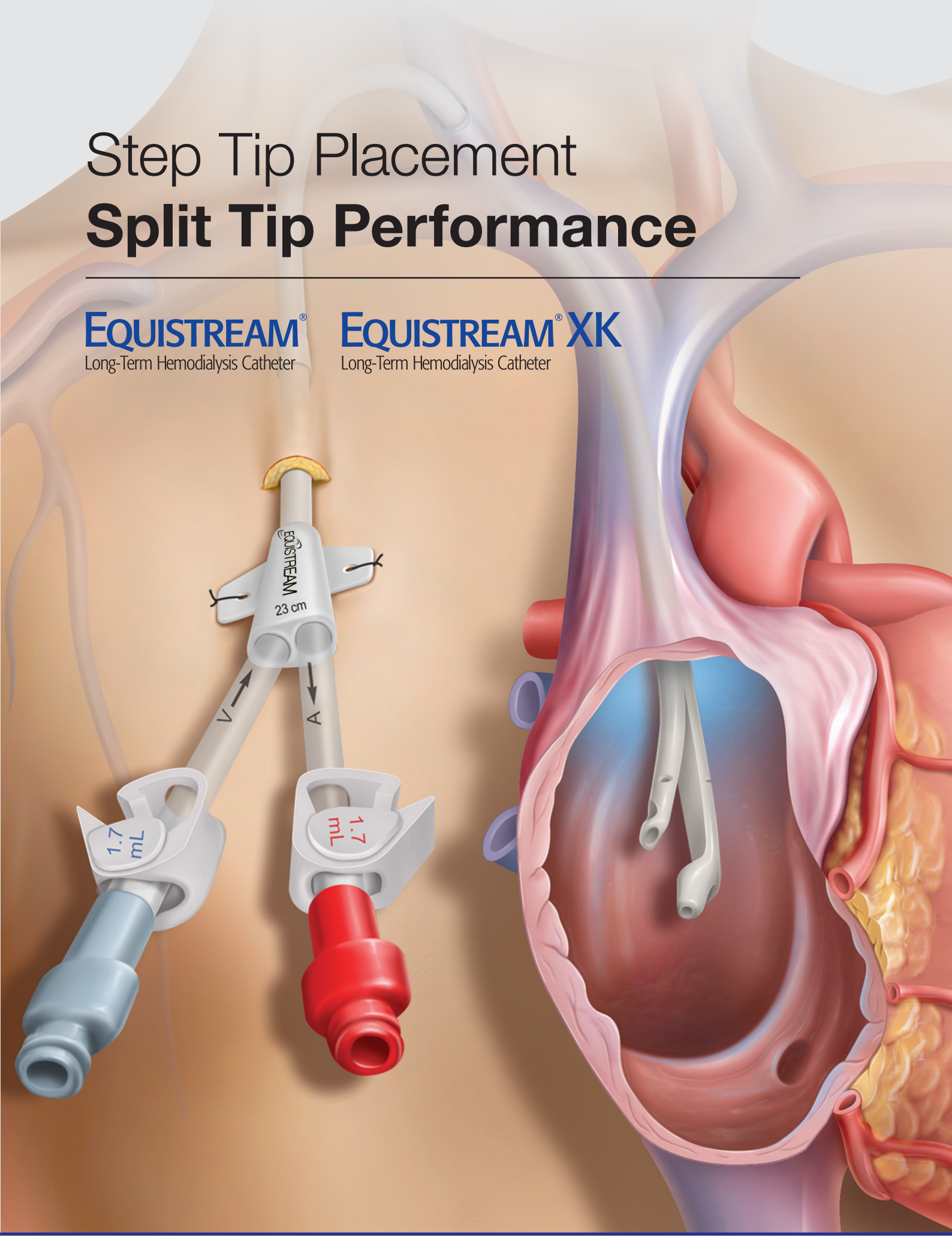
Step Tip Placement
Split Tip Performance

EQUISTREAM® Long-Term Hemodialysis Catheter

EQUISTREAM® XK Long-Term Hemodialysis Catheter



BD

BARD
has joined BD

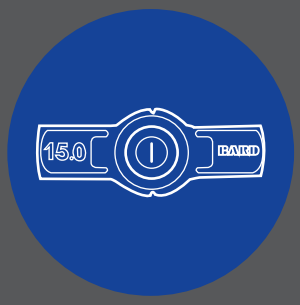
The split-tip technology of the 14.5F EQUISTREAM® and 16F EQUISTREAM® XK Long-Term Hemodialysis Catheters provides optimised flow for efficient dialysis and ease of access for right atrium placement.

Efficient Dialysis

- Nested tip design enables right atrium placement of both tips for optimal flow per KDOQI guidelines[1]
- Recirculation <2% on average in forward and reverse when tested in-vitro[2]
- High flow rates of 500 ml/min on average[3]

Multiple Choices

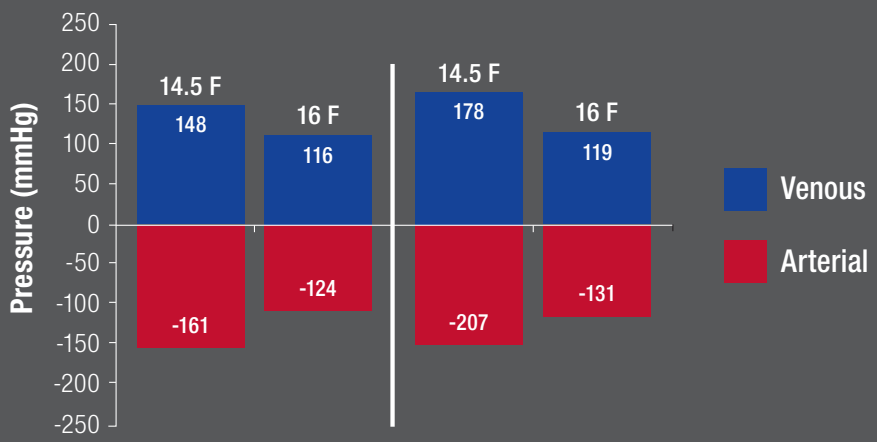
- Wide range of lengths
- Straight or ALPHACURVE® configurations



Ease of Use

- Preloaded stylet facilitates easier over-the-wire insertion[4]
- Kits include the AIRGUARD® Valved Introducer designed to reduce the risk of air embolism and blood loss

14.5 F vs. 16 F Catheter Performance (500 mL/min Flow Rate)



Bench data on file. May not necessarily correlate to clinical performance. Based on simulated testing. Different tests may yield different results.

1 NKF K-DOQI Guideline 12 (https://www.kidney.org/professionals/guidelines).
2 Data on file, Bard Access Systems, Inc. Bench test results may not be necessarily be indicative of clinical performance.
3 Blood pump setting using blood simulant.
4 Straight codes only.

Large luer connectors designed for durability during long-term use

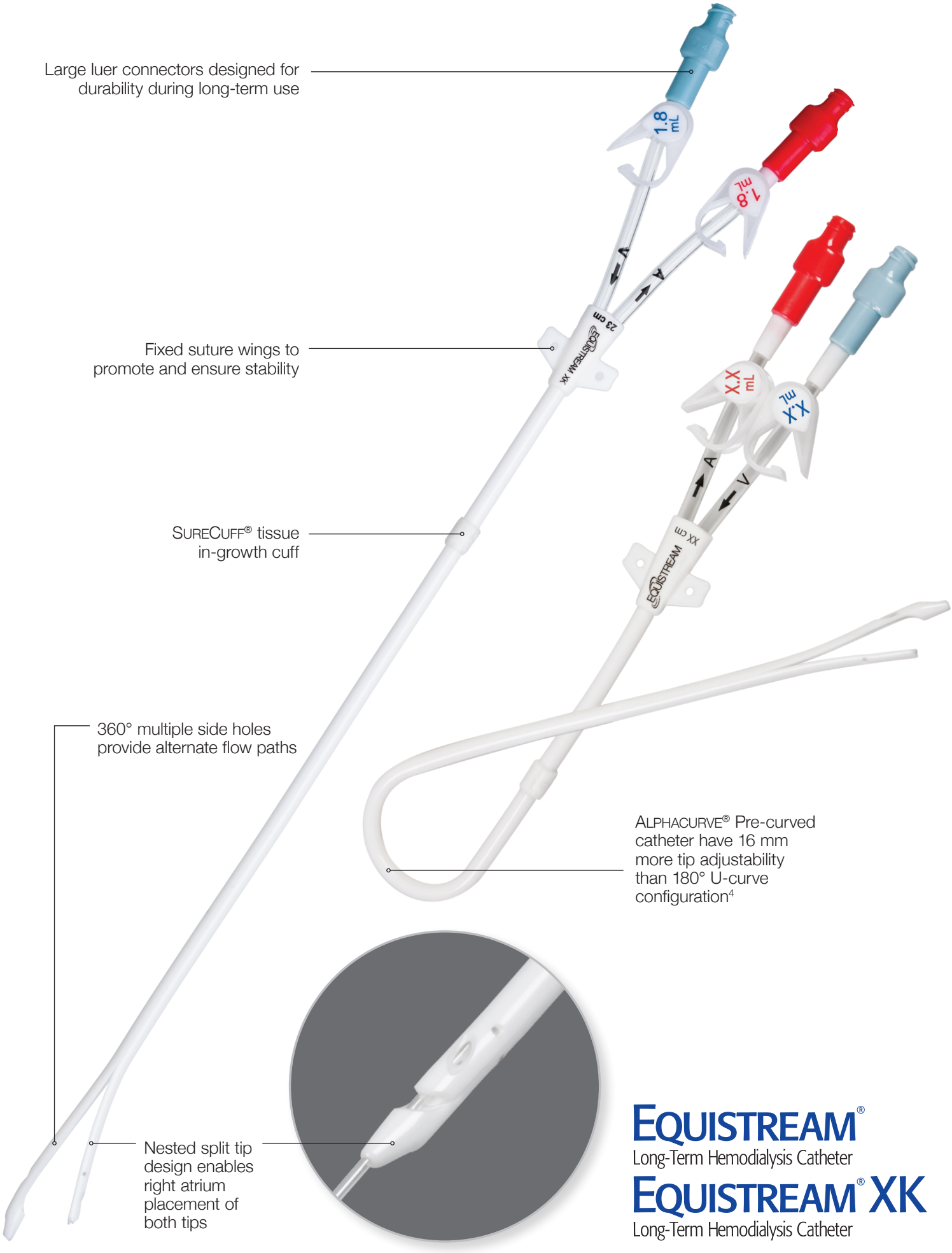
Fixed suture wings to promote and ensure stability

SURECUFF® tissue in-growth cuff

360° multiple side holes provide alternate flow paths

ALPHACURVE® Pre-curved catheter have 16 mm more tip adjustability than 180° U-curve configuration[4]

Nested split tip design enables right atrium placement of both tips



EQUISTREAM®
Long-Term Hemodialysis Catheter

EQUISTREAM® XK
Long-Term Hemodialysis Catheter

EQUISTREAM®
Long-Term Hemodialysis Catheter

Insertion Length	Catheter Length	Product Code
14.5F, Straight, Polyurethane Catheter, Standard Kit		
15 cm	19 cm	☐ 6903150
19 cm	24 cm	☐ 6903190
23 cm	28 cm	☐ 6903230
27 cm	32 cm	☐ 6903270
31 cm	36 cm	☐ 6903310
35 cm	40 cm	☐ 6903350
42 cm	47 cm	☐ 6903420
14.5F, ALPHACURVE®, Polyurethane Catheter, Standard Kit		
19 cm	24 cm	☐ 6905190
24 cm	29 cm	☐ 6905240
28 cm	33 cm	☐ 6905280
31 cm	36 cm	☐ 6905310

REPRESENTATIVE'S NAME

CONTACT PHONE NO.

EQUISTREAM® XK
Long-Term Hemodialysis Catheter

Insertion Length	Catheter Length	Product Code
16F, Straight, Polyurethane Catheter, Standard Kit		
19 cm	24 cm	☐ 6913190
23 cm	28 cm	☐ 6913230
27 cm	32 cm	☐ 6913270
31 cm	36 cm	☐ 6913310
35 cm	40 cm	☐ 6913350
42 cm	47 cm	☐ 6913420
16F, ALPHACURVE®, Polyurethane Catheter, Standard Kit		
19 cm	24 cm	☐ 6915190
24 cm	29 cm	☐ 6915240
28 cm	33 cm	☐ 6915280
31cm	36cm	☐ 6915310

Product and Packaging Are Not Made with Natural Rubber Latex

PHYSICIAN'S SIGNATURE

Standard Kit Contents - 14.5 F or 16 F (XK)

2 Each Adhesive Dressings
1 Each AIRGUARD® Valved Introducer – 15 F (16.5 F if XK)
1 Each Dilator – 8 F
1 Each Dual Lumen Catheter – 14.5 F (16 F if XK)
1 Each Dualator™ Vessel Dilator – 10-12 F
2 Each End Caps
1 Each Guidewire – 70 cm x 0.038 in.
1 Each Introducer Needle – 18 Ga.
1 Each Tunneler

Additional XK Standard Kit Contents - 16 F (XK)

1 Each Dualator™ Vessel Dilator – 14-16 F
1 Each Dualator™ Vessel Dilator – 15.5-17.5 F
1 Each Scalpel

Microintroducer Kit Contents - 14.5 F Only

2 Each Adhesive Dressings
1 Each AIRGUARD® Valved Introducer – 15 F
1 Each Dilator – 8 F
1 Each Dual Lumen Catheter – 14.5 F
1 Each Dualator™ Vessel Dilator – 10-12 F
1 Each Dualator™ Vessel Dilator – 14-16 F
1 Each Dualator™ Vessel Dilator – 15.5-17.5 F
2 Each End Caps
1 Each Guidewire – 45 cm x 0.018 in.
1 Each Guidewire – 120 cm x 0.038 in.
1 Each Introducer Needle – 21 Ga.
1 Each MicroIntroducer – 5 F
1 Each Tunneler

EQUISTREAM® and EQUISTREAM® XK Long-Term Hemodialysis Catheters

Indications For Use
The EQUISTREAM® and EQUISTREAM® 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 longer 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 embolisation 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). Solutions should be allowed to completely dry before applying dressing. • Acetone and Polyethylene Glycol (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 and/or stylet touches the walls of the right atrium. Use cardiac rhythm monitoring to detect arrhythmias. • 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. • Any sharp or acute angles that could compromise the opening of the catheter lumens need to be avoided. • To prevent air embolism and/or blood loss put patient in Trendelenburg position and always 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 heparinisation 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 resterilise 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.[7] • Alcohol should not be used to lock, soak or declot polyurethane Dialysis Catheters because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure. • Intended for Single Use. DO NOT REUSE. Reuse and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness or death of the patient.

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.[5,8] • Care should be taken NOT to force the dilator sheath introducer assembly into the vessel during insertion as vessel damage including perforation could result. • Stylet is intended for use over a guidewire to aid in placement. Inserting the stylet into the venotomy without tracking over a guidewire could result in vessel damage including perforation. • Failure to retract the stylet when inserting the tunneler into the catheter tip can result in damage to the stylet. • Ensure that the catheter does not move out of the vein while removing the insertion stylet. • Care should be taken not to advance the split sheath too far into vessel as a potential kink would create an impasse to the catheter. • Ensure that the introducer sheath is only torn externally. Catheter may need to be further pushed into the vessel as sheath is torn. • For optimal product performance, do not insert any portion of the cuff into the vein. • If the microintroducer guidewire must be withdrawn while the needle is inserted, remove both the needle and wire as a unit to prevent the needle from damaging or shearing the guidewire. • Before attempting the insertion of EQUISTREAM® Catheters, ensure that you are familiar with the complications listed below and their emergency treatment should any of them occur. • The complications listed below as well as other complications are well documented in medical literature and should be carefully considered before placing the catheter. Placement and care of EQUISTREAM® Catheters should be performed by persons knowledgeable of the risks involved and qualified in the procedures.

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 • Arterial Puncture • 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 • Hemomediastinum • 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 • Thoracic Duct Injury • Thromboembolism • Venous Stenosis • 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 Mickley, V., "Central venous catheters: many questions: few answers", Nephrol Dial Transplant, (2002) 17:1368-1373.

7 Sulek, CA., Blas, ML., Lobato, EB, "A randomised 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