

IMPORTANT RISK INFORMATION

Pro-Fuse® & Dignity® 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.

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.

Dignity® Dual Indications for Use

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.

Contraindications

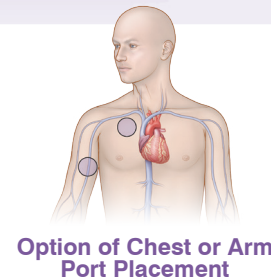
This device is contraindicated for catheter insertion in the subclavian vein medial to the border of the first rib, an area which is associated with higher rates of pinch-off.

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.

Medcomp® Implantable Ports



Medical Components, Inc.
1499 Delp Drive, Harleysville, PA 19438, U.S.A.
P: 215.256.4201 F: 215.256.1787
www.medcomp.net

ISO13485
Certified Quality System
PN2757US REV. A 2/23

medCOMP
www.medcomp.net

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

Medcomp® Dignity®

Made from an MRI-compatible lightweight plastic that allows for up to 5cc/sec power injection of contrast media for Contrast-Enhanced Computed Tomography (CECT) scans. Available in three sizes including midsize, low profile, and mini.

Medcomp® Dignity® Titanium

Made from an MRI-compatible metal that allows for up to 5cc/sec power injection of contrast media for Contrast-Enhanced Computed Tomography (CECT) scans. Available in three sizes including midsize, low profile, and mini.

Medcomp® Pro-Fuse®

Made from an MRI-compatible lightweight plastic that allows for up to 5cc/sec power injection of contrast media for Contrast-Enhanced Computed Tomography (CECT) scans. Available in two sizes including standard and low profile.

Medcomp® Dignity® Dual

Made from an MRI-compatible lightweight plastic that allows for up to 5cc/sec power injection of contrast media for Contrast-Enhanced Computed Tomography (CECT) scans.

Medcomp® Implantable Ports Features



Polyurethane or Titanium
Port body materials



Poyurethane or Silicone
Catheter materials

DIGNITY®, DIGNITY® TITANIUM, & PRO-FUSE® ORDERING INFORMATION

DIGNITY® MIDSIZE	Without Micro Introducer	With Micro Introducer	Silicone Filled Suture Holes without Micro Introducer	Silicone Filled Suture Holes with Micro Introducer
DIGNITY® ATTACHABLE, 9.6F	MRDP96AMN	–	–	–
DIGNITY® ATTACHABLE, 8F	MRDP80AMN	MIDP80AMN	MRDP80AMS	MIDP80AMS
DIGNITY® PRE-ATTACHED, 8F	MRDP80PMN	–	MRDP80PMS	–
DIGNITY® ATTACHABLE, 6.6F	MRDP66AMN	–	MRDP66AMS	MIDP66AMS
DIGNITY® PRE-ATTACHED, 6.6F	–	MIDP66PMN	MRDP66PMS	–

DIGNITY® LOW PROFILE	Without Micro Introducer	With Micro Introducer	Silicone Filled Suture Holes without Micro Introducer	Silicone Filled Suture Holes with Micro Introducer
DIGNITY® ATTACHABLE, 8F	MRDP80ALN	–	MRDP80ALS	–
DIGNITY® PRE-ATTACHED, 8F	MRDP80PLN	–	–	–
DIGNITY® ATTACHABLE, 6.6F	MRDP66ALN	–	MRDP66ALS	–
DIGNITY® PRE-ATTACHED, 6.6F	MRDP66PLN	–	MRDP66PLS	–

DIGNITY® MINI	Without Micro Introducer	With Micro Introducer	Silicone Filled Suture Holes without Micro Introducer	Silicone Filled Suture Holes with Micro Introducer
DIGNITY® ATTACHABLE, 8F	MRDP80ASN	–	MRDP80AXS	–
DIGNITY® ATTACHABLE, 6.6F	MRDP66ASN	–	MRDP66AXS	MIDP66AXS
DIGNITY® ATTACHABLE, 5F	–	–	MRDP50AXS	–
DIGNITY® PRE-ATTACHED, 5F	MRDP50PSN	–	–	–

DIGNITY® TITANIUM MIDSIZE	Without Micro Introducer	With Micro Introducer	Silicone Filled Suture Holes without Micro Introducer	Silicone Filled Suture Holes with Micro Introducer
DIGNITY® TITANIUM ATTACHABLE, 6.6F	MRDT66AMN	–	–	–
DIGNITY® TITANIUM ATTACHABLE, 8F	MRDT80AMN	–	–	–

DIGNITY® TITANIUM LOW PROFILE	Without Micro Introducer	With Micro Introducer	Silicone Filled Suture Holes without Micro Introducer	Silicone Filled Suture Holes with Micro Introducer
DIGNITY® TITANIUM PRE-ATTACHED, 6.6F	MRDT66PLN	–	–	–

DIGNITY® TITANIUM MINI	Without Micro Introducer	With Micro Introducer	Silicone Filled Suture Holes without Micro Introducer	Silicone Filled Suture Holes with Micro Introducer
DIGNITY® TITANIUM ATTACHABLE, 5F	MRDT50ASN	–	–	–
DIGNITY® TITANIUM ATTACHABLE, 6.6F	MRDT66ASN	–	–	–

PRO-FUSE®	Without Micro Introducer	With Micro Introducer	With Silicone Filled Suture Holes	Without Silicone Filled Suture Holes
PRO-FUSE® ATTACHABLE, 9.6F	–	–	MRPP96AFS	–
PRO-FUSE® ATTACHABLE, 8F	–	–	MRPP80AFS	–
PRO-FUSE® PRE-ATTACHED, 8F	–	–	MRPP80PFS	–

PRO-FUSE® LOW PROFILE	Without Micro Introducer	With Micro Introducer	With Silicone Filled Suture Holes	Without Silicone Filled Suture Holes
PRO-FUSE® ATTACHABLE, 8F	–	–	MRPP80ALS	–
PRO-FUSE® PRE-ATTACHED, 8F	–	–	MRPP80PLS	–
PRO-FUSE® ATTACHABLE, 6.6F	–	–	MRPP66ALS	–

Set Contents: (1) Power Injectable Implantable Port (1) Catheter (2) Catheter Lock (1) Scalpel (1) Introducer Needle (1) Guidewire with Advancer (1) 10cc Syringe (1) Peelable Introducer (1)2) Tunneler* (2) Huber Needle (1) Blunt Tip Needle (1) Peelable Introducer IFU (1) Port IFU (1) Patient Information Pack (1) Patient Chart Sticker

Micro Introducer Set Contents: (1) Power Injectable Implantable Port (1) Catheter (2) Catheter Lock (1) Scalpel (1) Introducer Needle (2) Guidewire (1) 10cc Syringe (1) Peelable Introducer (1) 5 FR Coaxial Dilator (1)2) Tunneler* (2) Huber Needle (1) Blunt Tip Needle (1) Peelable Introducer IFU (1) Port IFU (1) Patient Information Pack (1) Patient Chart Sticker

*8F Sets contain 2 Tunnelers

DIGNITY® DUAL ORDERING INFORMATION

DIGNITY® DUAL	Without Micro Introducer	With Silicone Filled Suture Holes	With Silicone Filled Suture Holes & Micro Introducer	Unfilled Suture Holes
DIGNITY® DUAL ATTACHABLE, 9.5F	MRDP95ADS	–	MIDP95ADS	MRDP95ADN

Set Contents: (1) Power Injectable Implantable Port (1) Catheter (2) Catheter Lock (1) Scalpel (1) Vein Pick (1) Introducer Needle (1) Guidewire with Advancer (1) 10cc Syringe (1) Peelable Introducer (1) Tunneler (2) Huber Needle (1) Blunt Tip Needle (1) Peelable Introducer IFU (1) Port IFU (1) Patient Information Pack (1) Patient Chart Sticker

Micro Introducer Set Contents: (1) Power Injectable Implantable Port (1) Catheter (2) Catheter Lock (1) Scalpel (1) Vein Pick (1) Introducer Needle (2) Guidewire (1) 10cc Syringe (1) Peelable Introducer (1) 5FR Coaxial Dilator (1) Tunneler (2) Huber Needle (1) Blunt Tip Needle (1) Peelable Introducer IFU (1) Port IFU (1) Patient Information Pack (1) Patient Chart Sticker