection of contrast media.
[b] Internal port pressure during maximum indicated CT flow rate using contrast media with 11.8 Centipoise (cp) viscosity.
[c] Maximum burst pressure is the static burst pressure of the port-catheter assembly.

Description

The PowerPort* implanted port is an implantable access device designed to provide repeated access to the vascular system. Port access is performed by percutaneous needle insertion using a non-coring needle. **Power injection is performed using a PowerLoc* Safety Infusion Set only.** The PowerPort* device consists of two primary components: an injection port with a self-sealing silicone septum and a radiopaque ChronoFlex® polyurethane catheter. PowerPort* implanted ports can be identified subcutaneously by feeling the top of the septum which includes three palpation points arranged in a triangle and by palpating the sides of the port, which is also triangular. **All materials are biocompatible, can be used with virtually all injectable solutions, are latex-free, and safe with CECT and MRI imaging.**

Indications For Use

The PowerPort* implanted port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples.

When used with the PowerLoc* Safety Infusion Set, the PowerPort* device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s.

Contraindications, Warnings, and Precautions

Contraindications

This device is contraindicated for catheter insertion in the subclavian vein medial to the border of the first rib, an area which is associated with higher rates of pinch-off[1,2]

The device is also contraindicated:
- When the presence of device related infection, bacteremia, or septicemia is known or suspected.
- When the patient's body size is insufficient for the size of the implanted device.
- When the patient is known or is suspected to be allergic to materials contained in the device.
- If severe chronic obstructive lung disease exists.
- If the prospective insertion site has been previously irradiated.
- If the prospective placement site has previously suffered episodes of venous thrombosis or vascular surgical procedures.
- If local tissue factors will prevent proper device stabilization and/or access.

Warnings

I. During Placement:
- Intended for Single Patient Use. DO NOT REUSE. Bard Access Systems, Inc. products are single use devices and should never be reimplanted. Any device that has been contaminated by blood should not be reused or resterilized.
- After use, this product may be a potential biohazard. Handle and discard in accordance with accepted medical practice and applicable local, state and federal laws and regulations.
- During placement through a sheath, hold thumb over exposed opening of sheath to prevent air aspiration. The risk of air aspiration is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver.
- Do not suture catheter to port. Any damage or constriction of catheter may compromise power injection performance.
- Avoid vessel perforation.
- Do not power inject through a port system that exhibits signs of clavicle-first rib compression or pinch-off as it may result in port system failure.

II. During Port Access:
- DO NOT USE A SYRINGE SMALLER THAN 10ml. Prolonged infusion pressure greater than 25 psi may cause damage to a patient's vessels or viscus.
- **PowerPort* ports are only power injectable when accessed with a PowerLoc* Safety Infusion Set.**
- Failure to warm contrast media to body temperature prior to power injection may result in port system failure.
- Failure to ensure patency of the catheter prior to power injection studies may result in port system failure.
- Power injector machine pressure limiting feature may not prevent over pressurization of an occluded catheter.
- Exceeding the maximum flow rate may result in port system failure and/or catheter tip displacement.
- PowerPort* device indication for power injection of contrast media implies the Port's ability to withstand the procedure, but does not imply appropriateness of the procedure for a particular patient nor for a particular infusion set. A suitably trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure and for evaluating the suitability of any infusion set used to access the port.
- Donot exceed a 300 psi pressure limit setting, or the maximum flow rate setting on the power injection machine, if power injecting through the PowerPort* device.

Signs of Pinch-off

Clinical:
- Difficulty with blood withdrawal
- Resistance to infusion of fluids
- Patient position changes required for infusion of fluids or blood withdrawal

Radiologic:
- Grade 1 or 2 distortion on chest X-ray.
  Pinch-off should be evaluated for degree of severity prior to explantation. Patients indicating any degree of catheter distortion at the clavicle/first rib area should be followed diligently. There are grades of pinch-off that should be recognized with appropriate chest x-ray as follows:[3,4]

Grade	Severity	Recommended Action
Grade 0	No distortion	No action.
Grade 1	Distortion present without luminal narrowing	Chest x-ray should be taken every one to three months to monitor progression of pinch off to grade 2 distortion. Shoulder positioning during chest x-rays should be noted as it can contribute to changes in distortion grades.
Grade 2	Distortion present with luminal narrowing	Removal of the catheter should be considered.
Grade 3	Catheter transection or fracture	Prompt removal of the catheter.

Precautions

- Carefully read and follow all instructions prior to use.
- Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- Only qualified healthcare practitioners should insert, manipulate and remove these devices.
- Avoid inadvertent puncture of the skin or fascia with the tip of the tunneler.
- If the guidewire must be withdrawn while the needle is inserted, remove both the needle and wire as a unit to help prevent the needle from damaging or shearing the guidewire.
- Use only non-coring needles with the port.
- Prior to advancing the catheter lock, ensure that the catheter is properly positioned. A catheter not advanced to the proper region may not seat securely and lead to dislodgment and extravasation. The catheter must be straight with no sign of kinking. A slight pull on the catheter is sufficient to straighten it. Advancing the catheter lock over a kinked catheter may damage the catheter.
- Follow Universal Precautions when inserting and maintaining the catheter.
- Follow all contraindications, warnings, precautions and instructions for all infusates as specified by their manufacturers.
- Precautions are intended to help avoid catheter damage and/or patient injury.

I. Prior to Placement:
- Examine package carefully before opening to confirm its integrity and that the expiration date has not passed. The device is supplied in a double sterile package and is non-pyrogenic. Do not use if package is damaged, opened or the expiration date has passed. Sterilized by ethylene oxide. Do not resterilize.
- Inspect kit for presence of all components.
- Check patient's records, and ask patient, whether they have any known allergies to chemicals or materials that will be used during the placement procedure.
- Fill (prime) the device with sterile heparinized saline or normal saline solution to help avoid air embolism. Remember that some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients must not have their port primed with heparinized saline.
- When using an introducer kit, verify that the catheter fits easily through the introducer sheath.

II. During Placement:
- Do not allow accidental device contact with sharp instruments. Mechanical damage may occur. Use only smooth edged, atraumatic clamps or forceps.
- Take care not to perforate, tear, or fracture the catheter during placement. After assembling catheter to port, check assembly for leaks or damage.
- Do not use the catheter if there is any evidence of mechanical damage or leaking.
- Do not bend catheter at sharp angles during implantation. This can compromise catheter patency.
- Carefully follow the connection technique given in these instructions to ensure proper catheter connection and to avoid catheter damage.
- Do not use sutures to secure catheter to the port stem as it could collapse or damage the catheter.
- When using peel-apart introducers:
  - Carefully insert the introducer and catheter to avoid inadvertent penetration to vital structures in the thorax.
  - Avoid blood vessel damage by maintaining a catheter or dilator as internal support when using a peel-apart introducer.
  - Avoid sheath damage by simultaneously advancing the sheath and dilator as a single unit using a rotational motion.

Possible Complications

The use of a subcutaneous port provides an important means of venous access for critically ill patients. However, the potential exists for serious complications, including the following:

- Air Embolism
- Bleeding
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Catheter or Port Erosion Through the Skin
- Catheter Embolism
- Catheter Occlusion
- Catheter Occlusion, Damage or Breakage due to Compression between the Clavicle and First Rib
- Catheter or port related Sepsis
- Device Rotation or Extrusion
- Endocarditis
- Extravasation
- Fibrin Sheath Formation
- Hematoma
- Hemothorax
- Hydrothorax
- Intolerance Reaction to Implanted Device
- Inflammation, Necrosis, or Scarring of Skin Over Implant Area
- Laceration of Vessels or Viscus
- Perforation of Vessels or Viscus
- Pneumothorax
- Spontaneous Catheter Tip Malposition or Retraction
- Thoracic Duct Injury
- Thromboembolism
- Vascular Thrombosis
- Vessel Erosion
- Risks Normally Associated with Local or General Anesthesia, Surgery, and Post-Operative Recovery

These and other complications are well documented in medical literature and should be carefully considered before placing the port.

Implantation Instructions

Please read through complete implantation instructions before implanting port, noting "Contraindications, Warnings, and Precautions" and "Possible Complications" sections of this manual before beginning procedure.

Preventing Pinch-Off

The risk of pinch-off syndrome can be avoided by inserting the catheter via the internal jugular vein (IJ). Subclavian insertion of the catheter medial to the border of the first rib may cause catheter pinch-off, which in turn results in occlusion causing port system failure during power injection.

Unit Labeling
Subject and Predicate Devices

PowerLoc™ Unit Label

An issued or revision date for these instructions is included for the user's information. In the event two years have elapsed between this date and product use, the user should contact **Bard Access Systems, Inc.** to see if additional product information is available.

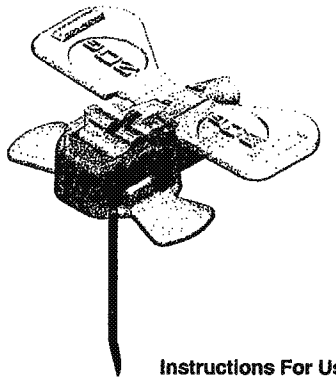
Revised Date: October 2006

0713901 / 0610R

Bard Access Systems, Inc.
Salt Lake City, UT 84116 USA
801-595-0700
Customer Service: 800-545-0890
Clinical Information: 800-443-3385

www.bardaccess.com

PowerLoc* Safety Infusion Set

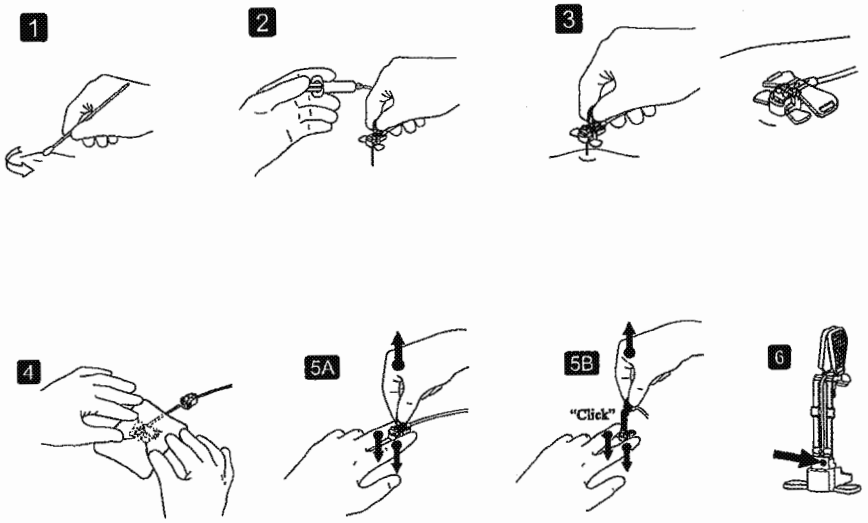


Instructions For Use

BARD Access Systems

Instructions for Use
Subject and Predicate Device

: 06691



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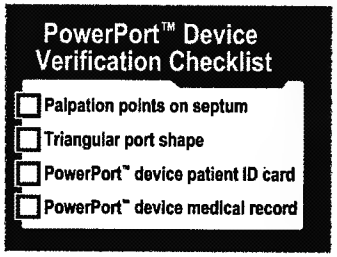
insert 1 BACK



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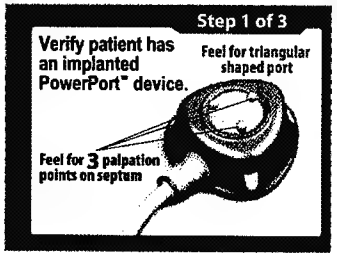

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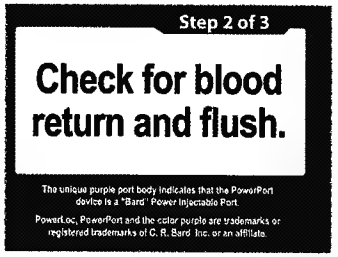

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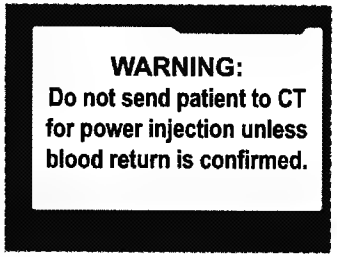

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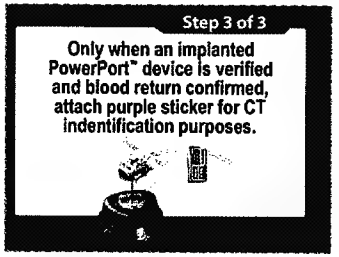
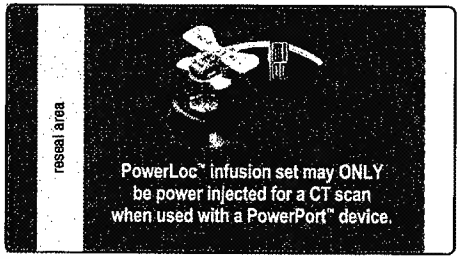


Hinge Area

Top Panel

Base Panel



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Subject and Predicate Devices

Attachment 5
In-Service Literature – Subject & Predicate

A. In-Service Education Literature:

- Nursing Guide
- CT Guide

B. Patient Discharge Kit Labeling:

- Patient Discharge Kit Folder
- PowerPort ID Card
- PowerPort Patient Guide
- PowerPort Key Chain Fob
- PowerPort Companion Checklist

Note: labeling images are not to scale

Subject
Nursing Guide

DEHP

This product and package does not contain natural rubber latex

CT MR

300 psi max

BARD
Access Systems

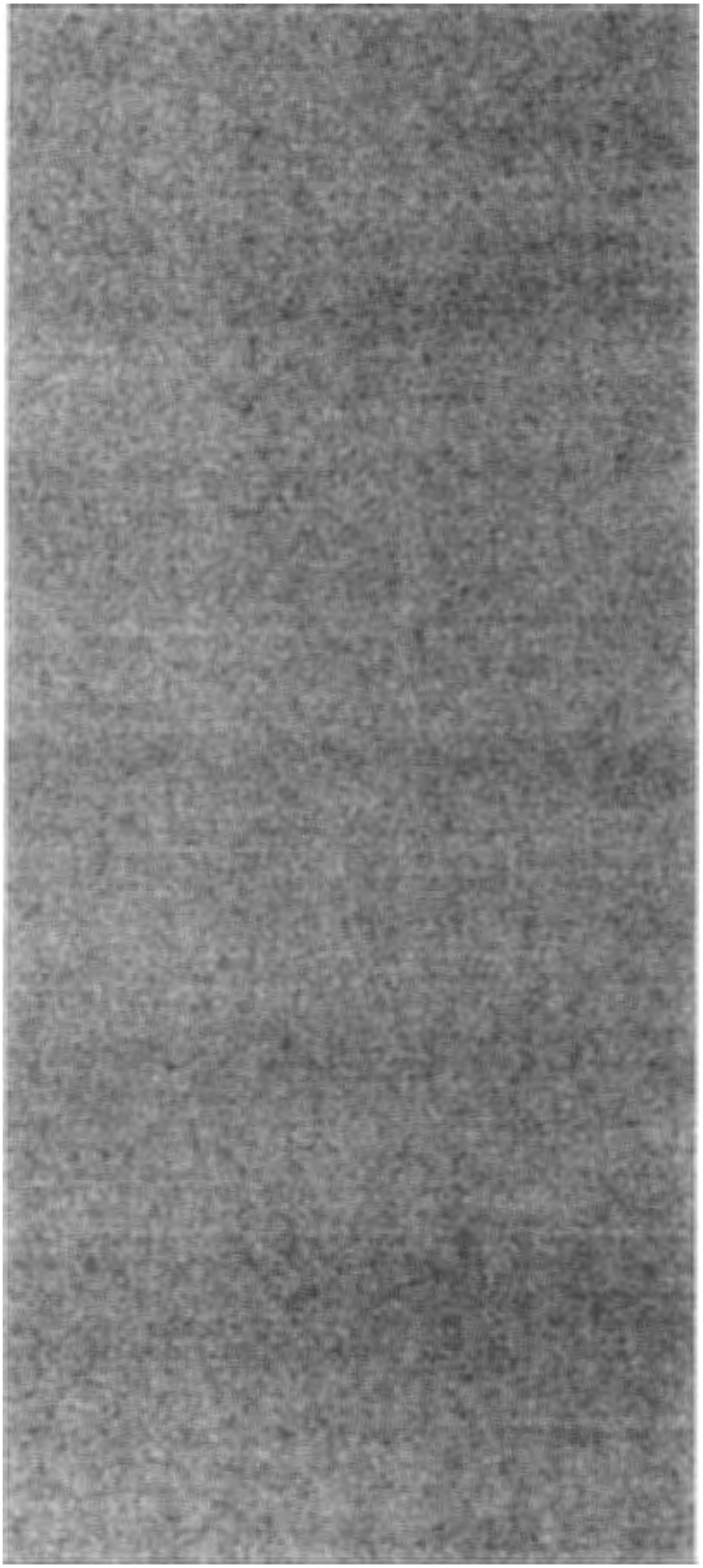


Table of Contents

Introduction:

Bard Access Systems' PowerPort* power-injectable port not only facilitates infusions, but is the first port indicated for the power injection of contrast media for CECT scans.

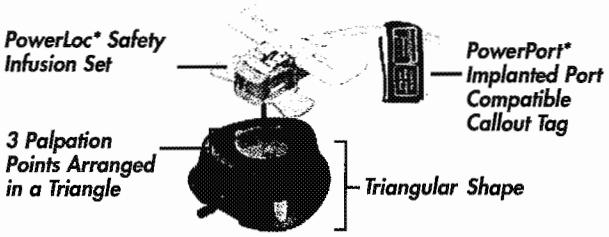
Contrast enhanced computed tomography (CECT) scans are simple, safe and non-invasive procedures that provide quick and accurate diagnostic information to help track tumor markers or diagnose pulmonary embolisms, for example. The scans are many times more sensitive than conventional x-rays. Radiologists can distinguish small differences in soft tissues that may not be detected with x-rays.

Before performing a CECT scan, the CT team will inject a contrast agent, which is a special fluid that acts like a dye, into the patient to help produce clearer pictures during the CECT scan procedure. For best results, the contrast agent is infused at a high rate into your bloodstream. This process is called power injection.

Bard's PowerPort* power-injectable port used with the PowerLoc* Safety Infusion Set has the unique ability to allow clinicians to perform power-injected CECT scans without having to use peripheral I.V. needles.

Important Information:

- A PowerLoc* Safety Infusion Set must always be used to access the PowerPort* implanted port for power injecting contrast media.



- Contrast media should be warmed to body temperature prior to power injection.
  Warning: Failure to warm contrast media to body temperature prior to power injection may result in port system failure.
- Check for patency, via aspiration, then vigorously flush the PowerPort* device using at least 10 ml of sterile normal saline prior to and immediately following the completion of power injection studies. It is important to ensure the patency of the PowerPort* device to prevent damage to the catheter. Resistance to flushing may indicate partial or complete catheter occlusion. Do not proceed with power injection study until occlusion has been cleared.
- For Implanted ports with **Groshong*** catheters, heparin lock procedures are not necessary; a sterile normal saline lock may be used.

Warning: Failure to ensure patency of the catheter prior to power injection studies may result in port system failure.
Warning: Do not power inject through a port system that exhibits signs of clavicle-first rib compression or pinch-off as it may result in port system failure.
Warning: Power injector machine pressure limiting feature may not prevent over pressurization of an occluded catheter.
Warning: Do not exceed a 300 psi pressure limit setting, or the maximum flow rate setting shown below, on the power injection machine if power injecting through the PowerPort* device:

PowerLoc* Safety Infusion Set Gauge Size	19 Ga.	20 Ga.	22 Ga.
PowerLoc* Safety Infusion Set Gauge Color	Cream	Yellow	Black
Maximum Flow Rate Setting	5 ml/sec	5 ml/sec	2 ml/sec

Warning: The PowerPort* implanted port indication for power injection of contrast media implies the device's ability to withstand the procedure, but does not imply appropriateness of the procedure for a particular patient. A suitably trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure. The PowerPort* device is only power injectable when accessed with a PowerLoc* Safety Infusion Set.

Description

The PowerPort* Implanted Port is an implantable access device designed to provide repeated access to the vascular system. Port access is performed by percutaneous needle insertion using a non-coring needle. Power injection is performed using a PowerLoc* Safety Infusion Set only. The PowerPort* device consists of two primary components: an injection port with a self-sealing silicone septum and a radiopaque catheter. PowerPort* implanted ports can be identified subcutaneously by feeling the top of the septum which includes three palpation points arranged in a triangle and by palpating the sides of the port, also in a triangular shape. All materials are biocompatible, can be used with virtually all injectable solutions and can be safely used with CECT.
For Implanted ports with **Groshong*** catheters, the **Groshong*** catheter valve helps provide security against blood reflux and air embolism into the

port/catheter system. The **Groshong*** catheter may be flushed with sterile normal saline and does not require heparin to maintain patency.

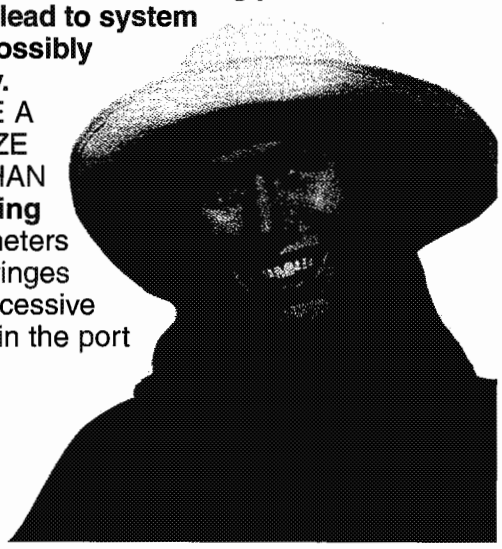
Indications For Use

The PowerPort* Implanted Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples.

When used with PowerLoc* Safety Infusion Set, the PowerPort* device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s.

Warnings

- Do not power inject through a port system that exhibits signs of clavicle-first rib compression or pinch-off as it may result in port system failure.
- Intended for Single Patient Use. DO NOT REUSE. These Bard Access Systems, Inc. products are single use devices and should never be reimplanted. Any device that has been contaminated by blood should not be reused or resterilized.
- After use, this product may be a potential biohazard. Handle and discard in accordance with accepted medical practice and applicable local, state and federal laws and regulations.
- **The use of an infusion set other than PowerLoc* Infusion Sets during power injection will lead to system failure and possibly patient injury.**
- DO NOT USE A SYRINGE SIZE SMALLER THAN 10 ml. **Flushing** occluded catheters with small syringes can create excessive pressure within the port system.



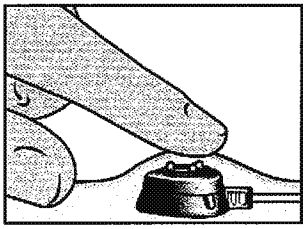
Precautions

- Carefully read and follow all instructions prior to use.
- Follow Universal Precautions when accessing the port.
- Follow all warnings, precautions and instructions for all infusates as specified by their manufacturers.
- Precautions are intended to help avoid product damage and/or patient injury.
- Only accessories and components with luer lock connections should be used with this device.
- If signs of extravasation exist, discontinue injections. Begin appropriate medical intervention immediately.
- Use only non-coring needles with the port.

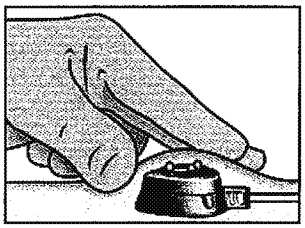
Identifying a PowerPort Port Patient*

- Power-injectable ports can be distinguished from traditional ports through the following means:
  - Check patient's chart for a PowerPort* port patient record sticker.

  - Palpate sides of port to identify triangular port housing.
  - Palpate top of port to identify three palpation points (bumps) on the septum, arranged in a triangle.

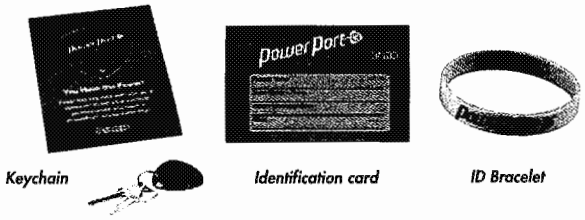


Feel the soft top of the port to locate the three palpation points arranged as a triangle.



Feel the sides of the port to identify its unique triangle shape.

- Request confirmation from the patient by asking them to show you the patient identification card, ID bracelet, or keychain they received when the port was implanted.



- Always verify the patient has a PowerPort* port by at least two means and ensure they are accessed with a PowerLoc* Infusion Set, prior to power injection.
- For additional guidance on recognizing a power injectable port / safety infusion set system, contact Bard's Clinical Information Hotline at 800-443-3385.

Possible Complications

The use of a subcutaneous port provides an important means of venous access for critically ill patients. However, the potential exists for serious complications, including, but not limited to the following:

- Air Embolism
- Bleeding
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Catheter or Port Erosion Through the Skin
- Catheter Embolism
- Catheter Occlusion
- Catheter Occlusion, Damage or Breakage due to Compression between the Clavicle and First Rib
- Catheter or Port related Sepsis
- Device Rotation or Extrusion
- Endocarditis
- Extravasation
- Fibrin Sheath Formation
- Hematoma
- Hemothroax
- Hydrothorax
- Intolerance Reaction to Implanted Device
- Inflammation, Necrosis, or Scarring of Skin Over Implant Area
- Laceration of Vessels or Viscus
- Perforation of Vessels or Viscus
- Pneumothorax
- Spontaneous Catheter Tip Malposition or Retraction
- Thoracic Duct Injury
- Thromboembolism
- Vascular Thrombosis
- Vessel Erosion
- Risks Normally Associated with Local or General Anesthesia, Surgery, and Post-Operative Recovery

These and other complications are well documented in medical literature.

Use and Maintenance Instructions

Site Preparation

Always inspect and aseptically prepare the injection site prior to accessing the port.

Note: It is recommended that catheter tip placement is verified through institutional protocol.

Equipment:

- Alcohol or chlorhexidine wipe
- Antiseptic swabs (3)
- Sterile gloves

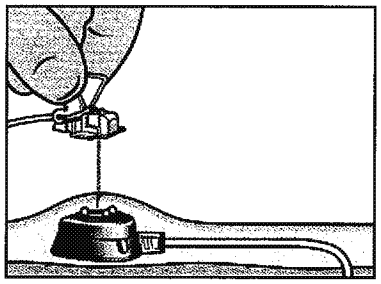
Procedure:

1. Explain procedure to patient. Warn of needle prick sensation. (Sensation of needle insertion decreases over time. Use of a topical anesthetic may be appropriate.)
2. Wash hands thoroughly.
3. Put on sterile gloves.
4. Cleanse or scrub the area according to the cleansing agent manufacturers instructions. We suggest an area of at least 10 – 13 cm (approximately 4 x 5 in.) diameter at the port insertion site.
   Directions for the use of ChloraPrep* preoperative skin preparation: Prepare the site with ChloraPrep* One-Step Applicator Solution or according to institutional policy using sterile technique. "Pinch-Off" the wings on the ChloraPrep* One-Step Applicator Solution to break the ampule and release the antiseptic. Do not touch the sponge. Wet the sponge against the treatment area until fluid is visible on the skin. Use repeated back-forth strokes of the sponge for approximately 30 seconds. Completely wet the treatment area with antiseptic. Allow the area to dry for approximately 30 seconds. Do not blot or wipe away. Maximum treatment area for one applicator is approximately 130 cm^2 (approximately 4 x 5 in.). Discard the applicator after use.

Note: Follow established hospital or institutional policy for changing I.V. tubing and accessing cannula. The Center for Disease Control (CDC) or Oncology Nursing Society (ONS) may have recommended guidelines.

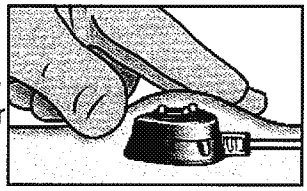
Accessing Implanted Ports
Equipment:

- Syringe
- If the port will be accessed for power injection, it must be accessed with a PowerLoc* Safety Infusion Set. If not power injecting, it can be accessed with any non-coring safety needle. Choose a needle length based on reservoir depth, tissue thickness, and the thickness of any dressing beneath the bend of the needle.

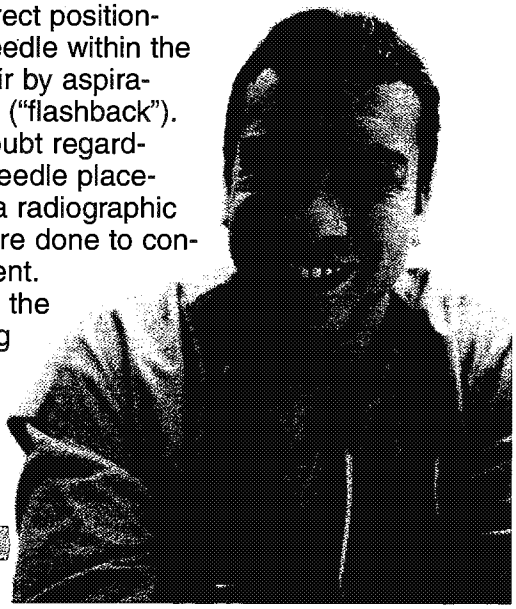


Procedure:

1. Perform aseptic site preparation.
2. Locate port septum by palpation.
   a. Locate base of port with non-dominant hand.
   b. Triangulate port between thumb and first two fingers of non-dominant hand. Aim for center point of these three fingers.



3. Insert PowerLoc* Safety Infusion Set or other non-coring safety needle perpendicular to port septum. Advance needle through the skin and septum until reaching bottom of reservoir. Make certain that needle tip is inserted fully within the port.
4. Confirm correct positioning of the needle within the port reservoir by aspiration of blood ("flashback"). If there is doubt regarding proper needle placement, have a radiographic dye procedure done to confirm placement.
5. Always flush the port following injection.



6. Perform heparin lock procedure for open-ended catheters. For implanted ports with **Groshong*** catheters, a sterile normal saline lock may be used. **Caution:** Remember that some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients must not have their port locked with heparinized saline.
7. When deaccessing the port, the needle should be removed using the positive pressure technique. Positive pressure is maintained while flushing the accessed port by clamping the infusion set tubing, while still flushing the line. This helps reduce the potential for blood backflow into the catheter tip, which could encourage catheter clotting. If using a PowerLoc* safety infusion set, activate safety mechanism while withdrawing the needle until you hear or feel a "click" at which time the needle should be captured within the safety mechanism of the PowerLoc* safety infusion set.

Bolus Injection Procedure Other Than Power Injection

Equipment:
- PowerLoc* Safety Infusion Set, or other non-coring safety needle. Choose a needle length based on reservoir depth, tissue thickness, and the thickness of any dressing beneath the bend of the needle.
- Syringe filled with sterile normal saline
- Extension set with clamp

Procedure:
Review Site Preparation and Accessing Implanted Port sections before proceeding with this section.
1. Explain procedure to patient and prepare injection site. Remember to check patient's records, and ask patient, to determine whether they have any known allergies to chemicals or materials that will be used during the injection procedure.
2. Attach PowerLoc* Safety Infusion Set or other non-coring safety needle to extension set and syringe filled with sterile normal saline. Expel all air and clamp extension.
3. Aseptically locate and access port. Confirm correct positioning of the needle within the port reservoir by aspiration of blood ("flashback").

If there is doubt regarding proper needle placement, have a radiographic dye procedure done to confirm placement.

4. Flush port with 10 ml sterile normal saline. Clamp the extension set and remove the syringe.
5. Connect syringe containing the drug to extension set. Release clamp and begin to administer injection.
6. Examine the injection site for signs of extravasation; if noted, immediately discontinue the injection and initiate appropriate intervention.
7. When the injection is completed, clamp the extension set.
8. Flush after each injection with 10 ml of sterile normal saline to help prevent interaction between incompatible drugs.
9. **For open-ended catheters:** Flush port with 5 ml heparinized saline after every use and at least once every 4 weeks.
   For Groshong* catheters: Flush port with 5ml of sterile normal saline after every use and at least once every 4 weeks.
   Caution: Remember that some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients must not have their port locked with heparinized saline.
   Note: For **Groshong*** and open-ended catheters, the needle hub should not be left open to air while it is in the port. Do not manipulate the needle once it is in the septum.
10. When deaccessing the port, the needle should be removed using the positive pressure technique. Positive pressure is maintained while flushing the accessed port by clamping the infusion set tubing, while still flushing the line. This helps reduce the potential for blood backflow into the catheter tip, which could encourage catheter clotting.

Continuous Infusion Procedure

Caution: DO NOT USE A SYRINGE SIZE SMALLER THAN 10 ml. **Flushing** occluded catheters with small syringes can create excessive pressures within the port system.

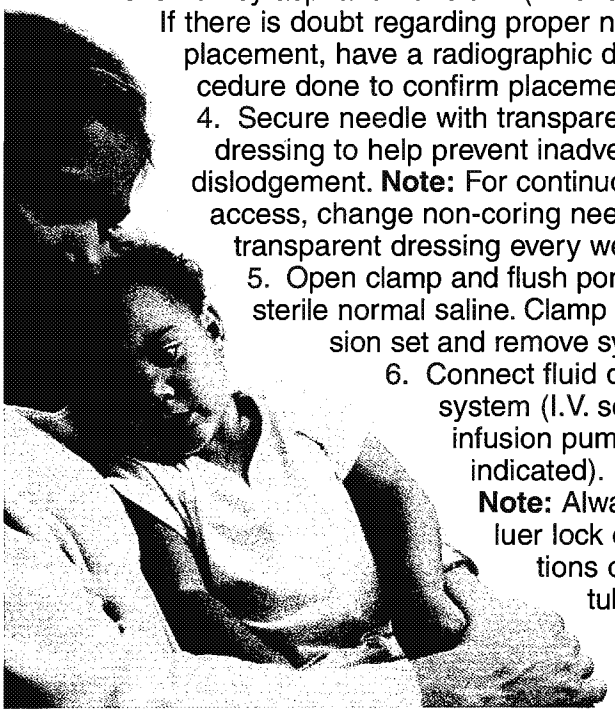
Equipment:

- Prescribed I.V. solution
- Extension set with clamp
- 10 ml syringe filled with sterile normal saline
- PowerLoc* Safety Infusion Set, or other non-coring safety needle. Choose a needle length based on reservoir depth, tissue thickness, and the thickness of any dressing beneath the bend of the needle.
- I.V. pole
- I.V. pump (if ordered)
- Transparent dressing
- 2 in. x 2 in. (5 cm x 5 cm) gauze pads

Procedure:

Review Site Preparation and Accessing Implanted Port sections before proceeding with this section.

1. Explain procedure to patient and prepare injection site. Remember to check patient's records, and ask patient, to determine whether they have any known allergies to chemicals or materials that will be used during the injection procedure.
2. Attach PowerLoc* Safety Infusion Set or other non-coring safety needle to extension set and syringe filled with sterile normal saline. Expel all air and clamp the extension set.
3. Aseptically locate and access port. Confirm correct positioning of the needle within the port reservoir by aspiration of blood ("flashback"). If there is doubt regarding proper needle placement, have a radiographic dye procedure done to confirm placement.
4. Secure needle with transparent dressing to help prevent inadvertent dislodgement. **Note:** For continuous access, change non-coring needle and transparent dressing every week.
5. Open clamp and flush port with sterile normal saline. Clamp extension set and remove syringe.
6. Connect fluid delivery system (I.V. set or infusion pump as indicated). **Note:** Always use luer lock connections on all tubings



and connections. Never use a slip tip connection. Pumps must incorporate a functional automatic pressure limiting switch which will shut pump off before pressure exceeds 25 psi.

7. Release clamp and initiate infusion. Examine the infusion site for signs of extravasation; if noted, or if patient experiences pain, immediately discontinue infusion and initiate appropriate intervention.
8. When infusion is completed, clamp extension set and then remove the fluid delivery system.
9. Flush after each infusion with 10 ml sterile normal saline to help prevent interaction between incompatible drugs.
10. **For open-ended catheters:** Flush port with 5 ml heparinized saline after every use and at least once every 4 weeks.
    For Groshong* catheters: Flush port with 5ml of sterile normal saline after every use and at least once every 4 weeks. **Caution:** Remember that some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients must not have their port locked with heparinized saline.
    Note: For **Groshong*** and open-ended catheters, the needle hub should not be left open to air while it is in the port. Do not manipulate the needle once it is in the septum.
11. When deaccessing the port, the needle should be removed using the positive pressure technique. Positive pressure is maintained while flushing the accessed port by clamping the infusion set tubing, while still flushing the line. This helps reduce the potential for blood backflow into the catheter tip, which could encourage catheter clotting.

Blood Sampling Procedure

Equipment:

- Extension set with clamp
- PowerLoc* Safety Infusion Set or other non-coring safety needle. Choose a needle length based on reservoir depth, tissue thickness, and the thickness of any dressing beneath the bend of the needle.
- Syringe filled with sterile normal saline
- Syringe (2) or evacuated blood collection vials (2)
- Sterile normal saline

Procedure:
Review Site Preparation and Accessing Implanted Ports sections before proceeding with this section.

1. Explain procedure to patient and prepare injection site.
2. Aseptically locate and access port with PowerLoc* Safety Infusion Set 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, have a radiographic dye procedure done to confirm placement.
3. Flush port with sterile normal saline.
4. Withdraw at least 5 ml of blood and discard syringe.
5. Aspirate desired blood volume into second syringe or evacuated blood collection system.
6. Once sample is obtained, perform saline lock procedure by immediately flushing the system with 20 ml of sterile normal saline.
7. Transfer sample into appropriate blood sample tubes.
8. Perform heparin lock procedure for open-ended catheters. **For implanted ports with Groshong* catheters, a sterile normal saline lock may be used.**
   Caution: Remember that some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients must not have their port locked with heparinized saline.
9. When deaccessing the port, the needle should be removed using the positive pressure technique. Positive pressure is maintained while flushing the accessed port by clamping the infusion set tubing, while still flushing the line. This helps reduce the potential for blood backflow into the catheter tip, which could encourage catheter clotting.

Lock Procedure for Catheters
To help prevent clot formation and catheter blockage, implanted ports should be flushed per institutional protocol using a turbulent push-pause flushing method after each use. Clamp the tubing while infusing the last 0.5 ml of fluid to reduce potential for blood back-flow into the catheter tip, which could encourage catheter clotting. If the port remains unused for long periods of time, the 5 ml

heparin solution or sterile normal saline solution should be changed at least every four weeks.
Caution: Remember that some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients must not have their port locked with heparinized saline.

Determining Port Volumes
For PowerPort* implanted ports, you will need to check the patient's chart to determine the length of catheter used for each individual patient. For PowerPort* implanted port catheters, multiply the catheter length in cm by 0.02 ml, then add 0.6 ml for the port reservoir:

Example:
Catheter length: _____ cm x 0.02 ml/cm + 0.6 ml (port septum) = _____ ml volume, total priming volume for patient port and catheter.

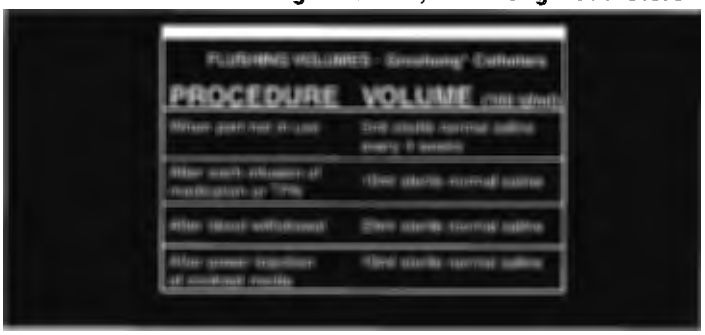
Recommended Flushing Volumes, Open-Ended Catheters

FLUSHING VOLUMES - Open-Ended Catheters	
PROCEDURE	**VOLUME (100 U/ml)**
When port not in use	5ml heparinized saline every 4 weeks
After each infusion of medication or TPN	10ml sterile normal saline then 5ml heparinized saline
After blood withdrawal	20ml sterile normal saline then 5ml heparinized saline
After power injection of contrast media	10ml sterile normal saline then 5ml heparinized saline

Equipment:

- PowerLoc* Safety Infusion Set, or other non-coring safety needle. Choose a needle length based on reservoir depth, tissue thickness, and the thickness of any dressing beneath the bend of the needle.
- 10 ml syringe filled with sterile heparinized saline (100 U/ml)

Recommended Flushing Volumes, Groshong* Catheters



Equipment:
- PowerLoc* Safety Infusion set, or other non-coring needle
- 10ml syringe filled with sterile normal saline

Procedure:
Review Site Preparation and Accessing Implanted Port sections before proceeding with the following:
1. Explain procedure to patient and prepare injection site.
2. Attach a syringe filled with sterile normal saline or heparinized saline (as applicable) to needle.
3. Aseptically locate and access port with PowerLoc* Safety Infusion Set 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, have a radiographic dye procedure done to confirm placement.
4. After therapy completion, flush port per institutional protocol. Close clamp while injecting last .05 ml of flush solution.
5. To deaccess PowerLoc* safety infusion set from the port, activate safety mechanism while withdrawing needle until you hear or feel a "click" at which time the needle should be captured within the safety mechanism of the PowerLoc* safety infusion set.

NOTE: Alcohol should not be used to soak or declot polyurethane catheters because alcohol is known to degrade the polyurethane catheters over time with repeated and prolonged exposure.

Power Injection Procedure

1. Access the port with a PowerLoc* Safety Infusion Set. Make certain that needle tip is inserted fully within the port.
   Warning: A PowerLoc* Safety Infusion Set must always be used to access the PowerPort* implanted port for power injecting contrast media. **Note:** Follow institutional protocol to verify correct catheter tip position prior to power injection.
2. Attach a syringe filled with sterile normal saline.
3. Instruct the patient to assume the position they will be in during the power injection proce-

dure, before checking for patency. Aspirate for adequate blood return and vigorously flush the port with at least 10 ml of sterile normal saline.
Warning: Failure to ensure patency of the catheter prior to power injection studies may result in port system failure.

4. Detach syringe.
5. After confirming the presence of a PowerPort* device and confirming patency, affix the PowerLoc* safety infusion set purple sticker to the PowerLoc* safety infusion set to inform CT that a power-injectable system is in place.
6. Warm contrast media to body temperature.
Warning: Failure to warm contrast to body temperature prior to power injection may result in port system failure.
7. If possible, the patient should receive power injection with arms vertically above the shoulder with the palms of the hands on the face of the gantry during injection. This allows for uninterrupted passage of injected contrast through the axillary and subclavian veins at the thoracic outlet.
8. Attach the power injection device to the PowerLoc* safety Infusion Set ensuring connection is secure. All connections should be luer lock connections.
Warning: Do not exceed a 300 psi pressure limit setting, or the maximum flow rate setting shown below, on the power injection machine if power injecting through the PowerPort* device:

PowerLoc* Safety Infusion Set Gauge Size	19 Ga.	20 Ga.	22 Ga.
PowerLoc* Safety Infusion Set Gauge Color	Cream	Yellow	Black
Maximum Flow Rate Setting	5 ml/sec	5 ml/sec	2 ml/sec

9. Instruct the patient to communicate immediately any pain or change in feeling during the injection. Inject warmed contrast, taking care not to exceed the flow rate limits.
Warning: If local pain, swelling or signs of extravasation are noted, the injection should stop immediately.
Warning: Exceeding the maximum flow rate may result in port system failure and/or catheter tip displacement.
10. Disconnect the power injection device. Always flush port following power injection with 10 ml of sterile normal saline followed by 5 ml heparinized saline for open-ended catheters or sterile normal saline for **Groshong*** catheters.

11. Perform heparin lock procedure for open-ended catheters. For implanted ports with **Groshong*** catheters, a sterile normal saline lock may be used.
    Caution: Remember that some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients must not have their port locked with heparinized saline.
12. When deaccessing the port, the needle should be removed using the positive pressure technique. Positive pressure is maintained while flushing the accessed port by clamping the infusion set tubing, while still flushing the line. This helps reduce the potential for blood backflow into the catheter tip, which could encourage catheter clotting. Pull the PowerLoc* safety infusion set top wings away from lower wings until you hear or feel a click, at which time the needle should be captured within PowerLoc* safety mechanism.

Troubleshooting Guide

I. Aspiration Difficulties: DO NOT POWER INJECT IF YOU CANNOT ASPIRATE AS PATIENT INJURY MAY RESULT

A. Possible Causes

1. Failure to flush adequately, resulting in lumen obstruction.
2. Catheter tip sucking up to vein wall with aspiration.
3. Blood clot, fibrin sheath, or particulate matter obstructing lumen when catheter is aspirated.
   - A clot or other obstruction in the catheter lumen can produce a one-way valve effect. During infusion, the catheter wall expands slightly and allows fluid to flow around the plug. During aspiration, the catheter wall contracts slightly, tightening down around the obstruction and preventing aspiration.
   - Fibrin sheaths usually begin to form within a few days after the insertion of a central venous catheter. If it has grown enough to extend beyond the tip of the catheter, it may be pulled into and obstruct the catheter opening when aspiration is attempted, but not resist infusion.
4. Compression or transection of the catheter between the clavicle and first rib ("pinch-off area").

5. Kinked catheter.
   - Catheter may be pulled too tight through skin tunnel, causing kink at vessel insertion site, or where it curves into the subcutaneous tunnel.
   - Catheter may be curled or kinked within the vessel, or under the dressing.
6. Malposition of catheter tip (i.e. jugular vein, outside of vein).
7. Improper catheter length selection for patient size.

B. Possible Solutions

1. If no resistance to infusion is felt, attempt to flush with 10 ml normal saline. Then pull back gently on syringe plunger 2-3 ml, pause and proceed with aspiration.
2. If resistance to infusion is felt, check for signs of extravasation. If present, notify physician of possible catheter leakage or transection and embolization. If not present, see step 4.
3. Attempt to aspirate with a 20 ml syringe.
4. Move patient's arm, shoulder and head to see if a change in position will allow aspiration. If aspiration can only be accomplished with the patient in a certain position, the patient should be examined to see if the catheter has been placed in the "pinch-off" area.
5. Obtain physician's order for a chest x-ray to determine the position of the catheter.
   - If the catheter tip is not in the superior vena cava, the catheter should be repositioned.
   - If the catheter tip is not in a vein, the catheter should be replaced.
   - If the catheter has been placed through the "pinch-off" area, between the clavicle and the first rib, and is being compressed enough to interfere with infusion or aspiration, it is at risk for catheter transection and embolization. The physician should evaluate the patient for catheter replacement.

II. Patient with Fever and/or Infection:
Symptoms:

- Inflammation at incision site
- Fever
- Positive site culture and/or blood cultures

If signs of infection are present:

- Notify physician

III. Insufficient Flow: DO NOT POWER INJECT IF RESISTANCE TO FLUSHING SEEMS EXCESSIVE

Excessive force must not be used to flush an obstructed lumen. Insufficient blood flow may be caused by the catheter contacting the wall of the vein or an occluding clot. The physician may attempt to dissolve the clot with a fibrinolytic agent before power injecting. Physician discretion advised.

Equipment:

- PowerLoc* Safety Infusion Set, or other non-coring safety needle. Choose a needle length based on reservoir depth, tissue thickness, and the thickness of any dressing beneath the bend of the needle.
- Syringe containing port priming volume of a fibrinolytic agent.
- Syringe filled with sterile normal saline.

Procedure:

Review Site Preparation and Accessing Implanted Ports sections before proceeding with this section.

1. Explain procedure to patient and prepare injection site.
2. Aseptically locate and access the desired septum with needle attached to syringe, void of air and filled with port priming volume of fibrinolytic agent. **Warning:** If accessing a PowerPort* port with PowerLoc* Safety Infusion Set do not affix the PowerLoc* Safety Infusion Set sticker that indicates the system can be power injected. Power injecting a blocked catheter could lead to catheter damage and patient injury.
3. Gently instill fibrinolytic solution. Use a gentle pull-push action on the syringe plunger to maximize solution mixing within port and catheter. **Warning:** Occluded catheters may not accept all of the solution. If strong resistance is felt, do not attempt to force into catheter.
4. Leave solution in place according to drug manufacturers recommendation and/or doctor's orders.
5. Attempt to aspirate solution and the clot(s).
6. If the clot(s) cannot be aspirated, repeat procedure.
7. Once the blockage has been aspirated and discarded, flush catheter with at least 20 ml of sterile normal saline.

8. Perform heparin lock procedure for open-ended catheters. For implanted ports with **Groshong*** catheters, a sterile normal saline lock may be used.
   Caution: Remember that some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients must not have their port locked with heparinized saline.
9. When deaccessing the port, the needle should be removed using the positive pressure technique. Positive pressure is maintained while flushing the accessed port by clamping the infusion set tubing, while still flushing the line. This helps reduce the potential for blood backflow into the catheter tip, which could encourage catheter clotting.

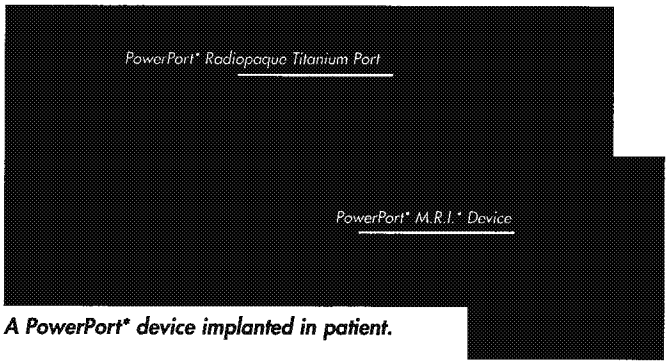
I.V. Catheter Occlusion: DO NOT POWER INJECT AN OCCLUDED DEVICE

A. Possible Causes

1. Blood clot completely obstructing lumen.
2. May be kinked, coiled, damaged, or compressed between the clavicle and the first rib.
3. Catheter tip may not be within vein.
4. May be partially or completely transected. Transection can occur from the repeated pressure of the clavicle and the first rib on the catheter during normal movement if it is placed through the "pinch-off" area.
5. Improper catheter length for patient size.
6. Catheter can be blocked from lipid and/or protein deposition.

B. Possible Solutions

1. Ask responsible nurse or physician to attempt to aspirate blood clot.
2. Move patient's arm, shoulder and head to see if position change affects ability to infuse.
3. Obtain physician's order for a chest x-ray to determine the position of the catheter to rule out "Pinch-off". The patient's arms should be down the patient's side to rule out "Pinch-off" syndrome.



A PowerPort® device implanted in patient.

- If the catheter tip is not in the superior vena cava, the catheter should be repositioned.
- If the catheter tip is not in a vein, the catheter should be replaced.
- If the catheter has been placed through the "pinch-off" area, between the clavicle and the first rib, and is being compressed enough to interfere with infusion or aspiration, it is at risk for catheter transection and embolization. The physician should evaluate the patient for catheter replacement.

V. Signs of Pinch-off

Clinical:

- Difficulty with blood withdrawal
- Resistance to infusion of fluids
- Patient position changes required for infusion of fluids or blood withdrawal

Radiologic:

- Grade 1 or 2 distortion on chest X-ray. Pinch-off should be evaluated for degree of severity prior to explantation. Patients indicating any degree of catheter distortion at the clavicle/first rib area should be followed diligently. There are grades of pinch-off that should be recognized with appropriate chest x-ray as follows: [2,3]

Grade	Severity	Recommended Action
Grade 0	No distortion	No action.
Grade 1	Distortion present **without** luminal narrowing	Chest x-ray should be taken every one to three months to monitor progression of pinch off to grade 2 distortion. Shoulder positioning during chest x-rays should be noted as it can contribute to changes in distortion grades.
Grade 2	Distortion present **with** luminal narrowing	Removal of the catheter should be considered.
Grade 3	Catheter transection or fracture	Prompt removal of the catheter.

VI. Use of Fibrinolytic Agent for Catheter Blockage
Use of a fibrinolytic agent has successfully cleared clotted catheters when gentle irrigation and aspiration have failed. The instructions provided by the drug manufacturer should be followed.

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.

References

1. Bard Access Systems; "*Your* Port Access Advantage: What Patients and Nurses Say About Ports", 2005, 0710420.
2. Hinke, D.H.; Zandt-Stastny, D.A.; Goodman, L.R.; et al. Pinch-off Syndrome: A complication of implantable subclavian venous access devices. Radiology 177: 353-356, 1990.
3. Ingle, Rebecca,; Nace, Corinne, Venous Access Devices: Catheter Pinch-off and Fracture, 1993, Bard Access Systems, Inc.
4. Venousaccess.com
5. www.nursingcenter.com
6. Camp-Sorrell, Dawn; "Access Device Guidelines: Recommendation for Nursing Practice and Education." 2004

Further Reading

- See PowerPort* port instructions for use, PowerPort* port CT Guide and/or PowerPort* port Patient Guide for more details
- Bard Access Systems is proud to offer "*Your* Port Access Advantage"* patient education module for helping patients select their best access option. See www.portadvantage.com for more details.
- See www.powerportadvantage.com

See a Bard Access Systems Sales Representative for more information about any of these products.

An issued or revision date for these instructions is included for the user's information. In the event two years have elapsed between this date and product use, the user should contact Bard Access Systems, Inc. to see if additional product information is available.

Revised date: March 2008

CT Contrast Enhanced Computed Tomography Information

This product and package does not contain natural rubber latex.

DEHP This device does not contain DEHP

MR **MR Conditional**

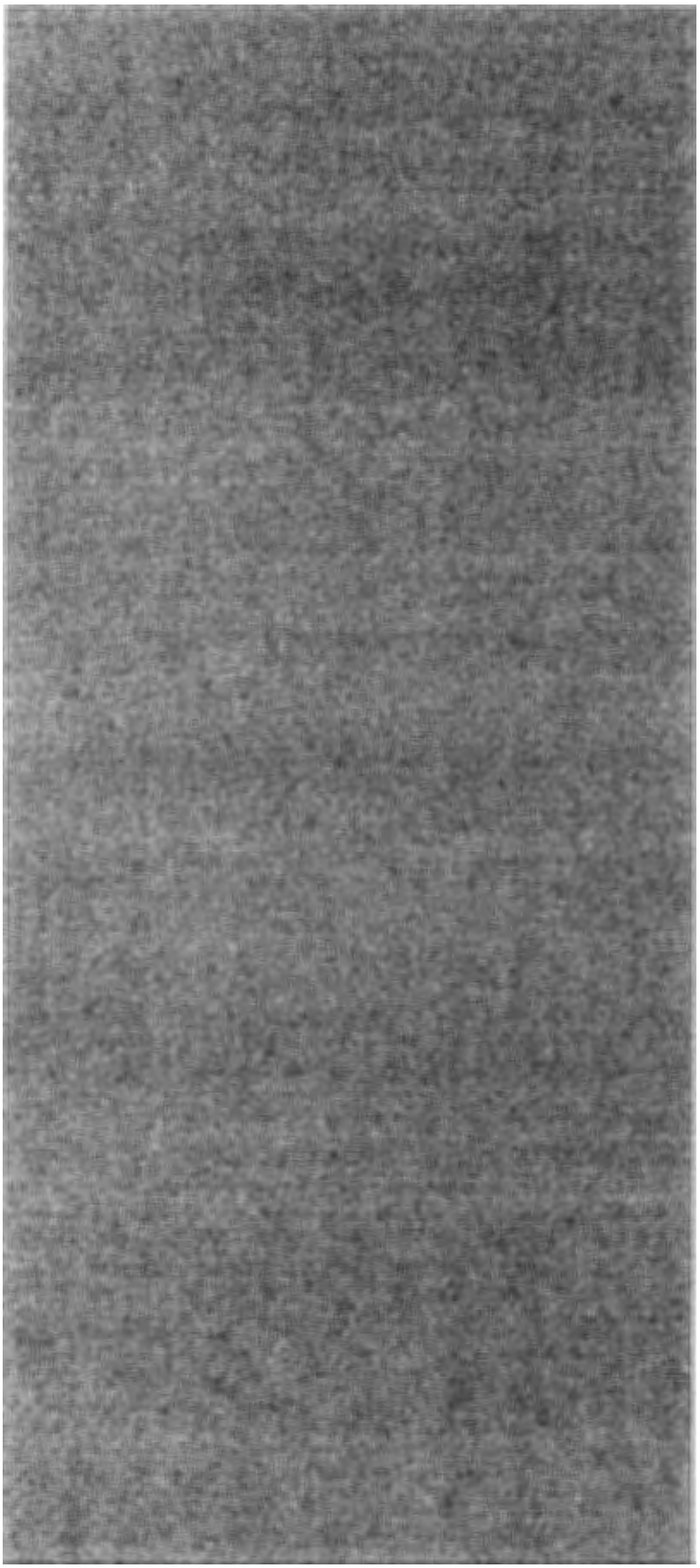
Non-clinical testing has demonstrated the device is MR Conditional. It can be scanned safely under:

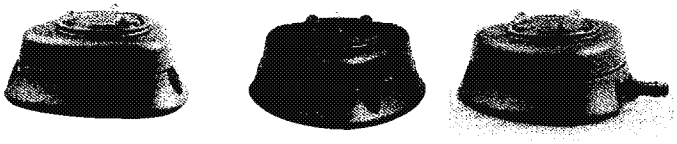
- static magnetic field of 3 Tesla or less
- spatial gradient field of 330 Gauss/cm or less
- maximum specific absorption rate (SAR) of 6 W/kg for 30 minutes of scanning.

In non-clinical testing, the device produced a temperature rise of less than 0.5 °C at a maximum specific absorption rate (SAR) of 6 W/kg for 30 minutes of MR scanning in a 3T Siemens Trio with software version VA25.

For Minimal Image artifact

- MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.





Bard Access Systems, Inc.
Salt Lake City, UT 84116 USA
801-595-0700

Clinical Information Hotline: 800-443-3385
Ordering Information: 800-545-0890
www.bardaccess.com
www.portadvantage.com
www.powerportadvantage.com

MC-0331-04 0803R1

Labeling Predicate Device

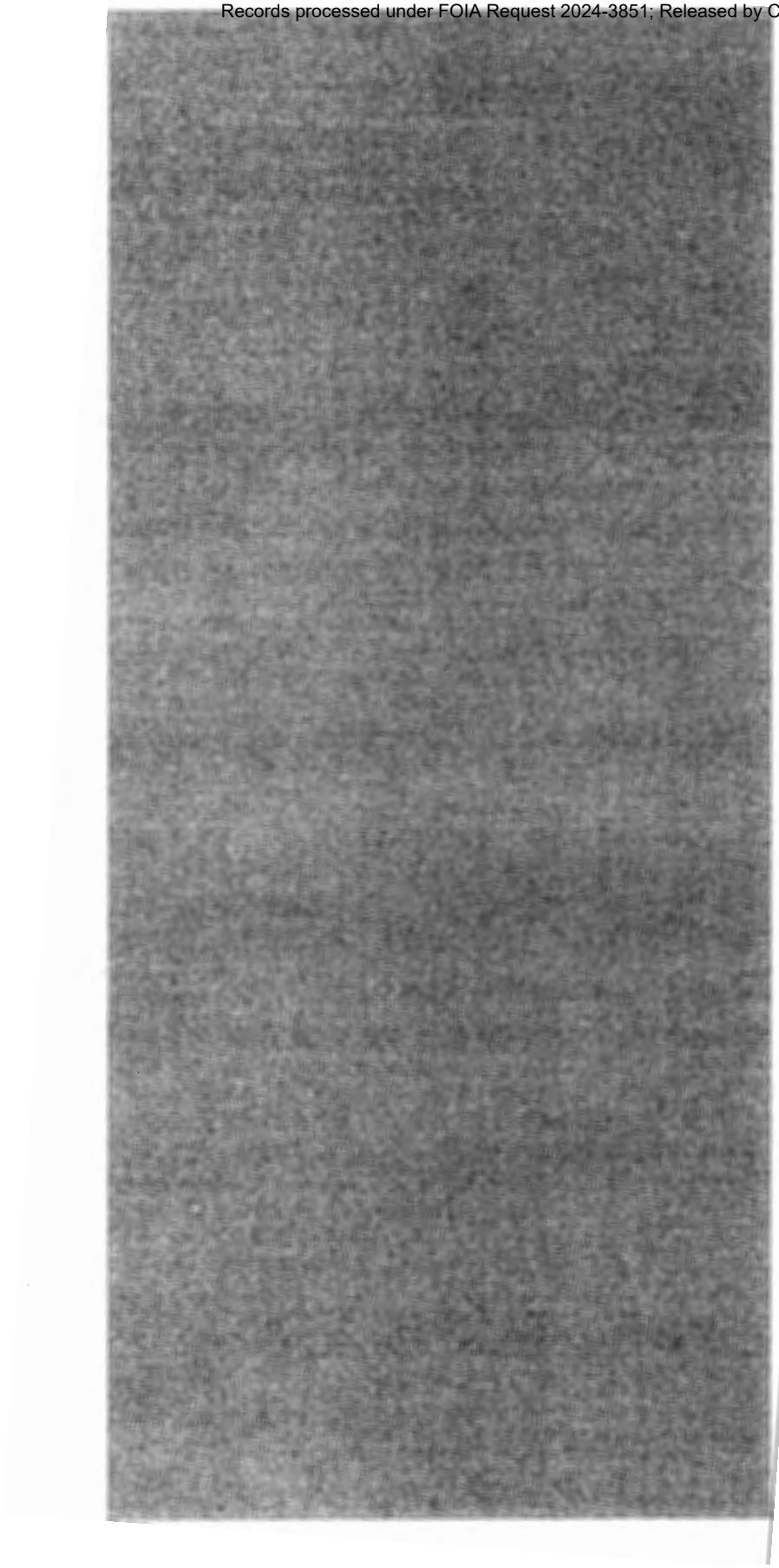


Table of Contents

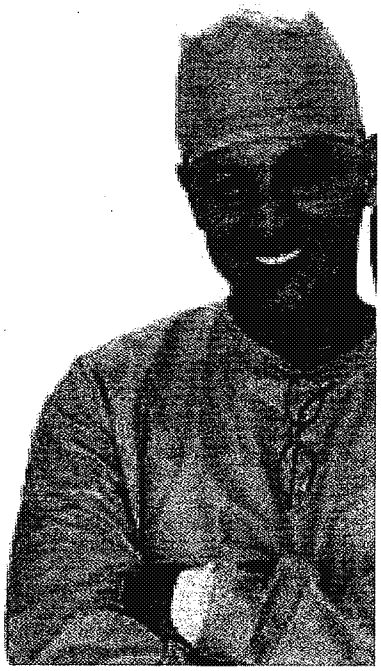
Introduction:

Bard Access Systems' PowerPort* power-injectable port not only facilitates infusions, but is the first port indicated for the power injection of contrast media for CECT scans.

Contrast enhanced computed tomography (CECT) scans are simple, safe and non-invasive procedures that provide quick and accurate diagnostic information to help track tumor markers or diagnose pulmonary embolisms, for example. The scans are many times more sensitive than conventional x-rays. Radiologists can distinguish small differences in soft tissues that may not be detected with x-rays.

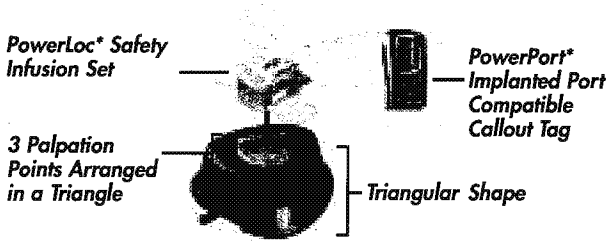
Before performing a CECT scan, the CT team will inject a contrast agent, which is a special fluid that acts like a dye, into the patient to help produce clearer pictures during the CECT scan procedure. For best results, the contrast agent is infused at a high rate into your bloodstream. This process is called power injection.

Bard's PowerPort* power-injectable port used with the PowerLoc* Safety Infusion Set has the unique ability to allow clinicians to perform power-injected CECT scans without having to use peripheral I.V. needles.



Important Information:

- A PowerLoc* Safety Infusion Set must always be used to access the PowerPort* implanted port for power injecting contrast media.



- Contrast media should be warmed to body temperature prior to power injection.
  Warning: Failure to warm contrast media to body temperature prior to power injection may result in port system failure.
- Check for patency, via aspiration, then vigorously flush the PowerPort* device using at least 10 ml of sterile normal saline prior to and immediately following the completion of power injection studies. It is important to ensure the patency of the PowerPort* device to prevent damage to the catheter. Resistance to flushing may indicate partial or complete catheter occlusion. Do not proceed with power injection study until occlusion has been cleared.

Warning: Failure to ensure patency of the catheter prior to power injection studies may result in port system failure.
Warning: Do not power inject through a port system that exhibits signs of clavicle-first rib compression or pinch-off as it may result in port system failure.
Warning: Power injector machine pressure limiting feature may not prevent over pressurization of an occluded catheter.
Warning: Do not exceed a 300 psi pressure limit setting, or the maximum flow rate setting shown below, on the power injection machine if power injecting through the PowerPort* device:

PowerLoc* Safety Infusion Set Gauge Size	19 Ga.	20 Ga.	22 Ga.
PowerLoc* Safety Infusion Set Gauge Color	Cream	Yellow	Black
Maximum Flow Rate Setting	5 ml/sec	5 ml/sec	2 ml/sec

Warning: The PowerPort* implanted port indication for power injection of contrast media implies the device's ability to withstand the procedure, but does not imply appropriateness of the procedure for a particular patient. A suitably trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure. The PowerPort* device is only power injectable when accessed with a PowerLoc* Safety Infusion Set.

Description

The PowerPort* Implanted Port is an implantable access device designed to provide repeated access to the vascular system. Port access is performed by percutaneous needle insertion using a non-coring needle. Power injection is performed using a PowerLoc* Safety Infusion Set only. The PowerPort* device consists of two primary components: an injection port with a self-sealing silicone septum and a radiopaque ChronoFlex* polyurethane catheter. PowerPort* implanted ports can be identified subcutaneously by feeling the top of the septum which includes three palpation points arranged in a triangle and by palpating the sides of the port, also in a triangular shape. All materials are biocompatible, can be used with virtually all injectable solutions, are latex-free, and safe for use with CECT and MRI imaging up to 3 Tesla (3T).

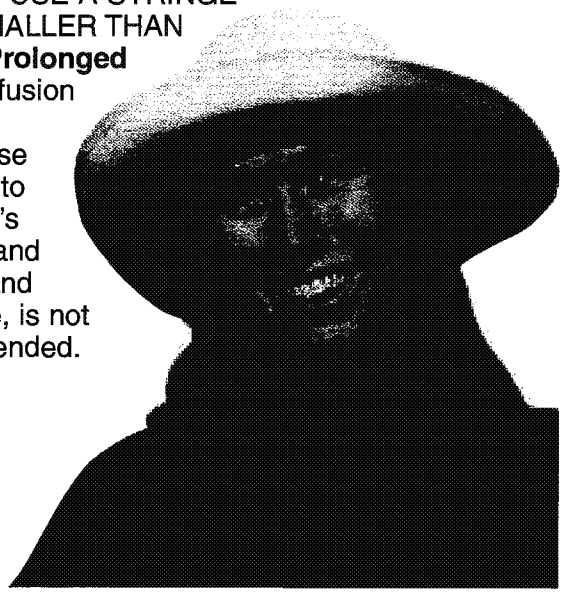
Indications For Use

The PowerPort* Implanted Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples.

When used with the PowerLoc* Safety Infusion Set, the PowerPort* device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s.

Warnings

- Do not power inject through a port system that exhibits signs of clavicle-first rib compression or pinch-off as it may result in port system failure.
- Intended for Single Patient Use. DO NOT REUSE. These Bard Access Systems, Inc. products are single use devices and should never be reimplanted. Any device that has been contaminated by blood should not be reused or resterilized.
- After use, this product may be a potential biohazard. Handle and discard in accordance with accepted medical practice and applicable local, state and federal laws and regulations.
- **The use of an infusion set other than PowerLoc* Infusion Sets during power injection will lead to system failure and possibly patient injury.**
- DO NOT USE A SYRINGE SIZE SMALLER THAN 10 ml. **Prolonged** 25 psi infusion pressure may cause damage to a patient's vessels and viscus, and therefore, is not recommended.



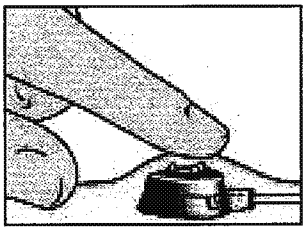
Precautions

- Carefully read and follow all instructions prior to use.
- Follow Universal Precautions when accessing the port.
- Follow all warnings, precautions and instructions for all infusates as specified by their manufacturers.
- Precautions are intended to help avoid product damage and/or patient injury.
- Only accessories and components with luer lock connections should be used with this device.
- If signs of extravasation exist, discontinue injections. Begin appropriate medical intervention immediately.
- Use only non-coring needles with the port.

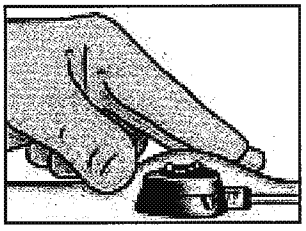
Identifying a PowerPort Port Patient*

- Power-injectable ports can be distinguished from traditional ports through the following means:
  - Check patient's chart for a PowerPort* port patient record sticker.

  - Palpate sides of port to identify triangular port housing.
  - Palpate top of port to identify three palpation points (bumps) on the septum, arranged in a triangle.

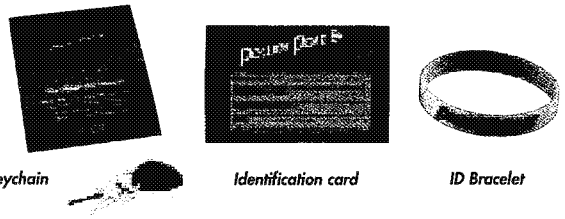


Feel the soft top of the port to locate the three palpation points arranged as a triangle.



Feel the sides of the port to identify its unique triangle shape.

- Request confirmation from the patient by asking them to show you the patient identification card, ID bracelet, or keychain they received when the port was implanted.



Keychain *Identification card* *ID Bracelet*

- Always verify the patient has a PowerPort* port by at least two means and ensure they are accessed with a PowerLoc* Infusion Set, prior to power injection.
- For additional guidance on recognizing a power injectable port / safety infusion set system, contact Bard's Clinical Information Hotline at 800-443-3385.

Possible Complications

The use of a subcutaneous port provides an important means of venous access for critically ill patients. However, the potential exists for serious complications, including, but not limited to the following:

- Air Embolism
- Bleeding
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Catheter or Port Erosion Through the Skin
- Catheter Embolism
- Catheter Occlusion
- Catheter Occlusion, Damage or Breakage due to Compression between the Clavicle and First Rib
- Catheter or Port related Sepsis
- Device Rotation or Extrusion
- Endocarditis
- Extravasation
- Fibrin Sheath Formation
- Hematoma
- Hemothroax
- Hydrothorax
- Intolerance Reaction to Implanted Device
- Inflammation, Necrosis, or Scarring of Skin Over Implant Area
- Laceration of Vessels or Viscus
- Perforation of Vessels or Viscus
- Pneumothorax
- Spontaneous Catheter Tip Malposition or Retraction
- Thoracic Duct Injury
- Thromboembolism
- Vascular Thrombosis
- Vessel Erosion
- Risks Normally Associated with Local or General Anesthesia, Surgery, and Post-Operative Recovery

These and other complications are well documented in medical literature.

Use and Maintenance Instructions

Site Preparation

Always inspect and aseptically prepare the injection site prior to accessing the port.

Note: It is recommended that catheter tip placement is verified through institutional protocol.

Equipment:

- Alcohol or chlorhexidine wipe
- Antiseptic swabs (3)
- Sterile gloves

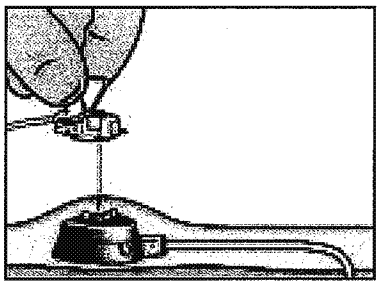
Procedure:

1. Explain procedure to patient. Warn of needle prick sensation. (Sensation of needle insertion decreases over time. Use of a topical anesthetic may be appropriate.)
2. Wash hands thoroughly.
3. Put on sterile gloves.
4. Cleanse or scrub the area according to the cleansing agent manufacturers instructions. We suggest an area of at least 10 – 13 cm diameter at the port insertion site.
   Directions for the use of ChloraPrep* preoperative skin preparation: Prepare the site with ChloraPrep* One-Step Applicator Solution or according to institutional policy using sterile technique. "Pinch-Off" the wings on the ChloraPrep* One-Step Applicator Solution to break the ampule and release the antiseptic. Do not touch the sponge. Wet the sponge against the treatment area until fluid is visible on the skin. Use repeated back-forth strokes of the sponge for approximately 30 seconds. Completely wet the treatment area with antiseptic. Allow the area to dry for approximately 30 seconds. Do not blot or wipe away. Maximum treatment area for one applicator is approximately 130 ml (approximately 4 x 5 in.). Discard the applicator after use.

Note: Follow established hospital or institutional policy for changing I.V. tubing and accessing cannula. The Center for Disease Control (CDC) or Oncology Nursing Society (ONS) may have recommended guidelines.

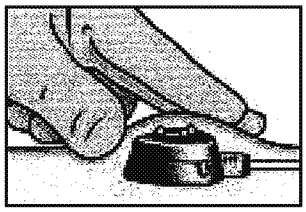
Accessing Implanted Ports
Equipment:

- Syringe
- If the port will be accessed for power injection, it must be accessed with a PowerLoc* Safety Infusion Set. If not power injecting, it can be accessed with any non-coring safety needle. Choose a needle length based on reservoir depth, tissue thickness, and the thickness of any dressing beneath the bend of the needle.

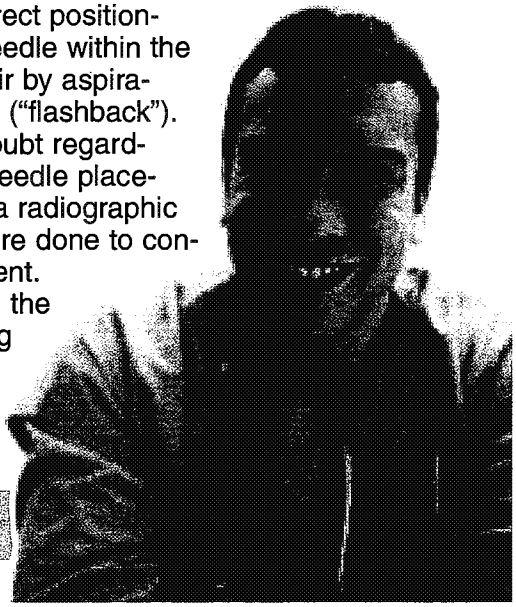


Procedure:

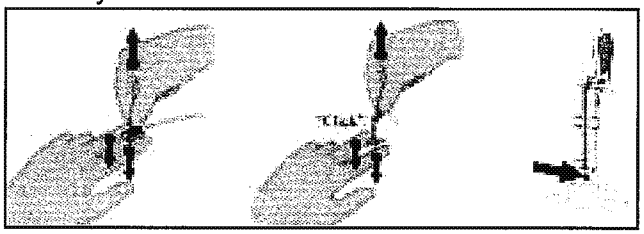
1. Perform aseptic site preparation.
2. Locate port septum by palpation.
   a. Locate base of port with non-dominant hand.
   b. Triangulate port between thumb and first two fingers of non-dominant hand. Aim for center point of these three fingers.



3. Insert PowerLoc* Safety Infusion Set or other non-coring safety needle perpendicular to port septum. Advance needle through the skin and septum until reaching bottom of reservoir. Make certain that needle tip is inserted fully within the port.
4. Confirm correct positioning of the needle within the port reservoir by aspiration of blood ("flashback"). If there is doubt regarding proper needle placement, have a radiographic dye procedure done to confirm placement.
5. Always flush the port following injection.



6. Perform heparin lock procedure for open-ended catheters. **Caution:** Remember that some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients must not have their port locked with heparinized saline
7. When deaccessing the port, the needle should be removed using the positive pressure technique. Positive pressure is maintained while flushing the accessed port by clamping the infusion set tubing, while still flushing the line. This helps reduce the potential for blood backflow into the catheter tip, which could encourage catheter clotting. If using a PowerLoc* safety infusion set, activate safety mechanism while withdrawing the needle until you feel a "click" at which time the needle should be captured within the safety mechanism of the PowerLoc* safety infusion set.



Bolus Injection Procedure Other Than Power Injection

Equipment:

- PowerLoc* Safety Infusion Set, or other non-coring safety needle. Choose a needle length based on reservoir depth, tissue thickness, and the thickness of any dressing beneath the bend of the needle.
- Syringe filled with sterile normal saline
- Extension set with clamp

Procedure:

Review Site Preparation and Accessing Implanted Port sections before proceeding with this section.

1. Explain procedure to patient and prepare injection site. Remember to check patient's records, and ask patient, to determine whether they have any known allergies to chemicals or materials that will be used during the injection procedure.
2. Attach PowerLoc* Safety Infusion Set or other non-coring safety needle to extension set and syringe filled with sterile normal saline. Expel all air and clamp extension.

3. Aseptically locate and access port. Confirm correct positioning of the needle within the port reservoir by aspiration of blood ("flashback"). If there is doubt regarding proper needle placement, have a radiographic dye procedure done to confirm placement.
4. Flush port with 10 ml sterile normal saline. Clamp the extension set and remove the syringe.
5. Connect syringe containing the drug to extension set. Release clamp and begin to administer injection.
6. Examine the injection site for signs of extravasation; if noted, immediately discontinue the injection and initiate appropriate intervention.
7. When the injection is completed, clamp the extension set.
8. Flush after each injection with 10 ml of sterile normal saline to help prevent interaction between incompatible drugs.
9. Flush port with 5 ml heparinized saline after every use and at least once every 4 weeks.
10. Remember that some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia and these patients must not have their port locked with heparinized saline. **Note:** The needle hub should not be left open to air while it is in the port. Do not manipulate the needle once it is in the septum.
11. When deaccessing the port, the needle should be removed using the positive pressure technique. Positive pressure is maintained while flushing the accessed port by clamping the infusion set tubing, while still flushing the line. This helps reduce the potential for blood backflow into the catheter tip, which could encourage catheter clotting.

Continuous Infusion Procedure
Caution: DO NOT USE A SYRINGE SIZE SMALLER THAN 10 ml. **Prolonged** 25 psi infusion pressure may cause damage to a patient's vessels and viscus, and therefore is not recommended.

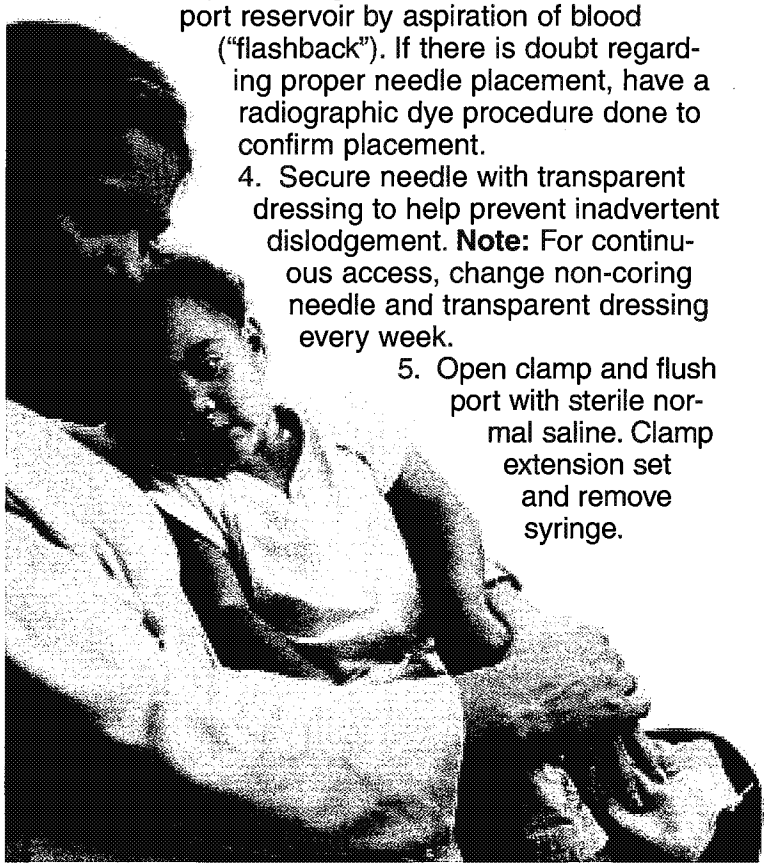
Equipment:
- Prescribed I.V. solution
- Extension set with clamp
- 10 ml syringe filled with sterile normal saline

- PowerLoc* Safety Infusion Set, or other non-coring safety needle. Choose a needle length based on reservoir depth, tissue thickness, and the thickness of any dressing beneath the bend of the needle.
- I.V. pole
- I.V. pump (if ordered)
- Transparent dressing
- 2 in. x 2 in. (5 cm x 5 cm) gauze pads

Procedure:

Review Site Preparation and Accessing Implanted Port sections before proceeding with this section.

1. Explain procedure to patient and prepare injection site. Remember to check patient's records, and ask patient, to determine whether they have any known allergies to chemicals or materials that will be used during the injection procedure.
2. Attach PowerLoc* Safety Infusion Set or other non-coring safety needle to extension set and syringe filled with sterile normal saline. Expel all air and clamp the extension set.
3. Aseptically locate and access port. Confirm correct positioning of the needle within the port reservoir by aspiration of blood ("flashback"). If there is doubt regarding proper needle placement, have a radiographic dye procedure done to confirm placement.
4. Secure needle with transparent dressing to help prevent inadvertent dislodgement. **Note:** For continuous access, change non-coring needle and transparent dressing every week.
5. Open clamp and flush port with sterile normal saline. Clamp extension set and remove syringe.



6. Connect fluid delivery system (I.V. set or infusion pump as indicated). **Note:** Always use luer lock connections on all tubings and connections. Never use a slip tip connection. Pumps must incorporate a functional automatic pressure limiting switch which will shut pump off before pressure exceeds 25 psi.
7. Release clamp and initiate infusion. Examine the infusion site for signs of extravasation; if noted, or if patient experiences pain, immediately discontinue infusion and initiate appropriate intervention.
8. When infusion is completed, clamp extension set and then remove the fluid delivery system.
9. Flush after each infusion with 10 ml sterile normal saline to help prevent interaction between incompatible drugs.
10. Flush port with 5 ml heparinized saline after every use and at least once per 4 weeks. Remember that some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients must not have their port locked with heparinized saline. **Note:** The needle hub should not be left open to air while it is in the port. Do not manipulate the needle once it is in the septum.
11. When deaccessing the port, the needle should be removed using the positive pressure technique. Positive pressure is maintained while flushing the accessed port by clamping the infusion set tubing, while still flushing the line. This helps reduce the potential for blood backflow into the catheter tip, which could encourage catheter clotting.

Blood Sampling Procedure

Equipment:

- Extension set with clamp
- PowerLoc* Safety Infusion Set or other non-coring safety needle. Choose a needle length based on reservoir depth, tissue thickness, and the thickness of any dressing beneath the bend of the needle.
- Syringe filled with sterile normal saline
- Syringe (2) or evacuated blood collection vials (2)
- Sterile normal saline

Procedure:
Review Site Preparation and Accessing Implanted Ports sections before proceeding with this section.

1. Explain procedure to patient and prepare injection site.
2. Aseptically locate and access port with PowerLoc* Safety Infusion Set 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, have a radiographic dye procedure done to confirm placement.
3. Flush port with sterile normal saline.
4. Withdraw at least 5 ml of blood and discard syringe.
5. Aspirate desired blood volume into second syringe or evacuated blood collection system.
6. Once sample is obtained, perform saline lock procedure by immediately flushing the system with 20 ml of sterile normal saline.
7. Transfer sample into appropriate blood sample tubes.
8. Perform heparin lock procedure. Remember that some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients must not have their port locked with heparinized saline.
9. When deaccessing the port, the needle should be removed using the positive pressure technique. Positive pressure is maintained while flushing the accessed port by clamping the infusion set tubing, while still flushing the line. This helps reduce the potential for blood backflow into the catheter tip, which could encourage catheter clotting.

Heparin Lock Procedure for Open-Ended Catheters
To help prevent clot formation and catheter blockage, implanted ports with open-ended catheters should be flushed with 10 ml sterile normal saline using a turbulent push-pause flushing method after each use followed by 5 ml of heparinized saline. Clamp the tubing while infusing the last 0.5 ml of fluid to reduce potential for blood back-flow into the catheter tip, which could encourage catheter clotting. If the port remains unused for long periods of time, the 5 ml heparin solution should be changed

at least every four weeks. **Caution:** Remember that some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients must not have their port locked with heparinized saline.

Determining Port Volumes
For PowerPort* implanted ports, you will need to check the patient's chart to determine the length of catheter used for each individual patient. For PowerPort* implanted port catheters, multiply the catheter length in cm by 0.02 ml, then add 0.6 ml for the port reservoir.

Example:
Catheter length: _____ cm x 0.02 ml/cm + 0.6 ml (port septum) = _____ ml volume, total priming volume for patient port and catheter.

Recommended Flushing Volumes:

FLUSHING VOLUMES - Open-Ended Catheters	
PROCEDURE	**VOLUME** (100 U/ml)
When port not in use	5ml heparinized saline every 4 weeks
After each infusion of medication or TPN	10ml sterile normal saline then 5ml heparinized saline
After blood withdrawal	20ml sterile normal saline then 5ml heparinized saline
After power injection of contrast media	10ml sterile normal saline then 5ml heparinized saline

Equipment:

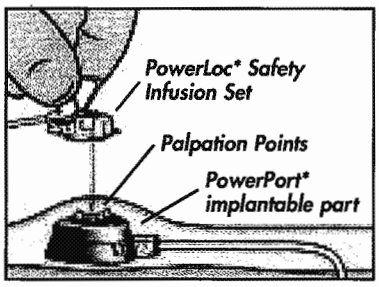
- PowerLoc* Safety Infusion Set, or other non-coring safety needle. Choose a needle length based on reservoir depth, tissue thickness, and the thickness of any dressing beneath the bend of the needle.
- 10 ml syringe filled with sterile heparinized saline (100 U/ml)
  Note: Other concentrations of heparinized saline (10 to 1000 U/ml) have been found to be effective. Determination of proper concentration and volume should be based on patient's medical condition, laboratory tests, prior history and doctors orders.
- **Note:** 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.

Procedure:
Review Site Preparation and Accessing Implanted Port sections before proceeding with this section.

1. Perform aseptic site preparation.
2. Locate port septum by palpation.
   a. Locate base of port with non-dominant hand.
   b. Triangulate port between thumb and first two fingers of non-dominant hand. Aim for center point of these three fingers.
3. Insert needle perpendicular to port septum. Advance PowerLoc* Safety Infusion set through the skin and septum until reaching bottom of reservoir.
4. Confirm correct needle placement and patency by blood aspiration and flushing.
5. Always flush the port following injection.
6. Perform heparin lock procedure for open-ended catheters. **Caution:** Remember that some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia and these patients must not have their port locked with heparinized saline.
7. When deaccessing the port, the needle should be removed using the positive pressure technique. Positive pressure is maintained while flushing the accessed port by clamping the infusion set tubing, while still flushing the line. This helps reduce the potential for blood backflow into the catheter tip, which could encourage catheter clotting. If using a PowerLoc* safety infusion set, activate safety mechanism while withdrawing the needle until you feel a "click" at which time the needle should be captured within the safety mechanism of the PowerLoc* safety infusion set.

Power Injection Procedure

1. Access the port with a PowerLoc* Safety Infusion Set. Make certain that needle tip is inserted fully within the port.
   Warning:
   A PowerLoc* Safety Infusion Set must always be used to access the PowerPort* implanted port for power injecting contrast media.



Note: Follow institutional protocol to verify correct catheter tip position prior to power injection.

2. Attach a syringe filled with sterile normal saline.
3. Instruct the patient to assume the position they will be in during the power injection procedure, before checking for patency. Aspirate for adequate blood return and vigorously flush the port with at least 10 ml of sterile normal saline.
   Warning: Failure to ensure patency of the catheter prior to power injection studies may result in port system failure.
4. Detach syringe.
5. After confirming the presence of a PowerPort* device and confirming patency, affix PowerLoc*'s safety infusion set purple sticker to the PowerLoc* safety infusion set to inform CT that a power-injectable system is in place.
6. Warm contrast media to body temperature.
   Warning: Failure to warm contrast to body temperature prior to power injection may result in port system failure.
7. If possible, the patient should receive power injection with arms vertically above the shoulder with the palms of the hands on the face of the gantry during injection. This allows for uninterrupted passage of injected contrast through the axillary and subclavian veins at the thoracic outlet.
8. Attach the power injection device to the PowerLoc* safety Infusion Set ensuring connection is secure. All connections should be luer lock connections.
   Warning: Do not exceed a 300 psi pressure limit setting, or the maximum flow rate setting shown below, on the power injection machine if power injecting through the PowerPort* device:

PowerLoc* Safety Infusion Set Gauge Size	19 Ga.	20 Ga.	22 Ga.
PowerLoc* Safety Infusion Set Gauge Color	Cream	Yellow	Black
Maximum Flow Rate Setting	5 ml/sec	5 ml/sec	2 ml/sec

9. Instruct the patient to communicate immediately any pain or change in feeling during the injection. Inject warmed contrast, taking care not to exceed the flow rate limits.
   Warning: If local pain, swelling or signs of extravasation are noted, the injection should stop immediately.
   Warning: Exceeding the maximum flow rate may result in port system failure and/or catheter tip displacement.

10. Disconnect the power injection device. Always flush port following power injection with 10 ml of sterile normal saline followed by 5 ml heparinized saline.
11. Perform heparin lock procedure for open-ended catheters. **Caution:** Remember that some patients may be hypersensitive to heparin or suffer heparin induced thrombocytopenia (HIT) and these patients must not have their port locked with heparinized saline.
12. When deaccessing the port, the needle should be removed using the positive pressure technique. Positive pressure is maintained while flushing the accessed port by clamping the infusion set tubing, while still flushing the line. This helps reduce the potential for blood backflow into the catheter tip, which could encourage catheter clotting. Pull the PowerLoc* safety infusion set top wings away from lower wings until you feel a click, at which time the needle should be captured within PowerLoc* safety mechanism.

Troubleshooting Guide

I. Aspiration Difficulties: DO NOT POWER INJECT IF YOU CANNOT ASPIRATE AS PATIENT INJURY MAY RESULT

A. Possible Causes

1. Failure to flush adequately, resulting in lumen obstruction.
2. Catheter tip sucking up to vein wall with aspiration.
3. Blood clot, fibrin sheath, or particulate matter obstructing lumen when catheter is aspirated.
   - A clot or other obstruction in the catheter lumen can produce a one-way valve effect. During infusion, the catheter wall expands slightly and allows fluid to flow around the plug. During aspiration, the catheter wall contracts slightly, tightening down around the obstruction and preventing aspiration.
   - Fibrin sheaths usually begin to form within a few days after the insertion of a central venous catheter. If it has grown enough to extend beyond the tip of the catheter, it may be pulled into and obstruct the catheter opening when aspiration is attempted, but not resist infusion.
4. Compression or transection of the catheter between the clavicle and first rib ("pinch-off area").

5. Kinked catheter.
   - Catheter may be pulled too tight through skin tunnel, causing kink at vessel insertion site, or where it curves into the subcutaneous tunnel.
   - Catheter may be curled or kinked within the vessel, or under the dressing.
6. Malposition of catheter tip (i.e. jugular vein, outside of vein).
7. Improper catheter length selection for patient size.

B. Possible Solutions

1. If no resistance to infusion is felt, attempt to flush with 10 ml normal saline. Then pull back gently on syringe plunger 2-3 ml, pause and proceed with aspiration.
2. If resistance to infusion is felt, check for signs of extravasation. If present, notify physician of possible catheter leakage or transection and embolization. If not present, see step 4.
3. Attempt to aspirate with a 20 ml syringe.
4. Move patient's arm, shoulder and head to see if a change in position will allow aspiration. If aspiration can only be accomplished with the patient in a certain position, the patient should be examined to see if the catheter has been placed in the "pinch-off" area.
5. Obtain physician's order for a chest x-ray to determine the position of the catheter.
   - If the catheter tip is not in the superior vena cava, the catheter should be repositioned.
   - If the catheter tip is not in a vein, the catheter should be replaced.
   - If the catheter has been placed through the "pinch-off" area, between the clavicle and the first rib, and is being compressed enough to interfere with infusion or aspiration, it is at risk for catheter transection and embolization. The physician should evaluate the patient for catheter replacement.

II. Patient with Fever and/or Infection:
Symptoms:

- Inflammation at incision site
- Fever
- Positive site culture and/or blood cultures

If signs of infection are present:

- Notify physician

III. Insufficient Flow: DO NOT POWER INJECT IF RESISTANCE TO FLUSHING SEEMS EXCESSIVE

Excessive force must not be used to flush an obstructed lumen. Insufficient blood flow may be caused by the catheter contacting the wall of the vein or an occluding clot. The physician may attempt to dissolve the clot with a fibrinolytic agent before power injecting. Physician discretion advised.

Equipment:

- PowerLoc* Safety Infusion Set, or other non-coring safety needle. Choose a needle length based on reservoir depth, tissue thickness, and the thickness of any dressing beneath the bend of the needle.
- Syringe containing port priming volume of a fibrinolytic agent.
- Syringe filled with sterile normal saline.

Procedure:

Review Site Preparation and Accessing Implanted Ports sections before proceeding with this section.

1. Explain procedure to patient and prepare injection site.
2. Aseptically locate and access the desired septum with needle attached to syringe, void of air and filled with port priming volume of fibrinolytic agent. **Warning:** If accessing a PowerPort* port with PowerLoc* Safety Infusion Set do not affix the PowerLoc* Safety Infusion Set sticker that indicates the system can be power injected. Power injecting a blocked catheter could lead to catheter damage and patient injury.
3. Gently instill fibrinolytic solution. Use a gentle pull-push action on the syringe plunger to maximize solution mixing within port and catheter. **Warning:** Occluded catheters may not accept all of the solution. If strong resistance is felt, do not attempt to force into catheter.
4. Leave solution in place according to drug manufacturers recommendation and/or doctor's orders.
5. Attempt to aspirate solution and the clot(s).
6. If the clot(s) cannot be aspirated, repeat procedure.
7. Once the blockage has been aspirated and discarded, flush catheter with at least 20 ml of sterile normal saline.

8. Flush the catheter with 5 ml of heparinized saline. Remember that some patients may be hypersensitive to heparin, or suffer from heparin induced thrombocytopenia (HIT). These patients must not have their ports flushed with heparinized saline.
9. When deaccessing the port, the needle should be removed using the positive pressure technique. Positive pressure is maintained while flushing the accessed port by clamping the infusion set tubing, while still flushing the line. This helps reduce the potential for blood backflow into the catheter tip, which could encourage catheter clotting.

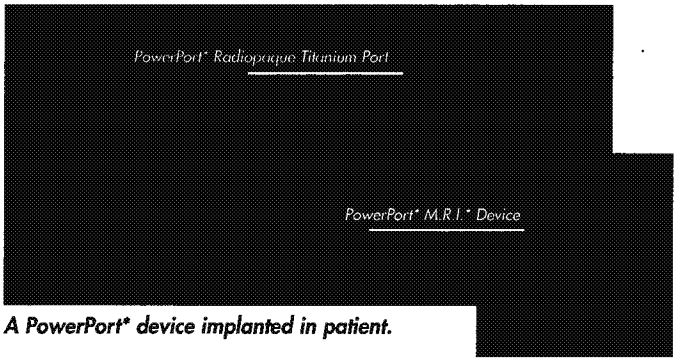
I.V. Catheter Occlusion: DO NOT POWER INJECT AN OCCLUDED DEVICE

A. Possible Causes

1. Blood clot completely obstructing lumen.
2. May be kinked, coiled, damaged, or compressed between the clavicle and the first rib.
3. Catheter tip may not be within vein.
4. May be partially or completely transected. Transection can occur from the repeated pressure of the clavicle and the first rib on the catheter during normal movement if it is placed through the "pinch-off" area.
5. Improper catheter length for patient size.
6. Catheter can be blocked from lipid and/or protein deposition.

B. Possible Solutions

1. Ask responsible nurse or physician to attempt to aspirate blood clot.
2. Move patient's arm, shoulder and head to see if position change affects ability to infuse.
3. Obtain physician's order for a chest x-ray to determine the position of the catheter to rule out "Pinch-off". The patient's arms should be down the patient's side to rule out "Pinch-off" syndrome.



A PowerPort® device implanted in patient.

- If the catheter tip is not in the superior vena cava, the catheter should be repositioned.
- If the catheter tip is not in a vein, the catheter should be replaced.
- If the catheter has been placed through the "pinch-off" area, between the clavicle and the first rib, and is being compressed enough to interfere with infusion or aspiration, it is at risk for catheter transection and embolization. The physician should evaluate the patient for catheter replacement.

V. Signs of Pinch-off

Clinical:

- Difficulty with blood withdrawal
- Resistance to infusion of fluids
- Patient position changes required for infusion of fluids or blood withdrawal

Radiologic:

- Grade 1 or 2 distortion on chest X-ray. Pinch-off should be evaluated for degree of severity prior to explantation. Patients indicating any degree of catheter distortion at the clavicle/first rib area should be followed diligently. There are grades of pinch-off that should be recognized with appropriate chest x-ray as follows: [2,3]

Grade	Severity	Recommended Action
Grade 0	No distortion	No action.
Grade 1	Distortion present **without** luminal narrowing	Chest x-ray should be taken every one to three months to monitor progression of pinch off to grade 2 distortion. Shoulder positioning during chest x-rays should be noted as it can contribute to changes in distortion grades.
Grade 2	Distortion present **with** luminal narrowing	Removal of the catheter should be considered.
Grade 3	Catheter transection or fracture	Prompt removal of the catheter.

VI. Use of Fibrinolytic Agent for Catheter Blockage
Use of a fibrinolytic agent has successfully cleared clotted catheters when gentle irrigation and aspiration have failed. The instructions provided by the drug manufacturer should be followed.

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.

References

1. Bard Access Systems; "*Your* Port Access Advantage: What Patients and Nurses Say About Ports", 2005, 0710420.
2. Hinke, D.H.; Zandt-Stastny, D.A.; Goodman, L.R.; et al. Pinch-off Syndrome: A complication of implantable subclavian venous access devices. Radiology 177: 353-356, 1990.
3. Ingle, Rebecca,; Nace, Corinne, Venous Access Devices: Catheter Pinch-off and Fracture, 1993, Bard Access Systems, Inc.
4. Venousaccess.com
5. www.nursingcenter.com
6. Camp-Sorrell, Dawn; "Access Device Guidelines: Recommendation for Nursing Practice and Education." 2004

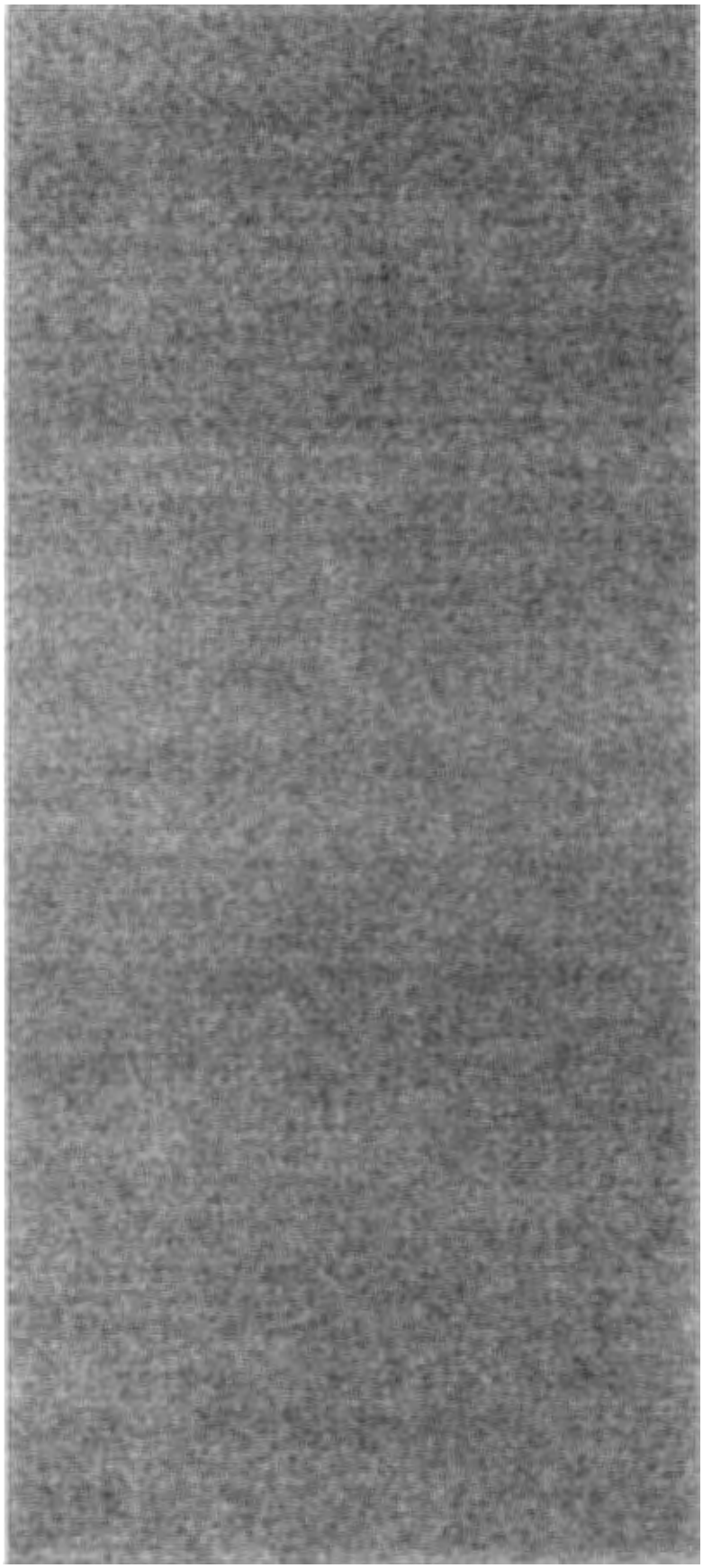
Further Reading

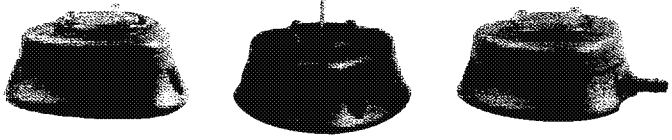
- See PowerPort* port instructions for use, PowerPort* port CT Guide and/or PowerPort* port Patient Guide for more details
- Bard Access Systems is proud to offer "*Your* Port Access Advantage"* patient education module for helping patients select their best access option. See www.portadvantage.com for more details.
- See www.powerportadvantage.com

See a Bard Access Systems Sales Representative for more information about any of these products.

An issued or revision date for these instructions is included for the user's information. In the event two years have elapsed between this date and product use, the user should contact Bard Access Systems, Inc. to see if additional product information is available.

Revised date: August 2007





Bard Access Systems, Inc.
Salt Lake City, UT 84116 USA
801-595-0700

Clinical Information Hotline: 800-443-3385
Ordering Information: 800-545-0890
www.bardaccess.com
www.portadvantage.com
www.powerportadvantage.com

MC-0931-02 0708R

DEHP

This product and package does not contain natural rubber latex

CT MR

300 psi max

BARD

Access Systems

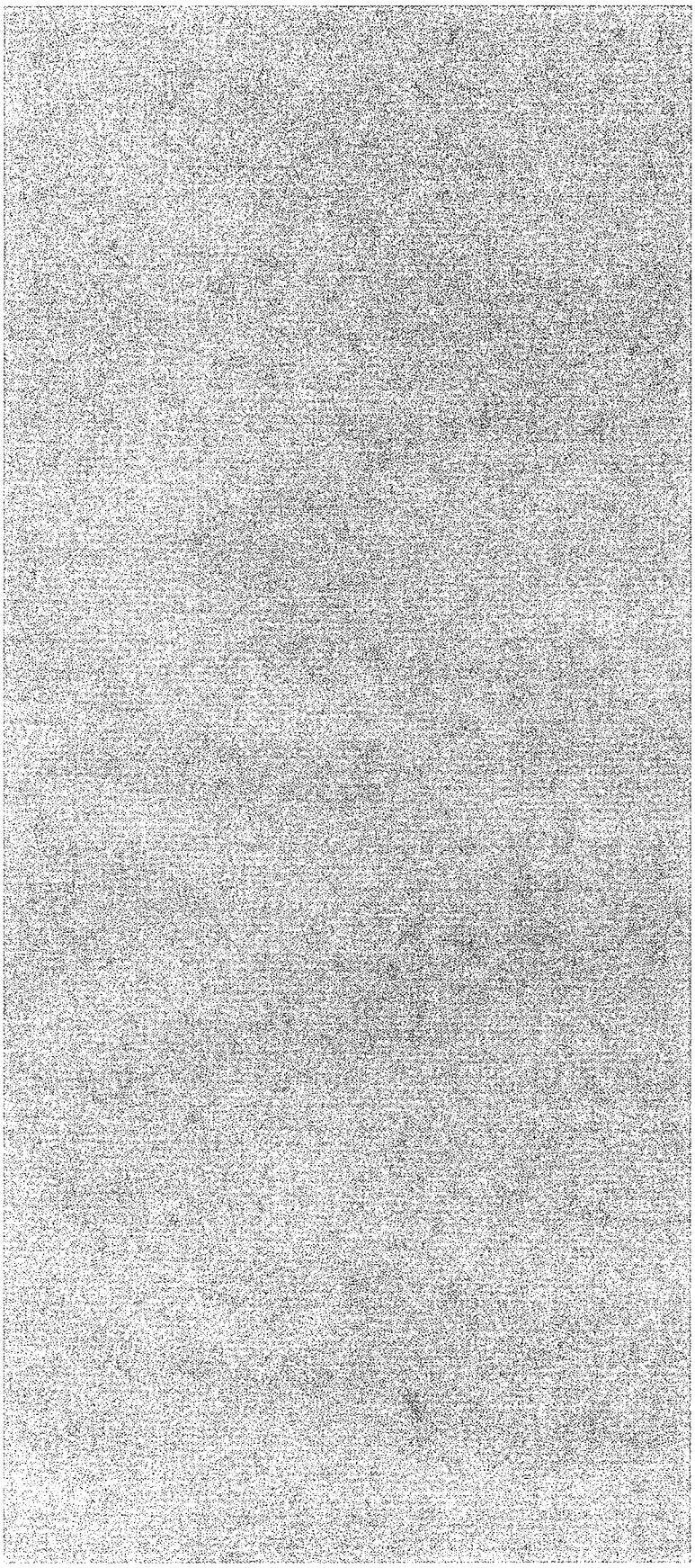
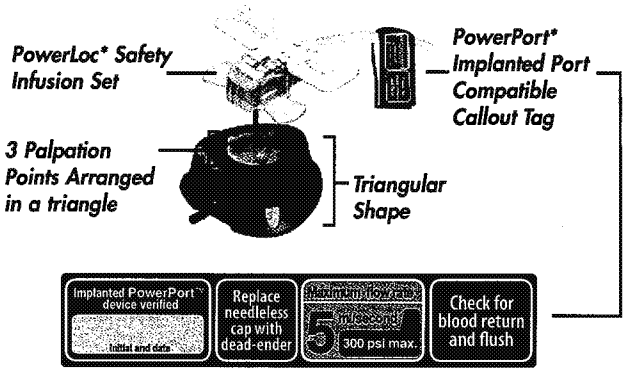


Table of Contents

Important Information:

- **A PowerLoc* Safety Infusion Set must always be used to access the PowerPort* implanted port for power injecting contrast media.**



- **Contrast media should be warmed to body temperature prior to power injection.**
  Warning: Failure to warm contrast media to body temperature prior to power injection may result in port system failure.
- **Check for blood return, then flush the PowerPort* device using at least 10 ml of sterile normal saline prior to and immediately following the completion of power injection studies. Always ensure the patency of the PowerPort* device to prevent damage to the port system. Resistance to flushing may indicate catheter occlusion. Do not proceed with power injection study until occlusion has been cleared.**
  Warning: Failure to ensure patency of the catheter prior to power injection studies may result in port system failure.
  Warning: Do not power inject through a port system that exhibits signs of clavicle-first rib compression or pinch-off as it may result in port system failure.
- **If possible, the patient should receive power injection with arms vertically above the shoulder with the palms of the hands on the face of the gantry during injection. This allows for uninterrupted passage of injected contrast through the axillary and subclavian veins at the thoracic outlet.**
  Warning: Power injector machine pressure limiting feature may not prevent over-pressurization of an occluded catheter.
- **For implanted ports with Groshong* catheters, heparin lock procedures are not necessary; sterile normal saline may be used.**
- **Do not exceed a 300 psi pressure limit setting, or the maximum flow rate setting shown below, on the power injection machine if power injecting through the PowerPort* device.**

PowerLoc* Safety Infusion Set Gauge Size	19 Ga.	20 Ga.	22 Ga.
PowerLoc* Safety Infusion Set Gauge Color	Cream	Yellow	Black
Maximum Flow Rate Setting	5 ml/sec	5 ml/sec	2 ml/sec
Max Pressure Setting	300 psi		

It is recommended that catheter tip placement be verified through institutional protocol.

Warning: Exceeding the maximum flow rate may result in port system failure and/or catheter tip displacement.

Warning: If local pain, swelling or signs of extravasation are noted, the injection should be stopped immediately.

Warning: The PowerPort* device indication for power injection of contrast media implies the device's ability to withstand the procedure, but does not imply appropriateness of the procedure for a particular patient. A suitably trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure. The PowerPort* implanted port is only power injectable when accessed with a PowerLoc* Safety Infusion Set.

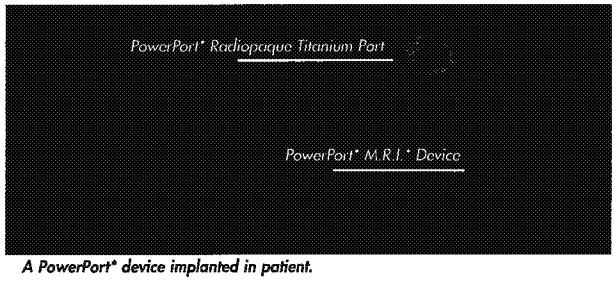
Power-Injection Checklist

1. Ensure that patient has a PowerPort* Implanted Port. (See "Identifying a PowerPort* Implanted Port" for verification methods).
2. Ensure the PowerPort* implanted port is accessed with a PowerLoc* Safety Infusion Set.
3. Replace any needleless cap on the PowerLoc* Safety Infusion Set Y-site with a dead-ender cap.
4. Check blood return and flush.
5. Check the maximum flow rate and maximum pressure setting in the table below before setting up the power injection.

PowerLoc* Safety Infusion Set Gauge Size	19 Ga.	20 Ga.	22 Ga.
PowerLoc* Safety Infusion Set Gauge Color	Cream	Yellow	Black
Maximum Flow Rate Setting	5 ml/sec	5 ml/sec	2 ml/sec
Max Pressure Setting	300 psi		

Power Injection Procedure

1. Verify patient has a PowerPort* implanted port. See "Identifying a PowerPort* Implanted Port".
   Note: It is recommended that catheter tip placement be verified through institutional protocol.



A PowerPort device implanted in patient.*

2. Ensure the port is accessed with a PowerLoc* Safety Infusion Set. Make certain that needle tip is inserted fully within the port.
   Warning: A PowerLoc* Safety Infusion Set must always be used to access the PowerPort* implanted port for power injecting contrast media.

3. Replace any needleless cap on the PowerLoc* Safety Infusion Set Y-site with a dead-ender cap.
4. Attach a syringe filled with sterile normal saline.
5. Check blood return and vigorously flush the port with at least 10 ml of sterile normal saline. Check for patency with the patient in the position that they will assume during CECT procedure.
   Warning: Failure to ensure patency of the catheter prior to power injection studies may result in port system failure.
6. Detach syringe.
7. Warm contrast media to body temperature.
8. If possible, the patient should receive power injection with arms vertically above the shoulder with the palms of the hands on the face of the gantry during injection. This allows for uninterrupted passage of injected contrast through the axillary and subclavian veins at the thoracic outlet.
9. Attach the power injection device securely to the PowerLoc* Infusion Set.
10. Check table below to confirm the maximum flow rate and maximum pressure setting.
11. Instruct the patient to communicate immediately any pain or change in feeling during the injection. Inject warmed contrast, taking care not to exceed the flow rate limits.
    Warning: If local pain, swelling or signs of extravasation are noted, the injection should stop immediately.
    Warning: Do not exceed a 300 psi pressure limit setting, or the maximum flow rate setting shown below, on the power injection machine if power injecting through the PowerPort* Implanted Port:

PowerLoc* Safety Infusion Set Gauge Size	19 Ga.	20 Ga.	22 Ga.
PowerLoc* Safety Infusion Set Gauge Color	Cream	Yellow	Black
Maximum Flow Rate Setting	5 ml/sec	5 ml/sec	2 ml/sec
Max Pressure Setting	300 psi		

12. Disconnect the power injection device.
13. Flush the PowerPort* device with 10 ml of sterile normal saline.
14. Have heparin lock procedure performed for open-ended catheters. **For implanted ports with Groshong* catheters, a sterile normal saline lock may be used.**
    Caution: Remember that some patients may be hypersensitive to heparin or suffer heparin induced thrombocytopenia (HIT) and these patients must not have their port locked with heparinized saline.
15. After therapy completion, flush port per institutional protocol. Close clamp while injecting last 0.5 ml of solution. This helps reduce the potential for blood backflow into the catheter tip, which could encourage catheter clotting.

Description

The PowerPort* Implanted Port is an implantable access device designed to provide repeated access to the vascular system. Port access is performed by percutaneous needle insertion using a non-coring needle. Power injection is performed using a PowerLoc* Safety Infusion Set only. The PowerPort* device consists of two primary components: an injection port with self-sealing septum and a radiopaque catheter. PowerPort* implanted ports can be identified by feeling the top of the septum which includes three palpation points arranged in a triangle and by palpating the sides of the port, also in a triangular shape.

identifier featured on the PowerPort M.R.I.* device aids in identification of a flipped port.*

All materials are biocompatible, can be used with virtually all injectable solutions and can be safely used with CECT.

For implanted ports with Groshong* catheters, the Groshong* catheter valve helps provide security against blood reflux and air embolism into the port/catheter system. The Groshong* catheter may be flushed with normal saline and does not require heparin to maintain patency.

Indications For Use

The PowerPort* Implanted Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples.

When used with PowerLoc* Safety Infusion Set, the PowerPort* device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s.

Warnings

- Intended for Single Patient Use. DO NOT REUSE. Bard Access Systems, Inc. PowerPort* implanted ports are single use devices and should never be reimplanted. Any device that has been contaminated by blood should not be reused or resterilized.
- After use, this product may be a potential biohazard. Handle and discard in accordance with accepted medical practice and applicable local, state and federal laws and regulations.
- The use of a non-power compatible infusion set during power injection will lead to system failure and possibly patient injury.
- DO NOT USE A SYRINGE SMALLER THAN 10ml. Flushing occluded catheters with small syringes can create excessive pressures within the part system.
- Do not power inject through the port if you cannot aspirate, if resistance to flushing seems excessive, or if the port system is occluded.
- Failure to warm contrast media to body temperature prior to power injection may result in port system failure.
- Failure to ensure patency of the catheter prior to power injection studies may result in port system failure.
- Do not power inject through a port system that exhibits signs of clavicle-first rib compression or pinch-off as it may result in port system failure.
- Power injector machine pressure limiting feature may not prevent over pressurization of an occluded catheter.
- Do not exceed a 300 psi pressure limit setting, or the maximum flow rate setting shown below, on the power injection machine if power injecting through the PowerPort* device.

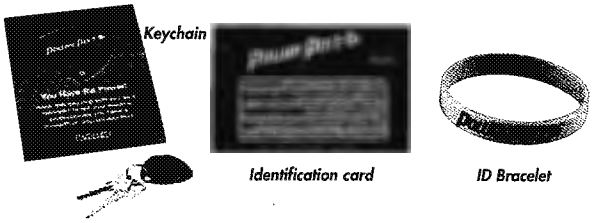
PowerLoc* Safety Infusion Set Gauge Size	19 Ga.	20 Ga.	22 Ga.
PowerLoc* Safety Infusion Set Gauge Color	Cream	Yellow	Black
Maximum Flow Rate Setting	5 ml/sec	5 ml/sec	2 ml/sec
Max Pressure Setting	300 psi		

- The PowerPort* device indication for power injection of contrast media implies the device's ability to withstand the procedure, but does not imply appropriateness of the procedure for a particular patient. A suitably trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure. The PowerPort* device is only power injectable when accessed with a PowerLoc* Safety Infusion Set.

Precautions

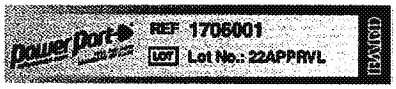
- Precautions are intended to help avoid product damage and/or patient injury.
- Carefully read and follow all instructions prior to use.
- Follow Universal Precautions when inserting and maintaining the catheter.
- Follow all contraindications, warnings, cautions, precautions and instructions for all infusates as specified by their manufacturers.
- Use only non-coring needles with the port.
- Only accessories and components with luer lock connections should be used with this device.
- If signs of extravasation exist, discontinue injections. Begin appropriate medical intervention immediately.
- Use only non-coring needles with the port.

Identifying a PowerPort* Implanted Port

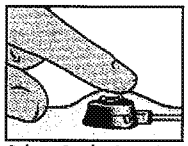


Identification card *ID Bracelet*

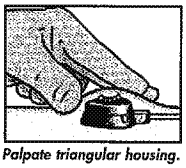
- Power-injectable PowerPort* ports can be distinguished from traditional ports through the following means:
  - **Check patient's chart for PowerPort* device's patient record sticker.**



  - Palpate top of port to identify three palpation points (bumps) on the septum, arranged in a triangle.
  - Palpate sides of port to identify triangular port housing.
  - Request confirmation from the patient by asking them to show you the patient identification card, ID bracelet, or key chain they received when the port was implanted.

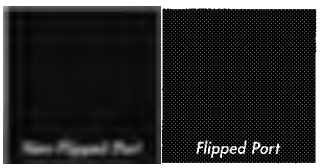


Palpate 3 palpation points on septum.



Palpate triangular housing.

- Always verify the patient has a PowerPort* implanted port by at least 2 means and ensure they are accessed with a PowerLoc* Infusion Set, prior to power injection.



- For the PowerPort* M.R.I.* Implanted Port, look under X-ray or fluoroscopy for the power symbol.
- The new unique radiopaque identifier on the PowerPort* M.R.I.* port aides in identification of a flipped port with reduced artifact.
- For additional guidance on recognizing a power injectable port / infusion set system, contact Bard's Clinical Information Hotline at 800-443-3385.

Possible Complications

The use of a subcutaneous port provides an important means of venous access for critically ill patients. However, the potential exists for serious complications including, but not limited to, the following:

- Air Embolism
- Bleeding
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Catheter or Port Erosion Through the Skin
- Catheter Embolism
- Catheter Occlusion
- Catheter Occlusion, Damage or Breakage due to Compression between the Clavicle and First Rib
- Catheter or port related Sepsis
- Device Rotation or Extrusion
- Endocarditis
- Extravasation
- Fibrin Sheath Formation
- Hematoma
- Hemothroax
- Hydrothorax
- Intolerance Reaction to Implanted Device
- Inflammation, Necrosis, or Scarring of Skin Over Implant Area
- Laceration of Vessels or Viscus
- Perforation of Vessels or Viscus
- Pneumothorax
- Spontaneous Catheter Tip Malposition or Retraction
- Thoracic Duct Injury
- Thromboembolism
- Vascular Thrombosis
- Vessel Erosion
- Risks Normally Associated with Local or General Anesthesia, Surgery, and Post-Operative Recovery

These and other complications are well documented in medical literature.

Use and Maintenance Instructions

Site Preparation

Always inspect and aseptically prepare the injection site prior to accessing the port.

Equipment:

- Alcohol or chlorhexidine wipe
- Antiseptic swabs (3)
- Sterile gloves

Note: Additional sterile precautions may be used according to hospital protocol.

Procedure:

1. Explain procedure to patient. Warn of needle prick sensation. (Sensation of needle insertion decreases over time. Use of a topical anesthetic may be appropriate.)
2. Wash hands thoroughly.
3. Don sterile gloves, and follow your hospital protocol for sterile precautions.
4. Cleanse or scrub the area according to the cleansing agent manufacturers instructions. We suggest an area of at least 10 – 13 cm diameter at the port insertion site. Allow to dry completely.
   Directions for the use of ChloraPrep* preoperative skin preparation: Prepare the site with ChloraPrep* One-Step

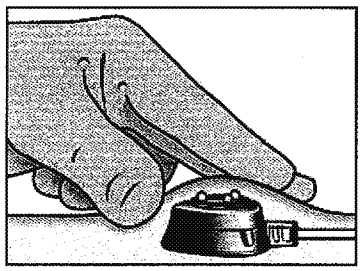
Applicator Solution or according to institutional policy using sterile technique. "Pinch-Off" the wings on the ChloraPrep* preoperative skin preparation One-Step Applicator to break the ampule and release the antiseptic. Do not touch the sponge. Wet the sponge against the treatment area until fluid is visible on the skin. Use repeated back-forth strokes of the sponge for approximately 30 seconds. Completely wet the treatment area with antiseptic. Allow the area to dry for approximately 30 seconds. Do not blot or wipe away. Maximum treatment area for one applicator is approximately 130 cm^2 (approximately 4 x 5 in.). Discard the applicator after use.

Note: Follow established hospital or institutional policy for changing I.V. tubing and accessing cannula. The Center for Disease Control (CDC) or Oncology Nursing Society (ONS) may have recommended guidelines.

Accessing Implanted Ports

Equipment:

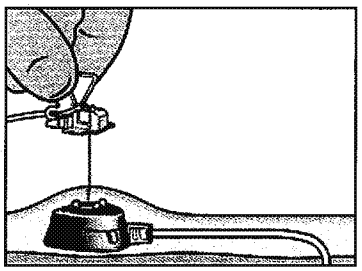
- Syringe
- Dead End Caps
- Sterile Gloves
- If the port will be accessed for power injection, it must be accessed with a PowerLoc* Safety Infusion Set to prevent damage to the device and injury to the patient.



Palpate triangular housing.

Procedure:

1. Perform aseptic site preparation.
2. Locate port septum by palpation.
   a. Locate base of port with non-dominant hand.
   b. Triangulate port between thumb and first two fingers of non-dominant hand. Aim for center point of these three fingers.
3. Insert needle perpendicular to port septum. Advance PowerLoc* Safety Infusion set through the skin and septum until reaching bottom of reservoir.



Access with PowerLoc Safety infusion Set.*

4. Confirm correct needle placement and patency by blood aspiration and flushing.
5. Always flush the port following injection.
6. Perform heparin lock procedure for open-ended catheters. **For implanted ports with Groshong* catheters, a sterile normal saline lock may be used.**
   Caution: Remember that some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia and these patients must not have their port locked with heparinized saline.

7. When deaccessing the port, the needle should be removed using the positive pressure technique. Positive pressure is maintained while flushing the accessed port by clamping the infusion set tubing, while still flushing the line. This helps reduce the potential for blood backflow into the catheter tip, which could encourage catheter clotting. If using a PowerLoc* safety infusion set, activate safety mechanism while withdrawing the needle until you hear or feel a "click" at which time the needle should be captured within the safety mechanism of the PowerLoc* safety infusion set.

Troubleshooting Guide

I. Aspiration Difficulties: DO NOT POWER INJECT IF YOU CANNOT ASPIRATE AS PATIENT INJURY MAY RESULT

A. Possible Causes

1. Failure to flush adequately, resulting in lumen obstruction.
2. Catheter tip sucking up to vein wall with aspiration.
3. Blood clot, fibrin sheath, or particulate matter obstructing lumen when catheter is aspirated.
   - A clot or other obstruction in the catheter lumen can produce a one-way valve effect. During infusion, the catheter wall expands slightly and allows fluid to flow around the plug. During aspiration, the catheter wall contracts slightly, tightening down around the obstruction and preventing aspiration.
   - Fibrin sheaths usually begin to form within a few days after the insertion of a central venous catheter. If it has grown enough to extend the tip of the catheter, it may be pulled into and obstruct the catheter opening when aspiration is attempted, but no resistance to infusion.
4. Compression or transection of the catheter between the clavicle and first rib ("pinch-off area").
5. Kinked catheter.
   - Catheter may be pulled too tight through skin tunnel, causing kink at vessel insertion site, or where it curves into the subcutaneous tunnel.
   - Catheter may be curled or kinked within the vessel, or under the dressing.
6. Malposition of catheter tip (i.e. jugular vein, outside of vein).
7. Improper catheter length selection for patient size.

B. Possible Solutions

1. If no resistance to infusion is felt, attempt to flush with 10 ml normal saline. Then pull back gently on syringe plunger 2-3 ml, pause and proceed with aspiration.
2. If resistance to infusion is felt, check for signs of extravasation. If present, notify physician of possible catheter leakage or transection and embolization. If not present, see step 4.
3. Attempt to aspirate with a 20 ml syringe (creates a greater vacuum).
4. Move patient's arm, shoulder and head to see if a change in position will allow aspiration. If aspiration can only be accomplished with the patient in a certain position, the patient should be examined to see if the catheter has been placed in the "pinch-off" area. See step 5.

5. Obtain physician's order for a chest x-ray to determine the position of the catheter.
   - If the catheter tip is not in the superior vena cava, the catheter should be repositioned.
   - If the catheter tip is not in a vein, the catheter should be replaced.
   - If the catheter has been placed through the "pinch-off" area, between the clavicle and the first rib, and is being compressed enough to interfere with infusion or aspiration, it is at risk for catheter transection and embolization. The physician should evaluate the patient for catheter replacement.

II. Patient with Fever and/or Infection:

Symptoms:

- Inflammation at incision site
- Fever
- Positive site culture and/or blood cultures

If signs of infection are present:

- Notify physician

III. Insufficient Flow: DO NOT POWER INJECT IF RESISTANCE TO FLUSHING SEEMS EXCESSIVE

Excessive force must not be used to flush an obstructed lumen. Insufficient blood flow may be caused by the catheter contacting the wall of the vein or an occluding clot. The physician may attempt to dissolve the clot with a fibrolytic agent before power injecting. Physician discretion advised.

IV. Catheter Occlusion: DO NOT POWER INJECT AN OCCLUDED DEVICE

A. Possible Causes

1. Blood clot completely obstructing lumen.
2. May be kinked, coiled, damaged, or compressed between the clavicle and the first rib.
3. Catheter tip may not be within vein.
4. May be partially or completely transected. Transection can occur from the repeated pressure of the clavicle and the first rib on the catheter during normal movement if it is placed through the "pinch-off" area. (For subclavian placements only.)
5. Improper catheter length for patient size.

B. Possible Solutions

1. Ask responsible nurse or physician to attempt to aspirate blood clot.
2. Move patient's arm, shoulder and head to see if position change affects ability to infuse. If so, see step 3 (could be pinch-off).
3. Obtain physician's order for a chest x-ray to determine the position of the catheter.
   - Move patient's arm, shoulder and head to see if position change affects ability to infuse.
   - If the catheter tip is not in the superior vena cava, the catheter should be repositioned.

- If the catheter tip is not in a vein, the catheter should be replaced.
- If the catheter has been placed through the "pinch-off" area, between the clavicle and the first rib, and is being compressed enough to interfere with infusion or aspiration, it is at risk for catheter transection and embolization. The physician should evaluate the patient for catheter replacement.
- 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.

V. Signs of Pinch-off

Clinical:

- Difficulty with blood withdrawal
- Resistance to infusion of fluids
- Patient position changes required for infusion of fluids or blood withdrawal

Radiologic:

- Grade 1 or 2 distortion on chest X-ray.

Pinch-off should be evaluated for degree of severity prior to explantation. Patients indicating any degree of catheter distortion at the clavicle/first rib area should be followed diligently. There are grades of pinch-off that should be recognized with appropriate chest x-ray as follows: [1,2]

Grade	Severity	Recommended Action
Grade 0	No distortion	No action.
Grade 1	Distortion present **without** luminal narrowing	Chest x-ray should be taken every one to three months to monitor progression of pinch off to grade 2 distortion. Shoulder positioning during chest x-rays should be noted as it can contribute to changes in distortion grades.
Grade 2	Distortion present **with** luminal narrowing	Removal of the catheter should be considered.
Grade 3	Catheter transection or fracture	Prompt removal of the catheter.

VI. Use of Fibrinolytic Agent for Catheter Blockage

Use of a fibrinolytic agent has successfully cleared clotted catheters when gentle irrigation and aspiration have failed. The instructions provided by the drug manufacturer should be followed.

References

1. Hinke, D.H.; Zandt-Stastny, D.A.; Goodman, L.R.; et al. "Pinch-off syndrome: A complication of implantable subclavian venous access devices." Radiology 177: 353-356, 1990.
2. Ingle, Rebecca; Nace, Corinne. "Venous Access Devices: Catheter Pinch-off and Fracture." 1993, Bard Access Systems, Inc.
3. Camp-Sorrell, Dawn. "Access Device Guidelines" 2nd Edition Oncology Nursing Society, 2004.

Further Reading

- See PowerPort* port IFU, PowerPort* port Nursing Guide and/or PowerPort* port Patient Guide for more details
- Bard Access Systems is proud to offer "*Your* Port Access Advantage"* patient education module for helping patients select their best access option.
- See www.powerportadvantage.com

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Revised date: March 2008

CT Contrast Enhanced Computed Tomography Information

This product and package does not contain natural rubber latex.

DEHP This device does not contain DEHP

MR Conditional

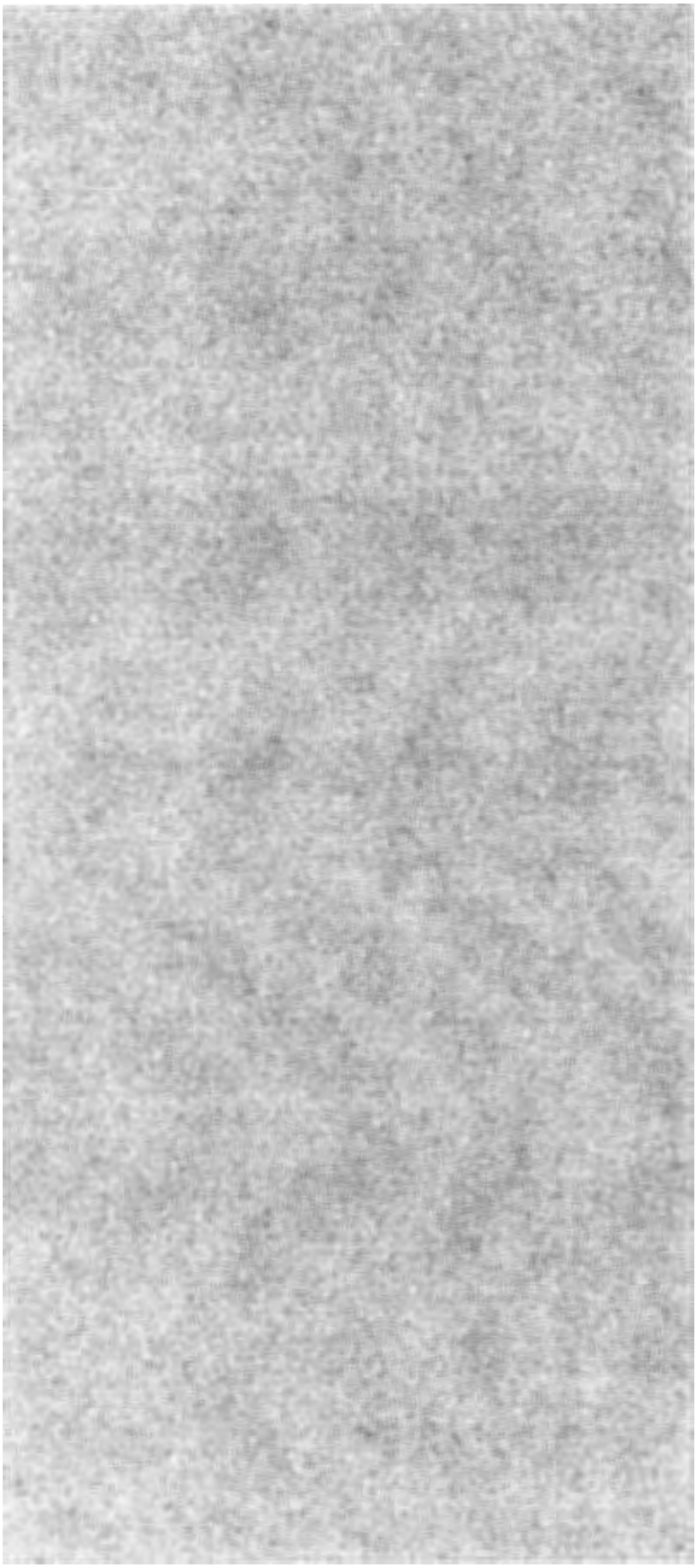
Non-clinical testing has demonstrated the device is MR Conditional. It can be scanned safely under:

- static magnetic field of 3 Tesla or less
- spatial gradient field of 330 Gauss/cm or less
- maximum specific absorption rate (SAR) of 6 W/kg for 30 minutes of scanning.

In non-clinical testing, the device produced a temperature rise of less than 0.5 °C at a maximum specific absorption rate (SAR) of 6 W/kg for 30 minutes of MR scanning in a 3T Siemens Trio with software version VA25.

For Minimal Image artifact

- MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.



Bard Access Systems, Inc.

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Ordering Information: 800-545-0890
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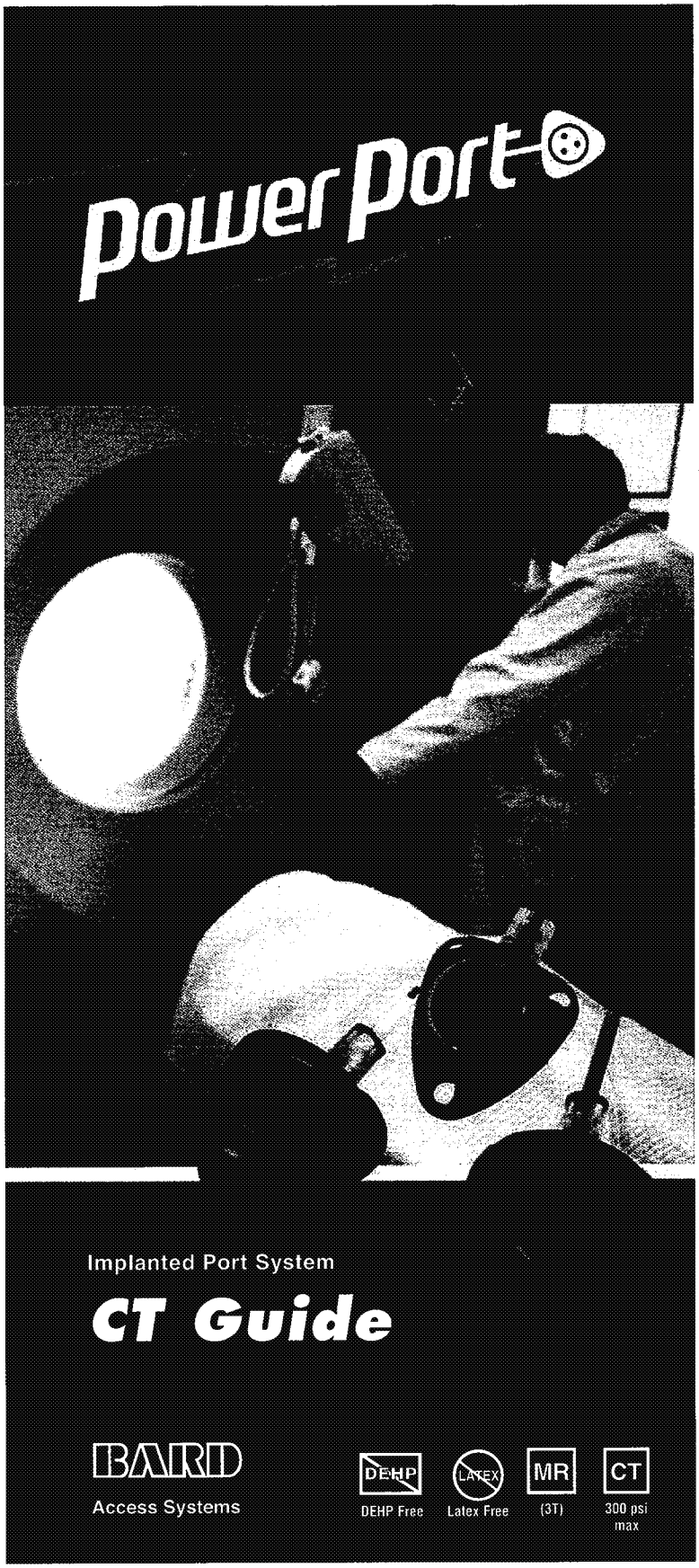
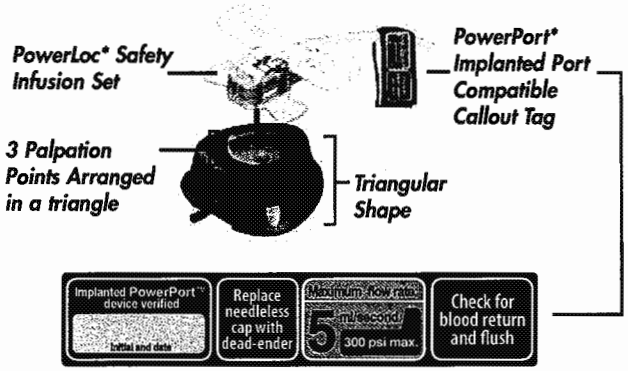


Table of Contents

Important Information:

- A PowerLoc* Safety Infusion Set must always be used to access the PowerPort* implanted port for power injecting contrast media.



- **Contrast media should be warmed to body temperature prior to power injection.**
  Warning: Failure to warm contrast media to body temperature prior to power injection may result in port system failure.
- **Check for blood return, then flush the PowerPort* device using at least 10 ml of sterile normal saline prior to and immediately following the completion of power injection studies. Always ensure the patency of the PowerPort* device to prevent damage to the port system. Resistance to flushing may indicate catheter occlusion. Do not proceed with power injection study until occlusion has been cleared.**
  Warning: Failure to ensure patency of the catheter prior to power injection studies may result in port system failure.
  Warning: Do not power inject through a port system that exhibits signs of clavicle-first rib compression or pinch-off as it may result in port system failure.
- **If possible, the patient should receive power injection with arms vertically above the shoulder with the palms of the hands on the face of the gantry during injection. This allows for uninterrupted passage of injected contrast through the axillary and subclavian veins at the thoracic outlet.**
  Warning: Power injector machine pressure limiting feature may not prevent over-pressurization of an occluded catheter.
- **Do not exceed a 300 psi pressure limit setting, or the maximum flow rate setting shown below, on the power injection machine if power injecting through the PowerPort* device.**

PowerLoc* Safety Infusion Set Gauge Size	19 Ga.	20 Ga.	22 Ga.
PowerLoc* Safety Infusion Set Gauge Color	Cream	Yellow	Black
Maximum Flow Rate Setting	5 ml/sec	5 ml/sec	2 ml/sec
Max Pressure Setting	300 psi		

It is recommended that catheter tip placement be verified through institutional protocol.

Warning: Exceeding the maximum flow rate may result in port system failure and/or catheter tip displacement.

Warning: If local pain, swelling or signs of extravasation are noted, the injection should be stopped immediately.

Warning: The PowerPort* device indication for power injection of contrast media implies the device's ability to withstand the procedure, but does not imply appropriateness of the procedure for a particular patient. A suitably trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure. The PowerPort* implanted port is only power injectable when accessed with a PowerLoc* Safety Infusion Set.

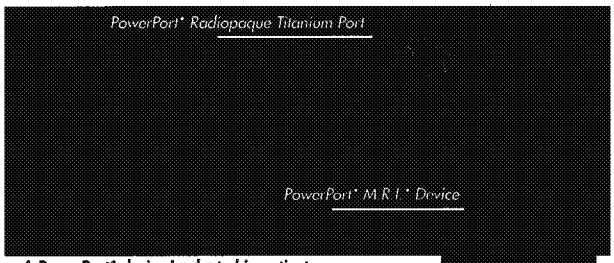
Power-Injection Checklist

1. Ensure that patient has a PowerPort* Implanted Port. (See "Identifying a PowerPort* Implanted Port" for verification methods.
2. Ensure the PowerPort* implanted port is accessed with a PowerLoc* Safety Infusion Set.
3. Replace any needleless cap on the PowerLoc* Safety Infusion Set Y-site with a dead-ender cap.
4. Check blood return and flush.
5. Check the maximum flow rate and maximum pressure setting in the table below before setting up the power injection.

PowerLoc* Safety Infusion Set Gauge Size	19 Ga.	20 Ga.	22 Ga.
PowerLoc* Safety Infusion Set Gauge Color	Cream	Yellow	Black
Maximum Flow Rate Setting	5 ml/sec	5 ml/sec	2 ml/sec
Max Pressure Setting	300 psi		

Power Injection Procedure

1. Verify patient has a PowerPort* implanted port. See "Identifying a PowerPort* Implanted Port".
   Note: It is recommended that catheter tip placement be verified through institutional protocol.



A PowerPort device implanted in patient.*

2. Ensure the port is accessed with a PowerLoc* Safety Infusion Set. Make certain that needle tip is inserted fully within the port.
   Warning: A PowerLoc* Safety Infusion Set must always be used to access the PowerPort* implanted port for power injecting contrast media.
3. Replace any needleless cap on the PowerLoc* Safety Infusion Set Y-site with a dead-ender cap.

4. Attach a syringe filled with sterile normal saline.
5. Check blood return and vigorously flush the port with at least 10 ml of sterile normal saline. Check for patency with the patient in the position that they will assume during CECT procedure.
   Warning: Failure to ensure patency of the catheter prior to power injection studies may result in port system failure.
6. Detach syringe.
7. Warm contrast media to body temperature.
8. If possible, the patient should receive power injection with arms vertically above the shoulder with the palms of the hands on the face of the gantry during injection. This allows for uninterrupted passage of injected contrast through the axillary and subclavian veins at the thoracic outlet.
9. Attach the power injection device securely to the PowerLoc* Infusion Set.
10. Check table below to confirm the maximum flow rate and maximum pressure setting.
11. Instruct the patient to communicate immediately any pain or change in feeling during the injection. Inject warmed contrast, taking care not to exceed the flow rate limits.
    Warning: If local pain, swelling or signs of extravasation are noted, the injection should stop immediately.
    Warning: Do not exceed a 300 psi pressure limit setting, or the maximum flow rate setting shown below, on the power injection machine if power injecting through the PowerPort* Implanted Port:

PowerLoc* Safety Infusion Set Gauge Size	19 Ga.	20 Ga.	22 Ga.
PowerLoc* Safety Infusion Set Gauge Color	Cream	Yellow	Black
Maximum Flow Rate Setting	5 ml/sec	5 ml/sec	2 ml/sec
Max Pressure Setting	300 psi		

12. Disconnect the power injection device.
13. Flush the PowerPort* device with 10 ml of sterile normal saline.
14. Have heparin lock procedure performed for open-ended catheters. **Caution:** Remember that some patients may be hypersensitive to heparin or suffer heparin induced thrombocytopenia (HIT) and these patients must not have their port locked with heparinized saline.
15. After therapy completion, flush port per institutional protocol. Close clamp while injecting last 0.5 ml of solution. This helps reduce the potential for blood backflow into the catheter tip, which could encourage catheter clotting.

Description

The PowerPort* Implanted Port is an implantable access device designed to provide repeated access to the vascular system. Port access is performed by percutaneous needle insertion using a non-coring needle. Power injection is performed using a PowerLoc* Safety Infusion Set only. The PowerPort* device consists of two primary components: an injection port with self-sealing septum and a radiopaque ChronoFlex* polyurethane catheter. PowerPort* implanted ports can be identified by feeling the top of the septum which includes three palpation points arranged in a triangle and by palpating the sides of the port, also in a triangular shape. All materials are biocompatible, can be used with virtually all injectable solutions, are latex-free, and are safe with CECT and MRI imaging.

Indications For Use

The PowerPort* Implanted Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples.

When used with the PowerLoc* Safety Infusion Set, the PowerPort* device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s.

Warnings

- Intended for Single Patient Use. DO NOT REUSE. Bard Access Systems, Inc. PowerPort* implanted ports are single use devices and should never be reimplanted. Any device that has been contaminated by blood should not be reused or resterilized.
- After use, this product may be a potential biohazard. Handle and discard in accordance with accepted medical practice and applicable local, state and federal laws and regulations.
- The use of a non-power compatible infusion set during power injection will lead to system failure and possibly patient injury.
- DO NOT USE A SYRINGE SMALLER THAN 10ml. Prolonged infusion pressure greater than 25 psi may cause damage to a patient's vessels or viscus.
- Do not power inject through the port if you cannot aspirate, if resistance to flushing seems excessive, or if the port system is occluded.
- Failure to warm contrast media to body temperature prior to power injection may result in port system failure.
- Failure to ensure patency of the catheter prior to power injection studies may result in port system failure.
- Do not power inject through a port system that exhibits signs of clavicle-first rib compression or pinch-off as it may result in port system failure.
- Power injector machine pressure limiting feature may not prevent over pressurization of an occluded catheter.
- Do not exceed a 300 psi pressure limit setting, or the maximum flow rate setting shown below, on the power injection machine if power injecting through the PowerPort* device.

PowerLoc* Safety Infusion Set Gauge Size	19 Ga.	20 Ga.	22 Ga.
PowerLoc* Safety Infusion Set Gauge Color	Cream	Yellow	Black
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Max Pressure Setting	300 psi		

- The PowerPort* device indication for power injection of contrast media implies the device's ability to withstand the procedure, but does not imply appropriateness of the procedure for a particular patient. A suitably trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure. The PowerPort* device is only power injectable when accessed with a PowerLoc* Safety Infusion Set.

Precautions

- Precautions are intended to help avoid product damage and/or patient injury.
- Carefully read and follow all instructions prior to use.
- Follow Universal Precautions when inserting and maintaining the catheter.
- Follow all contraindications, warnings, cautions, precautions and instructions for all infusates as specified by their manufacturers.
- Use only non-coring needles with the port.
- Only accessories and components with luer lock connections should be used with this device.
- If signs of extravasation exist, discontinue injections. Begin appropriate medical intervention immediately.
- Use only non-coring needles with the port.

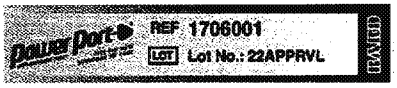
Identifying a PowerPort* Implanted Port


Keychain

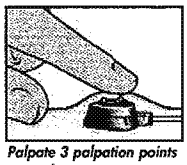

Identification card

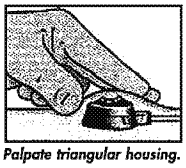

ID Bracelet

- Power-injectable PowerPort* ports can be distinguished from traditional ports through the following means:
  - **Check patient's chart for PowerPort* device's patient record sticker.**

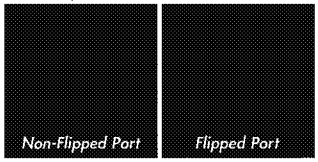


  - Palpate top of port to identify three palpation points (bumps) on the septum, arranged in a triangle.
  - Palpate sides of port to identify triangular port housing.
  - Request confirmation from the patient by asking them to show you the patient identification card, ID bracelet, or key chain they received when the port was implanted.


Palpate 3 palpation points on septum.


Palpate triangular housing.

- Always verify the patient has a PowerPort* implanted port by at least 2 means and ensure they are accessed with a PowerLoc* Infusion Set, prior to power injection.
- For the PowerPort* M.R.I.* Implanted Port, look under X-ray or fluoroscopy for the power symbol.
- The new unique radiopaque identifier on the PowerPort* M.R.I.* port aides in identification of a flipped port with reduced artifact.



- For additional guidance on recognizing a power injectable port / infusion set system, contact Bard's Clinical Information Hotline at 800-443-3385.

Possible Complications

The use of a subcutaneous port provides an important means of venous access for critically ill patients. However, the potential exists for serious complications including, but not limited to, the following:

- Air Embolism
- Bleeding
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Catheter or Port Erosion Through the Skin
- Catheter Embolism
- Catheter Occlusion
- Catheter Occlusion, Damage or Breakage due to Compression between the Clavicle and First Rib
- Catheter or port related Sepsis
- Device Rotation or Extrusion
- Endocarditis
- Extravasation
- Fibrin Sheath Formation
- Hematoma
- Hemothroax
- Hydrothorax
- Intolerance Reaction to Implanted Device
- Inflammation, Necrosis, or Scarring of Skin Over Implant Area
- Laceration of Vessels or Viscus
- Perforation of Vessels or Viscus
- Pneumothorax
- Spontaneous Catheter Tip Malposition or Retraction
- Thoracic Duct Injury
- Thromboembolism
- Vascular Thrombosis
- Vessel Erosion
- Risks Normally Associated with Local or General Anesthesia, Surgery, and Post-Operative Recovery

These and other complications are well documented in medical literature.

Use and Maintenance Instructions

Site Preparation

Always inspect and aseptically prepare the injection site prior to accessing the port.

Equipment:

- Alcohol or chlorhexidine wipe
- Antiseptic swabs (3)
- Sterile gloves

Note: Additional sterile precautions may be used according to hospital protocol.

Procedure:

1. Explain procedure to patient. Warn of needle prick sensation. (Sensation of needle insertion decreases over time. Use of a topical anesthetic may be appropriate.)
2. Wash hands thoroughly.
3. Don sterile gloves, and follow your hospital protocol for sterile precautions.
4. Cleanse or scrub the area according to the cleansing agent manufacturers instructions. We suggest an area of at least 10 – 13 cm diameter at the port insertion site. Allow to dry completely.

   Directions for the use of ChloraPrep* preoperative skin preparation: Prepare the site with ChloraPrep* One-Step Applicator Solution or according to institutional policy using sterile technique. "Pinch-Off" the wings on the ChloraPrep* preoperative skin preparation One-Step Applicator to break the ampule and release the antiseptic. Do not touch the sponge. Wet the sponge against the treatment area until fluid is visible on the skin. Use repeated back-forth strokes of the sponge for approximately 30 seconds. Completely wet the treatment area with antiseptic. Allow the area to dry for approximately 30 seconds. Do not blot or wipe away. Maximum treatment area for one applicator is approximately 130 ml (approximately 4 x 5 in.). Discard the applicator after use.

Note: Follow established hospital or institutional policy for changing I.V. tubing and accessing cannula. The Center for Disease Control (CDC) or Oncology Nursing Society (ONS) may have recommended guidelines.

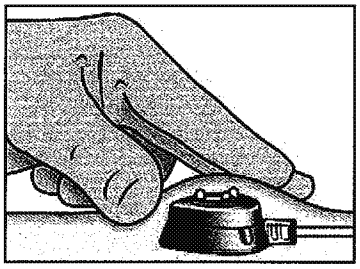
Accessing Implanted Ports

Equipment:

- Syringe
- Dead End Caps
- Sterile Gloves
- If the port will be accessed for power injection, it must be accessed with a PowerLoc* Safety Infusion Set to prevent damage to the device and injury to the patient.

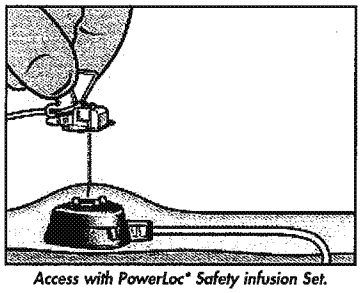
Procedure:

1. Perform aseptic site preparation.
2. Locate port septum by palpation.
   a. Locate base of port with non-dominant hand.
   b. Triangulate port between thumb and first two fingers of non-dominant hand. Aim for center point of these three fingers.



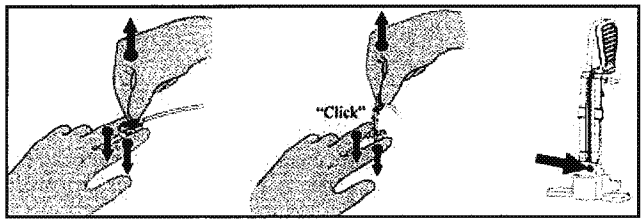
Palpate triangular housing.

3. Insert needle perpendicular to port septum. Advance PowerLoc* Safety Infusion set through the skin and septum until reaching bottom of reservoir.
4. Confirm correct needle placement and patency by blood aspiration and flushing.



Access with PowerLoc Safety infusion Set.*

5. Always flush the port following injection.
6. Perform heparin lock procedure for open-ended catheters. **Caution:** Remember that some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia and these patients must not have their port locked with heparinized saline.
7. When deaccessing the port, the needle should be removed using the positive pressure technique. Positive pressure is maintained while flushing the accessed port by clamping the infusion set tubing, while still flushing the line. This helps reduce the potential for blood backflow into the catheter tip, which could encourage catheter clotting. If using a PowerLoc* safety infusion set, activate safety mechanism while withdrawing the needle until you feel a "click" at which time the needle should be captured within the safety mechanism of the PowerLoc* safety infusion set.



Troubleshooting Guide

I. Aspiration Difficulties: DO NOT POWER INJECT IF YOU CANNOT ASPIRATE AS PATIENT INJURY MAY RESULT

A. Possible Causes

1. Failure to flush adequately, resulting in lumen obstruction.
2. Catheter tip sucking up to vein wall with aspiration.
3. Blood clot, fibrin sheath, or particulate matter obstructing lumen when catheter is aspirated.
   - A clot or other obstruction in the catheter lumen can produce a one-way valve effect. During infusion, the catheter wall expands slightly and allows fluid to flow around the plug. During aspiration, the catheter wall contracts slightly, tightening down around the obstruction and preventing aspiration.
   - Fibrin sheaths usually begin to form within a few days after the insertion of a central venous catheter. If it has grown enough to extend the tip of the catheter, it may be pulled into and obstruct the catheter opening when aspiration is attempted, but no resistance to infusion.
4. Compression or transection of the catheter between the clavicle and first rib ("pinch-off area").
5. Kinked catheter.
   - Catheter may be pulled too tight through skin tunnel, causing kink at vessel insertion site, or where it curves into the subcutaneous tunnel.
   - Catheter may be curled or kinked within the vessel, or under the dressing.
6. Malposition of catheter tip (i.e. jugular vein, outside of vein).
7. Improper catheter length selection for patient size.

B. Possible Solutions

1. If no resistance to infusion is felt, attempt to flush with 10 ml normal saline. Then pull back gently on syringe plunger 2-3 ml, pause and proceed with aspiration.
2. If resistance to infusion is felt, check for signs of extravasation. If present, notify physician of possible catheter leakage or transection and embolization. If not present, see step 4.
3. Attempt to aspirate with a 20 ml syringe (creates a greater vacuum).
4. Move patient's arm, shoulder and head to see if a change in position will allow aspiration. If aspiration can only be accomplished with the patient in a certain position, the patient should be examined to see if the catheter has been placed in the "pinch-off" area. See step 5.
5. Obtain physician's order for a chest x-ray to determine the position of the catheter.
   - If the catheter tip is not in the superior vena cava, the catheter should be repositioned.

- If the catheter tip is not in a vein, the catheter should be replaced.
- If the catheter has been placed through the "pinch-off" area, between the clavicle and the first rib, and is being compressed enough to interfere with infusion or aspiration, it is at risk for catheter transection and embolization. The physician should evaluate the patient for catheter replacement.

II. Patient with Fever and/or Infection:

Symptoms:

- Inflammation at incision site
- Fever
- Positive site culture and/or blood cultures

If signs of infection are present:

- Notify physician

III. Insufficient Flow: DO NOT POWER INJECT IF RESISTANCE TO FLUSHING SEEMS EXCESSIVE

Excessive force must not be used to flush an obstructed lumen. Insufficient blood flow may be caused by the catheter contacting the wall of the vein or an occluding clot. The physician may attempt to dissolve the clot with a fibrolytic agent before power injecting. Physician discretion advised.

IV. Catheter Occlusion: DO NOT POWER INJECT AN OCCLUDED DEVICE

A. Possible Causes

1. Blood clot completely obstructing lumen.
2. May be kinked, coiled, damaged, or compressed between the clavicle and the first rib.
3. Catheter tip may not be within vein.
4. May be partially or completely transected. Transection can occur from the repeated pressure of the clavicle and the first rib on the catheter during normal movement if it is placed through the "pinch-off" area. (For subclavian placements only.)
5. Improper catheter length for patient size.

B. Possible Solutions

1. Ask responsible nurse or physician to attempt to aspirate blood clot.
2. Move patient's arm, shoulder and head to see if position change affects ability to infuse. If so, see step 3 (could be pinch-off).
3. Obtain physician's order for a chest x-ray to determine the position of the catheter.
   - Move patient's arm, shoulder and head to see if position change affects ability to infuse.
   - If the catheter tip is not in the superior vena cava, the catheter should be repositioned.
   - If the catheter tip is not in a vein, the catheter should be replaced.
   - If the catheter has been placed through the "pinch-off" area, between the clavicle and the first rib, and is being

compressed enough to interfere with infusion or aspiration, it is at risk for catheter transection and embolization. The physician should evaluate the patient for catheter replacement.

- 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.

V. Signs of Pinch-off

Clinical:

- Difficulty with blood withdrawal
- Resistance to infusion of fluids
- Patient position changes required for infusion of fluids or blood withdrawal

Radiologic:

- Grade 1 or 2 distortion on chest X-ray.

Pinch-off should be evaluated for degree of severity prior to explantation. Patients indicating any degree of catheter distortion at the clavicle/first rib area should be followed diligently. There are grades of pinch-off that should be recognized with appropriate chest x-ray as follows: [1,2]

Grade	Severity	Recommended Action
Grade 0	No distortion	No action.
Grade 1	Distortion present **without** luminal narrowing	Chest x-ray should be taken every one to three months to monitor progression of pinch off to grade 2 distortion. Shoulder positioning during chest x-rays should be noted as it can contribute to changes in distortion grades.
Grade 2	Distortion present **with** luminal narrowing	Removal of the catheter should be considered.
Grade 3	Catheter transection or fracture	Prompt removal of the catheter.

VI. Use of Fibrinolytic Agent for Catheter Blockage

Use of a fibrinolytic agent has successfully cleared clotted catheters when gentle irrigation and aspiration have failed. The instructions provided by the drug manufacturer should be followed.

References

1. Hinke, D.H.; Zandt-Stastny, D.A.; Goodman, L.R.; et al. "Pinch-off syndrome: A complication of implantable subclavian venous access devices." Radiology 177: 353-356, 1990.
2. Ingle, Rebecca; Nace, Corinne. "Venous Access Devices: Catheter Pinch-off and Fracture." 1993, Bard Access Systems, Inc.
3. Camp-Sorrell, Dawn. "Access Device Guidelines" 2nd Edition Oncology Nursing Society, 2004.

Further Reading

- See PowerPort* port IFU, PowerPort* port Nursing Guide and/or PowerPort* port Patient Guide for more details

- Bard Access Systems is proud to offer "*Your* Port Access Advantage"* patient education module for helping patients select their best access option.
- See www.powerportadvantage.com

See Bard Access Systems Sales Representative for more information about any of these products.

An issued or revision date for these instructions is included for the user's information. In the event two years have elapsed between this date and product use, the user should contact Bard Access Systems, Inc. to see if additional product information is available.

Revised date: August 2007

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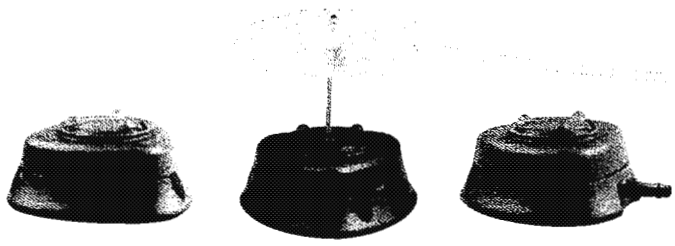
* ChronoFlex is a registered trademark of CardioTech International, Inc. or an affiliate. ChloraPrep is a trademark and/or registered trademark of Enturia, Inc. or an affiliate.



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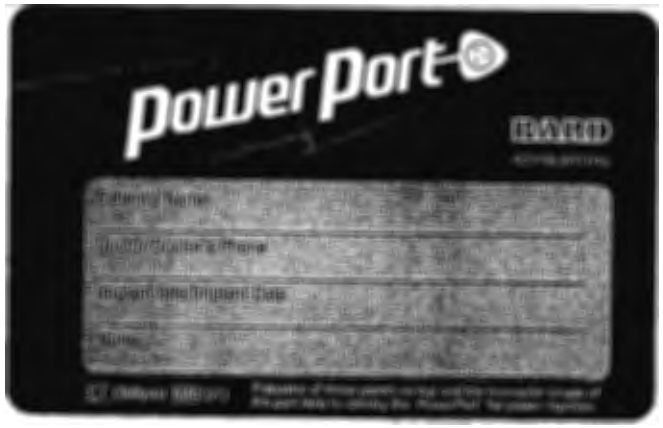

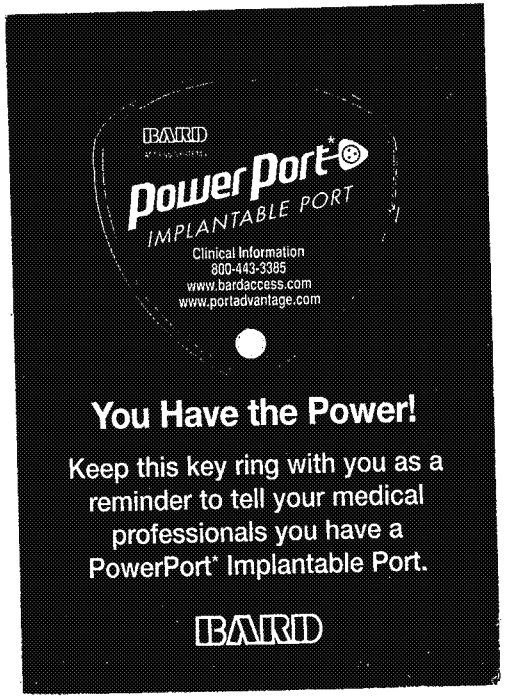

PowerPort

Companion Checklist ✓

Feel the New Standard of Care*

Thank you for being a companion to someone who has received a PowerPort* Implanted Port. Here are some valuable things to know:

- ❑ The PowerPort device is a new kind of implanted port that provides clinicians access for both IV therapy treatments and power-injected Contrast-Enhanced Computed Tomography (CECT) scans. It is also safe for MRI scans.
- ❑ Upon receiving their PowerPort device, patients also receive an identification card, bracelet and key ring identifying them as a patient with a PowerPort Implanted Port.
- ❑ **Patients with a PowerPort device should carry their Patient Identification Card at all times,** and may wish to wear the bracelet or carry the key ring as convenient reminders.
- ❑ Patients with a PowerPort device should show their Patient Identification Card to clinicians whenever their port is accessed for a procedure, especially power-injected CECT scans.
- ❑ The PowerPort device Patient Identification Card contains important information for the clinician. If clinicians need more information, they may contact the Bard Access Systems Clinical Information Hotline at 800-443-3385.
- ❑ Speak up! Share information with clinicians and ask about anything that concerns or seems unusual to the patient or you.

BARD
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IMPLANTABLE PORT

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PATIENT GUIDE

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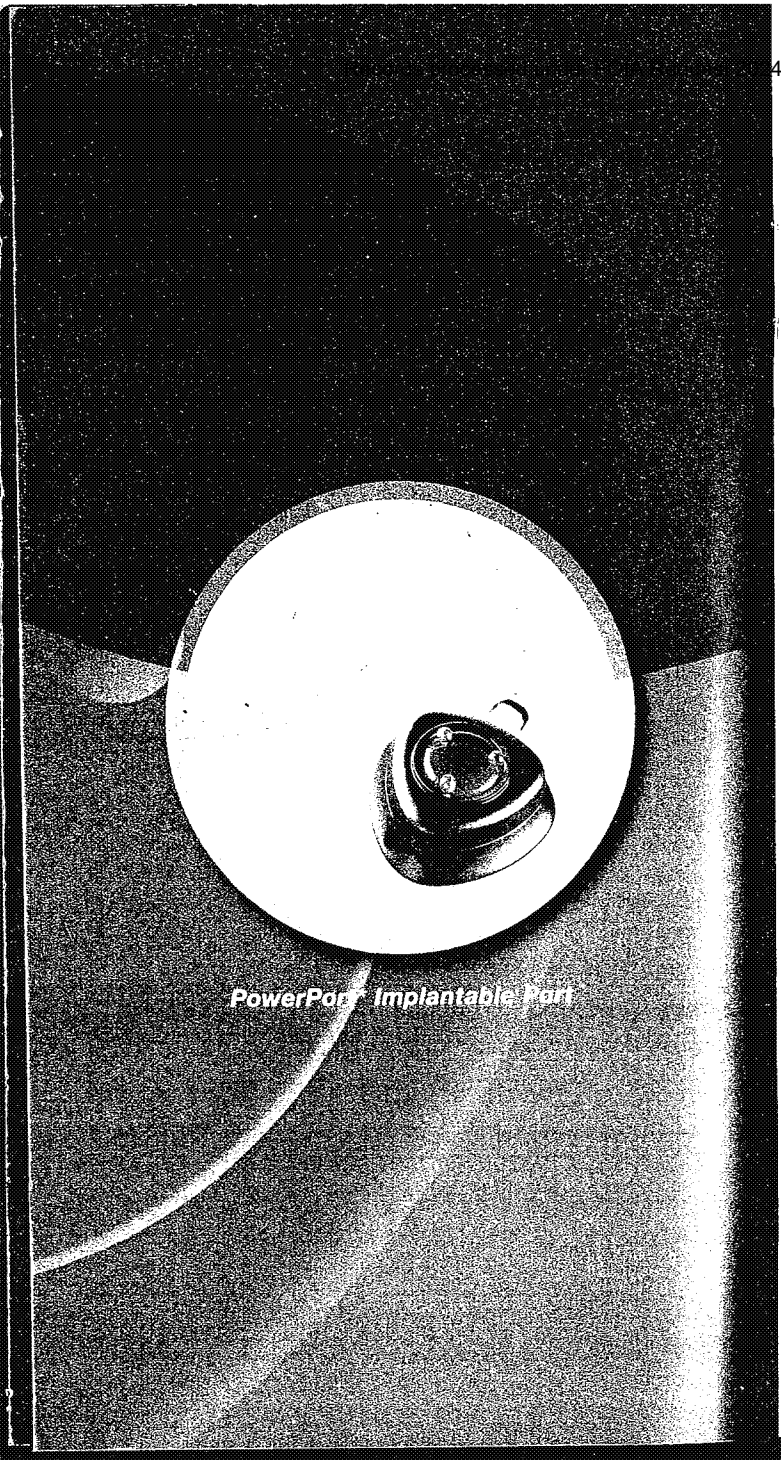
Access Systems

Table of Contents



INTRODUCTION

Feel the New Standard of Care*.

Your doctor has prescribed the **PowerPort*** Implanted Port for your IV therapy treatments. This new kind of implanted port offers the unique ability to provide access for power-injected Contrast-Enhanced Computed Tomography (CECT) scans. Power-injected CECT scans produce superior images of your body to help the medical team better manage your treatment. With your **PowerPort** Implanted Port, you'll be able to receive IV therapy and CECT scans without having to undergo repeated needlesticks in your peripheral (arm or wrist) veins.

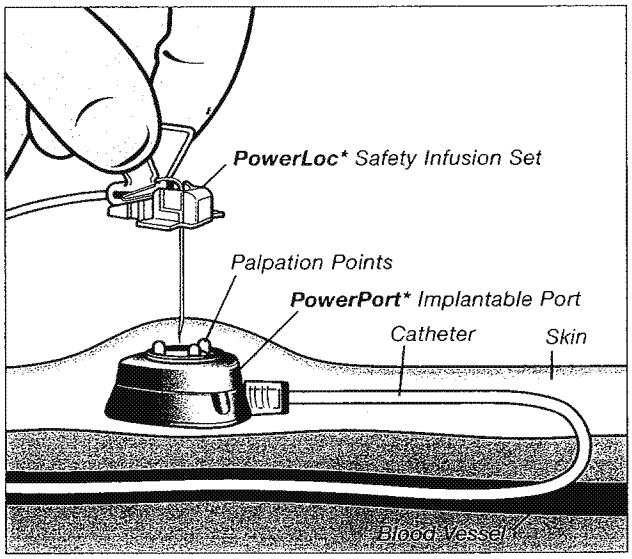
Please read all of the information contained in this Patient Guide. It gives you the knowledge to understand and feel comfortable with your **PowerPort** Implanted Port. Just as your **PowerPort** device is new to you, it may not yet be familiar to all clinicians involved in your care. That's because the **PowerPort** Implanted Port is a new technology designed to accommodate power-injected CECT scans. The patient-specific information contained in this Guide gives you the power to inform clinicians about your **PowerPort** device, so that you can take advantage of power-injected CECT scans and avoid unnecessary needlesticks.

You should also carry your **PowerPort** device Patient Identification Card with you to show to clinicians whenever your port is accessed. It informs clinicians that you have a **PowerPort** Implanted Port and provides a summary of important information they should know about the port.

If you need additional information about your **PowerPort** device, please talk with your doctor or nurse.

Presenting Your PowerPort* Implanted Port

Your **PowerPort** Implanted Port is a small device placed completely beneath your skin in a short procedure. It is a cylinder with a hollow space inside that is sealed by a soft top. The **PowerPort** device connects to a small, flexible tube called a catheter that is inserted inside one of the large central veins that deliver blood to your heart. When a special needle is put into the soft top of the **PowerPort** device, it creates "access" to your bloodstream, meaning that medications and fluids can be given and blood samples withdrawn.



For power-injected CECT scans, the PowerPort device is used with a needle designed especially for power injection called the PowerLoc* Safety Infusion Set. Your **PowerPort** Implanted Port has unique triangular arrangement of three bumps called Palpation Points on the top of the port and a distinctive triangle shape. These features help to identify its special design for power-injected CECT scans.

How Your PowerPort* Device Is Used

Your **PowerPort** Implanted Port allows clinicians to easily deliver medications or fluids or withdraw blood samples without having to repeatedly stick your peripheral veins directly with a needle. This makes it more comfortable for you. Because the **PowerPort** device places medications into the large central veins instead of the small peripheral veins, the medications mix more thoroughly in the blood, diluting them so they are less harmful to your vascular system.

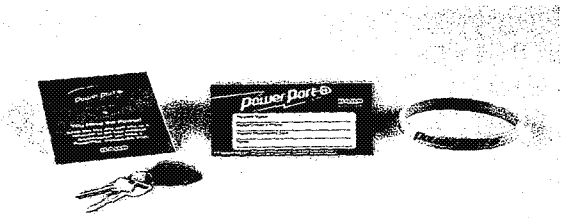
The **PowerPort** Implanted Port is used with the **PowerLoc*** Safety Infusion Set. This enables fluids called contrast agents to be power-injected (delivered at a high rate) into your bloodstream. As a result, tissues in your body show up more clearly, making it easier for your doctors to monitor the status of your condition. Power-injected CECT scans are safe, non-invasive procedures that provide important information for disease diagnosis and treatment.

IDENTIFICATION

How to Know You Have a PowerPort* Implanted Port

There are several ways that you and your clinicians can recognize that you have a **PowerPort** device instead of a traditional type of implanted port.

Identify Yourself!



Key Ring Card *Identification Card* *Bracelet*

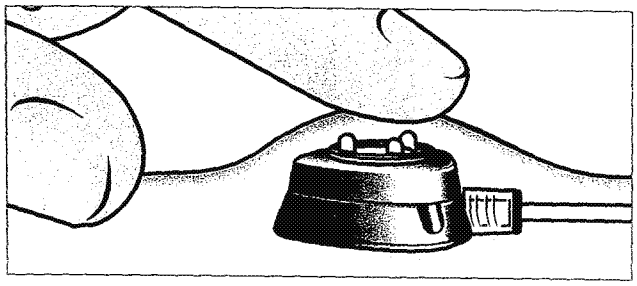
Upon receiving your **PowerPort** Implanted Port, you are provided with an identification card, bracelet and key ring card identifying you as a patient with a **PowerPort** device. **Carry your PowerPort device Patient Identification Card with you at all times.** Show it to the clinician beforehand whenever your port is accessed for a procedure. You may wear the bracelet or carry the key ring as convenient reminders that you have a **PowerPort** Implanted Port.

In addition, if you have received a **PowerPort** Implanted Port, your patient chart should show a **PowerPort** device record sticker noting this fact.

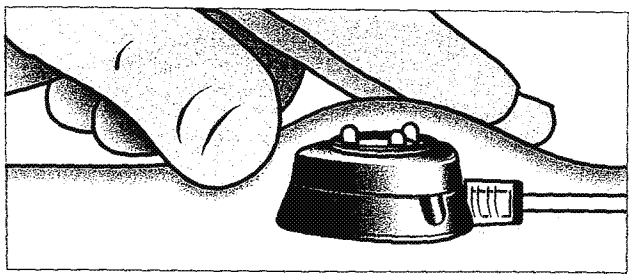
Feel the Difference!

Your **PowerPort*** Implanted Port has a unique shape and design that distinguishes it from traditional ports. Trained clinicians can recognize these distinctive features under your skin by feeling for them with their fingers, a process called palpation. A trained clinician palpating the sides of your **PowerPort** device should recognize its unique triangle shape. A trained clinician palpating the top of your **PowerPort** device should be able to feel three bumps called Palpation Points that are arranged like a triangle on the port.

Ask your doctor or nurse to help you feel the difference by showing you how to palpate your new **PowerPort** Implanted Port.



Feel the soft top of the port to locate the three Palpation Points arranged as a triangle.

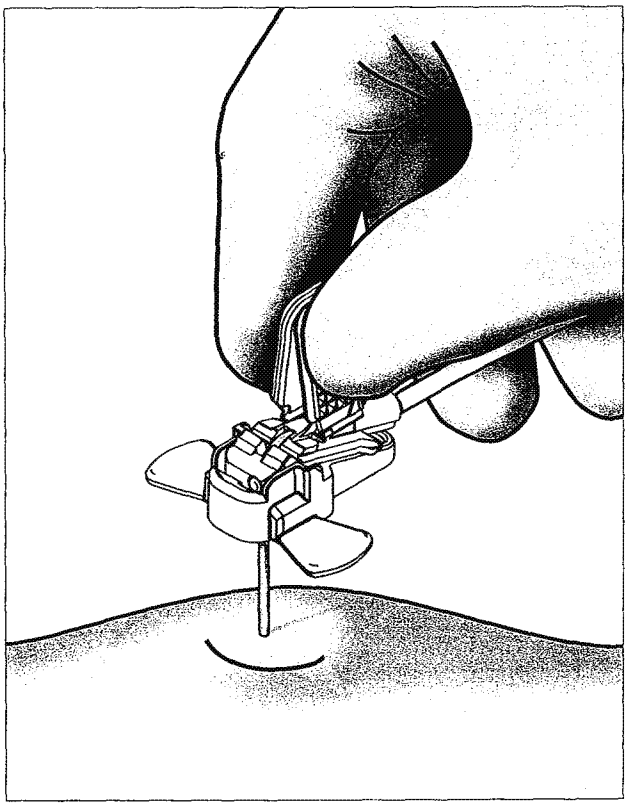


Feel the sides of the port to identify its unique triangle shape.

ACCESS

How Your PowerPort* Device Is Accessed

Your clinicians will use the **PowerPort** Implanted Port whenever they need to infuse medications or fluids into your body or withdraw samples of your blood. To do this, they will first access the **PowerPort** device by inserting a special needle into the soft top of the device. Ask the clinician about what to expect in your own procedure.



HEPARIN LOCKS

About Heparin Locks

Sometimes when blood clots, it can block the catheter, preventing medications and fluids from flowing through it. However, blood will not clot when it is thinned with a medication called heparin. To help prevent clots from forming, implanted ports are typically filled with sterile heparinized saline after each use. This process is called a heparin lock. If your **PowerPort** Implanted Port will not be used for long periods of time, the clinician will typically change the heparin lock every four weeks.

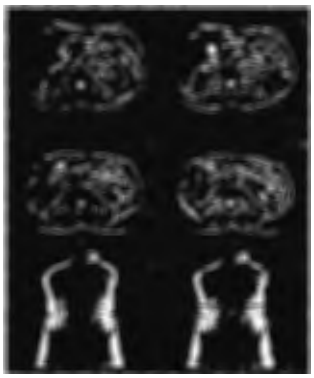
If you have been diagnosed as being allergic to heparin or as having heparin induced thrombocytopenia (HIT), it is important to remind the clinician of this fact anytime your **PowerPort** device is accessed.

What to Expect During Power Injection for CECT Scans

About Power-Injected CECT Scans

Contrast-Enhanced Computed Tomography (CECT) scans are simple, safe and non-invasive procedures that provide quick and accurate diagnostic information to help your medical team manage your care. These scans are many times more sensitive than conventional x-rays. Radiologists can distinguish small differences in your soft tissues that may not be detected with x-rays.

CECT Workstation

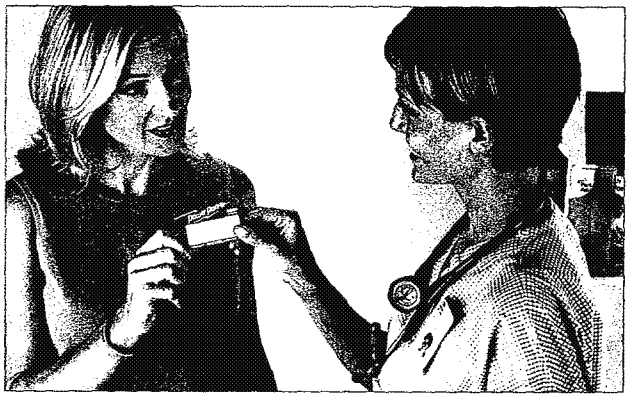


Contrast-Enhanced Computed Tomography (CECT) Scans

Before performing a CECT scan, the radiology team will inject a contrast agent, which is a special fluid that acts like a dye, into your body to help produce clearer pictures during the CECT scan procedure. For best results, the contrast agent is infused at a high rate into your bloodstream. This process is called power injection. **Your PowerPort* Implanted Port used with the PowerLoc* Safety Infusion Set has the unique ability to allow clinicians to perform power-injected CECT scans without having to make a needlestick in your arm or wrist veins.**

What Your Clinician Should Know

Always show your **PowerPort** device Patient Identification Card to clinicians who perform your CECT scan. It informs them that you have a **PowerPort** Implanted Port.



Show your Identification Card beforehand whenever your port is being accessed for a procedure.

Common Questions and Answers

How do I take care of my **PowerPort*** Implanted Port?

During the first few days after receiving the **PowerPort** Implanted Port, avoid heavy exertion and follow the instructions your doctor or nurse has given you for taking care of the small incision. Once the incision has healed, the beauty of your **PowerPort** Implanted Port is that you do not have to take any special care of it, and you can resume normal daily activities.

Will the **PowerPort** Implanted Port affect my daily activities?

Once the incision heals following implantation, you should be able to return to your normal daily activities, such as bathing, swimming or jogging. Ask your doctor or nurse about specific activities and the appropriate time to resume them.

Will I need to wear a bandage over the **PowerPort** Implanted Port?

A bandage will be required until your incision heals. After the incision has healed, a bandage is not required when the **PowerPort** device is not being used. If you are receiving continuous infusion of fluids, a bandage may be applied to stabilize and protect the needle while it is in place.

Do I have to stop wearing certain types of clothing?

Ask your doctor or nurse because the answer will depend on where your **PowerPort** device is placed.

Who pays for the **PowerPort*** Implanted Port?

Insurance policies vary, so check with your insurance company first.

Will the **PowerPort** Implanted Port activate security alarms?

Security systems most likely will not detect the small amount of metal in the device. If it does occur, simply show your **PowerPort** device Patient Identification Card.

How long will I have my **PowerPort** Implanted Port?

The **PowerPort** Implanted Port can stay in place for as long as your doctor determines that you need it.

Will my **PowerPort** device need to be accessed when not in use?

Yes. It will need to be flushed every 4 weeks.

Can the **PowerPort** device be removed if I no longer need it?

Yes. When no longer needed, the **PowerPort** Implanted Port can be removed in a simple procedure similar to the one used to implant it.

Is the **PowerPort** device safe with CT and MRI?

Yes. The materials used in the **PowerPort/PowerLoc** system are latex-free, non-ferromagnetic and safe with CT, CECT and magnetic resonance imaging (MRI) procedures and all injectable fluids used with these procedures.

What if the clinician has not seen a patient with a PowerPort device before?

The **PowerPort** Implanted Port is a new technology. It may not yet be familiar to all clinicians involved in your care. Always show clinicians your **PowerPort** device Patient Identification Card, especially if your PowerPort device will be accessed for power-injected CECT scans. Your **PowerPort** device Patient Identification Card contains a summary of important information for the clinician. If clinicians need more information, they may contact the Bard Access Systems Clinical Information Hotline at 800-443-3385.

TELL YOUR CLINICIAN

Tell Your Clinician You've Got the Power!

As a new patient with a **PowerPort** Implanted Port, you've got the power to take an active role in your treatment. The best way you can be involved is to share information and concerns with your clinicians. Speak up! Ask questions about anything that concerns you or if you notice anything that seems unusual.

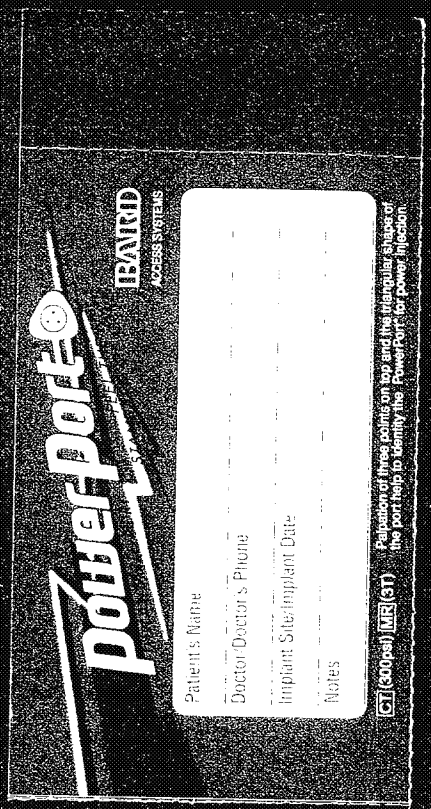
What to Report to Your Clinician

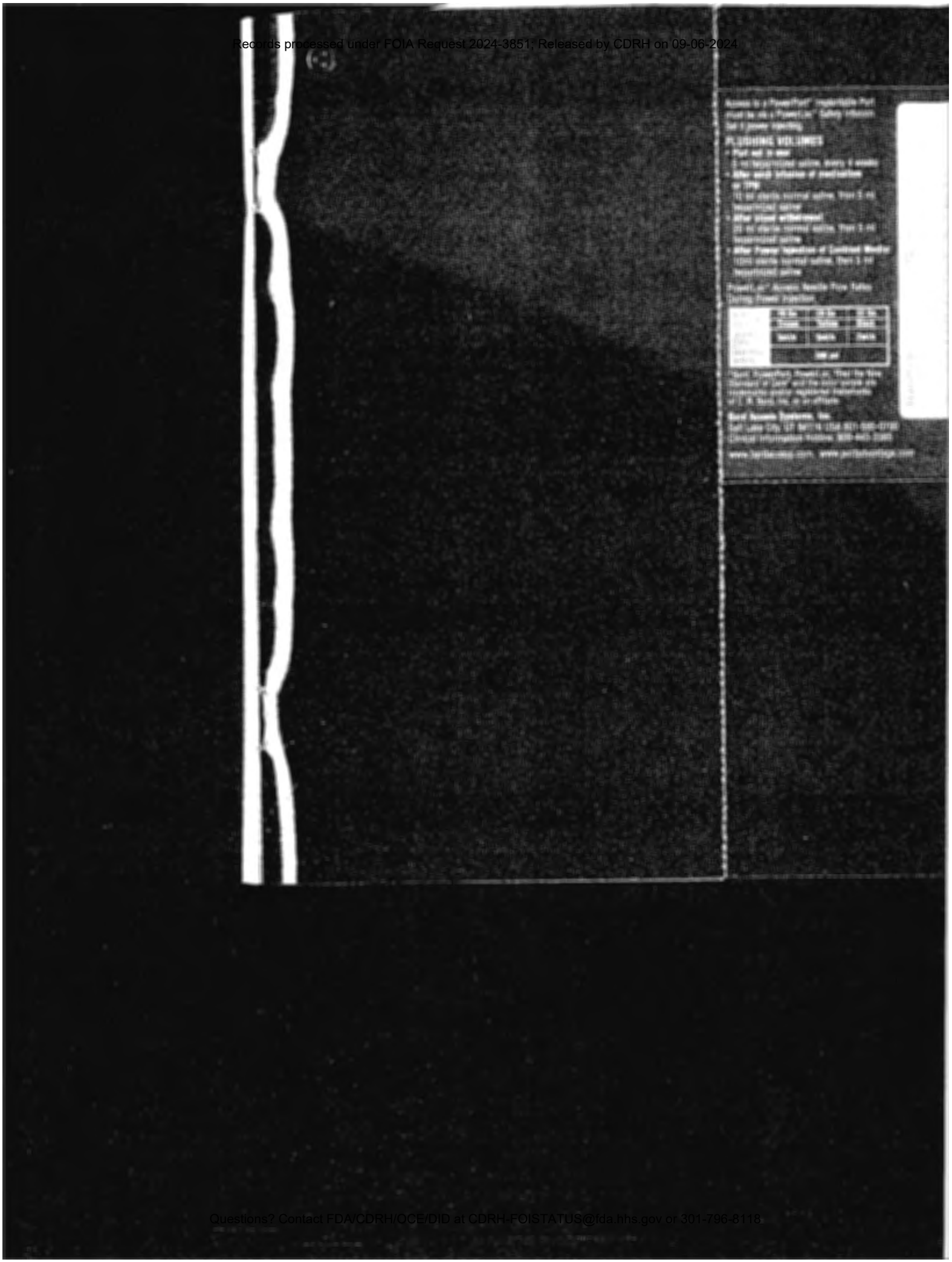
Here are some important things to tell your clinician:

- You have a **PowerPort** Implanted Port.
- If you notice any redness or inflammation at the site of your **PowerPort** Implanted Port after the incision heals.
- If you have a fever.
- If you have allergies to any medications or materials.
- If you have an allergy to heparin.
- If you have heparin induced thrombocytopenia (HIT)
- If you have ever been prescribed anticoagulant (blood-thinning) medications such as heparin or warfarin.
- If you have previously been treated with radiation.
- If you have ever been diagnosed with lung disease.
- If you have ever been diagnosed with, or treated for, venous thrombosis.
- If you have ever been diagnosed with any tissue diseases or suffered from tissue erosion.
- If you have ever been diagnosed or tested for "pinch-off" syndrome.
- If other clinicians have ever had difficulty withdrawing blood or infusing fluids through your implanted port, including whether other clinicians have ever required you to change position to allow blood or fluid to flow.

PATIENT CHECKLIST ✔

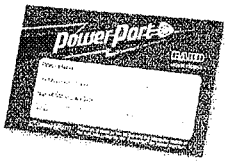
- ❑ The **PowerPort*** device is a new kind of implanted port that provides access for both IV therapy treatments and power-injected Contrast-Enhanced Computed Tomography (CECT) scans.
- ❑ Upon receiving your **PowerPort** device, you will also receive an Identification Card, Bracelet and Key Ring Card that identify you as a patient with a PowerPort Implanted Port.
- ❑ **Carry your Identification Card at all times. You may also wear the bracelet or carry the key ring as convenient reminders to tell your medical professionals that you have a PowerPort Implanted Port.**
- ❑ Show your Identification Card to the clinician whenever your port is accessed for a procedure, especially power-injected CECT scans.
- ❑ The Identification Card contains important information for the clinician. If clinicians need more information, they may contact the Bard Access Systems Clinical Information Hotline at 800-443-3385.
- ❑ Speak up! Share information with clinicians and ask about anything that concerns or seems unusual to you.





PowerPort

Patient Discharge Packet Contents:

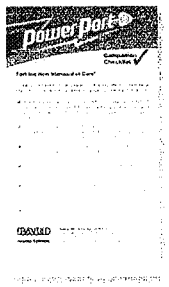


Identification Card
Carry this card with you to show your medical professional whenever your port is accessed. Your Identification Card provides a summary of important information they should know about your PowerPort* device.

Bracelet
Wear this bracelet as a reminder to tell your medical professional that you have a PowerPort* Implanted Port.

Key Ring Card
Keep this key ring with you as a reminder to tell your medical professional that you have a PowerPort* Implanted Port.

Patient Guide
The patient-specific information contained in this guide gives you the knowledge to understand and feel comfortable with your PowerPort* Implanted Port. It also gives you the power to inform medical professionals about your PowerPort* device.



Companion Checklist
The checklist provides your companion with valuable information about your PowerPort* Implanted Port and how to use the contents of this packet.

BARD

Access Systems

Bard Access Systems, Inc.
Salt Lake City, UT 84116 USA 801-595-0700
Clinical Information Hotline 800-443-3385
www.bardaccess.com • www.portadvantage.com

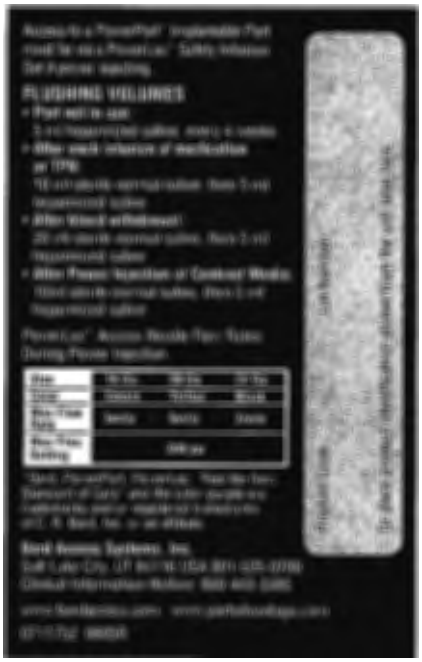
0713273 0605R

PowerPort* Implantable Port Patient Discharge Packet 800-443-3385 BARD

Labeling Subject Device

Patient ID Card
Subject Device

Labeling Predicate Device



Groshong® Catheter with

PowerPort

BARD ACCESS SYSTEMS

Patient's Name

Doctor/Doctor's Phone

Implant Site/Implant Date

*Palpation of three points on top and the triangular shape of the port help to identify the PowerPort® for power injection.

CT (300psi) For MR conditions call 800-443-3385

PowerPort

BARD

Access Systems

Bard Access Systems, Inc.
Salt Lake City, UT 84116 USA 801-595-0700
Clinical Information Hotline 800-443-3385
www.bardaccess.com
www.portadvantage.com

0716413 0803R

PowerPort

PATIENT GUIDE

BARD

Access Systems

Subject
Patient Brochure

Access to a PowerPort® Implantable Port must be via a PowerLoc® Safety Infusion Set if power injecting.

FLUSHING VOLUMES

- **Port not in use:**
  5 ml sterile normal saline every 4 weeks
- **After each infusion of medication or TPN:**
  10 ml sterile normal saline
- **After blood withdrawal:**
  20 ml sterile normal saline
- **After Power Injection of Contrast Media:**
  10ml sterile normal saline

PowerLoc® Access Needle Flow Rates During Power Injection

Size	19 Ga.	20 Ga	22 Ga.
Color	Cream	Yellow	Black
Max Flow Rate	5ml/s	5ml/s	2ml/s
Max Pres. Setting	300 psi		

Lot Number:

Product Code:

Or place product identification sticker from the unit label here.

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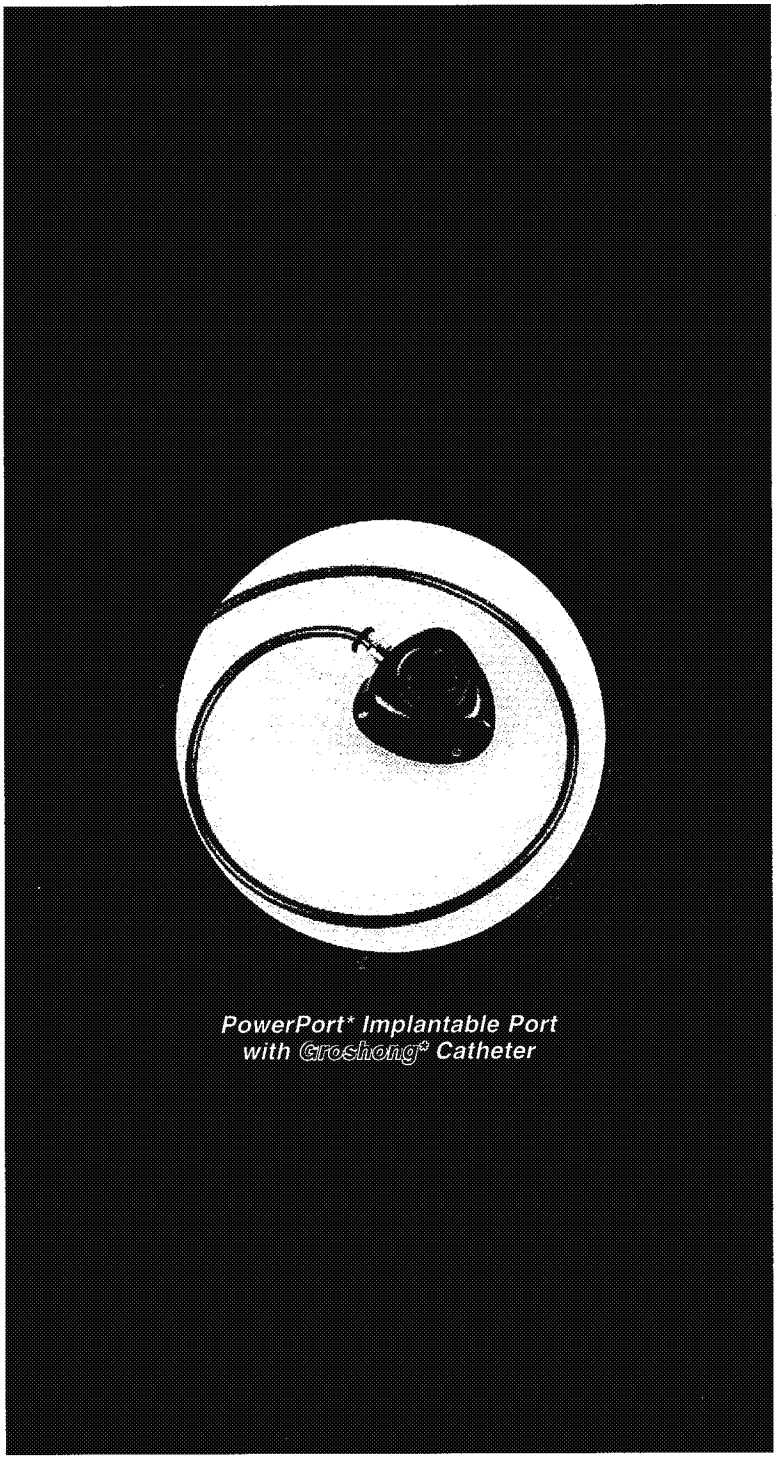
Table of Contents



INTRODUCTION

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Please read all of the information contained in this Patient Guide. It gives you the knowledge to understand and feel comfortable with your **PowerPort*** Implanted Port. Just as your **PowerPort*** device is new to you, it may not yet be familiar to all clinicians involved in your care. That's because the **PowerPort*** Implanted Port is a new technology designed to accommodate power-injected CECT scans. The patient-specific information contained in this Guide gives you the power to inform clinicians about your **PowerPort*** device, so that you can take advantage of power-injected CECT scans and avoid unnecessary needlesticks.

You should also carry your **PowerPort*** device with **Groshong*** catheter Patient Identification Card with you to show to clinicians when-ever your port is accessed. It informs clinicians that you have a **PowerPort*** Implanted Port with **Groshong*** catheter and provides a summary of important information they should know about the port.

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Presenting Your PowerPort* Implanted Port

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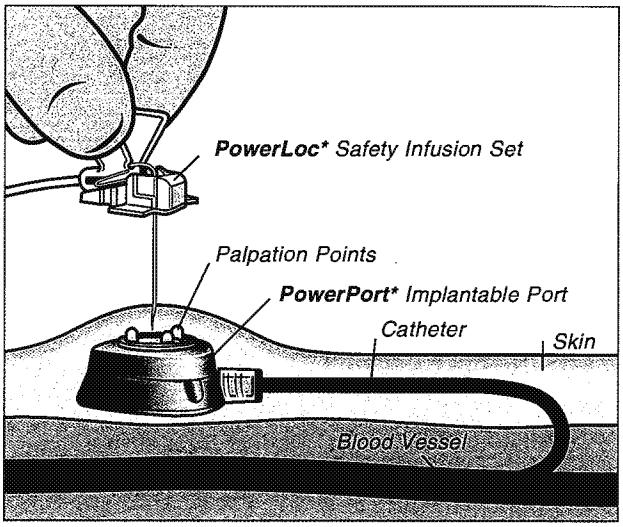

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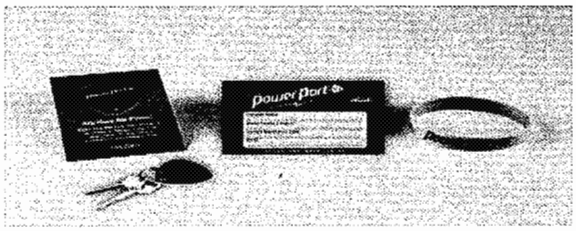

Key Ring Card *Identification Card* *Bracelet*

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In addition, if you have received a **PowerPort*** Implanted Port with **Groshong*** catheter, your patient chart should show a **PowerPort*** device with **Groshong*** catheter record sticker noting this fact.

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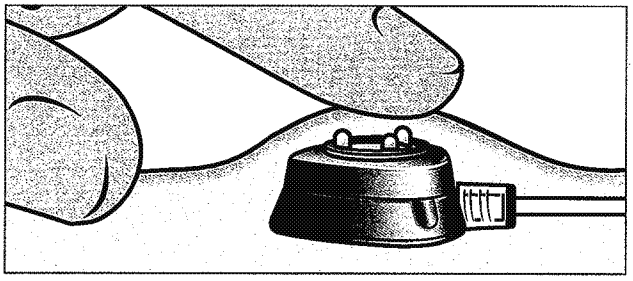

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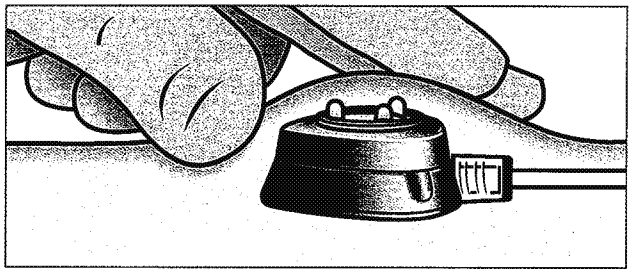

Feel the sides of the port to identify its unique triangle shape.

ACCESS

How Your PowerPort* Device Is Accessed

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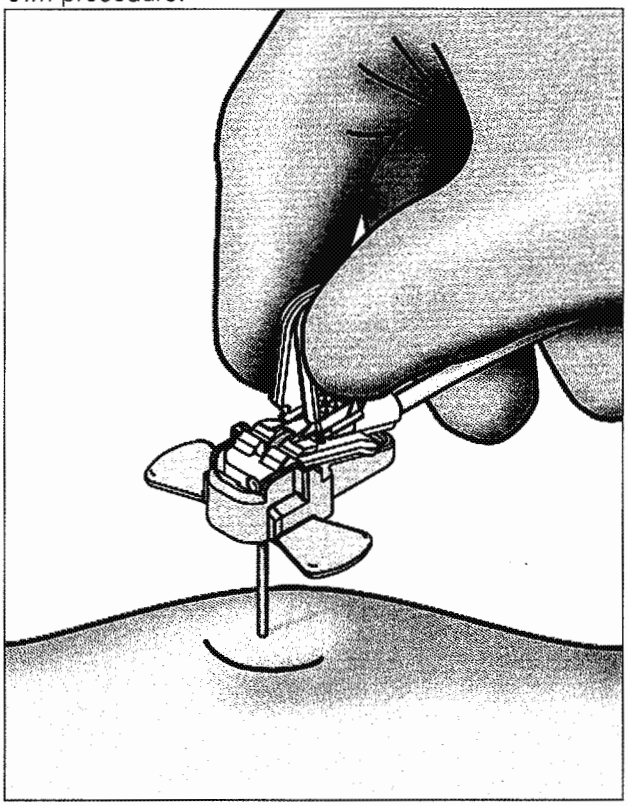

THE GROSHONG* CATHETER

What is a Groshong* Catheter?

The **Groshong*** catheter is a rounded tip, silicone catheter with a three-position valve placed in the side of the catheter near the tip. The valve of the **Groshong*** catheter allows fluids to flow in or out of the catheter but remains closed when it is not being used.

How does the Valve Work?

The valve works when pressure is applied to it. When a negative pressure (suction) is applied (usually by a syringe), it causes the valve to open inward, allowing your blood to flow through the catheter into the syringe. When a liquid, (e.g. medication, nutritional supplements, saline or blood) is introduced into the catheter lumen, the positive pressure pushes the valve open outwards, letting liquid enter the bloodstream. At neutral pressure, the valve remains closed, reducing the risk of air entering or fluids moving in or out of the catheter.

Why use the Groshong* Catheter?

Some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT). The **Groshong*** catheter may be flushed with sterile normal saline and does not require heparin to maintain patency.

Aspiration Infusion Closed

What to Expect During Power Injection for CECT Scans

About Power-Injected CECT Scans

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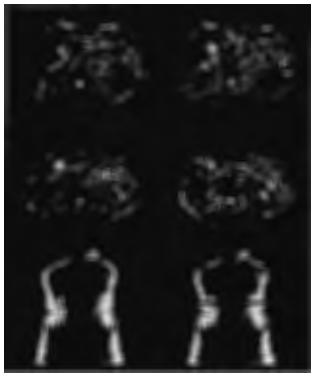
CECT Workstation



Contrast-Enhanced Computed Tomography (CECT) Scans

Before performing a CECT scan, the radiology team will inject a contrast agent, which is a special fluid that acts like a dye, into your body to help produce clearer pictures during the CECT scan procedure. For best results, the contrast agent is infused at a high rate into your bloodstream. This process is called power injection. **Your PowerPort* Implanted Port used with a PowerLoc* Safety Infusion Set has the unique ability to allow clinicians to perform power-injected CECT scans without having to make a needlestick in your arm or wrist veins.**

What Your Clinician Should Know

Always show your **PowerPort*** device with **Groshong*** catheter Patient Identification Card to clinicians who perform your CECT scan. It informs them that you have a **PowerPort*** Implanted Port with **Groshong*** catheter.

Show your Identification Card beforehand whenever your port is being accessed for a procedure.

Common Questions and Answers

How do I take care of my **PowerPort*** Implanted Port?

During the first few days after receiving the **PowerPort*** Implanted Port, avoid heavy exertion and follow the instructions your doctor or nurse has given you for taking care of the small incision. Once the incision has healed, the beauty of your **PowerPort*** Implanted Port is that you do not have to take any special care of it, and you can resume normal daily activities.

Will the **PowerPort*** Implanted Port affect my daily activities?

Once the incision heals following implantation, you should be able to return to your normal daily activities, such as bathing, swimming or jogging. Ask your doctor or nurse about specific activities and the appropriate time to resume them.

Will I need to wear a bandage over the **PowerPort*** Implanted Port?

A bandage will be required until your incision heals. After the incision has healed, a bandage is not required when the **PowerPort*** device is not being used. If you are receiving continuous infusion of fluids, a bandage may be applied to stabilize and protect the needle while it is in place.

Do I have to stop wearing certain types of clothing?

Ask your doctor or nurse because the answer will depend on where your **PowerPort*** device is placed.

Who pays for the PowerPort* Implanted Port?

Insurance policies vary, so check with your insurance company first.

Will the PowerPort* Implanted Port activate security alarms?

Security systems most likely will not detect the small amount of metal in the device. If it does occur, simply show your **PowerPort*** device Patient Identification Card.

How long will I have my PowerPort* Implanted Port?

The **PowerPort*** Implanted Port can stay in place for as long as your doctor determines that you need it.

Will my PowerPort* device need to be accessed when not in use?

Yes. It will need to be flushed every 4 weeks.

Can Heparin be infused through a PowerPort* Implantable Port with Groshong* catheter?

Yes. Heparin will not harm the **Groshong*** catheter. However, the **Groshong*** catheter may be flushed with sterile normal saline and does not require heparin to maintain patency.

Can the PowerPort* device be removed if I no longer need it?

Yes. When no longer needed, the **PowerPort*** Implanted Port can be removed in a simple procedure similar to the one used to implant it.

What if the clinician has not seen a patient with a **PowerPort*** device before?

The **PowerPort*** Implanted Port is a new technology. It may not yet be familiar to all clinicians involved in your care. Always show clinicians your **PowerPort*** device with **Groshong*** catheter Patient Identification Card, especially if your **PowerPort*** device will be accessed for power-injected CECT scans. Your **PowerPort*** device with **Groshong*** catheter Patient Identification Card contains a summary of important information for the clinician. If clinicians need more information, they may contact the Bard Access Systems Clinical Information Hotline at 800-443-3385.

Can I get a CT procedure with an implanted PowerPort* device?

Yes. The materials used in the **PowerPort*** system are non-ferromagnetic and are safe for use in CT and CECT procedures.

Can I get an MRI procedure with an implanted PowerPort* device?

The device can be scanned safely under the following conditions.

Non-clinical testing has demonstrated the device is MR Conditional. It can be scanned safely under:

- static magnetic field of 3 Tesla or less
- spatial gradient field of 330 Gauss/cm or less
- maximum specific absorption rate (SAR) of 6 W/kg for 30 minutes of scanning.

In non-clinical testing, the device produced a temperature rise of less than 0.5 °C at a maximum specific absorption rate (SAR) of 6 W/kg for 30 minutes of MR scanning in a 3T Siemens Trio with software version VA25.

For Minimal Image artifact

- MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

TELL YOUR CLINICIAN

Tell Your Clinician You've Got the Power!

As a new patient with a **PowerPort*** Implanted Port, you've got the power to take an active role in your treatment. The best way you can be involved is to share information and concerns with your clinicians. Speak up! Ask questions about anything that concerns you or if you notice anything that seems unusual.

What to Report to Your Clinician

Here are some **important** things to tell your clinician:

- You have a **PowerPort*** Implanted Port with **Groshong*** catheter.
- Your PowerPort* device with **Groshong*** catheter may be flushed with normal saline and does not require heparin to maintain patency.
- If you notice any redness or inflammation at the site of your **PowerPort*** Implanted Port after the incision heals.
- If you have a fever.
- If you have allergies to any medications or materials.
- If you have an allergy to heparin.
- If you have heparin induced thrombocytopenia (HIT)
- If you have ever been prescribed anticoagulant (blood-thinning) medications such as heparin or warfarin.
- If you have previously been treated with radiation.
- If you have ever been diagnosed with lung disease.
- If you have ever been diagnosed with, or treated for, venous thrombosis.
- If you have ever been diagnosed with any tissue diseases or suffered from tissue erosion.
- If you have ever been diagnosed or tested for "pinch-off" syndrome.
- If other clinicians have ever had difficulty withdrawing blood or infusing fluids through your implanted port, including whether other clinicians have ever required you to change position to allow blood or fluid to flow.

PATIENT CHECKLIST ✔

- ❑ The **PowerPort*** device is a new kind of implanted port that provides access for both Intra-venous therapy treatments and power-injected Contrast-Enhanced Computed Tomography (CECT) scans.

- ❑ Upon receiving your **PowerPort*** device with **Groshong*** catheter, you will also receive an Identification Card, Bracelet and Key Ring Card that identify you as a patient with a PowerPort* Implanted Port with **Groshong*** catheter.

- ❑ **Carry your Identification Card at all times. You may also wear the bracelet or carry the key ring as convenient reminders to tell your medical professionals that you have a PowerPort* Implanted Port with Groshong* catheter.**

- ❑ Show your Identification Card to the clinician whenever your port is accessed for a procedure, especially power-injected CECT scans.

- ❑ The Identification Card contains important information for the clinician. If clinicians need more information, they may contact the Bard Access Systems Clinical Information Hotline at 800-443-3385.

- ❑ Speak up! Share information with clinicians and ask about anything that concerns or seems unusual to you.

PowerPort

BARD

Patient's Name

Doctor/Doctor's Phone

Implant (date/type) Info

Notes

PowerPort

PowerPort

PowerPort

PATIENT GUIDE

BARD

Access Systems

BARD

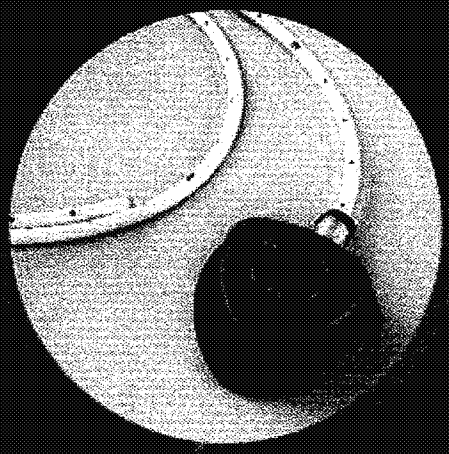
Access Systems

Bard Access Systems, Inc.
Salt Lake City, UT 84116 USA 801-595-0700
Clinical Information Hotline 800-443-3385
www.bardaccess.com
www.portadvantage.com

0711427 Rev1 0605R

Labeling Predicate Device

Table of Contents



PowerPort® Implantable Port

INTRODUCTION

Feel the New Standard of Care*.

Your doctor has prescribed the **PowerPort*** Implanted Port for your IV therapy treatments. This new kind of implanted port offers the unique ability to provide access for power-injected Contrast-Enhanced Computed Tomography (CECT) scans. Power-injected CECT scans produce superior images of your body to help the medical team better manage your treatment. With your **PowerPort** Implanted Port, you'll be able to receive IV therapy and CECT scans without having to undergo repeated needlesticks in your peripheral (arm or wrist) veins.

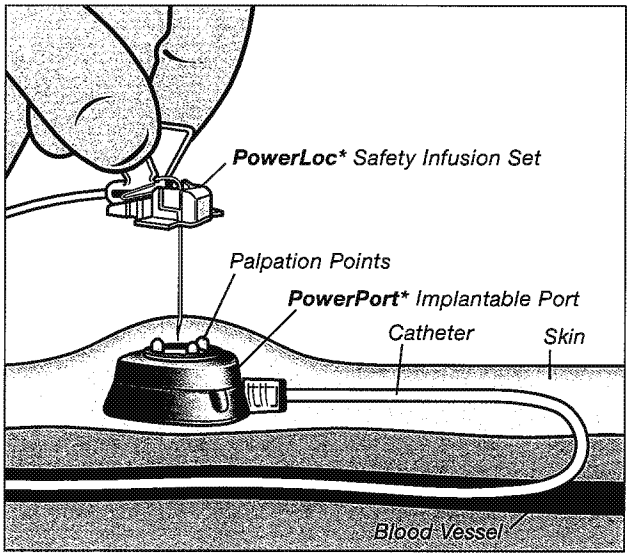
Please read all of the information contained in this Patient Guide. It gives you the knowledge to understand and feel comfortable with your **PowerPort** Implanted Port. Just as your **PowerPort** device is new to you, it may not yet be familiar to all clinicians involved in your care. That's because the **PowerPort** Implanted Port is a new technology designed to accommodate power-injected CECT scans. The patient-specific information contained in this Guide gives you the power to inform clinicians about your **PowerPort** device, so that you can take advantage of power-injected CECT scans and avoid unnecessary needlesticks.

You should also carry your **PowerPort** device Patient Identification Card with you to show to clinicians whenever your port is accessed. It informs clinicians that you have a **PowerPort** Implanted Port and provides a summary of important information they should know about the port.

If you need additional information about your **PowerPort** device, please talk with your doctor or nurse.

Presenting Your PowerPort* Implanted Port

Your **PowerPort** Implanted Port is a small device placed completely beneath your skin in a short procedure. It is a cylinder with a hollow space inside that is sealed by a soft top. The **PowerPort** device connects to a small, flexible tube called a catheter that is inserted inside one of the large central veins that deliver blood to your heart. When a special needle is put into the soft top of the **PowerPort** device, it creates "access" to your bloodstream, meaning that medications and fluids can be given and blood samples withdrawn.



For power-injected CECT scans, the PowerPort device is used with a needle designed especially for power injection called the PowerLoc* Safety Infusion Set. Your **PowerPort** Implanted Port has unique triangular arrangement of three bumps called Palpation Points on the top of the port and a distinctive triangle shape. These features help to identify its special design for power-injected CECT scans.

How Your PowerPort* Device Is Used

Your **PowerPort** Implanted Port allows clinicians to easily deliver medications or fluids or withdraw blood samples without having to repeatedly stick your peripheral veins directly with a needle. This makes it more comfortable for you. Because the **PowerPort** device places medications into the large central veins instead of the small peripheral veins, the medications mix more thoroughly in the blood, diluting them so they are less harmful to your vascular system.

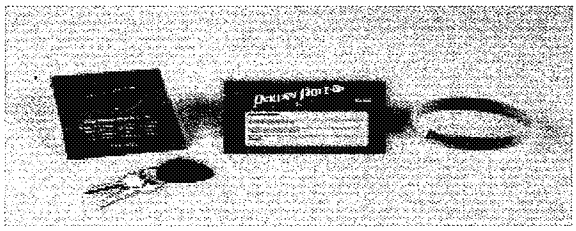
The **PowerPort** Implanted Port is used with the **PowerLoc*** Safety Infusion Set. This enables fluids called contrast agents to be power-injected (delivered at a high rate) into your bloodstream. As a result, tissues in your body show up more clearly, making it easier for your doctors to monitor the status of your condition. Power-injected CECT scans are safe, non-invasive procedures that provide important information for disease diagnosis and treatment.

IDENTIFICATION

How to Know You Have a PowerPort* Implanted Port

There are several ways that you and your clinicians can recognize that you have a **PowerPort** device instead of a traditional type of implanted port.

Identify Yourself!



Key Ring Card *Identification Card* *Bracelet*

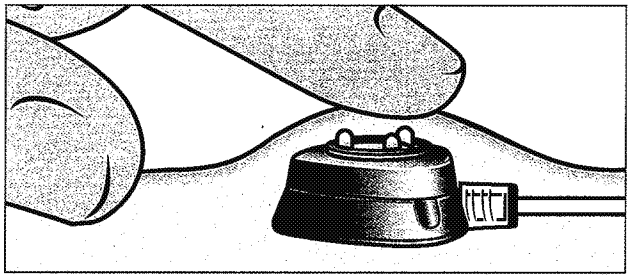
Upon receiving your **PowerPort** Implanted Port, you are provided with an identification card, bracelet and key ring card identifying you as a patient with a **PowerPort** device. **Carry your PowerPort device Patient Identification Card with you at all times.** Show it to the clinician beforehand whenever your port is accessed for a procedure. You may wear the bracelet or carry the key ring as convenient reminders that you have a **PowerPort** Implanted Port.

In addition, if you have received a **PowerPort** Implanted Port, your patient chart should show a **PowerPort** device record sticker noting this fact.

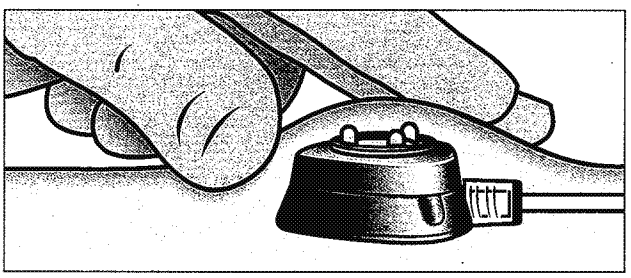
Feel the Difference!

Your **PowerPort*** Implanted Port has a unique shape and design that distinguishes it from traditional ports. Trained clinicians can recognize these distinctive features under your skin by feeling for them with their fingers, a process called palpation. A trained clinician palpating the sides of your **PowerPort** device should recognize its unique triangle shape. A trained clinician palpating the top of your **PowerPort** device should be able to feel three bumps called Palpation Points that are arranged like a triangle on the port.

Ask your doctor or nurse to help you feel the difference by showing you how to palpate your new **PowerPort** Implanted Port.



Feel the soft top of the port to locate the three Palpation Points arranged as a triangle.

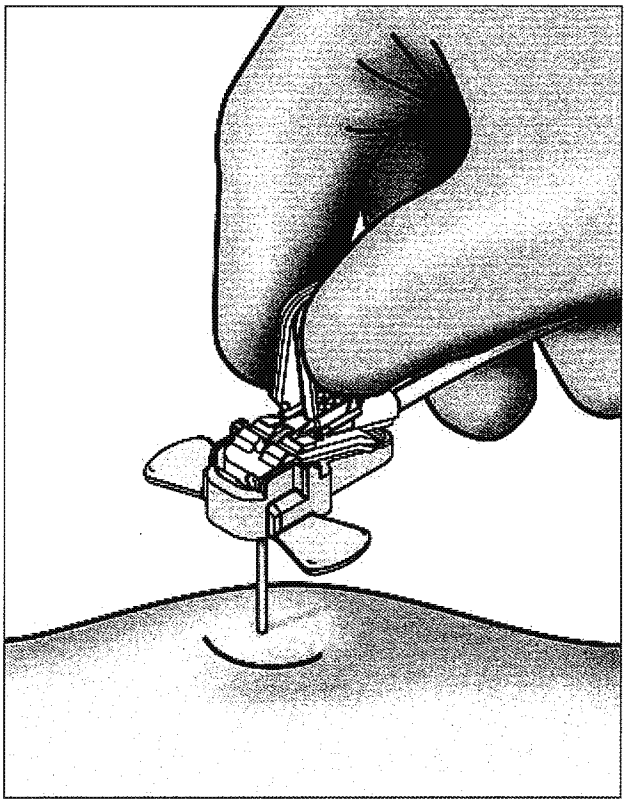


Feel the sides of the port to identify its unique triangle shape.

ACCESS

How Your PowerPort* Device Is Accessed

Your clinicians will use the **PowerPort** Implanted Port whenever they need to infuse medications or fluids into your body or withdraw samples of your blood. To do this, they will first access the **PowerPort** device by inserting a special needle into the soft top of the device. Ask the clinician about what to expect in your own procedure.



HEPARIN LOCKS

About Heparin Locks

Sometimes when blood clots, it can block the catheter, preventing medications and fluids from flowing through it. However, blood will not clot when it is thinned with a medication called heparin. To help prevent clots from forming, implanted ports are typically filled with sterile heparinized saline after each use. This process is called a heparin lock. If your **PowerPort** Implanted Port will not be used for long periods of time, the clinician will typically change the heparin lock every four weeks.

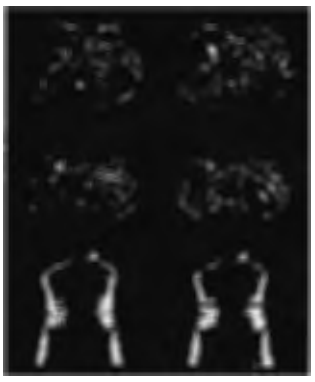
If you have been diagnosed as being allergic to heparin or as having heparin induced thrombocytopenia (HIT), it is important to remind the clinician of this fact anytime your **PowerPort** device is accessed.

What to Expect During Power Injection for CECT Scans

About Power-Injected CECT Scans

Contrast-Enhanced Computed Tomography (CECT) scans are simple, safe and non-invasive procedures that provide quick and accurate diagnostic information to help your medical team manage your care. These scans are many times more sensitive than conventional x-rays. Radiologists can distinguish small differences in your soft tissues that may not be detected with x-rays.

CECT Workstation



Contrast-Enhanced Computed Tomography (CECT) Scans

Before performing a CECT scan, the radiology team will inject a contrast agent, which is a special fluid that acts like a dye, into your body to help produce clearer pictures during the CECT scan procedure. For best results, the contrast agent is infused at a high rate into your bloodstream. This process is called power injection. **Your PowerPort* Implanted Port used with the PowerLoc* Safety Infusion Set has the unique ability to allow clinicians to perform power-injected CECT scans without having to make a needlestick in your arm or wrist veins.**

What Your Clinician Should Know

Always show your **PowerPort** device Patient Identification Card to clinicians who perform your CECT scan. It informs them that you have a **PowerPort** Implanted Port.

Show your Identification Card beforehand whenever your port is being accessed for a procedure.

Q & A

Common Questions and Answers

How do I take care of my PowerPort* Implanted Port?

During the first few days after receiving the **PowerPort** Implanted Port, avoid heavy exertion and follow the instructions your doctor or nurse has given you for taking care of the small incision. Once the incision has healed, the beauty of your **PowerPort** Implanted Port is that you do not have to take any special care of it, and you can resume normal daily activities.

Will the PowerPort Implanted Port affect my daily activities?

Once the incision heals following implantation, you should be able to return to your normal daily activities, such as bathing, swimming or jogging. Ask your doctor or nurse about specific activities and the appropriate time to resume them.

Will I need to wear a bandage over the PowerPort Implanted Port?

A bandage will be required until your incision heals. After the incision has healed, a bandage is not required when the **PowerPort** device is not being used. If you are receiving continuous infusion of fluids, a bandage may be applied to stabilize and protect the needle while it is in place.

Do I have to stop wearing certain types of clothing?

Ask your doctor or nurse because the answer will depend on where your **PowerPort** device is placed.

Who pays for the PowerPort* Implanted Port?

Insurance policies vary, so check with your insurance company first.

Will the PowerPort Implanted Port activate security alarms?

Security systems most likely will not detect the small amount of metal in the device. If it does occur, simply show your **PowerPort** device Patient Identification Card.

How long will I have my PowerPort Implanted Port?

The **PowerPort** Implanted Port can stay in place for as long as your doctor determines that you need it.

Will my PowerPort device need to be accessed when not in use?

Yes. It will need to be flushed every 4 weeks.

Can the PowerPort device be removed if I no longer need it?

Yes. When no longer needed, the **PowerPort** Implanted Port can be removed in a simple procedure similar to the one used to implant it.

Is the PowerPort device safe with CT and MRI?

Yes. The materials used in the **PowerPort/PowerLoc** system are latex-free, non-ferromagnetic and safe with CT, CECT and magnetic resonance imaging (MRI) procedures and all injectable fluids used with these procedures.

What if the clinician has not seen a patient with a PowerPort device before?

The **PowerPort** Implanted Port is a new technology. It may not yet be familiar to all clinicians involved in your care. Always show clinicians your **PowerPort** device Patient Identification Card, especially if your PowerPort device will be accessed for power-injected CECT scans. Your **PowerPort** device Patient Identification Card contains a summary of important information for the clinician. If clinicians need more information, they may contact the Bard Access Systems Clinical Information Hotline at 800-443-3385.

TELL YOUR CLINICIAN

Tell Your Clinician You've Got the Power!

As a new patient with a **PowerPort** Implanted Port, you've got the power to take an active role in your treatment. The best way you can be involved is to share information and concerns with your clinicians. Speak up! Ask questions about anything that concerns you or if you notice anything that seems unusual.

What to Report to Your Clinician

Here are some important things to tell your clinician:

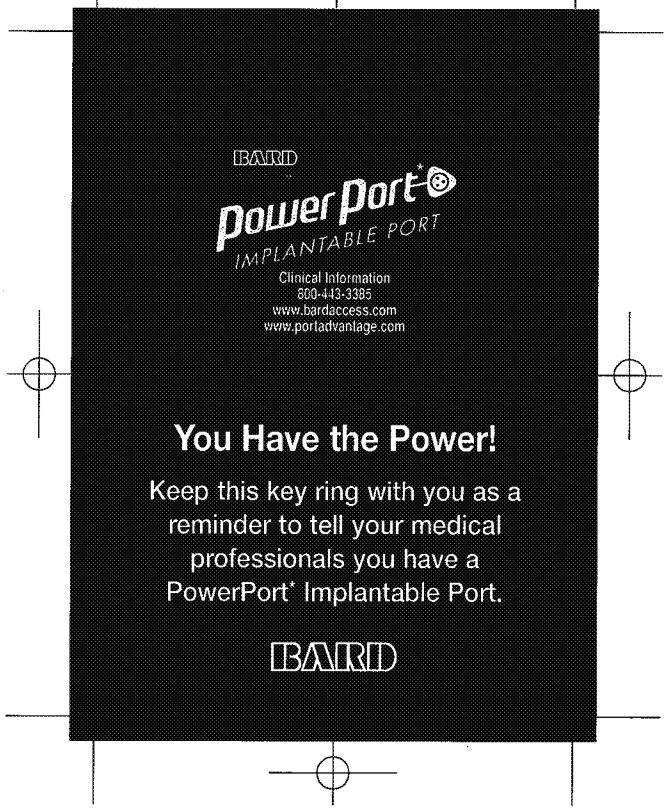
- You have a **PowerPort** Implanted Port.
- If you notice any redness or inflammation at the site of your **PowerPort** Implanted Port after the incision heals.
- If you have a fever.
- If you have allergies to any medications or materials.
- If you have an allergy to heparin.
- If you have heparin induced thrombocytopenia (HIT)
- If you have ever been prescribed anticoagulant (blood-thinning) medications such as heparin or warfarin.
- If you have previously been treated with radiation.
- If you have ever been diagnosed with lung disease.
- If you have ever been diagnosed with, or treated for, venous thrombosis.
- If you have ever been diagnosed with any tissue diseases or suffered from tissue erosion.
- If you have ever been diagnosed or tested for "pinch-off" syndrome.
- If other clinicians have ever had difficulty withdrawing blood or infusing fluids through your implanted port, including whether other clinicians have ever required you to change position to allow blood or fluid to flow.

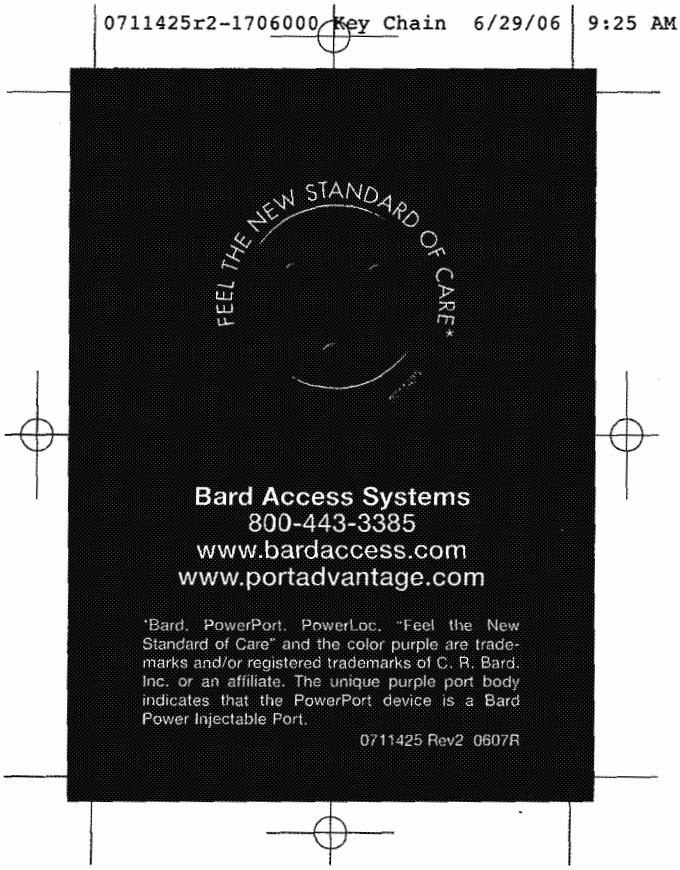
PATIENT CHECKLIST ✔

- ❑ The **PowerPort*** device is a new kind of implanted port that provides access for both IV therapy treatments and power-injected Contrast-Enhanced Computed Tomography (CECT) scans.
- ❑ Upon receiving your **PowerPort** device, you will also receive an Identification Card, Bracelet and Key Ring Card that identify you as a patient with a PowerPort Implanted Port.
- ❑ **Carry your Identification Card at all times. You may also wear the bracelet or carry the key ring as convenient reminders to tell your medical professionals that you have a PowerPort Implanted Port.**
- ❑ Show your Identification Card to the clinician whenever your port is accessed for a procedure, especially power-injected CECT scans.
- ❑ The Identification Card contains important information for the clinician. If clinicians need more information, they may contact the Bard Access Systems Clinical Information Hotline at 800-443-3385.
- ❑ Speak up! Share information with clinicians and ask about anything that concerns or seems unusual to you.

Implant Record

Subject and Predicate Devices





Groshong* Catheter with

PowerPort

Companion Checklist

Feel the New Standard of Care*

Thank you for being a companion to someone who has received a PowerPort* Implanted Port. Here are some valuable things to know:

- ❑ The PowerPort* device is a new kind of implanted port that provides clinicians access for both IV therapy treatments and power-injected Contrast-Enhanced Computed Tomography (CECT) scans.
- ❑ The PowerPort* Implanted Port has been equipped with a Groshong* catheter, which allows for simplified maintenance and a saline lock.
- ❑ Upon receiving their PowerPort* device, patients also receive an identification card, bracelet and key ring identifying them as a patient with a PowerPort* Implanted Port with Groshong* catheter.
- ❑ **Patients with a PowerPort* device should carry their Patient Identification Card at all times,** and may wish to wear the bracelet or carry the key ring as convenient reminders.
- ❑ Patients with a PowerPort* device should show their Patient Identification Card to clinicians whenever their port is accessed for a procedure, especially power-injected CECT scans.
- ❑ The PowerPort* device Patient Identification Card contains important information for the clinician. If clinicians need more information, they may contact the Bard Access Systems Clinical Information Hotline at 800-443-3385.
- ❑ Speak up! Share information with clinicians and ask about anything that concerns or seems unusual to the patient or you.

BARD
Access Systems

Bard Access Systems, Inc.
Salt Lake City, UT 84116 USA 801-595-0700
Clinical Information Hotline 800-443-3385
www.bardaccess.com • www.portadvantage.com

07/16/14 0803R

Labeling Subject Device

- ❑ Patients with a PowerPort device should show their Patient Identification Card to clinicians whenever their port is accessed for a procedure, especially power-injected CECT scans.
- ❑ The PowerPort device Patient Identification Card contains important information for the clinician. If clinicians need more information, they may contact the Bard Access Systems Clinical Information Hotline at 800-443-3385.
- ❑ Speak up! Share information with clinicians and ask about anything that concerns or seems unusual to the patient or you.

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0711428 Rev1 0605R

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 2008

Ms. Ji-Hyun Kim
Regulatory Affairs Manager
C.R. Bard, Incorporated
Bard Access Systems, Incorporated
605 North 5600 West
Salt Lake City, Utah 84116

Re: K081311
Trade/Device Name: PowerPort™ Implanted Port with Groshong™ Catheter
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: May 8, 2008
Received: May 9, 2008

Dear Ms. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

Reviewer Alan M. Stevens

Division/Branch: DAGID / GHDB

Device Name: PowerPort Implanted Port with Groshong Catheter

Product To Which Compared (510(K) Number If Known): K060812

(b)(5)

(b)(5)

(b)(5)

(b)(5)

Bard Access Systems, Inc.
605 North 5600 West
Salt Lake City, UT 84116
Phone: 801-595-0700
Fax: 801-595-4969

BARD

May 30, 2008

LT Alan Stevens
Regulatory Review Officer
General Hospital Devices Branch
Office of Device Evaluation
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Re: K081311, PowerPort™ Implanted Port with Groshong™ Catheter
Response to Request for Additional Information

Dear Mr. Stevens,

Bard Access Systems, Inc., (BAS) a division of C.R. Bard, Inc., is submitting this response for additional information concerning K081311, PowerPort ™ Implanted Port with Groshong™ Catheter, currently under your Special 510(k) review auspices. This supplemental provision contains a full response to your question, in accordance with the teleconference conversation held directly with you on May 30, 2008 and the subsequent request made by e-mail on the same day.

(b)(4) the 510(k) summary has been revised. (See attachment)

(b)(4) the PowerPort™ Implanted Titanium Port [K060812] is used as the primary predicate device for the subject PowerPort™ Implanted Port with Groshong™ Catheter submission [K081311]. (b)(4)

(b)(4)

(b)(4) Section 11 of K081311.

Regarding your e-mail request, please see the attached response.

If you have any additional questions, please feel free to contact me directly at (801)595-7175.

Sincerely,

(b)(6)

Ji-Hyun Kim
Regulatory Affairs Manager
Bard Access Systems, Inc.
Phone: 801) 595-7175
Fax: 801) 595-5425
jihyun.kim@crbard.com

10

Attachment

(b)(4)

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name ALAN STEVENS JUNE 2, 2008

Subject: 510(k) Number K081311

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☒ Final Decision (SE) SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary/510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			X
Is this a combination product? (Please specify category N, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			X
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age<=21			X
Neonate/Newborn (Birth to 28 days)			X
Infant (29 days -< 2 years old)			X
Child (2 years -< 12 years old)			X
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			X
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			X
Nanotechnology			X

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.* N
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.* N

Regulation Number	Class*	Product Code
21 CFR 882.5965	II	LJT

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: _____ (Branch Chief) CZ 6/2/08 | GNDB (Branch Code) | 6/1/08 (Date)

Final Review: _____ (Division Director) | 6/4/08 (Date)

5

K081311

BARD
ACCESS SYSTEMS

May 8, 2008

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Re: **Special 510(k): Device Modification**
PowerPort™ Implanted Port with Groshong™ Catheter
80 LJT – Subcutaneous, Implanted, Intravascular Infusion Port & Catheter
21 CFR § 880.5965 – Class II
General Hospital

Dear Madam/Sir:

In accordance with section 510(k) of the Federal Food, Drug and Cosmetic Act and pursuant to 21 CFR §807.81, Bard Access Systems, of C.R. Bard, Inc. hereby submits this premarket notification of intent to introduce into interstate commerce the PowerPort™ implanted port with Groshong™ catheter. Enclosed is one hard copy and one compact disk copy of the 510(k) notification for FDA review.

The "Special 510(k): Device Modification" pathway has been selected since the subject device represents a modification to Bard Access Systems' predicate PowerPort™ Implanted Titanium Port [K060812], (b)(4) (b)(4) Neither the fundamental, scientific technology, nor the intended use of the product are being altered with this modification.

The introduction of the subject PowerPort™ Implanted Port with Groshong™ catheter will expand Bard's current PowerPort™ family of power-injectable implanted port products. As with Bard's current PowerPort™ family of products, the subject device can be used with any non-coring infusion set for routine vascular access, but must be combined with a Bard PowerLoc™ safety infusion set for power injection of contrast media.

The terms "substantially equivalent", "similar", and related terms and descriptions in this notification are defined terms or words of art defined by the Food and Drug Administration as those words are used in the Federal Food, Drug and Cosmetic Act as amended and the regulations promulgated there under and are not to be construed or interpreted for any other purpose.

It is the understanding of C.R. Bard, Inc. that written notification will be received from FDA if this device is subject to §522 of the Federal Food, Drug and Cosmetic Act, *i.e.*, Postmarket Surveillance.

C.R. Bard. Inc. requests that the FDA keep and maintain confidential both the existence and the contents of this Premarket Notification in accordance with 21 CFR §807.95(b). C.R. Bard, Inc. also requests that the FDA keep and maintain confidential the contents of this letter.

If you have any questions or require any additional information related to this notification, please contact me at your convenience through any of the contact information listed below. I hereby authorize the FDA to communicate with me regarding this submission via fax and/or e-mail. Thank you in advance for your consideration of our application.

Sincerely,

(b)(6)

Ji Hyun Kim
Regulatory Affairs Manager
Bard Access Systems
605 North 5600 West
Salt Lake City, UT 84116

Tel: (801) 595-0700 x7105
Fax: (801) 595-5425
jihyun.kim@crbard.com

510(k) Summary

JUN - 4 2008

General Provisions	Submitter Name:	Bard Access Systems, Inc. (BAS) [Wholly owned subsidiary of C.R. Bard, Inc.]
	Address:	605 N 5600 W Salt Lake City, UT 84116
	Telephone Number:	(801) 595-0700 ext. 7105
	Fax Number:	(801) 595-5425
	Contact Person:	Ji Hyun Kim
	Date of Preparation:	May 30, 2008
	Registration Number:	3006260740 BAS 2212754 C. R. Bard
Subject Device	Trade Name:	PowerPort™ Implanted Port with Groshong® Catheter
	Common/Usual Name:	Implanted Infusion Port & Catheter
	Classification Name:	80 LJT – Subcutaneous, Implanted, Intravascular Infusion Port & Catheter
Predicate Devices	Trade Name:	PowerPort™ Implanted Titanium Port
	Common/Usual Name:	Implanted Infusion Port & Catheter
	Classification Name:	80 LJT – Subcutaneous, Implanted, Intravascular Infusion Port & Catheter
	Premarket Notification:	K060812, clearance date July 14, 2006
Classification	Class II 21 CFR §880.5965 General Hospital	
Performance Standards	Performance standards have not been established by FDA under section 514 of the Federal Food, Drug and Cosmetic Act.	
Intended Use	PowerPort™ devices are totally implanted vascular access devices designed to provide long-term, repeated access to the vascular system.	
Indications for Use	The PowerPort™ implanted port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medication, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples. When used with a PowerLoc™ safety infusion set, the PowerPort™ device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s.	

K081311
pg 1 of 2

Device Description	The subject PowerPort™ implanted port with Groshong™ catheter is a member of the PowerPort™ series of power injectable implanted ports. The subject device consists of a titanium port and silicone Groshong® tipped and valved catheter that is attached to the port with a cathlock compression fitting. The subject port is distinguishable as a member of BAS's power injectable port series by the triangular body shape, unique purple coloring, and three palpation bumps on the septum. PowerPort™ implanted ports can be used for routine vascular access using a non-coring access needle. However, for power injection procedures, PowerPort™ ports must be accessed with a Bard PowerLoc™ safety infusion set to create a power injectable system.
Technological Characteristics	Technological characteristics of the subject PowerPort™ implanted port with Groshong™ catheter are equivalent to those of the Bard Access Systems predicate PowerPort™ Implanted Titanium Port [K060812].
Safety & Performance Tests	No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for this device. However, design verification testing was performed according to protocols based on the recommendations/requirements of applicable FDA guidance and FDA recognized international standards. Verification testing, determined to be applicable to the safety and efficacy of the device, was shown to meet predetermined acceptance criteria listed therein. Risk management, including a failure modes and effects analysis (FMEA), of the subject device was conducted in accordance with an internal protocol based on ISO 14971:2007, *Medical Devices – Application of Risk Management to Medical Devices (General)*. The analysis did not identify any new types of safety or efficacy questions for the subject PowerPort™ implanted port with Groshong™ catheter.
Summary of Substantial Equivalence	Based on the indications for use, technological characteristics, and safety and performance testing, the subject PowerPort™ implanted port with Groshong™ catheter meets the minimum requirements that are considered adequate for its intended use and is substantially equivalent in design, materials, sterilization, principles of operation and indications for use to current commercially available implanted ports cited as predicates.

K081311
pg 2 of 2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 2008

Ms. Ji-Hyun Kim
Regulatory Affairs Manager
C.R. Bard, Incorporated
Bard Access Systems, Incorporated
605 North 5600 West
Salt Lake City, Utah 84116

Re: K081311
Trade/Device Name: PowerPort™ Implanted Port with Groshong™ Catheter
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: May 8, 2008
Received: May 9, 2008

Dear Ms. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K081311

Device Name: PowerPort™ Implanted Port with Groshong™ Catheter

Indications for Use:

The PowerPort™ implanted port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medication, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples. When used with a PowerLoc™ safety infusion set, the PowerPort™ device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s.

Prescription Use ✓ (Part 21 CFR §801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR §801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081311

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

May 09, 2008

C.R. BARD, INC.
BARD ACCESS SYSTEMS
605 NORTH 5600 WEST
SALT LAKE CITY, UT 84116
ATTN: JIHYUN KIM

510(k) Number: K081311
Received: 09-MAY-2008
Product: POWERPORT IMPLANTED PORT WITH GROSHONG CATHETER

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/cdrh/mdufma/index.html for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf.

A new provision of the Food and Drug Administration Amendments Act of 2007, 42 U.S.C. 282(j)(5)(B), requires that a certification form (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf) accompany all 510(k)/HDE/PMA submissions on or after December 26, 2007. You are responsible for registering certain device clinical trials in the Clinical Trials Data Bank (http://prsinfo.clinicaltrials.gov). If your submission does not include FDA Form 3674, please send 2 hardcopies of the completed certification form referencing the submission number identified above. Additional information about the new certification

form may be found at the following link to the Federal Register Notice (http://www.fda.gov/OHRMS/DOCKETS/98fr/07-6023.htm).

Please note the following documents as they relate to 510(k) review: 1)Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1655.pdf. Please refer to this guidance for information on a formalized interactive review process. 2)Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/". If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsma/dsmastaf.html. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

13