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Dignity® Dignity® Titanium Pro-Fuse® Dignity® Dual

MEDCOMP® CT PORTS

Tech Guide

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DEVICE DESCRIPTION

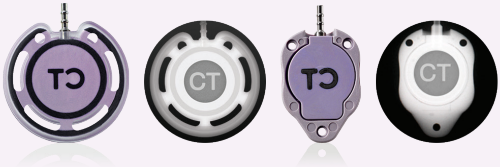
The Medcomp® CT Ports are devices designed to provide intravenous access in patients who require frequent or continuous administration of intravenous substances. In addition, the Medcomp® CT Ports have the ability to withstand the elevated pressures experienced during power injection. The ports consist of a reservoir component sealed by a puncture-able silicone septum and a connected catheter. All materials are bio-compatible, latex-free, and are safe with CECT and MRI imaging. The port is accessed utilizing a percutaneous insertion with a non-coring needle. Power injection is performed using a power injectable needle only. All Medcomp® CT Ports can be identified under radiographic imaging which will reveal the letters “CT” printed on the port base.

IDENTIFICATION

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

Radiographic Imaging

Radiographic imaging of the port reveals the letters "CT" printed on the port.



Patient Identification Card & Key Ring Tag

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 215.256.4201 or visit www.medcomp.net.

INDICATIONS FOR USE

Adult Dignity® & Pro-Fuse® Ports

The Medcomp® Gen III Power Injectable 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 power injectable needle, the power injectable infusion 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- or 20-gauge non-coring power injectable needle. The maximum recommended infusion rate is 2 ml/s with a 22-gauge non-coring power injectable needle.

Pediatric Dignity® Ports

The CT Power Injectable Implantable Infusion Ports are indicated for pediatric 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. The maximum recommended infusion rate is 5ml/s with a 19 or 20 gauge non-coring power injectable needle. The maximum recommended infusion rate is 2 ml/s with a 22 gauge non-coring power injectable needle.

Dignity® Titanium Ports

The CT Power Injectable Implantable Infusion 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 power injectable needle, the Power Injectable Implantable Infusion Port device 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- or 20-gauge non-coring power injectable needle. The maximum recommended infusion rate is 2 ml/s with a 22-gauge non-coring power injectable needle.

Dignity® Dual Ports

The Dignity® Dual Port is a power injectable implantable infusion port that is indicated for patient therapies requiring repeated access to the vascular system. The Dignity® Dual Port 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 power injectable needle, the Dignity® Dual 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 or 20 gauge non-coring power injectable needle. The maximum recommended infusion rate is 2 ml/s with a 22 gauge non-coring power injectable needle.

USE & MAINTENANCE INSTRUCTIONS

Standard

- Skin asepsis is performed prior to each access of the implanted device.
- Implanted devices are accessed only with non-coring needles. Only power injectable non-coring needles should be used power injection equipment for radiological imaging.
- A sterile dressing is maintained over the access site if the port remains accessed.

Access Procedure

Note: Follow established hospital or institutional policy for implanted port access and maintenance.

- Assess port site in preparation for port access: observe/palpate for swelling, pain, erythema, and drainage.
- Perform skin antisepsis and allow to fully dry prior to port access.
- Don sterile gloves to palpate or locate port site after skin antisepsis and prior to insertion of non-coring needle.
- Access the port with the smallest-gauge non-coring needle to

accommodate the prescribed therapy.

- When a dual port is present, each port should be considered independent for access and maintenance.
- Flush and lock the port to assess function and maintain patency.
- Ensure presence of a blood return upon insertion of a non-coring needle and prior to each infusion to ensure patency.
- Flush and lock.

Power Injection Procedure

1. Verify patient has a Medcomp® CT Port. See "Identifying Medcomp® CT Port."
   Note: It is recommended that catheter tip placement be verified through institutional protocol.
2. Ensure the port is accessed with a power injectable needle. Make certain that the needle tip is inserted fully within the port.
   Warning: A power injectable 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. For the Dignity® Dual Port, aspirate and flush both reservoirs/lumens.
   Warning: Failure to ensure patency of the catheter prior to power injection studies may result in port system failure.
5. Detach syringe.
6. Ensure contrast is at proper viscosity prior to power injection. Refer to contrast agent manufacturer recommendations.
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 needle.

9 Check the tables below to confirm the maximum flow rate and maximum pressure setting:

Dignity® Titanium & Pediatric Ports			
Needle Gauge Size	19 GA	20 GA	22 GA
Maximum Flow Rate*	5ml/sec	5ml/sec	2ml/sec
Max Pressure*	300 psi	300 psi	300 psi

*Machine Setting

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

Adult Plastic Dignity® & Pro-Fuse® Ports			
Needle Gauge Size	19 GA	20 GA	22 GA
Maximum Flow Rate*	5ml/sec	5ml/sec	2ml/sec
Max Pressure*	325 psi	325 psi	325 psi

*Machine Setting

Warning: Do not exceed a 325 psi pressure limit setting, or the maximum flow rate setting shown.

10 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.

11 Disconnect the power injection device.

12 Flush the Medcomp® CT Port with 10 ml of sterile normal saline.

13 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.

14 After therapy completion, flush port per institutional protocol. Close clamp while injecting last 0.5ml of flush solution.

TROUBLESHOOTING GUIDE

I Aspiration Difficulties

Do not power inject if you cannot aspirate as patient injury may result.

Possible Causes:

1. Intraluminal clotting complete or partial.
   a. Complete intraluminal clotting fully obstructs infusion or aspiration.
   b. Partial intraluminal clotting freely or with resistance infuses but produces little or no blood return during aspiration.
2. Malposition of the distal catheter tip.
3. Compression or transection of the catheter between the clavicle and first rib (pinch-off syndrome).
4. Kinked catheter.

Possible Interventions:

1. If port flushes without resistance but does not aspirate a blood return, reposition patient and re-attempt flush and aspiration.
2. If flush or infusion resistance is noted immediately stop and inform physician.

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.

If resistance with flushing or infusion is noted immediately stop and notify the physician.

IV Catheter Occlusion

Do not power inject an occluded device.

Possible Causes:

1. Intraluminal clotting complete or partial.
   a. Complete intraluminal clotting fully obstructs infusion or aspiration.
   b. Partial intraluminal clotting freely or with resistance infuses but produces little or no blood return during aspiration.
2. Malposition of the distal catheter tip.
3. Compression or transection of the catheter between the clavicle and first rib (pinch-off syndrome).
4. Kinked catheter.

Possible Interventions:

1. If port flushes without resistance but does not aspirate a blood return, reposition patient and re-attempt flush and aspiration.
2. If flush or infusion resistance is noted immediately stop and inform physician.

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 indicated by the table on the next page:[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.

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, 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

IMPORTANT RISK INFORMATION

Adult Dignity® & Pro-Fuse® Ports Indications for Use

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Dignity® Titanium Ports Indications for Use

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Dignity® Dual Ports Indications for Use

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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,] 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.

Refer to Instructions for Use provided with the product for complete instructions, warnings, precautions and contraindications. Observe all Instructions for Use prior to using products. Failure to do so may result in patient complications.

References

1 Jacobs, D.M. et. al., "Anatomical and Morphological Evaluation of Pacemaker Lead Compression. PACE. 1993 Mar; 16(1):434-444.

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.

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PN2780US Rev. A 11/25