GrantAdler
Vascular Access Systems

RHAPSODY CT +

Power Port w/SurePlace High-Integrity Catheter System

Instructions for Use

A revision date and version number for these instructions are included for reference. In the event two years have elapsed between this date and product use, the user should contact GrantAdler to determine if additional product information is available.

Revision Number: 3.2

Revision Date: June 9th, 2010

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Helpful Words

Throughout the manual and shown below, are words which indicate special information of warning, caution and/or precaution. Please take extra care when reading the information that appears alongside these words.

WARNING: A statement or event that indicates a possible or impending danger, or problem.

CAUTION: Care or actions that should be taken to avoid danger or mistakes.

PRECAUTION: A measure taken in advance to prevent danger or mistakes.

Introduction

Implantable vascular access devices improve patient health and lifestyle by reducing the distress and complications associated with multiple punctures or the inconvenience and inefficiency of an external catheter.

Description

The GrantAdler Rhapsody CT+ implantable vascular access system consists of One implantable access port, One guidewire and One trim-able wire-reinforced catheter.

GrantAdler ports are Power-injectable, MR conditional single chamber devices manufactured of the highest quality biocompatible materials. Our ports are constructed with durable titanium shells and high compression self-sealing silicone septums.

Suture sites are incorporated into the base of ports to facilitate anchorage. Catheter materials include flexible silicone and stainless steel reinforcing wire.

Indications for Use

The GrantAdler Rhapsody port line is intended to facilitate reliable and repeated access of the vascular system for delivery of medications, nutritional supplementation, fluids, blood, blood products, or the sampling of blood. Access is performed by percutaneous needle insertion, using only non-coring, Huber, needles.

When used with a Power injectable needle, the Rhapsody CT+, is indicated for power injection of contrast media. For Power injection of contrast media, the maximum recommended infusion rate is 5 ml/s through a 19 or 20 gauge non-coring Power-rated injection needle and 2 ml/s through a 22 gauge non-coring Power-rated injection needle.

Contraindications

The GrantAdler Rhapsody CT+ port system should not be implanted:

- In the presence of known or suspected infections, bacteremia, septicemia, and peritonitis.
- In patients who have exhibited prior intolerance to the materials of construction.
- In patients whose body size or tissue is insufficient to accommodate the size of the port or catheter.
- When severe chronic obstructive lung disease exists.
- When irradiation of prospective insertion site has occurred in the past.
- When a history of venous thrombosis or vascular surgical procedures at the prospective placement site exists.
- When local tissue factors will prevent proper device stabilization and/or access.
- When catheter insertion is in the subclavian vein medial to the border of the first rib.

Possible Complications:

The use of the GrantAdler Rhapsody port systems involves the same risks normally associated with local and general anesthesia, surgery, and post-operative recovery.

Occlusion may result from clot formation inside the lumen of the catheter, precipitate formation inside the port from incompatible drugs, or from malposition of the catheter tip against a vein wall or valve.

Potential for other serious complications exists, including the following:

- Air Embolism
- Bleeding
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Puncture
- Cardiac Tamponade
- Catheter Embolism
- Catheter Malposition
- Catheter Occlusion, Damage or Breakage due to Compression Between the Clavicle and First Rib
- Catheter or Port Erosion Through the Skin
- Catheter or Port-related Sepsis
- Clot formation
- Device Occlusion
- Device Rotation or Extrusion
- Drug Extravasation
- Embolization
- Endocarditis
- Fibrin Sheath Formation
- Hematoma
- Hemorrhage
- Hemothorax
- Hydrothorax
- Implant Rejection
- Infection
- Inflammation, Necrosis, or Scarring of Skin over Implant Area
- Intolerance Reaction to Implanted Device
- Laceration of Vessels or Viscus
- Migration and Inadequate Anchoring
- Occlusion
- Other Vessel Trauma
- Perforation of Vessels or Viscus
- Pneumothorax
- Spontaneous Catheter Tip Malposition or Retraction
- Thoracic Duct Injury
- Thromboembolism
- Thrombophlebitis
- Thrombosis
- Vascular Thrombosis
- Vessel Erosion

Warnings:

General

- GrantAdler ports are supplied as sterile devices intended for single patient use only. Do not reuse.
- GrantAdler ports and catheters are sterilized by EtO. Do not re-sterilize.
- At no time should the system be left open to air.
- Avoid vessel perforation.
- Only GrantAdler guidewires and catheters may be used with the system.
- Although the GrantAdler Rhapsody has been designed to help reduce the incidence of catheter pinch-off and fragmentation, the following should be considered:
- Catheters placed percutaneously or through a cut-down, into the subclavian vein, should be inserted at the junction of the outer and middle thirds of the clavicle, lateral to the thoracic outlet.

- The catheter should not be inserted into the subclavian vein medially, as this placement could lead to catheter occlusion, damage, rupture, shearing, or fragmentation due to compression of the catheter between the first rib and clavicle.
- Do not ever cut, trim, or manually adjust the length of any GrantAdler / Trim-able Catheter above the wire-reinforcement.
- Always use the GrantAdler Guidewire to determine appropriate GrantAdler / Trim-able catheter length.
- Never withdraw any GrantAdler Guidewire backwards through a needle. If a guidewire exchange is required, use a standard percutaneous guidewire exchange technique.
- Practitioners must carefully read, understand, and follow all instructions in this manual prior to use of any part of the GrantAdler system.
- Federal law within the United States restricts the sale, order and use of this device to licensed physicians only.
- Only qualified healthcare practitioners should implant, manipulate or remove implanted GrantAdler devices.
- Tunnelers should be used with care so as to avoid inadvertent skin puncture.
- Care should be taken to ensure that catheter hub is advanced completely over the port stem. Catheters not advanced to the proper region of the stem may not seat securely and lead to dislodgment and extravasation.

Precautions:

General:

- Do not use this product or any of its accessories if the package integrity has been, or appears to be, compromised.
- Follow manufacturer contraindications, warnings, cautions, precautions and instructions for use.
- Strict sterile technique is of critical importance when implanting any device.
- Each access of a GrantAdler port should be performed using sterile technique.
- Before handling the port, ensure that surgical gloves are free of talc.
- Sutures should never be placed directly on catheters to prevent occlusion of the catheter.
- The non-coring Huber needle should be advanced through the septum until it contacts the base of the port body.
- Do not continue to apply force once the needle has reached the bottom of the port.
- Do not rock, tilt or otherwise shift the needle once it is in the septum.
- Do not use a syringe smaller than 10cc.
- Do not exceed 25 psi Power when administering fluid into system.

Port Placement:

- Do not allow the device to make contact with sharp instruments as mechanical damage may occur.
- Use only smooth edged, atraumatic clamps or forceps.
- Proper port placement includes support by underlying boney structure.

- The port site should be distal to the vein insertion site in upper arm placements.
- A minimum of three sutures should be used to secure the port to the body.
- Port location should be comfortable for the patient.
- Avoid placing the port directly under the port pocket incision.
- Avoid placing the port too deep or too shallow. The minimum placement depth should be 0.5 cm and the maximum placement depth should be 2 cm under the surface of the skin.
- Pre-operative mapping of port location is recommended whenever possible.

GrantAdler Catheter and GrantAdler Guidewire:

- GrantAdler Trim-able Catheter and Guidewire are unique. They have special properties that can be a benefit to clinicians as well as patients. (care must be taken to ensure that are used properly).
- Only use the GrantAdler Guidewire with the GrantAdler Trim-able Catheter. (See Identification and Markings)
- Before connecting the catheter to the port, ensure that the correct length has been chosen. Each Trim-able Catheter has length markings to help facilitate proper length selection. (See Identification and Markings)

Catheter Attachment and Placement:

- Carefully follow the connection technique given in these instructions to ensure proper catheter connection and to avoid catheter malfunction.
- Do not perforate, tear, or fracture the catheter when using a guidewire.
- Do not use the catheter if there is any evidence of mechanical damage.
- Do not use the catheter if it does not attached to the port securely.
- The catheter tip should be placed in an area of high blood flow.
- The port should be positioned at the selected site of therapy and secured by accepted surgical technique to prevent catheter dislodgment.
- Positioning should be confirmed by appropriate radiographic procedures.
- Sufficient slack should be left between the catheter insertion point and the port body to preclude strain on the catheter.
- Once the catheter is connected to the port, do not pull on or attempt to remove the catheter from the port stem. If the catheter is not or does not appear to be completely advanced over and secured to the stem, use a brand new port and catheter.

Important Information about Power Injection:

1. This device is contraindicated for catheter insertion in the subclavian vein medial to the border of the first rib, an area associated with higher rates of pinch-off.
2. For Power injecting contrast media, a needle indicated for Power injection must always be used to access the Rhapsody CT+ port.
3. 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.
4. 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.

5. Check for patency, via aspiration, and then vigorously flush the system with a syringe and sterile normal saline prior to and immediately following the completion of Power injection studies. Resistance to flushing may indicate partial or complete catheter occlusion. Do not proceed until occlusion has been cleared. WARNING: Failure to ensure patency of the catheter prior to Power injection may result in port system failure.
6. Do not exceed a 300 psi Power limit setting of the Power injection machine employed as shown below.

Power-rated Injection Needle Size	19 GA	20 GA	22 GA
Maximum Flow Rate Setting	5ml/s	5ml/s	2ml/s

WARNINGS

- Do not Power inject through a port system that exhibits signs of compression or pinch-off.
- Failure to ensure patency of the catheter prior to Power injection may result in port system failure.
- Power injector machine Power limiting feature may not prevent over pressurization of an occluded catheter.
- Injections should be stopped if pain or swelling is detected.
- This product's Power injection indication for contrast media studies implies the port's ability to withstand the procedure. However, it does not imply appropriateness of the procedure for a particular patient or for a particular infusion set.
- A suitably trained clinician is responsible for evaluating the health status of a patient with respect to a Power injection procedure and for evaluating the suitability of any infusion set used to access the port system.
- Follow institutional protocol to verify correct catheter position prior to Power injection.

Catheter	Maximum Indicated Power Injection Flow-Rate (cc/sec)*	Maximum Internal System Power During Maximum Flow Rate*	Average Static/Burst Power**
8FR Reinforced Catheter	5ml/s	29 psi	108 psi

- Pressurized flow rates are determined using viscous fluid at 11.8 centipoise (cP) and represent approximate flow capabilities of Power injection of contrast media.

** Maximum static/burst Power is the static burst Power failure point of the catheter.

Instructions for Use:

Before Use:

- Do not use the device if there is any evidence of physical or mechanical damage or leaking. Damage to the catheter may lead to rupture, fragmentation, possible embolism, and require surgical removal.
- If signs of extravasation exist, discontinue injections immediately and seek appropriate medical intervention.
- Choose a needle length based on reservoir depth, tissue thickness, and the thickness of any dressing beneath the bend of the needle.
- Confirm correct positioning of the needle within the port reservoir by aspiration of blood before infusion of any substance. If there is doubt regarding proper needle placement, perform a radiographic dye procedure to confirm placement.
- Follow institutional guidelines for infusion set use. The Center for Disease Control (CDC) recommends that I.V. tubing be changed every 48 hours.
- Never inject fluid or materials which are not labeled sterile or are not approved for human infusion.
- Do not use this system if there are any questions or uncertainty regarding these instructions.

Site Preparation:

- Inspect site and prepare for injection using sterile technique prior to accessing the port.

Bolus Injection:

1. Identify the port septum by palpating outer perimeter of the port utilizing sterile technique.
2. Attach a 10ml syringe filled with sterile normal saline to the infusion tubing with non-coring needle. Remove all air.
3. Insert the non-coring needle through the skin perpendicular to the port septum and advance slowly until contact with the base is made.
4. Aspirate, check for blood return. Discard blood aspirate. Inject 3-5ml of sterile normal saline to flush port, clamp tubing and remove saline syringe.
5. Attach drug syringe.
6. Unclamp tubing and inject drug slowly.
7. When injection is complete, clamp the tubing.
8. Flush system after each injection with 10cc of normal saline to ensure the entire volume of therapeutic solution is washed through the system and into the circulation.
9. Perform heparin lock procedure at completion.

CAUTION: Examine injection site for extravasation. If noted, immediately discontinue infusion and notify physician. At no time should the system be left open to air. Do not rock, tilt or otherwise shift the needle once it is in the septum.

Continuous Infusion:

1. Apply antibacterial cream to injection site.
2. Connect non-coring needle to extension set and 10 ml syringe filled with sterile normal saline. Remove all air and clamp the extension set.

3. Locate and access port using proper sterile technique.
4. Place a gauze pad under needle hub. Secure needle to help prevent dislodgement.
5. Open clamp and flush port with sterile normal saline. Clamp extension set and remove syringe.
6. Connect fluid delivery system as indicated. As an additional precaution, tape all tubing connections during pump infusion. Pumps must incorporate a functional automatic Power limiting switch which will shut pump off before Power exceeds 25 psi (172 kPa).
7. Release clamp and initiate infusion. Inspect the infusion site for signs of extravasation. If noted, or if patient experiences pain, immediately discontinue infusion and initiate appropriate intervention.
8. After the infusion is complete, clamp the extension set and remove the fluid delivery system.
9. Flush the system after each infusion with 10 ml of sterile normal saline.
10. Perform standard heparin lock procedure.

Caution: Examine injection site for extravasation. If noted, immediately discontinue infusion and notify physician.

Blood Sampling:

1. Blood sampling may be performed as an isolated procedure, at the time of bolus injection, or during the continuous infusion process subject to physician judgment.
2. Insert the non-coring needle into the prepared site.
3. Withdraw “discard sample” consisting of 5 ml of blood. Discard this sample and syringe. Perform required blood sampling.
4. Immediately flush the catheter with a minimum of 10 ml of saline followed by 5 ml of heparinized saline (100 units/ml) solution to establish the heparin lock.

Heparin Lock Procedure

1. Attach syringe containing 5 ml of heparinized saline (100 units/ml) to infusion tubing.
2. Unclamp.
3. Flush tubing and catheter.
4. Maintaining positive Power while removing syringe and needle will prevent blood reflux.

CAUTION: Maximum flow rate of 5 ml/min is recommended for heparin lock procedure. This flow will minimize blood reflux into catheter.

CAUTION: Examine injection site closely. If patient feels an abnormal sensation or pain at injection site, it may indicate the drug has extravasated. Discontinue infusion immediately and proceed with accepted extravasation protocol. Notify physician immediately.

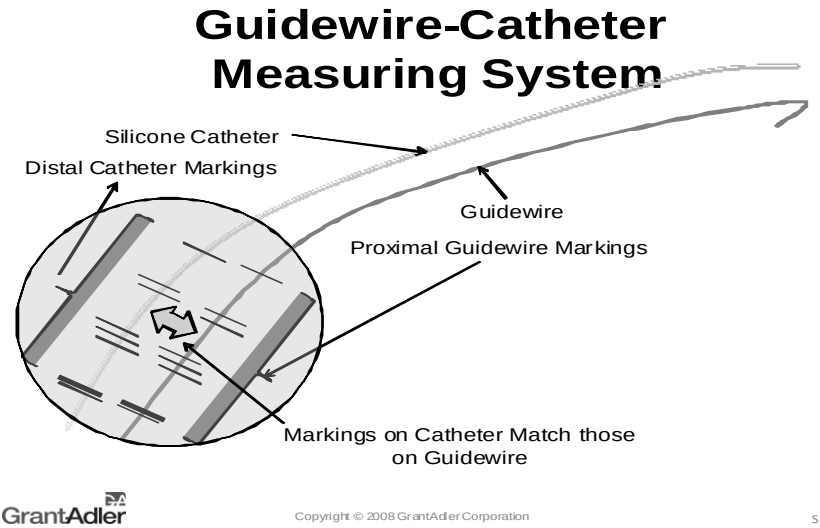
De-accessing the Port:

1. Stabilize the port using two fingers.
2. Slowly remove the non-coring needle while injecting the remaining 0.5ml of solution. Maintaining positive Power while removing syringe and needle will prevent blood reflux.
3. Position and secure height adjustable wings of infusion set.

Catheter and Guidewire Measuring System:

Introduction:

Reinforced catheters offer several tangible advantages over non-reinforced catheters including resistance to rupture, fracture pinch-off and kinking.



The table below shows the relationship between the GrantAdler Guidewire markers and GrantAdler / Trim-able catheter trim marks.

Guidewire catheter trim mark	
1 Band	23.0 cm
2 Bands	27.0 cm
3 Bands	32.0 cm
4 Bands	38.0 cm

Caution: Catheter fit, length, and positioning should always be verified using fluoroscopy, or appropriate technology.

System Assembly Procedures:

1. Align port stem with catheter lumen.

2. Advance catheter over port stem.

3. Ensure the catheter completely covers the port stem and is flush with the port body.

WARNING: A catheter not fully advanced to the proper region of the stem may not seat securely and lead to dislodgment and extravasation.

CAUTION: Under qualified testing procedures, the port to catheter connection allows for 16-18 pounds of axial load and 25-28 pounds of lateral load. However, once the catheter is connected to the port, do not pull on or attempt to remove the catheter from the port stem. If the catheter is not completely secured to the stem, replace with a new port and catheter.

PRECAUTION: Do not use surgical instruments for assembly. Cleanse all system components with irrigation.

Implantation

Initial Procedures:

1. The Rhapsody CT+ Vascular Access System is supplied in a double sterile tray.

2. Examine all packaging before opening to confirm tray, lid, or pouch integrity.

3. Do not use any device if any part of its packaging is damaged, punctured, or opened.

4. Visually inspect the tray to ensue the presence of all necessary components.

5. Complete patient implant record, including product reorder number and lot number.

6. Select implantation procedure to be used.

7. Select the site for port placement.

8. Select the site for vein access.

9. Select the tunneling technique.

10. Perform adequate anesthesia.

11. Create sterile field and open tray.

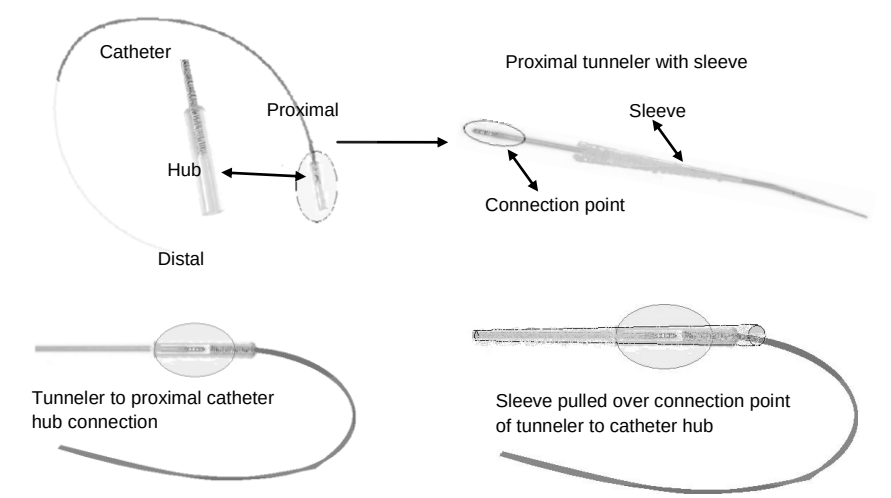
12. Surgically prep and drape the implantation and vein access site.

Tunneler Instructions:

Individual operator preference will dictate tunneling technique. The GrantAdler Rhapsody CT+ Vascular Access System is designed to accommodate either standard ante-grade or standard retrograde tunneling technique.

Retrograde Technique:

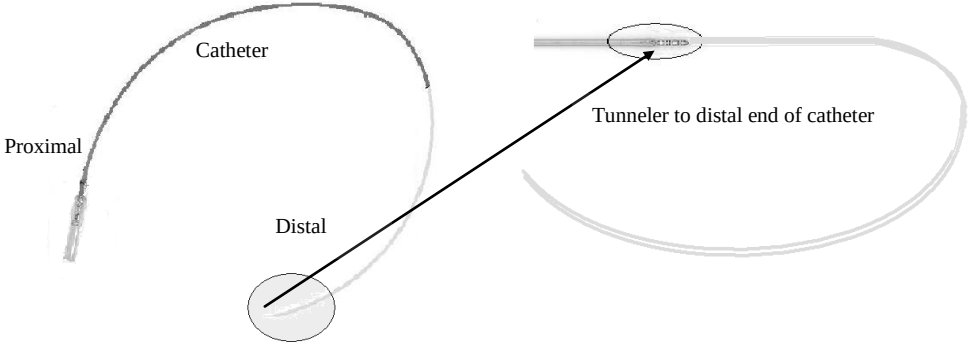
1. Attach the proximal end of the catheter (larger end with catheter-port hub) to the proximal tunneler (the bent tunneler). Be sure that the hub is completely attached to the tunneler. Slide the sleeve down so that it completely covers the tunneler-catheter connection point. (See diagrams below)



2. Using either a mosquito clamp or hemostat, gently stretch the 1-3 mm incision made at the venous access site.
3. Carefully work the tapered blunt end of the proximal tunneler (the bent tunneler) through the access incision passing it through the tissue so that it emerges in the port pocket.
4. Carefully draw the tunneler, with catheter attached, completely through the pocket pulling the catheter-port hub from the access site to the pocket. Care should be taken to ensure that the hub is not drawn too far into the pocket. It should be drawn far enough to ensure proper port attachment length.
5. Detach the tunneler from catheter hub.
6. Continue with procedure.

Ante-Grade Technique:

1. Attach the distal end of the catheter (small thin end) to the distal tunneler (the straight tunneler). Be sure that the catheter is completely attached to the tunneler.



2. Carefully work the tapered blunt end of the distal tunneler (the straight tunneler) through the pocket passing through the tissue so that it emerges at the access site.

3. Carefully draw the tunneler, with catheter attached, completely through the access site pulling the catheter from the pocket to the access site. Care should be taken to ensure the catheter is drawn through the pocket leaving sufficient length to ensure proper port attachment.

4. Detach the tunneler from catheter.

5. Continue with procedure.

Procedure Utilizing Remote Percutaneous Vein Access and A GrantAdler Trim-able Catheter

1. Read the “Contraindications, Warnings, Cautions, and Possible Complications” sections of this manual before beginning procedure.

2. Follow general port placement guidelines described under “Initial Procedures”.

3. Select site for Port. Port pocket site selection should allow for port placement in an anatomic area for good port stability.

4. Create a subcutaneous pocket for the port using an incision by either sharp or blunt dissection down to underlying fascia.

5. Select appropriate venous access point.

6. Access vein using standard needle technique.

7. Insert the distal tip of the GrantAdler Guidewire through needle and advance the wire 5-10 cm into the vein.

Caution: In order to utilize the Rhapsody CT+ Vascular Access System the operator must always use the GrantAdler Guidewire to determine appropriate GrantAdler Catheter length selection.

8. Verify guidewire position with real time fluoroscopy.

9. Remove the access needle.

10. Under fluoroscopic control advance the GrantAdler Guidewire so that the distal tip is positioned at the junction of the Superior Vena Cava (SVC) and Right Atrium (RA).

11. After the distal end of the guidewire is positioned at the Superior Vena Cava / Right Atrium junction, overlay the external part of the guidewire from venous access point over site of pocket. There should be 4 catheter length markers visible over the pocket site. The distance from the distal end of the guidewire to the marking point on the guidewire which overlies the pocket site will determine the correct catheter length.

12. Identify the guidewire marking pattern which properly overlays the pocket site.

13. Match the GrantAdler Guidewire pattern which overlays the pocket site to the corresponding pattern on the GrantAdler Trim-able Catheter to select the appropriate catheter trim point. Secure the guidewire to prevent further advancement into the vascular system. (See Catheter and Guidewire Selection)

14. Trim the catheter below the wire-reinforcement.

Caution: Do not ever cut, trim, or adjust the catheter above the wire-reinforcement. Doing so may expose the wire-reinforcement embedded in the catheter wall.

15. Enlarge skin incision over guidewire vein insertion point by 3 mm using either a number 11 blade or a hemostat. (See Tunneler Instructions)

16. Attach a saline filled syringe to the proximal end of the catheter and flush the catheter leaving the syringe attached.

17. Select appropriate French-size sheath introducer.

18. Advance the dilator/sheath over the exposed guidewire.
19. Release the guidewire and remove the dilator and guidewire leaving the sheath in place.

Warning: Hold thumb over exposed opening of sheath to prevent air aspiration.

20. Insert the distal end of the saline filled catheter into the sheath.
21. Peel away the sheath.
22. Remove syringe from proximal catheter end and attach the proximal catheter end to the port in the port pocket. (See System Assembly)
23. Secure port body to underlying fascia using non-absorbable sutures and a minimum of 3 suture sites. Care should be exercised so that the incision does not cross the septum of the port after closure.

Caution: Avoid piercing catheter with suture needle.

24. Prior to site closure; aspirate the port-catheter system thoroughly via the septum using a non-coring needle to confirm ability to withdraw blood.
25. Flush port with 20cc of sterile saline to remove all blood from the system.
26. Follow heparin lock procedure.
27. Maintain positive Power on syringe plunger to avoid reflux of blood into catheter tip.
28. Stabilize port while withdrawing needle.

Precaution: A 90 degree non-coring needle with winged infusion set may be positioned, at the surgeon's discretion, transcutaneously in the port septum intra-operatively for patient comfort during initial access.

29. Close incision after site irrigation by appropriate standard surgical technique. Dress site per hospital protocol.
30. Follow heparin lock protocol.

Surgical Cut-Down:

1. Read the "Contraindications, Warnings, Cautions, and Possible Complications" sections of this manual before beginning procedure.
2. Follow general port placement guidelines described under "Initial Procedures."
3. A small incision is made to expose the target vein using standard technique. Isolate vessel, using standard surgical technique.
4. Introduce the distal tip of the GrantAdler Guidewire through an appropriate venotomy and advance until the tip is confirmed to be at the Superior Vena Cava and Right Atrium junction via radiograph. Use standard technique to avoid air entry to the vein.
5. Use the length marking patterns on the GrantAdler Guidewire to select the appropriate trim point on the catheter. (See Instructions)
6. Always trim the catheter below the wire-reinforcement.

Caution: Do not ever cut, trim, or adjust the catheter above the wire-reinforcement. Doing so may expose the wire-reinforcement embedded in the catheter wall.

7. Slide appropriately trimmed catheter over guidewire.
8. Remove guidewire.
9. Attach port to the catheter. (See System Assembly)
10. Secure port body to patient. (See Percutaneous Procedure)

11. Anchor catheter at venotomy site. Avoid excessive suture tightness to prevent catheter occlusion.
12. Confirm catheter position and port placement by appropriate radiographic technique. Follow with closing instructions #24 – #30 from previous section.

Caution: Sufficient slack should be left between port and catheter insertion point to mitigate strain on the catheter. When using external jugular vein, carefully position the catheter over clavicle to avoid kinking or occlusion.

Precaution: A 90 degree non-coring needle with winged infusion set may be positioned in the port septum intraoperatively for patient comfort during initial access.

Power Injection Procedure:

Confirm the catheter's distal tip is in the appropriate location using established institutional protocol to verify correct catheter position prior to Power injection.

1. Access the port with an infusion set indicated for Power injection of contrast media. Make certain the needle tip is inserted completely into the port. Listen for a "click". WARNING: The Rhapsody CT+ system is only Power injectable when accessed with needles indicated for Power injection.
2. Prior to checking patency, attach a syringe filed with sterile normal saline. Instruct the patient to assume the position they will be in during the Power injection procedure. 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.
3. Check for patency by aspirating for adequate blood return and vigorously flushing the port with at least 10 ml of sterile normal saline. WARNING Failure to ensure patency of the catheter prior to Power injection may result in port system failure.
4. Detach syringe and warm contrast media to body temperature.
5. Attach the Power injection device to the Power-rated injection needle. Ensure connection is secure. Check indicated flow rate of infusion set and confirm CT machine settings.

Power-rated Injection Needle Size	19 GA	20 GA	22 GA
Maximum Flow Rate Setting	5ml/s	5ml/s	2ml/s

6. Instruct the patient to immediately communicate any pain, discomfort, or any change during the injection.
7. Inject the pre-warmed contrast, while not exceeding the flow rate limits. WARNING Failure to warm contrast media to body temperature prior to Power injection may result in port system failure. Injections should be stopped if pain or swelling is detected. Do not exceed maximum flow rates.
8. Disconnect the Power injection device.
9. Flush the system with 10ml of sterile normal saline.
10. Perform heparin lock procedure. WARNING: Do not use heparin with patients who are hyper-sensitive to heparin or suffer.
11. At the conclusion of the Power injection procedure, flush the port system following institutional protocols. Close clamp while injecting the remaining 0.5 ml of flush solution.
12. Remove the Power injection needle from the device and dispose of properly.

WARNING: Do not exceed Power injection setting limit of 300psi on the Power injection machine being used. Do not exceed maximum flow rate setting per needle gauge on the Power injection machine being used.

Label

This product is free of latex content.

This product is free of DEHP content.

This product is single use only. Do not re-sterilize.

See warnings and cautions in this manual.

United States Federal law restricts the sale, order and use of this device to licensed physicians only.

Maximum CT Power of 300 psi.

MR Conditional up to 3T.

MR Safety Information:

Non-clinical testing has demonstrated that the Rhapsody CT+ Vascular Access System is MR Conditional. A patient with this implant can be scanned safely immediately after placement under the following conditions:

— Static magnetic field of 3-Tesla or less

— Spatial gradient magnetic field of 720-Gauss/cm or less

— Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 3-W/kg for 15 minutes of scanning. In non-clinical testing, the Rhapsody CT+ Vascular Access System produced a temperature rise of 0.7°C at a maximum MR system-reported whole body averaged specific absorption rate (SAR) of 3-W/kg for 15-minutes of MR scanning in a 3-Tesla MR system using a transmit/receive body coil (Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI).

For Minimal Image artifact:

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Rhapsody CT+ Vascular Access System. Therefore, optimization of MR imaging parameters to compensate for the presence of this implant may be necessary.

Summary of MRI artifacts at 3-Tesla:

(T1-SE, T1-weighted spin echo; GRE, gradient echo; N/A, not applicable)

Signal Void Size	2,559-mm2	478-mm2	7,084-m2	4,662-mm2
Static Magnetic Field (T)	3	3	3	3
Pulse Sequence	T1-SE	T1-SE	GRE	GRE
TR (msec.)	500	500	100	100
TE (msec.)	20	20	15	15
Flip Angle	N/A	N/A	30˚	30˚
Bandwidth	16 kHz	16 kHz	16 kHz	16 kHz

Signal Void Size	2,559-mm2	478-mm2	7,084-m2	4,662-mm2
Field of View	24 cm	24 cm	24 cm	24 cm
Matrix Size	256 x 256	256 x 256	256 x 256	256 x 256
Section Thickness	10 mm	10 mm	10 mm	10 mm
Imaging Plane	parallel (long axis)	perpendicular (short axis)	parallel (long axis)	perpendicular (short axis)

System Maintenance and Care:

Syringes: 10CC syringes or larger are required for all flushing or injection procedures. Use of smaller syringes may result in system damage.

Needles: Use only non-coring (Huber point) needles for routine therapeutic access and Power-rated injection needles for contract injection during imaging.

Septum Puncture Life: Under qualified testing procedures, the septum allows up to 2,000 punctures when tested at 10 psi using a 22 gauge non-coring needle. This Power exceeds typical levels experienced in clinical practice.

Site Preparation: Always access the system using proper sterile technique.

Saline Flushes: Prior to drug administration, aspirate the system with saline solution to remove heparin. If more than one drug is administered, flush the system with saline solution between each drug. After patient treatment is completed, always flush the system with 10 cc of sterile normal saline using the heparin lock procedure. This will cleanse the catheter and port chamber.

Venous Systems: After each use, the port should be flushed with at least 20 ml of normal saline. A heparin lock should follow. Heparin lock should be administered every 4 weeks if the port is not in use.

Heparin Flush Schedule: To help prevent clot formation the system must be flushed with heparinized saline at regular intervals.

Heparin Concentration: (100 units/ml) of heparinized saline. The typical volume is 5 ml.

Patient Identification Card: A Patient Identification Card and 4 stickers accompany each port. The completed card should be given to the patient and carried at all times. 1 sticker should be place on patient identification card and the remaining should be used to document charts per hospital procedures.

Questions: Questions regarding use of GrantAdler products may be directed to the GrantAdler Corporation via our toll free number 800-605-4815 or at our website www.grantadler.com.

Discontinuing use:

Explanting of the System: GrantAdler recommends that the system be explanted once it has been determined that it is no longer required for therapy. After removal, the system may present a potential biohazard. Handle and discard all materials in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

Returns: Should it become necessary to explant the port-catheter system due to suspected or confirmed malfunction, the system must be returned to GrantAdler for analysis. GrantAdler's customer service department is available via our toll free number 800-605-4815 or our website www.grantadler.com to answer questions regarding returns. Please obtain a Return Authorization number, RA, by contacting GrantAdler prior returning any products. Returns will not be accepted without RA numbers assigned and must be properly packaged in an explant kit.

Explant Kits: GrantAdler will provide an explant kit for use in storage and shipment of the explanted device. Hospitals must advise GrantAdler of any infectious diseases that the patient is known to have.

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