

## PEDIATRIC IMPORTANT RISK INFORMATION

### PEDIATRIC DIGNITY®

**Indications for Use:** 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.

**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.

### PEDIATRIC SPLIT CATH®

**Indications for Use:** The Medcomp® Pediatric Split Cath® is indicated for use in attaining Long-Term vascular access for Hemodialysis and Apheresis and in pediatric, adolescent, and adult patients as determined by the prescribing physician. It may be inserted percutaneously and is primarily placed in the internal jugular vein. Alternate insertion sites include the Subclavian and femoral vein.

**Contraindications:** This catheter is intended for Long-Term vascular access only and should not be used for any purpose other than indicated in these instructions.

### PEDIATRIC MST

**Indications for Use:** The 2F and 3F Vasco-Sheath Tearaway Introducer is intended for percutaneous venous access by modified Seldinger Technique in neonates, infants, and children.

#### **Contraindications:**

- This catheter is not intended for any use other than that which is indicated. Do not implant catheter in thrombosed vessels.
- The presence of skin related problems around the insertion site (infection, phlebitis, scars, etc.)
- The presence of device related bacteremia or septicemia.
- Previous history of venous/ subclavian thrombosis or vascular surgical procedures at insertion site.
- Fever of unknown origin.
- The patient's body size is insufficient to accommodate the size of the implanted device.
- The patient is known or is suspected to be allergic to materials contained in the device.
- Past irradiation of prospective insertion site.

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.

# SPLIT CATH®

**Polyurethane**

Material

**Split Tip**

Tip Design

**10F**

French Size

**Straight**

Configuration

**Antegrade**

Insertion Type



## 10F SPLIT CATH® III

DASPC15P-XL	10F X 15CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX
DASPC18P-XL	10F X 18CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX
DASPC24P-XL	10F X 24CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX

## BASIC SET CONTENTS:

- (1) Catheter
- (1) Introducer Needle
- (1) Guidewire
- (2) Dilators
- (1) Scalpel
- (1) Tunneler
- (1) Peelable Introducer
- (1) Adhesive Wound Dressing
- (2) End Caps
- (1) Patient ID Card

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