medCOMP®

ProFUSE CT
CT Implantable Port
& Dignity

CT PORTS
Nurse Guide

ProFUSE CT

CT Implantable Port

& Dignity™

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DEVICE DESCRIPTION

The MedComp® CT Port is a device designed to provide repeated access to the vascular system as well as withstand the elevated pressures experienced during power injection. The port consists of a reservoir component sealed by a puncture-able silicone septum and a connected catheter. All materials are biocompatible, can be used with virtually all injectable solutions, are latex-free, and are safe with CECT and MRI imaging. Port access is performed by percutaneous needle insertion using a non-coring needle. Power injection is performed using a power injectable Huber needle only. MedComp® CT Ports can be identified by an x-ray scan which will reveal the letters “CT” printed on the port base, the Medcomp® CT Port record sticker, patient information card, and patient identification key ring tag.

INDICATIONS FOR USE

The Medcomp® CT 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, and for the withdrawal of blood samples.

When used with a power injectable Huber needle, the Medcomp® CT Port is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s with a 19 GA or 20 GA non-coring needle and 2 ml/s with a 22 GA non-coring needle. The machine pressure setting should not exceed 300 psi.

WARNINGS

- Intended for Single Patient Use. DO NOT REUSE. Medcomp 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 a non-power injectable needle during the power injection will lead to system failure and possible 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 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.

WARNINGS ▸CONTINUED

- 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 port.

NEEDLE GAUGE SIZE	19 GA	20 GA	22 GA
MAXIMUM FLOW RATE*	5ml/s	5ml/s	2ml/s
MAX PRESSURE*	300 psi		

**Machine setting*

- The MedComp® CT 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. MedComp® CT Ports are only power injectable when accessed with a power injectable Huber needle.

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.

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 Erosion Through the Skin
- Catheter Embolism
- 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

IDENTIFYING A MEDCOMP® CT PORT PATIENT

It is possible to differentiate a Medcomp® CT Port from a non-power injectable port through the following means:

Check patient's chart for Medcomp®CT Port patient record sticker.

X-ray imaging of the port reveals the letters "CT" printed on the port.

Patients may aid in port confirmation by presenting the patient identification card or key ring tag they received when the port was implanted.

◀ Pro-Fuse® Packet

Dignity™ Packet ▶

A minimum of two forms of identification should be used to confirm any Medcomp® CT Port.

For additional guidance on recognizing a Medcomp® CT Port, contact Medcomp at 800-220-3791 or www.**medcompnet**.com.

USE AND MAINTENANCE

SITE PREPARATION

Inspect and aseptically prepare the injection site prior to and whenever accessing the port. Additional sterile precautions may follow hospital protocol.

Equipment

- Alcohol or Chlorhexidine Wipe
- Antiseptic Swabs
- 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. Don sterile gloves and follow your hospital protocol for sterile precautions. Cleanse or scrub the area according to the cleansing agent manufacturers' instructions and institutional protocol. Allow to dry completely.

   DIRECTIONS FOR THE USE OF CHLORAPREP: Prepare the site with ChloraPrep One-Step Applicator or according to the institutional policy using sterile technique. "Pinch-Off" the wings on the ChloraPrep 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 circular motions working outward with 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 (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
- Non-Coring Needle
- Sterile Gloves
- If the port will be accessed for power injection, it must be accessed with a power injectable Huber needle 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 top of port with non-dominant hand.
   b. Position port between thumb and first two fingers of non-dominant hand. Aim for center point of these three fingers. Insert non-coring needle perpendicular to port septum. Advance needle through the skin and septum until reaching bottom of reservoir.
3. Verify correct needle placement and patency by blood aspiration and flushing.
4. Always flush the port following injection.
5. Perform heparin lock procedure. 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.
6. When deaccessing the port, the needle should be removed using the positive pressure technique, 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.

BOLUS INJECTION PROCEDURE OTHER THAN POWER INJECTION

Equipment

- A 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 a 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. With vascular access confirm correct needle placement within the port reservoir by aspiration of blood ("flashback").
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 inject drug administration slowly.

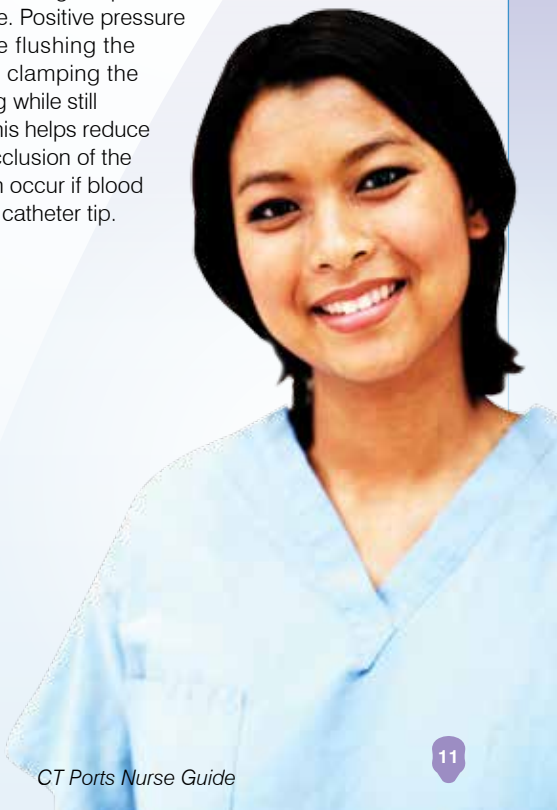
   CAUTION: Examine the injection site closely for signs of extravasation; if noted, immediately discontinue the injection and initiate accepted extravasation protocol and notify physician immediately.
6. When the injection is completed, clamp the extension set.
7. Flush after each injection with 10 ml of sterile normal saline to help prevent interaction between incompatible drugs.

8. Flush port with 5 ml heparinized saline after every use and at least once every 4 weeks.

   NOTE: 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.

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 occlusion of the catheter which can occur if blood backflows into the catheter tip.



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
- A 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
- 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 a 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. With vascular access confirm correct needle placement within the port reservoir by aspiration of blood ("flashback").
4. Secure needle with transparent dressing to help prevent inadvertent dislodgement.
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. 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.

    NOTE: 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 occlusion of the catheter which can occur if blood backflows into the catheter tip.

USE AND MAINTENANCE ▸CONTINUED

BLOOD SAMPLING PROCEDURE

Equipment

- Extension set with clamp
- A 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 using aseptic technique.
2. Aseptically locate and access port with a non-coring safety needle. With vascular access confirm correct needle placement within the port reservoir by aspiration of blood ("flashback").
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 flush 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.

POWER INJECTION PROCEDURE

1. Verify patient has a Medcomp® CT Port. See "Identifying a Medcomp® CT Port Patient".

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

2. Ensure the port is accessed with a power injectable Huber needle. Make certain that the needle tip is inserted fully within the port.

   WARNING: A power injectable Huber needle must always be used to access the Medcomp® CT Port for power injecting contrast media.

3. Attach a syringe filled with sterile normal saline.
4. 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 the CECT procedure.

   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. 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 auxillary and subclavian veins at the thoracic outlet.
8. Attach the power injection device securely to the power injectable Huber needle.
9. Check table on following page to confirm the maximum flow rate and maximum pressure setting.

USE AND MAINTENANCE ▸CONTINUED

POWER INJECTION PROCEDURE ▸CONTINUED

NEEDLE GAUGE SIZE	19 GA	20 GA	22 GA
MAXIMUM FLOW RATE*	5ml/s	5ml/s	2ml/s
MAX PRESSURE*	300 psi		

**Machine setting*

WARNING: *Do not exceed a 300 psi pressure limit setting, or the maximum flow rate setting shown.*

1. Inject warmed contrast, taking care not to exceed the flow rate limits.
2. Disconnect the power injection device.
3. Flush the Power Injectable Implantable Infusion Port with 10 ml of sterile normal saline.
4. Perform heparin lock procedure. 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.
5. After therapy completion, flush port per institutional protocol.

HEPARIN LOCK PROCEDURE

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 (positive pressure technique) 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 Medcomp® CT Port devices, you will need to determine the length of catheter used for each individual patient, check the patient's chart for the length that was used.
- For system priming volume, multiply the catheter length in cm by 0.02 ml/cm then add the priming volume for the particular port configuration as follows:

  Low Profile Ports: 0.39 ml
  Intermediate Ports: 0.56 ml
  Standard Ports: 0.64 ml

Example

CATHETER LENGTH
_____ cm x 0.02 ml/cm + 0.56ml (Intermediate port) = _____ ml volume, total priming volume for patient port and catheter.

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

USE AND MAINTENANCE ▸CONTINUED

RECOMMENDED FLUSHING VOLUMES

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

Equipment

- Non-coring safety Huber 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 doctor's 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. Position 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 non-coring safety Huber needle 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.

   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 Pro-Pierce™ 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 Pro-Pierce™ safety infusion set.

TROUBLESHOOTING GUIDE

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 obstruction. 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 past 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 the 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 sterile normal saline. 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 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.

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 fibrolytic agent before power injecting. Physician discretion advised.

TROUBLESHOOTING GUIDE ▸CONTINUED

CATHETER OCCLUSION

DO NOT POWER INJECT AN OCCLUDED DEVICE.

A. Possible Causes

1. Blood clot completely obstructing lumen.
2. Catheter may be kinked, coiled, damaged or compressed between the clavicle and the first rib.
3. Catheter tip may not be within vein.
4. Catheter 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

Ask responsible nurse or physician to attempt to aspirate blood clot.

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.

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:

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

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.

FURTHER INFORMATION

Patient Education Card

Medcomp® CT Port Tech Guide

Medcomp® CT Port Tech Guide Poster

See a Medcomp sales representative for more information about these products.

NOTES

CT PORTS Nurse Guide

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