

## PORT IMPORTANT RISK INFORMATION

### DIGNITY® CT PORTS

**Indications for Use:** 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.

**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. 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.

### DIGNITY® TITANIUM

**Indications for Use:** 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.

**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. 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.

### PRO-FUSE® CT

**Indications for Use:** 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.

**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. 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.



Plastic  
Port Material

Mini,  
Low Profile,  
Mid-Sized,  
Dual  
Configurations

Polyurethane,  
Silicone  
Catheter Materials

5cc/sec  
@ 325psi  
Injection Rating

Attachable,  
Pre-Attached  
Catheter  
Configurations

5F, 6.6F,  
8F, 9.5F, 9.6F  
French Sizes

Ports



CT UNDER X-RAY



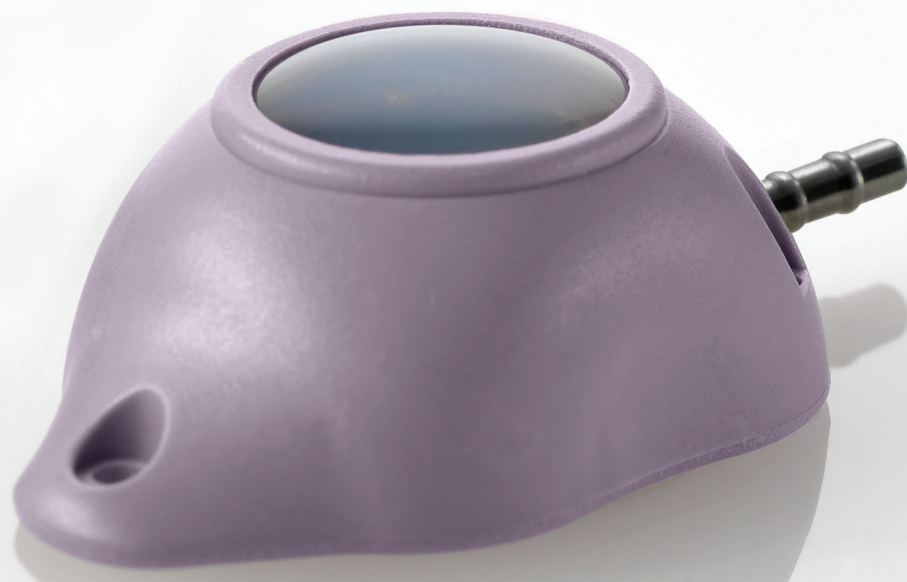


	OPEN SUTURE HOLES		SILICONE FILLED SUTURE HOLES		
		WITH MICRO INTRODUCER		WITH MICRO INTRODUCER	
<b>DIGNITY® MINI</b>					
5F ATTACHABLE	MRDP50ASN	–	MRDP50AXS	MIDP50AXS	5/BOX
6.6F ATTACHABLE	MRDP66ASN	MIDP66ASN	MRDP66AXS	MIDP66AXS	5/BOX
8F ATTACHABLE	MRDP80ASN	–	MRDP80AXS	MIDP80AXS	5/BOX
5F PRE-ATTACHED	MRDP50PSN	–	–	–	5/BOX
<b>DIGNITY® LOW PROFILE</b>					
6.6F ATTACHABLE	MRDP66ALN	–	MRDP66ALS	–	5/BOX
8F ATTACHABLE	MRDP80ALN	–	MRDP80ALS	MIDP80ALS	5/BOX
5F PRE-ATTACHED	–	–	MRDP50PLS	–	5/BOX
6.6F PRE-ATTACHED	MRDP66PLN	–	MRDP66PLS	–	5/BOX
8F PRE-ATTACHED	MRDP80PLN	–	–	–	5/BOX
<b>DIGNITY® MID-SIZED</b>					
6.6F ATTACHABLE	MRDP66AMN	MIDP66AMN	MRDP66AMS	MIDP66AMS	5/BOX
8F ATTACHABLE	MRDP80AMN	MIDP80AMN	MRDP80AMS	MIDP80AMS	5/BOX
6.6F PRE-ATTACHED	MRDP66PMN	MIDP66PMN	MRDP66PMS	–	5/BOX
8F PRE-ATTACHED	MRDP80PMN	MIDP80PMN	MRDP80PMS	–	5/BOX
<b>DIGNITY® MID-SIZED WITH SILICONE CATHETER</b>					
9.6F ATTACHABLE	MRDP96AMN	–	–	–	5/BOX
9.6F PRE-ATTACHED	–	–	MRDP96PMS	–	5/BOX
<b>DIGNITY® MID-SIZED DMP</b>					
6.6 ATTACHABLE DMP	MDDP66AMN	–	MDDP66AMS	–	5/BOX
8F ATTACHABLE DMP	MDDP80AMN	–	MDDP80AMS	–	5/BOX
<b>DIGNITY® DUAL</b>					
9.5F ATTACHABLE	MRDP95ADN	–	MRDP95ADS	MIDP95ADS	5/BOX

 Silicone Catheters



MR Conditional – 3 Tesla (artifacts may present imaging problems if MRI area of interest is on or near area where device is located)



Refer to the Table of Contents for Important Risk Information regarding this device.

**DIGNITY® MINI, LP & MID SET CONTENTS:**

- (1) CT Implantable Port
- (1) Catheter
- (2) Catheter Locks
- (1) Scalpel
- (1) Introducer Needle
- (1) Guidewire
- (1) 10cc Syringe
- (1) Peelable Introducer
- (1) Tunneler\*
- (2) 22ga Huber Needles  
(1 Straight, 1 Right Angle)
- (1) Blunt Tip Needle
- (1) Patient Information Pack
- (1) Patient Chart Sticker

**DIGNITY® DUAL SET CONTENTS:**

- (1) CT Implantable Port
- (1) Catheter
- (2) Catheter Locks
- (1) Scalpel
- (1) Vein Pick
- (1) Guidewire
- (1) 10cc Syringe
- (1) Peelable Introducer
- (1) Tunneler
- (2) 22ga Huber Needle  
(1 Straight, 1 Right Angle)
- (1) Blunt Tip Needle
- (1) Patient Information Pack
- (1) Patient Chart Sticker

**DIGNITY® MID DMP SET CONTENTS:**

- (1) CT Implantable Port
- (1) Catheter
- (2) Catheter Locks
- (1) Scalpel
- (1) Introducer Needle
- (1) Guidewire
- (1) 10cc Syringe
- (1) Peelable Introducer
- (1) Tunneler\*
- (2) 22ga Huber Needle  
(1 Straight, 1 Right Angle)
- (1) Blunt Tip Needle
- (1) Patient Information Pack
- (1) Patient Chart Sticker

**ADDITIONAL MICRO KITS CONTENTS:**

- (1) 5F Coaxial Micro-Stick®
- (1) Guidewire with Radiopaque Tip
- (1) 21ga Introducer Needle with Echogenic tip

\* 8F KITS have (2) Tunnelers