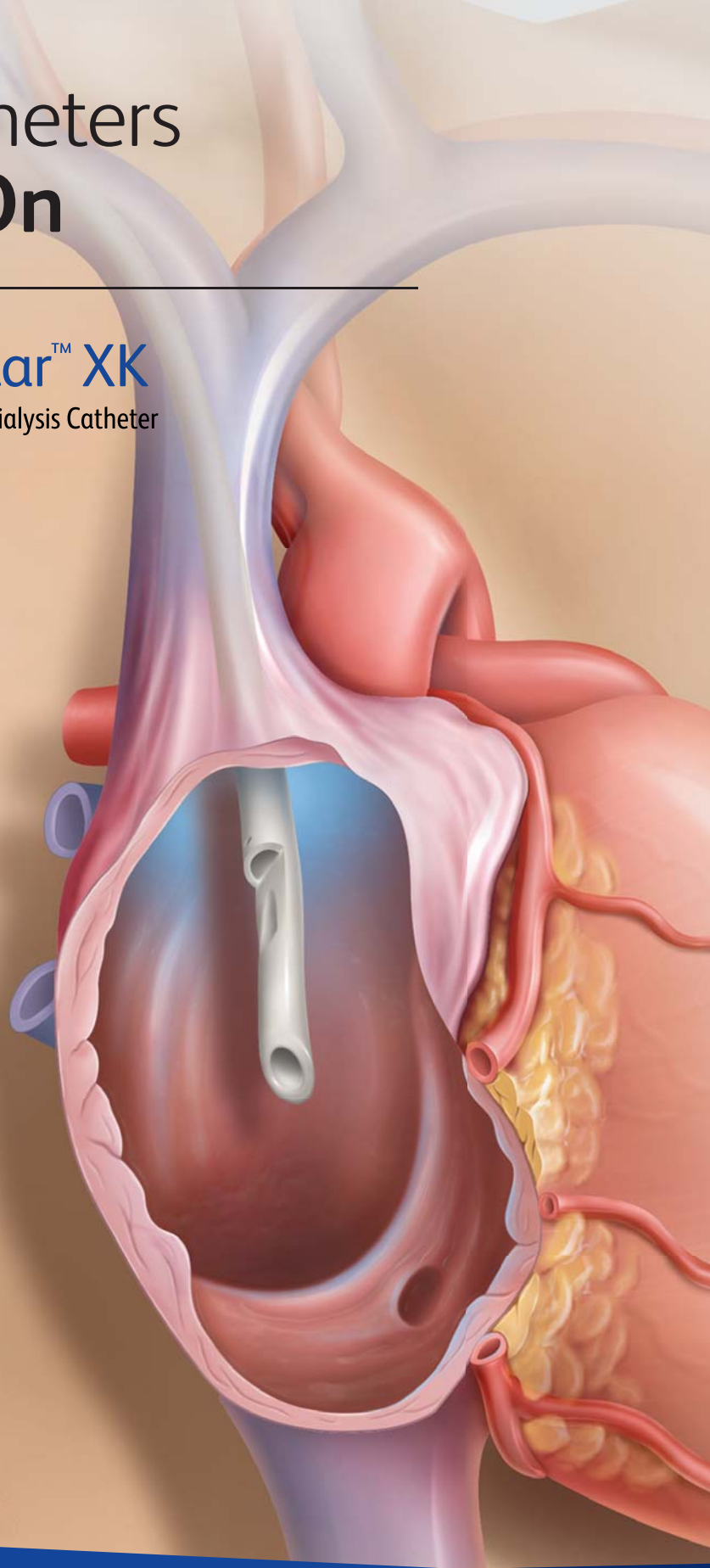


Hemodialysis Catheters You Can Count On

HemoStar™
Long-Term Hemodialysis Catheter

HemoStar™ XK
Long-Term Hemodialysis Catheter



The HemoStar™ and HemoStar™ XK Catheters provide exceptional performance and easy insertion.



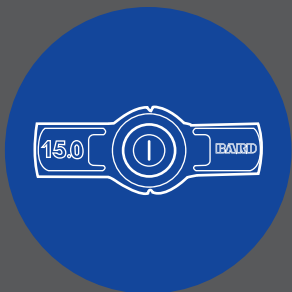
Efficient Flow

- Large lumens and non-restrictive tip design enable flow rates as high as 500 ml/min¹



Ease of Use

- Guidewire channel on the venous tip facilitates threading for easy over-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

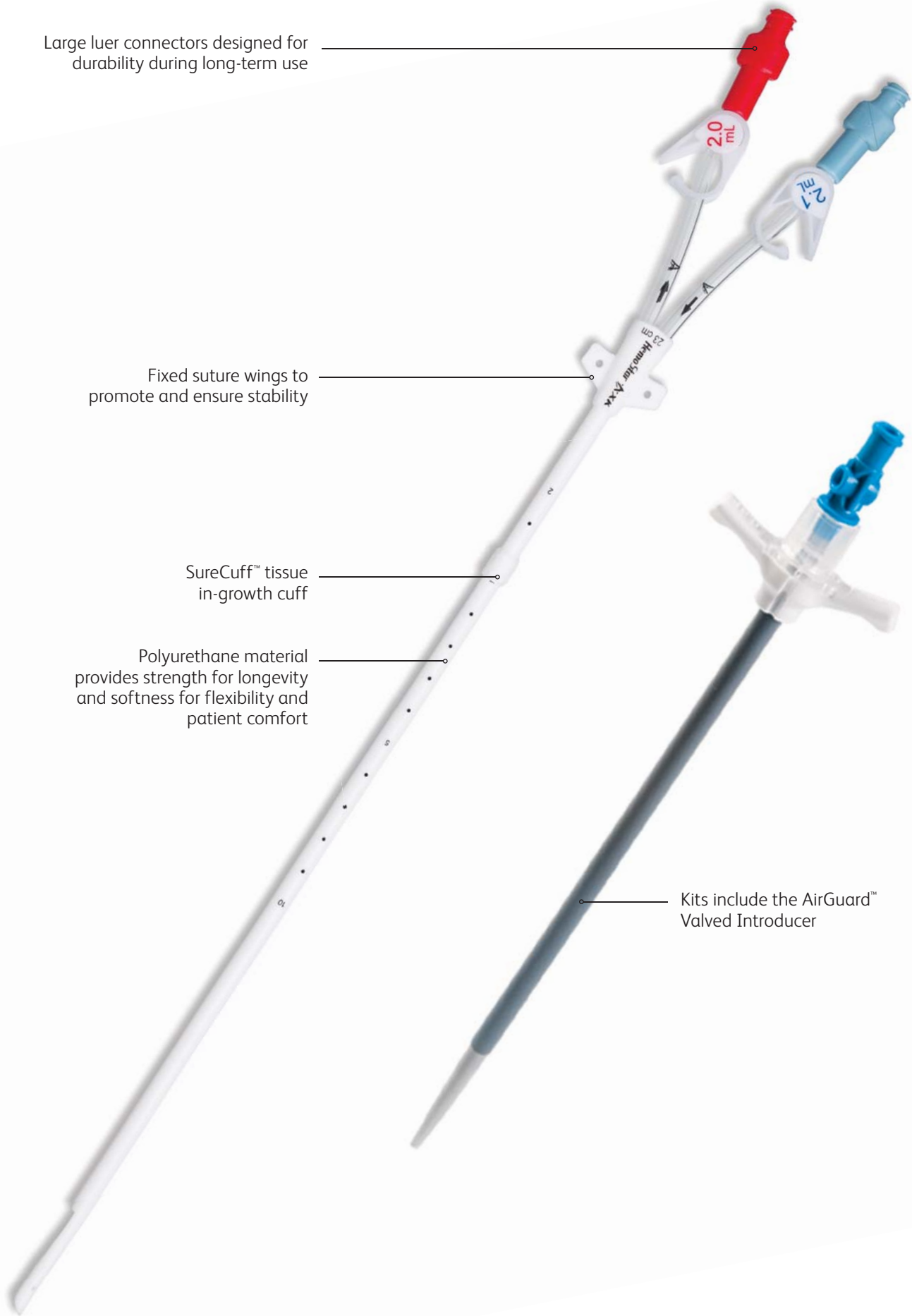
Large luer connectors designed for durability during long-term use

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

Kits include the AirGuard™ Valved Introducer



HemoStar™

Long-Term Hemodialysis Catheter

Insertion Length	Catheter Length	Product Code
Straight, Polyurethane Catheter, Standard Kit		
15 cm	20 cm	<input type="checkbox"/> 5833150
19 cm	24 cm	<input type="checkbox"/> 5833690
23 cm	28 cm	<input type="checkbox"/> 5833730
27 cm	32 cm	<input type="checkbox"/> 5833270
31 cm	36 cm	<input type="checkbox"/> 5833310
35 cm	40 cm	<input type="checkbox"/> 5833350
42 cm	47 cm	<input type="checkbox"/> 5834420
Alphacurve™, Polyurethane Catheter, Standard Kit		
19 cm	25 cm	<input type="checkbox"/> 5835150
24 cm	29 cm	<input type="checkbox"/> 5835190
28 cm	33 cm	<input type="checkbox"/> 5835230
31 cm	37 cm	<input type="checkbox"/> 5835270

REPRESENTATIVE'S NAME

CONTACT PHONE NO.

HemoStar™ XK

Long-Term Hemodialysis Catheter

Insertion Length	Catheter Length	Product Code
Straight, Polyurethane Catheter, Standard Kit		
19 cm	24 cm	<input type="checkbox"/> 5883690
23 cm	28 cm	<input type="checkbox"/> 5883730
27 cm	32 cm	<input type="checkbox"/> 5883270
31 cm	36 cm	<input type="checkbox"/> 5883310
35 cm	40 cm	<input type="checkbox"/> 5883350
42 cm	47 cm	<input type="checkbox"/> 5884420
Alphacurve™, Polyurethane Catheter, Standard Kit		
19 cm	25 cm	<input type="checkbox"/> 5885150
24 cm	29 cm	<input type="checkbox"/> 5885190
28 cm	33 cm	<input type="checkbox"/> 5885230

PHYSICIAN'S SIGNATURE

Hemostar™ and Hemostar™ XK Catheters

Indications For Use: The HemoStar™ and HemoStar™ 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.

Contraindication: This device is contraindicated for patients exhibiting severe, uncontrolled thrombocytopenia or coagulopathy.

Warnings: Warning: 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. 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. 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 10ml 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 3ml syringe generates pressure in excess of 30 psi (206 kPa) whereas the same three pound (13.3 Newton) force on the plunger of a 10ml 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.

Cautions: 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. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. 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^{3,8}. 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 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 hemodialysis 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

Standard Kit Contents - 14.5 F or 16 F (XK)
<ul style="list-style-type: none"> • Catheter • AirGuard™ Valved Introducer with Peel-Away Sheath/Dilator • Dilator – 8F • Dualator™ Dilator – 10-12 F • J-Tip Guidewire – 0.038 in. • Introducer Needle – 18 Gauge • Tunneler • (2) Adhesive Dressings • (2) End Cap

Additional XK Standard Kit Contents - 16 F (XK)
<ul style="list-style-type: none"> • Dualator™ Dilator – 14-16 F • Dualator™ Dilator – 15.5-17.5 F • Stiffening Wire • Scalpel

Product and Packaging Are Not Made with Natural Rubber Latex

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 Rib¹ · 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 · Spontaneous Catheter Tip Malposition or Retraction · Thoracic Duct Injury · Thromboembolism · Venous Thrombosis · Ventricular Thrombosis · Vessel Erosion · Risks Normally Associated with Local and General Anesthesia, Surgery, and Post-Operative Recovery.

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.
- 5 Mickle, V., "Central venous catheters: many questions: few answers", Nephrol Dial Transplant, (2002) 17:1368-1373.
- 7 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.
- 8 Tan, P.L., Gibson, M., "Central Venous Catheters: the role of radiology", Clin Rad. 2006, 61:13-22.

Please consult package inserts for more detailed safety information and instructions for use.

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