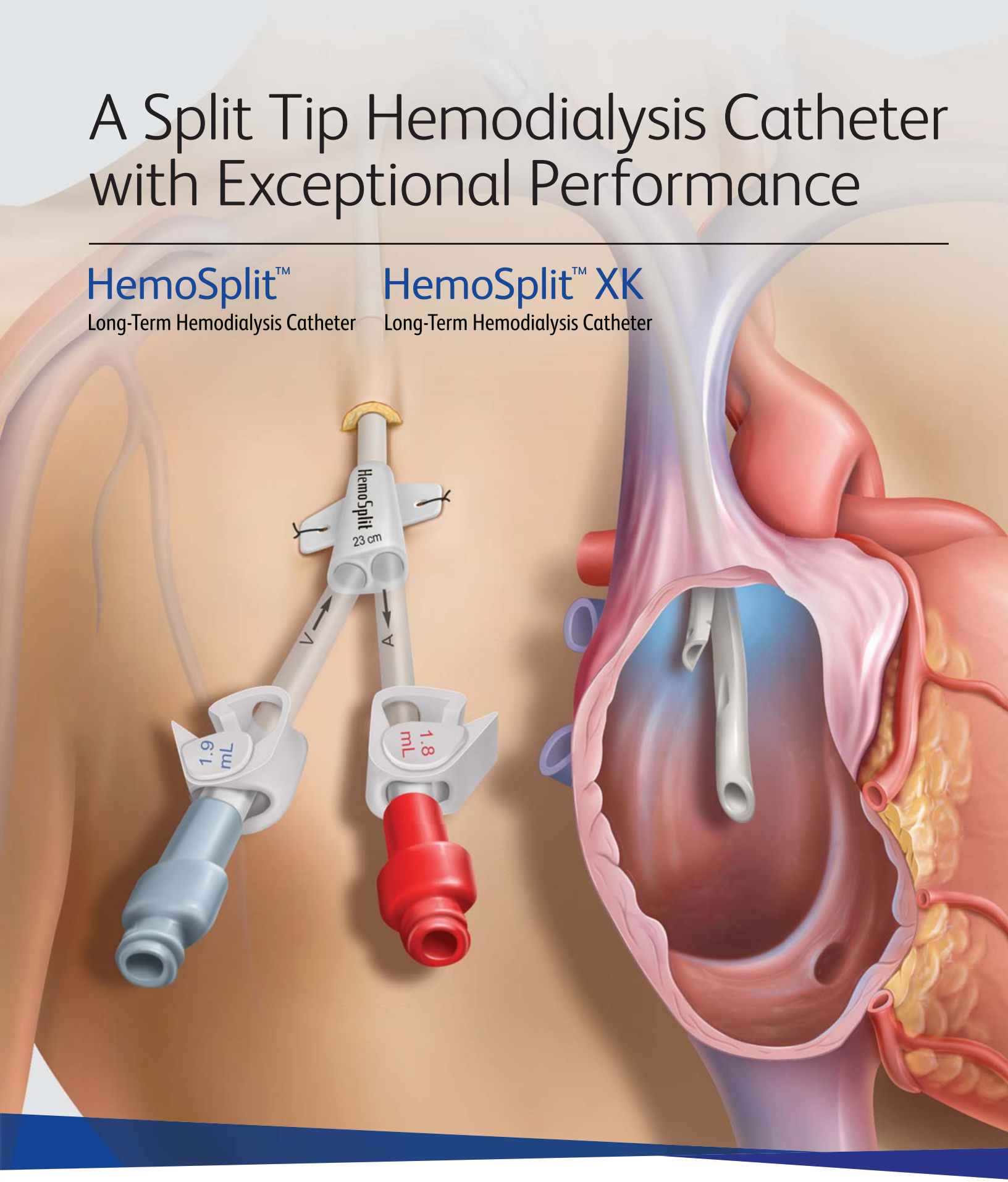
A Split Tip Hemodialysis Catheter with Exceptional Performance

HemoSplit™
Long-Term Hemodialysis Catheter

HemoSplit™ XK
Long-Term Hemodialysis Catheter



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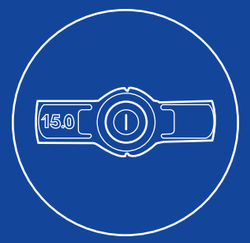
Exceptional Performance And Easy Insertion

Efficient Flow

- Large lumens and non-restrictive tip design enable flow rates as high as 500 ml/min[1]

Ease of Use

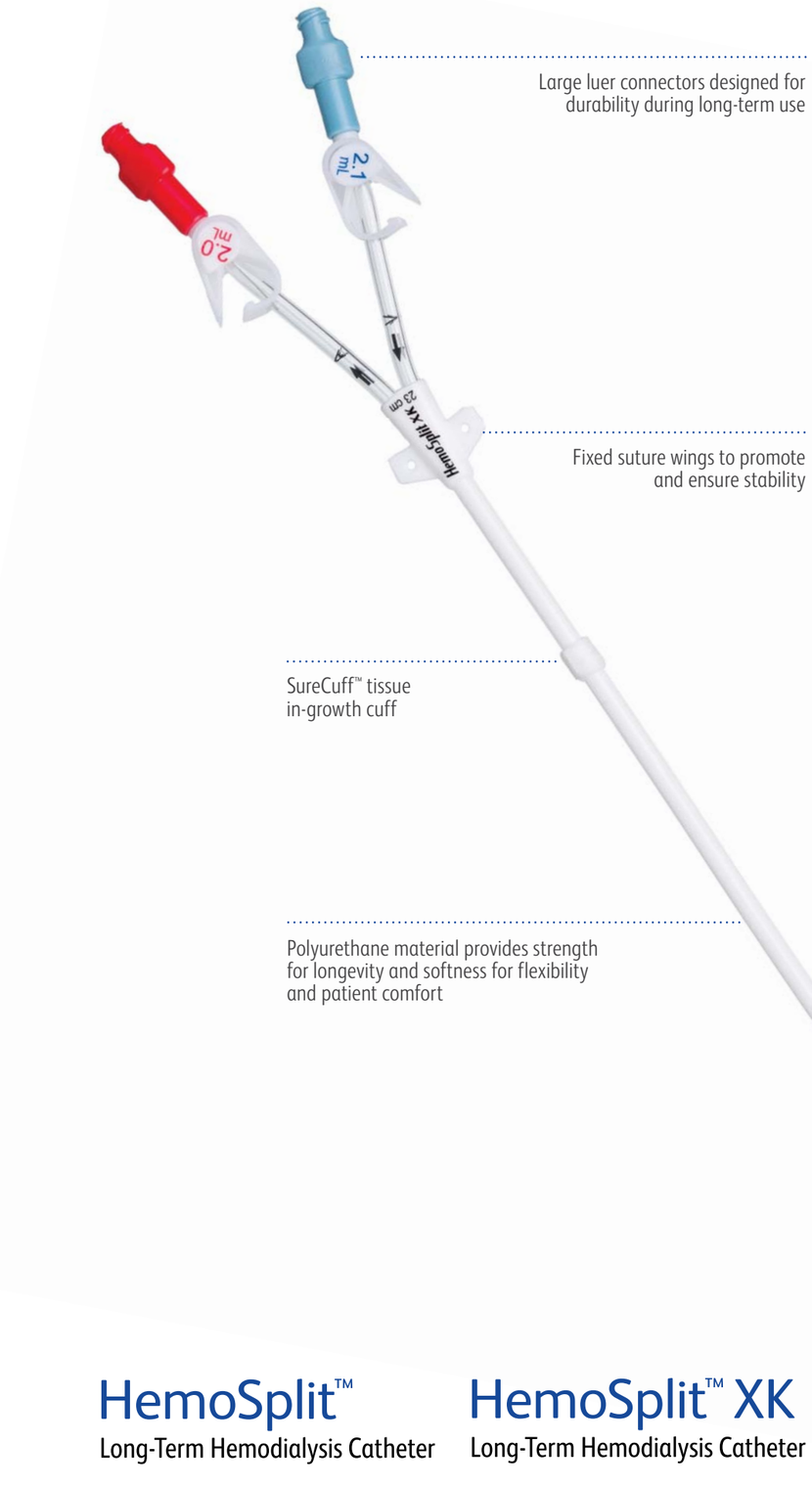
- Guidewire channel on the venous tip facilitates threading for easy onver-the-wire insertion
- Exceptional kink resistance simplifies insertion by allowing greater flexibility in tunnel location



AirGuard™ Valved Introducer

- Kits include the AirGuard™ Valved Introducer
- Integrated valve offers improved protection from air embolism and blood loss compared to non-valved introducers

Bench data on file. May not necessarily correlate to clinical performance. Based on simulated testing. Different tests may yield different results.
[1] Data on file. HemoSplit™ 14.5F and 16F straight catheters



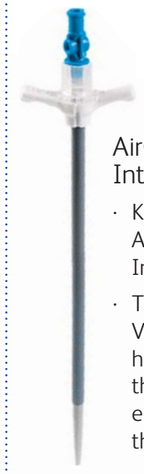
Large luer connectors designed for durability during long-term use

Fixed suture wings to promote and ensure stability

SureCuff™ tissue in-growth cuff

Polyurethane material provides strength for longevity and softness for flexibility and patient comfort

360° multiple side holes to help reduce the risk of catheter occlusion by the vessel wall



AirGuard™ Valved Introducer

- Kits include the AirGuard™ Valved Introducer
- The AirGuard™ Valved Introducer helps to reduce the risk of air embolism during the procedure

HemoSplit™
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HemoSplit™

Long-Term Hemodialysis Catheter

Insertion Length	Catheter Length	Product Code
Straight, Polyurethane Catheter, Standard Kit		
19 cm	24 cm	☐ 5733694
23 cm	28 cm	☐ 5733734
27 cm	32 cm	☐ 5733274
31 cm	36 cm	☐ 5733314
15 cm	20 cm	☐ 5733150
19 cm	24 cm	☐ 5733690
23 cm	28 cm	☐ 5733730
27 cm	32 cm	☐ 5733270
31 cm	36 cm	☐ 5733310
35 cm	40 cm	☐ 5733350
42 cm	47 cm	☐ 5734420
Alphacurve™, Polyurethane Catheter, Standard Kit		
19 cm	25 cm	☐ 5735150
24 cm	29 cm	☐ 5735190
28 cm	33 cm	☐ 5735230
31 cm	37 cm	☐ 5735270
Straight, Polyurethane Catheter, Microintroducer Kit		
19 cm	24 cm	☐ 5743690
23 cm	28 cm	☐ 5743730
27 cm	32 cm	☐ 5743270
31 cm	36 cm	☐ 5743310
35 cm	40 cm	☐ 5743350
42 cm	47 cm	☐ 5744420

Product and Packaging Are Not Made with Natural Rubber Latex

REPRESENTATIVE NAME

CONTACT PHONE NO.

PHYSICIAN'S SIGNATURE

HemoSplit™ XK

Long-Term Hemodialysis Catheter

Insertion Length	Catheter Length	Product Code
Straight, Polyurethane Catheter, Standard Kit		
19 cm	24 cm	☐ 5683690
23 cm	28 cm	☐ 5683730
27 cm	32 cm	☐ 5683270
31 cm	36 cm	☐ 5783310
35 cm	40 cm	☐ 5683350
42 cm	47 cm	☐ 5684420
Alphacurve™, Polyurethane Catheter, Standard Kit		
19 cm	25 cm	☐ 5685150
24 cm	29 cm	☐ 5685190
28 cm	33 cm	☐ 5685230
31 cm	37 cm	☐ 5865270
Straight, Polyurethane Catheter, Microintroducer Kit		
19 cm	24 cm	☐ 5693690
23 cm	28 cm	☐ 5693730
27 cm	32 cm	☐ 5693270

Standard Kit Contents - 14.5F or 16F (XK)	
1 Each	Catheter
1 Each	AirGuard™ Valved Introducer with Peel-Away Sheath/Dilator
1 Each	Dilator - 8F
1 Each	Dualtor™ Dilator - 10-12F
1 Each	J-Tip Guidewire - 0.038"
1 Each	Introducer Needle - 18G
1 Each	Tunneler
2 Each	Adhesive Dressings
2 Each	End Cap
Additional XK Standard Kit Contents - 16F (XK)	
1 Each	Dualator™ Dilator - 14-16F
1 Each	Dualator™ Dilator - 15.5-17.5F
1 Each	Stiffening Wire
1 Each	Scalpel
Microintroducer Kit Contents - 14.5F or 16F (XK)	
1 Each	Catheter
1 Each	AirGuard™ Valved Introducer with Peel-Away Sheath/Dilator
1 Each	Dilator - 8F
1 Each	Dualator™ Dilator - 10-12F
1 Each	Dualator™ Dilator - 14-16F
1 Each	Dualator™ Dilator - 15.5-17.5F
1 Each	Microintroducer - 5F
1 Each	Introducer Needle - 21G
1 Each	Stiffening Wire
1 Each	Guidewire - 120 cm x 0.038"
1 Each	Guidewire - 45 cm x 0.018"
1 Each	Introducer Needle - 18F
1 Each	Tunneler
2 Each	Adhesive Dressing
2 Each	End Cap

HemoSplit™ and HemoSplit™ XK (Straight and Alphacurve™ Configuration) Catheters

Indications for Use: The HemoSplit™ and HemoSplit™ XK Long-Term Hemodialysis Catheters are indicated for use in attaining short-term or long-term vascular access for hemodialysis, hemoperfusion, or apheresis therapy. Access is attained via the internal jugular vein, external jugular vein, subclavian vein, or femoral vein. Catheters greater than 40 cm are intended for femoral vein insertion.

Contraindications: The HemoSplit™ and HemoSplit™ XK Long-Term Hemodialysis Catheters are contraindicated for patients exhibiting severe, uncontrolled thrombocytopenia or coagulopathy.

Warnings: Percutaneous insertion of the catheter should be made into the axillary-subclavian vein at the junction of the outer and mid-thirds of the clavicle lateral to the thoracic outlet. The catheter should not be inserted into the subclavian vein medially, because such placement can lead to compression of the catheter between the first rib and clavicle and can lead to damage or fracture and embolization of the catheter.[1] Fluoroscopic or radiographic confirmation of catheter tip placement should be helpful in demonstrating that the catheter is not being pinched by the first rib and clavicle[1] · Alcohol or alcohol-containing antiseptics (such as chlorhexidine) may be used to clean the catheter/skin site; however, care should be taken to avoid prolonged or excessive contact with the solution(s) · Acetone and PEG-containing ointments can cause failure of this device and should not be used with polyurethane catheters. Chlorhexidine patches or bacitracin zinc ointments (e.g., Polysporin™ ointment) are the preferred alternative · Follow Universal Precautions when inserting and maintaining this device · Cardiac arrhythmias may result if the guidewire is allowed to pass into the right atrium · Close all clamps only in the center of the extension legs. Extensions may develop cuts or tears if subjected to excessive pulling or contact with rough edges. Repeated clamping near or on the luer lock connectors may cause tubing fatigue and possible disconnection · Catheters should be implanted carefully to avoid any sharp or acute angles which could compromise the opening of the catheter lumens · To prevent air embolism and/or blood loss, place thumb over the exposed orifice of the sheath introducer · To avoid damage to vessels and viscus, infusion pressures should not exceed 25 psi (172 kPa). The use of a 10 ml or larger syringe is recommended because smaller syringes generate more pressure than larger syringes. Note: A three pound (13.3 Newton) force on the plunger of a 3 ml syringe generates pressure in excess of 30 psi (206 kPa) whereas the same three pound (13.3 Newton) force on the plunger of a 10 ml syringe generates less than 15 psi (103 kPa) of pressure · Accessories and components used in conjunction with this catheter should incorporate luer-lock adapters · The heparin solution must be aspirated out of both lumens immediately prior to using the catheter to prevent systemic heparinization of the patient · Failure to clamp extensions when not in use may lead to air embolism · In the rare event of a leak, the catheter should be clamped immediately. Necessary remedial action must be taken prior to resuming dialysis or infusion procedure · The risk of infection is increased with femoral vein insertion · Do not resterilize the catheter or components by any method. The manufacturer will not be liable for any damages caused by reuse of the catheter or accessories · Cannulation of the left internal jugular vein was reportedly associated with a higher incidence of complications compared to catheter placement in the right internal jugular vein.[2]

Caution: HemoSplit™ and HemoSplit™ XK Long-Term Hemodialysis Catheters: Federal (USA) law restricts this device to sale by or on the order of a physician · Microintroducer Kits Only. If using the supplied stiffening wire during placement, do not place it into the arterial lumen because the tip of the wire will protrude from the lumen and may cause vessel trauma. Do not adjust pre-set length of wire · Repeated over tightening of blood lines, syringes and caps will reduce connector life and could lead to potential connector failure. In case of damage, clamp the catheter between the patient and the damaged area with a smooth-edged, atraumatic clamp · Sterile and non-pyrogenic only if packaging is not opened, damaged or broken · Read the instructions for use carefully before using this device. Left sided placement in particular, may provide unique challenges due to the right angles formed by the innominate vein and at the left brachiocephalic junction with the SVC[3,4] · Care should be taken NOT to force the dilator sheath introducer assembly into the vessel during insertion as vessel damage including perforation could result · Before attempting the insertion of HemoSplit™ and HemoSplit™ XK catheters, ensure that you are familiar with the following complications and their emergency treatment should any of them occur · These and other complications are well documented in medical literature and should be carefully considered before placing the catheter. Placement and care of HHemoSplit™ and HemoSplit™ XK catheters should be performed by persons knowledgeable of the risks involved and qualified in the procedures · For optimal performance, do not insert any portion of the cuff into the vein · Do not pull back standard guidewire over needle bevel as this could sever the end of the guidewire. The introducer needle must be removed first · Ensure that the introducer sheath is only torn externally. Catheter may need to be further pushed into the vessel as sheath is torn.

Possible Complications: The use of an indwelling central venous catheter provides an important means of venous access for critically ill patients; however, the potential exists for serious complications including the following: · Air Embolism · Bleeding · Brachial Plexus Injury · Cardiac Arrhythmia · Cardiac Tamponade · Catheter or Cuff Erosion Through the Skin · Catheter Embolism · Catheter Occlusion · Catheter Occlusion, Damage or Breakage due to Compression Between the Clavicle and First Rib[1] · Catheter-related Sepsis · Endocarditis · Exit Site Infection · Exit Site Necrosis · Extravasation · Fibrin Sheath Formation · Hematoma · Hemothorax · Hydrothorax · Inflammation, Necrosis or scarring of skin over implant area · Intolerance Reaction to Implanted Device · Laceration of Vessels or Viscus · Perforation of Vessels or Viscus · Pneumothorax · Risks Normally Associated with Local and General Anesthesia, Surgery, and Post-Operative Recovery · Thoracic Duct Injury · Thromboembolism · Venous Thrombosis · Ventricular Thrombosis · Vessel Erosion

References

1 Aitken, D.R. and Minton, J.P. "The Pinch-Off Sign: A Warning of Impending Problems with Permanent Subclavian Catheters", American Journal of Surgery, Vol. 148, Nov. 1984, pp.633-638.

2 Sulek, CA., Blas, ML., Lobato, EB, "A randomized study of left versus right internal jugular vein cannulation in adults."J Clin Anesth. 2000 Mar;12(2):142-5

3 Mickley, V., "Central venous catheters: many questions: few answers", Nephrol Dial Transplant, (2002) 17:1368-1373.

4 Tan, P.L., Gibson, M., "Central Venous Catheters: the role of radiology", Clin Rad. 2006, 61:13-22