SHORT TERM CATHETERS IMPORTANT RISK INFORMATION

SLX®

Indications for Use: The Medcomp[®] SLX Double Lumen Catheter can be utilized for temporary access for hemodialysis, hemoperfusion, or apheresis therapy. The cannula may be inserted via the Seldinger technique due to the inner Teflon stylet, increasing linear strength. The stylet is removed after insertion, leaving the soft silicone cannula in the body. The flexible silicone make-up conforms well to the vessel anatomy, resulting in higher patient tolerance during extended use.

Contraindications: The Subclavian Approach is NOT recommended for use with the Medcomp® SLX Double Lumen Subclavian-Femoral Catheter in Hemodialysis or Hemoperfusion Procedures used for the management of acute poisoning or other situations in which a ventilator might be used due to risk of traumatic pneumothorax posing a dangerous complication for the patient.

DUO-SPLIT®

Indications for Use: The Medcomp® Duo-Split® Double Lumen Catheter is designed for acute hemodialysis and apheresis. It may be inserted percutaneously and is ideally placed in the internal jugular vein. Although this catheter may be inserted into the subclavian vein or femoral vein, the internal jugular vein is the preferred site.

Contraindications: This catheter is not intended for any use other than that which is indicated. Do not insert catheter in thrombosed vessels.

HEMO-CATH® ST

Indications for Use: The Medcomp[®] Hemo-Cath[®] ST Silicone Double Lumen Catheter can be utilized for temporary access for hemodialysis, hemoperfusion, or apheresis therapy. The cannula may be inserted via the Seldinger technique due to the inner Teflon stylet, increasing linear strength. The stylet is removed after insertion, leaving the soft silicone cannula in the body. The flexible silicone make-up conforms well to the vessel anatomy, resulting in higher patient tolerance during extended use.

Contraindications: The Subclavian Approach is NOT recommended for use with the Medcomp[®] Hemo-Cath[®] ST Double Lumen Subclavian-Femoral Catheter in Hemodialysis or Hemoperfusion Procedures used for the management of acute poisoning or other situations in which a ventilator might be used due to risk of traumatic pneumothorax posing a dangerous complication for the patient.

DUO-FLOW® 400XL

Indications for Use: The Medcomp® Duo-Flow and Duo-Flow 400XL Double Lumen Catheters are designed for acute hemodialysis and apheresis. They may be inserted percutaneously and are ideally placed in the internal jugular vein. Although these catheters may be inserted into the subclavian or femoral vein, the internal jugular is the preferred site.

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

DUO-FLOW®

Indications for Use: The Medcomp[®] Duo-Flow[®] Catheter is indicated for use in attaining Short-Term vascular access for Hemodialysis and Apheresis. It may be inserted percutaneously and is primarily placed in the internal jugular vein of an adult patient. Alternate insertion sites include subclavian vein or femoral vein as required. The curved Duo-Flow[®] Catheter is intended for internal jugular vein insertion. This catheter is indicated for a duration less than (30) days. For femoral placement, monitor catheter condition closely.

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

DUO-FLOW® SIDE X SIDE

Indications for Use: The Duo-Flow® Side X Side double lumen catheter is intended for short-term central venous access for hemodialysis, apheresis and infusion.

Contraindications: The catheter is not intended for any purpose other than indicated in these instructions. The Duo-Flow® Side X Side double lumen catheter is intended for short-term (less than 30 days) use. Do not use this catheter in thrombosed vessels or for subclavian puncture when a ventilator is in use. Do not use this catheter when: The patient's body size is insufficient to accommodate the implanted device. The superficial or deep tissue will not permit adequate device stabilization and/or access. There are known physiological limitations that will not allow placement of the device. The patient has known or suspected allergies to any of the materials in the device. The patient has received significant radiation at the intended exit site or tunnel. The patient has severe chronic obstructive lung disease.

DUO-FLOW® SOFT-LINE®

Indications for Use: The Medcomp[®] Duo-Flow[®] Soft-Line[®] and Raulerson/Duo-Flow[®] Double Lumen Internal Jugular Catheters are designed for acute hemodialysis and apheresis. They may be inserted percutaneously and are ideally placed in the jugular vein.

Contraindications: This catheter is not intended for any use other than that which is indicated. Do not implant catheter in thrombosed vessels.

T-3® CT

Indications for Use: The Medcomp[®] T-3[®] CT Catheter is a triple lumen catheter indicated for use in attaining short-term vascular access for hemodialysis, apheresis. The third internal lumen is intended for infusion, power injection of contrast media and central venous pressure monitoring. The catheter is intended to be inserted in the jugular, femoral or subclavian vein as required. The maximum recommended infusion rate is 5ml/sec for power injection of contrast media.

Contraindications: This catheter is intended for short-term (less than 30 days) vascular access only and should not be used for any purpose other than indicated in these instructions. This 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 to accommodate the size of the implanted device. When the patient is known or is suspected to be allergic to materials contained in the device. 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 may prevent proper device stabilization and/or access.

TRI-FLOW

Indications for Use: The 12F Tri-Flow Triple Lumen Catheter is indicated for use in attaining Short-Term vascular access for Hemodialysis and Apheresis. It may be inserted percutaneously and is primarily placed in the internal jugular vein of an adult patient. Alternate insertion sites include subclavian vein or femoral vein as required. The 12F Tri-Flow Triple Lumen Catheter is intended to be used less than (30) days.

Contraindications: This catheter is intended for Short-Term vascular access only and should not be used for any purpose other than indicated in these instructions. Do not insert catheter in thrombosed vessels..

TRIO-CT®

Indications for Use: The Trio-CT[®] Triple Lumen Catheter is indicated for use in attaining short-term (less than 30 days) vascular access for hemodialysis and apheresis. The third internal lumen is intended for infusion, power injection of contrast media and central venous pressure monitoring. The catheter is intended to be inserted in the jugular, femoral or subclavian vein as required. The maximum recommended infusion rate is 5ml/sec for power injection of contrast media.

Contraindications: This catheter is intended for short-term (less than 30 days) vascular access only and should not be used for any purpose other than indicated in these instructions. This 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 to accommodate the size of the implanted device. When the patient is known or is suspected to be allergic to materials contained in the device. 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 may 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.



