

#### INDICATIONS FOR USE:

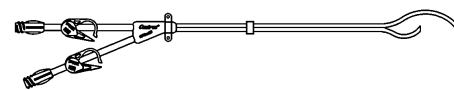
- The Centros® hemodialysis catheter is indicated for use in attaining Long-Term vascular access for Hemodialysis and Apheresis.
- It may be inserted percutaneously and is primarily placed in the internal jugular vein of an adult patient.
- This catheter is indicated for > 30 days (long term) placement.
- Catheter should be removed in accordance with CDC (Center for Disease Control) and DOQI (Disease Outcomes Quality Initiative) guidelines.

#### 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.
- This catheter is not intended for pediatric use.
- The valved peelable introducer sheath is NOT designed for use in the arterial system or as a hemostatic device.

#### DESCRIPTION:

- The Centros® chronic hemodialysis catheter is a dual lumen radiopaque catheter with a polyester cuff. The Centros® catheter is a 15 French catheter, featuring an innovative dual radiused distal configuration. This distinctively shaped design is intended to leverage the outside of the arc of both the arterial and venous lumens with the intention of eliminating the vein walls as an obstruction.



- By convention, the outflow of blood from the body is called “arterial” and is marked red and the return of blood is called “venous” and is marked blue.

#### POTENTIAL COMPLICATIONS:


Air Embolus	Lumen Thrombosis
Allergic Reactions	Mediastinal Injury
Bacteremia	Perforation of the Vessel
Brachial Plexus Injury	Pleural Injury
Cardiac Arrhythmia	Pneumothorax
Cardiac Tamponade	Retroperitoneal Bleed
Central Venous Thrombosis	Right Atrial Puncture
Endocarditis	Septicemia
Exit Site Infection	Subclavian Artery Puncture
Exsanguination	Subcutaneous Hematoma
Hematoma	Superior Vena Cava Puncture
Hemorrhage	Thoracic Duct Laceration
Hemothorax	Tunnel Infection
Laceration of the Vessel	Vascular Thrombosis

- Before attempting the insertion, ensure that you are familiar with the above complications and their emergency treatment should any of them occur.

#### WARNINGS:

- In the rare event that a hub or connector separates from any component during insertion or use, take all necessary steps and precautions to prevent blood loss or air

embolism and remove catheter.

- Do not advance the guidewire or catheter if unusual resistance is encountered.
- Do not insert or withdraw the guidewire forcibly from any component. The wire may break or unravel. If the guidewire becomes damaged, the introducer needle or sheath introducer and guidewire must be removed together.
- Use of excessive force on the catheter may cause the suture wing to detach from the bifurcate.
- In the event that a clamp breaks, replace the catheter at the earliest opportunity.
-  This catheter is for Single Use Only.
- Re-Use of single use device creates a potential risk of patient/user infections. Contamination may lead to injury, illness, or death of the patient.
- Re-processing may compromise the integrity of the device and/or lead to device failure.
- Do not re-sterilize the catheter or accessories by any method.
- The manufacturer shall not be liable for any damages caused by reuse or re-sterilization of this catheter or accessories.
- Contents sterile in unopened, undamaged package.

#### STERILIZED BY ETHYLENE OXIDE

STERILE EO

- Do not use catheter or accessories if package is opened or damaged.
- Do not use catheter or accessories if any sign of product damage is visible.
- CAUTION:** Federal Law (USA) restricts the device to sale by or on the order of a physician.

#### CATHETER PRECAUTIONS:

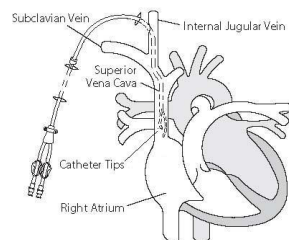
- The Centros® hemodialysis catheter materials have been tested for compatibility with the following cleaning solutions:
  - Chloraprep
  - Alcavis 50
  - Aqueous-based Povidone iodine
  - Shur-Clens
  - Epi-Clenz
  - Hydrogen peroxide
  - Silver sulfadiazine cream 1%
- The catheter should be accessed or have site care only when the staff and patient wear a mask and the staff wears clean gloves.
- Clamping of the tubing repeatedly in the same location may weaken tubing. Avoid clamping near the luer and hub of the catheter.
- Do not use sharp instruments near the extension tubing or catheter lumen.
- Repeated over tightening of bloodlines, syringes, and caps will reduce connector life and could lead to potential connector failure.
- Use only Luer Lock (threaded) Connectors with this catheter.
- Examine catheter lumen and extensions before and after each treatment for damage.
- To prevent accidents, assure the security of all caps and bloodline connections prior to and between treatments.
- Excessive force should NOT be used to flush obstructed lumen. **DO NOT** use a syringe smaller than 10 ml (cc).

- Do not use scissors to remove dressing.

#### INSERTION SITES:

##### RIGHT INTERNAL JUGULAR VEIN

- 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.
- Have patient lift his/her head from the bed to define the sternomastoid muscle. Catheterization will be performed at the apex of a triangle formed between the two heads of the sternomastoid muscle. The apex should be approximately three fingerbreadths above the clavicle. The carotid artery should be palpated medial to the point of catheter insertion.
- Using ultrasound, ensure the jugular vein is patent and distended.
- Confirm final position of catheter with chest x-ray. Routine x-ray should always follow the initial insertion of this catheter to confirm proper tip placement prior to use. The arterial tip should be positioned in the lower third of the vena cava, and the venous tip approximately at the junction of the right atrium and superior vena cava.



#### WARNING:

- Patients requiring ventilator support are at increased risk of pneumothorax during subclavian vein cannulation, which may cause complications.

#### DIRECTIONS FOR SELDINGER INSERTION

- Real Time ultrasound and fluoroscopy are recommended for placement
  - Read instructions carefully before using this device. The catheter should be inserted, manipulated, and removed by a qualified, licensed physician or other qualified health care professional under the direction of a physician.
  - The medical techniques and procedures described in these instructions for use do not represent all medically acceptable protocols, nor are they intended as a substitute for the physician’s experience and judgment in treating any specific patient.
  - Use standard hospital protocols when applicable.
- Strict aseptic technique must be used during insertion, maintenance, and catheter removal procedures. Provide a sterile operative field. The Operating Room is the preferred location for catheter placement. Use sterile drapes, instruments, and accessories. Shave the skin above and below the insertion site. Perform surgical scrub. Wear gown, cap, gloves, and mask. Have patient wear mask.
  - The selection of the appropriate catheter length is at the sole discretion of the physician. To achieve proper tip placement, proper catheter length selection is important. Routine x-ray should always follow the initial insertion of this catheter to confirm proper placement prior to use.
  - Administer sufficient local anesthetic to completely anesthetize the insertion site.

- Determine site for needle entry into vein. Insert the introducer needle with attached syringe into the target vein using ultrasound in real time if possible. Aspirate to ensure proper placement.

**NOTE:** For alternate insertion methods, see the OVER-THE-WIRE TECHNIQUE section.

- Remove the syringe and place thumb over the end of the needle to prevent blood loss or air embolism. Draw flexible end of guidewire back into advancer so that only the end of the guidewire is visible. Insert advancer’s distal end into the needle hub. Advance guidewire with forward motion into and past the needle hub into the target vein. Observe progress of the wire with fluoroscopy when possible and advance the wire into the superior vena cava.

**CAUTION:** Monitor patient for arrhythmia throughout this procedure. Cardiac arrhythmia may result if guidewire is allowed to pass into the right atrium or ventricle. The guidewire should be held securely during this procedure.

- Remove needle and leave guidewire in the vena cava.

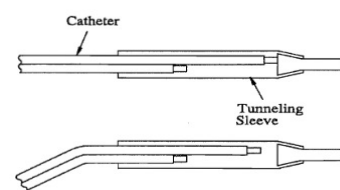
- Make small secondary incision at the exit site on the chest wall below the clavicle. Make the incision at the exit site wide enough to accommodate the catheter and dilate skin with hemostats.

- Irrigate catheter with saline, then clamp catheter extension sets to ensure that the saline is not inadvertently drained from lumens.

**NOTE: Use only the clamps provided on the extension sets**

- Slide the catheter into the tunneling sleeve as far as possible.

**NOTE: There is a slight interference fit between the catheter and the tunneling sleeve.**



- Insert the tunneler into the exit site and into the subcutaneous tissue. Create a short subcutaneous tunnel. **DO NOT** tunnel through muscle. Advance the tip of the tunneler through the lateral portion of the incision.

- Pull and push the tunneling sleeve into the tunnel gently until the tip of the sleeve emerges from the primary incision. Push the catheter through the tunnel while pulling the sleeve.

- Using small hemostats, compress the cuff and push through the exit site while pulling gently on the catheter.

**CAUTION: DO NOT** pull tunneler out of the primary incision at an angle. Keep tunneler straight to prevent damage to the catheter tip. The catheter can be bent slightly.

**NOTE:** A tunnel with a gentle arc lessens the risk of kinking. The tunnel should be short enough to keep the hub of the catheter from entering the exit site, yet long enough to keep the cuff 2 cm (minimum) from the skin opening.

#### SafeSheath D-Pro® Instructions Precautions:

- Dilators and catheters should be removed slowly from the sheath. Rapid removal may damage the valve members resulting in blood flow through the valve. Never advance or withdraw guide wire or sheath when

resistance is met. Determine cause by fluoroscopy and take remedial action.

- Insert vessel dilator into sheath until the dilator cap folds over valve housing and secures the dilator onto sheath assembly.
- Thread the dilator/sheath assembly over the guide wire.
- Advance the dilator and sheath together with a twisting motion over the guide wire and into the vessel. Fluoroscopic observation may be advisable. Attaching a clamp or hemostat to the proximal end of the guide wire will prevent inadvertently advancing the guide wire entirely into the patient.

- Once assembly is fully introduced into the venous system, separate the dilator cap from the sheath valve housing by rocking the dilator cap off the hub. (see figure A)

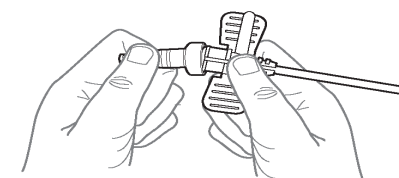


Figure A

- Slowly retract the guide wire and dilator, leaving the sheath in position. The hemostasis valve will reduce the loss of blood and the inadvertent aspiration of air through the sheath.

- Introduce catheter through the hemostasis valve/sheath and advance it into position.

- Sharply snap the tabs of valve housing in a plane perpendicular to the long axis of the sheath to split the valve and peel sheath apart while withdrawing from the vessel. (see figure B)

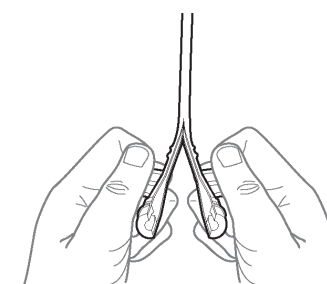


Figure B

- Remove the sheath from the patient.
- Make any adjustments to catheter under fluoroscopy. The arterial tip should be placed in the lower third of the vena cava and the venous tip should be placed approximately at the junction of the right atrium and the superior vena cava.
- Observe the apex of the catheter at the primary incision. If a kink is visible, dilate beneath the catheter using hemostats.
- Attach syringes to both extensions and open clamps. Blood should aspirate easily from both arterial and venous sides. If either side exhibits excessive resistance to blood aspiration, the catheter may need to be rotated or repositioned to obtain adequate blood flows.
- Once adequate aspiration has been achieved, both lumens should be irrigated with saline filled syringes using quick bolus technique. Assure that extension clamps are open during irrigation procedure.
- Attach syringes with an anticoagulant solution. Infuse with the anticoagulant solution, close the extension set clamps, remove the syringes, and place a sealing cap

on each Luer Lock Connector. Avoid air embolism by keeping extension tubing clamped at all times when not in use and by aspirating and then irrigating the catheter with saline prior to each use. With each change in tubing connections, purge air from all the connecting tubing.

**CAUTION:** Ensure that extension set clamps are closed between uses.

- Confirm proper catheter placement with fluoroscopy or x-ray. The arterial tip should be placed in the lower third of the vena cava and the venous tip should be placed approximately at the junction of the right atrium and the superior vena cava.

**CAUTION:** Failure to verify catheter placement may result in serious trauma or fatal complications.

#### SECURE CATHETER AND DRESS WOUND:

- Suture the catheter to the skin using the suture wing. Do not suture the catheter tubing.

**CAUTION:** Care must be taken when using sharp objects or needles in close proximity to catheter tubing. Contact from sharp objects may cause catheter failure.

- Cover the insertion and exit site with an occlusive dressing.

- Catheter must be secured/sutured for entire duration of implantation.

- Record or place patient label that contains catheter length and catheter lot number on patient’s chart.

#### WARNING:

Confirm final position of catheter placement with fluoroscopy or x-ray. The “arterial” distal tip should be positioned in the lower third of the superior vena cava while the “venous” distal tip is positioned approximately at the junction of the right atrium and the superior vena cava to ensure optimal blood flow.

#### HEMODIALYSIS TREATMENT

- The anticoagulant solution must be removed from each lumen prior to treatment to prevent systemic heparinization of the patient. Aspiration should be based on dialysis unit protocol.

- Before dialysis begins all connections to catheter and extracorporeal circuits should be examined carefully. Tubing should be properly primed with saline.

- Frequent visual inspection should be conducted to detect leaks to prevent blood loss or air embolism.

- If a leak is found, the catheter should be clamped immediately.

- CAUTION:** Only clamp extension sets with in-line clamps provided. **DO NOT** clamp the catheter body tubing.

- Necessary remedial action must be taken prior to the continuation of the dialysis treatment if a leak is detected.

- NOTE:** Excessive blood loss may lead to patient shock.

- Hemodialysis should be performed under physician’s instructions.

#### ANTICOAGULANT SOLUTION FOR THE CATHETER

- If the catheter is not to be used immediately for treatment, follow the suggested catheter patency guidelines.

- To maintain patency between treatments, a heparin or other anticoagulant solution lock must be created in each lumen of the catheter.

- Follow hospital protocol for heparin concentration.

1. Draw solution into two syringes, corresponding to the amount designated on the arterial and venous extensions (as shown). Ensure that the syringes are free of air.

Catheter Length	Priming Volumes	
	Lumen	
	Arterial (cc)	Venous (cc)
20 Straight	1.7	1.8
22 Straight	1.8	1.8
24 Straight	1.8	2.0
28 Straight	1.9	2.0
32 Straight	2.2	2.2
36 Straight	2.3	2.4
20 Curved	1.7	1.8
22 Curved	1.8	1.8
24 Curved	1.8	2.0
28 Curved	1.9	2.0
32 Curved	2.2	2.2
36 Curved	2.3	2.4

2. Ensure that the extension set clamps are closed.
3. Remove sealing caps from the extensions.
4. Attach a syringe containing anticoagulant solution to the female luer of each extension.
5. Open extension clamps.
6. Aspirate to insure that no air will be forced into the patient.
7. Inject heparin into each lumen using quick bolus technique.

- **NOTE:** Each lumen should be completely filled with heparin to ensure effectiveness.

8. Close extension clamps.

- **CAUTION:** Extension clamps should only be open for aspiration, flushing, and dialysis treatment.

9. Remove syringes.

10. Attach a sterile sealing cap onto the female luers of the extensions.

- **NOTE:** No Further anticoagulant solution is necessary between treatments provided the lumens are not being aspirated or flushed.

#### SITE CARE

- **WARNING: DO NOT** use acetone or PEG-containing ointments of any kind with this catheter.
- Clean skin around catheter. Cover the exit site with occlusive dressing and leave extensions, clamps, and caps exposed for access by staff.
- Wound dressings 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

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

**WARNING:** Only a physician familiar with the appropriate techniques should attempt the following procedures.

#### INSUFFICIENT FLOWS:

The following may cause insufficient blood flows for dialysis:

- Occluded arterial lumen due to clotting or fibrin sheath around the catheter.
- Occlusion of the venous lumen due to clotting or fibrin sheath around the catheter.

Solutions include:

- Chemical intervention utilizing a thrombolytic agent.
- Vigorous flushing of the catheter with saline.

#### MANAGEMENT OF ONE-WAY OBSTRUCTIONS:

One-way obstructions exist when a lumen can be flushed easily but blood cannot be aspirated. This is usually caused by tip malposition but is sometimes due to a clot or fibrin sheath.

One of the following adjustments may resolve the obstruction:

- Reposition catheter.
- Reposition patient.
- Have patient cough.
- Provided there is no resistance, flush the catheter vigorously with sterile normal saline to try to open or move the tip.
- Other interventions as above.

#### INFECTION:

There is a risk of infection related to use of the catheter.

**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.

- Sterile technique should always be strictly adhered to.

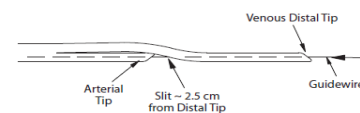
- Clinically recognized infection at a catheter exit site should be treated promptly with the appropriate antibiotic therapy.

- If a fever occurs in a patient with a catheter in place, take cultures from a peripheral site (or dialysis line) and from one catheter lumen. Culture catheter exit site if purulence is seen. Implement the appropriate antibiotic therapy and consider removing catheter if there are signs of sepsis. Wait 48 hours before catheter replacement. Insertion should be made on opposite side of original catheter exit site, if possible.

#### OVER- THE- WIRE TECHNIQUE

**CAUTION: Over the wire placement should only be performed by a physician familiar with this technique. The split sheath is not used with this placement.**

1. Advance guidewire with forward motion through the introducer needle into the target vein.
2. Remove needle leaving the guidewire in the target vein.
3. Thread dilator(s) over guidewire into the vein (a slight twisting motion may be used). Remove dilator(s) when vein is sufficiently dilated, leaving the guidewire in place. Apply pressure to incision when dilators are removed.
4. Thread the proximal end of the guidewire through the distal tip of the venous lumen and the slit as shown in the figure:



5. Thread the guidewire through the distal tip of the arterial lumen and through the catheter lumen until the proximal end of the guidewire exits the arterial luer on the extension set.

6. Advance the catheter until the distal tip of the arterial lumen is within the primary incision.

**NOTE:** Ensure blood is coming out of the arterial lumen while advancing the catheter.

**CAUTION: DO NOT** advance guidewire with catheter into vein. Cardiac arrhythmia may result if guidewire is allowed to pass into the right atrium. The guidewire should be held securely during catheter placement.

7. Gently remove the guidewire, leaving catheter in place.

8. Make any adjustments to catheter under fluoroscopy. The arterial tip should be positioned in the lower third of the vena cava, and the venous tip approximately at the junction of the right atrium and superior vena cava.

9. Continue with step #22 under SafeSheath D-Pro® insertion section.

#### CATHETER REMOVAL

**WARNING:** Only a physician familiar with the appropriate techniques should attempt the following procedures.

**CAUTION:** Always review hospital or unit protocol, potential complications and their treatment, warnings, and precautions prior to catheter removal.

1. Palpate the catheter exit tunnel to locate the cuff.
2. Administer sufficient local anesthetic to exit site and cuff location to completely anesthetize the area.
3. Cut sutures from suture wing. Follow hospital protocol for removal of skin sutures.

4. Make a 2 cm incision over the cuff, parallel to the catheter.

5. Dissect down to the cuff using blunt and sharp dissection as indicated. Isolate catheter and surrounding tunnel between cuff and jugular vein. Place loop of suture through subcutaneous and deep tissue surrounding the tunnel.

6. Free cuff from surrounding tissue.

7. Cut tunnel just lateral and medial to cuff. Avoid cutting the catheter.

8. Withdraw the catheter through the exit site.

9. Pull suture tight.

10. Close primary incision.

11. Apply pressure to proximal tunnel for approximately 10-15 minutes or until bleeding stops.

12. Suture incision and apply dressing in a manner to promote optimal healing.

13. Check catheter integrity for tears and measure catheter length when removed. It must equal the length of the catheter when it was inserted.

#### Flow vs. Pressure Data

Catheter Length (cm)	Pressure at flow (mm Hg)					
	200ml/min		300 ml/min		400 ml/min	
	A	V	A	V	A	V
20 cm Straight	-63	72	-106	108	-155	153
22 cm Straight	-70	70	-114	107	-167	152
24 cm Straight	-74	75	-125	113	-182	157
28 cm Straight	-75	80	-123	119	-177	169
32 cm Straight	-84	89	-138	134	-197	187
36 cm Straight	-93	90	-151	134	-213	186
20cm Curved	-66	69	-107	104	-158	148
22cm Curved	-66	72	-109	110	-159	156
24cm Curved	-61	80	-100	120	-147	171
28cm Curved	-74	83	-121	126	-175	178
32cm Curved	-87	90	-146	134	-210	184
36cm Curved	-84	95	-139	142	-199	200

NOTE: FLOW TESTING REPRESENTS OPTIMUM LABORATORY CONDITIONS

#### REFERENCES:

Lebanc, M., Bosc, J., Paganini, E., & Canaud, B., Central Venous Dialysis Catheter Dysfunction: Advances in Renal Replacement Therapy. 1997;4(4):377-389.

Hirsch, D., Bergen, P., & Jindal, K., Polyurethane Catheters for Long-Term Hemodialysis Access: Artificial Organs. 1997;21(5):349-354.

ANGIODYNAMICS® and Centros® are registered trademarks of ANGIODYNAMICS, Inc.

SafeSheath D-Pro® is a registered trademark of Pressure Products Medical Supplies, Inc.

The SafeSheath D-Pro® introducer is covered under U.S. Patent Nos. 5,125,904, 5,312,355, and 5,409,463.

The Centros® catheter is covered under pending US and foreign patents.

·STORE IN A COOL DRY PLACE·PROTECT FROM UV LIGHT·



Kit contents will include (1) Hemodialysis Catheter and accessories. For exact kit contents refer to the product label.

## ANGIODYNAMICS®

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IC 041 Rev. B