The Medcomp® Biv-Flex® Catheter is indicated for use in minimizing Long-Term vascular access for Hemodialysis and Apheresis.

**INDICATIONS FOR USE**
- The Medcomp® Biv-Flex® Catheter is indicated for use in minimizing Long-Term vascular access only and should not be used for any purpose other than indicated in these directions.
- To maintain peak performance of the Lock Right® Adapters, it is recommended that the adapters be replaced every 6 months.

**DESCRIPTION**
- The Biv-Flex® Catheter is manufactured from soft radiopaque polyurethane material which provides increased patient comfort while providing excellent guidewire crossability.

**CATHETER PRECAUTIONS**
- Use only Medcomp® Lock Right® Adapters with this catheter.
- Do not use sharp instruments near the trocar, dilator, or sheath.
- Do not use scissors to remove dressing.
- Catheter will be damaged if clamps other than what is provided with this kit are used.
- Clamping of the tubing repeatedly in the same location may weaken tubing. Avoid clamping near adapter or luer of catheter.
- Examine catheter lumen and Lock Right® Adapter after each treatment for damage.
- To prevent accidents, assure the security of all caps and bloodline connections prior to and between treatments.

**STERILE EO**
- Do not use catheter or accessories if package is opened or damaged.
- Do not use catheter or accessories if any signs of product damage is visible.

**DESCRIPTION**
- The patient should be in a modified Trendelenburg position, with the upper chest exposed and the head turned slightly to the side opposite the insertion area. A small rolled towel may be inserted between the shoulder blades to facilitate the extension of the chest area.

**INSERTION SITES**
- Internal Jugular Vein
- Subclavian Vein

**USE ONLY Luer Lock (threaded) Connectors with this catheter.
- Repeated over tightening of bloodlines, syringes, and caps will reduce connector life and could lead to failure of the Lock Right® Adapter Luer Connector.

**DISINFECTION OF CATHETER**
- To prevent accidents, assure the security of all caps and bloodline connections prior to and between treatments.
- Do not use any disinfected catheter or accessories if package is opened or damaged.
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**HEMODIALYSIS TREATMENT**

- The heparin solution must be removed from each lumen prior to treatment to prevent systemic hapatization of the patient. Anticoagulation should be based on dialysis unit protocol.
- Before dialysis begins, all connections to catheter and extracorporeal circuits should be clamped immediately.
- Frequent visual inspection should be conducted to detect leaks or erosion of the vessel wall.
- If a leak is found, the catheter should be clamped immediately.

**SITE CARE**

- Clean skin around catheter. Cover the exit site with occlusive dressing or smooth jawed hemostat.
- Dressing must be kept clean and dry.
- Caution: Patients must not swim, shower, or soak dressing while bathing.
- If profuse perspiration or accidental wetting compromises adhesion of dressing, the medical or nursing staff must change the dressing under sterile conditions.

**CATHETER PERFORMANCE**

- Always review hospital or unit protocols, potential complications of their treatment, warnings, and precautions prior to undertaking any type of mechanical or chemical intervention in response to catheter performance problems.

**INSUFFICIENT FLOWS**

The following may cause insufficient blood flows:

- Occluded arterial holes due to clotting or fibrin sheath.
- Occlusion of the arterial side holes due to mechanical clogging with vein wall.

**MANAGEMENT OF ONE-WAY OBSTRUCTIONS**

One-way obstructions exist when a lumen cannot be flushed. The following steps may be taken to remove obstructions:

1. Administer sufficient local anesthetic to exit site and cuff location to completely anesthetize the area.
2. Apply a firm, steady, downward force on the catheter near the exit site. The catheter should detach from the vessel and be removed in its entirety.

**INFECTION**

- Caution: Due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens, health care professionals should always use Universal Blood and Body Fluid Precautions in the care of all patients.

**CATHETER REMOVAL**

- Caution: Only a physician familiar with the appropriate techniques should attempt the following procedures.
- 1. Administer sufficient local anesthetic to exit site and cuff location to completely anesthetize the area.
- 2. Apply a firm, steady, downward force on the catheter near the exit site. The catheter should detach from the vessel and be removed in its entirety.

**MR LABELING BASED ON THE TEST RESULTS**

- MR Safety Information

**MR Information. The Tesio Catheter (polyurethane with embedded stainless steel connector) was determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-03. Standard Practice for Marking Medical Devices and Evaluating Medical Device Safety in the Magnetic Resonance Environment, 2003.**

Non-clinical testing demonstrated that the Tesio Catheter (polyurethane with embedded stainless steel connector) is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

- - Static magnetic field of 3-Tesla or less
- - Maximum spatial gradient magnetic field of 720-Gauss/cm or less

**MR-Related Heating**

In non-clinical testing, the Tesio Catheter (polyurethane with embedded stainless steel connector) produced the following temperature rise during MRI scanning for 3-5 minutes at 3-Tesla (3-Tesla: 128-MHz, Excite, HDx, Software 14.X.5, GE, General Electric Healthcare, Milwaukee, WI) MR System:

- Maximum temperature change: +1.6°C

Therefore, the MR-related heating experiments for the Tesio Catheter (polyurethane with embedded stainless steel connector) at 3-Tesla using a transmural rectal pad to asure accurate body temperature showed that the reported whole body averaged SAR of 0.9-W/kg (i.e., associated with a calorimeter measured temperature of 37.2°C) and whole body averaged SAR of 2.7-W/kg indicated that the greatest temperature increase that occurred in these studies with these specific conditions was equal to or less than +1.6°C.

**Artificial Information**

The image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Tesio Catheter (polyurethane with embedded stainless steel connector). Therefore, the optimization of MR imaging parameters to compensate for the presence of this device may be necessary.