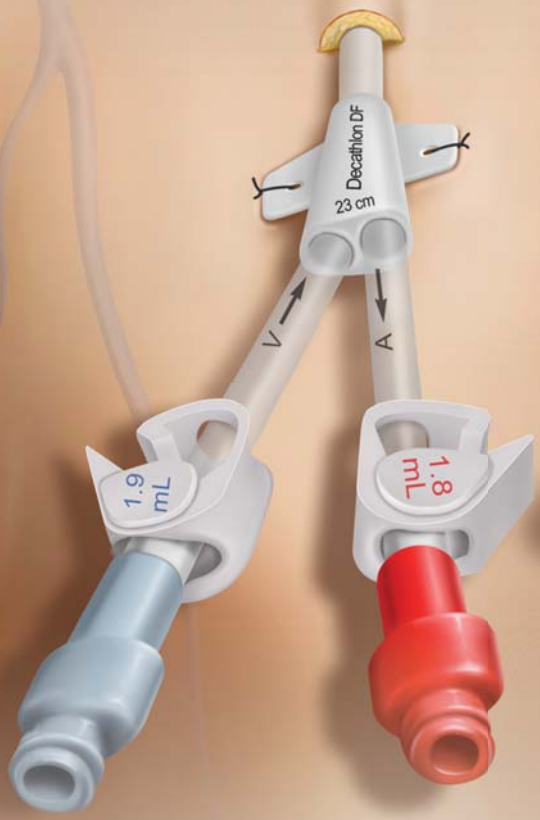
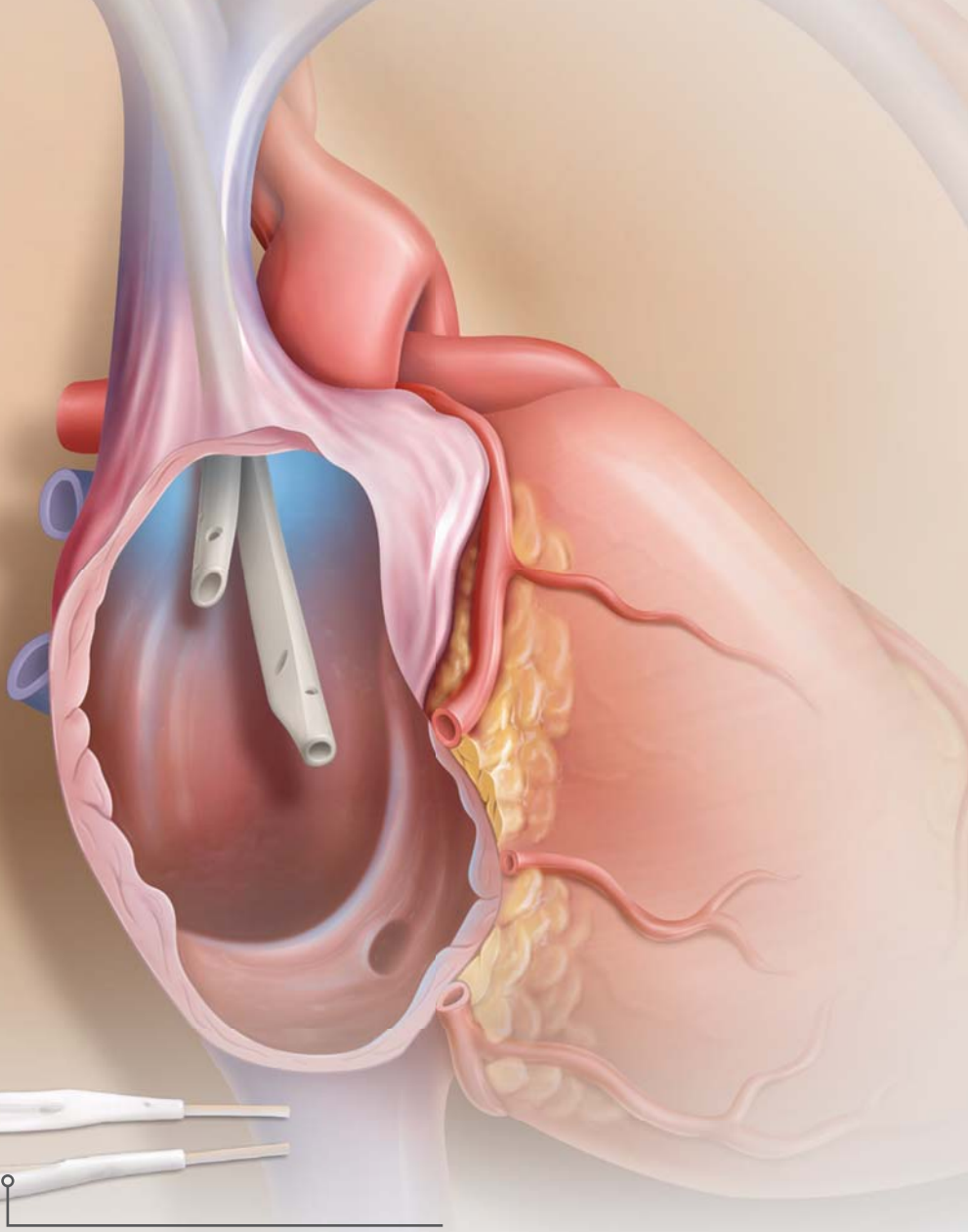
The Easy-to-Place, **Tapered Split Tip** Catheter

Decathlon™ DF

Long-Term Hemodialysis Catheter





16 F catheter made of soft biocompatible polyurethane material

Tapered Split-Tips with Stylet for Over-the-Wire Placements
Tapered tips and preloaded stylet facilitate standard or over-the-wire insertion technique

BD

Decathlon™ DF

Long-Term Hemodialysis Catheter

Decathlon™ DF Standard Kit

Tip to Cuff Length	Tip to Hub Length	Order Codes
19 cm	24 cm	☐ DF19SH24K
23 cm	28 cm	☐ DF23SH28K
27 cm	32 cm	☐ DF27SH32K
31 cm	36 cm	☐ DF31SH36K
35 cm	40 cm	☐ DF35SH40K
50 cm	55 cm	☐ DF50SH55K

Decathlon™ DF Exchange Kit

Tip to Cuff Length	Tip to Hub Length	Order Codes
19 cm	24 cm	☐ DF19IT24K
23 cm	28 cm	☐ DF23IT28K
27 cm	32 cm	☐ DF27IT32K
31 cm	36 cm	☐ DF31IT36K
35 cm	40 cm	☐ DF35IT40K
50 cm	55 cm	☐ DF50IT55K

Standard Kit Contents

- 16 F Catheter
- 16.5 F AirGuard™ Valved Introducer with peel-away sheath/dilator
- 18 gauge introducer needle
- J Tip Guidewire/straight 0.038 inch marked guidewire
- 10 - 12 F Dualator™ Dilator
- 14 - 16 F Dualator™ Dilator
- Scalpel
- Tunneler
- Adhesive dressing
- (2) End caps
- Insertion stylet

Exchange Kit Contents:

- 16 F Catheter
- 16.5 F AirGuard™ Valved Introducer with peel-away sheath/dilator
- 10 - 12 F Dualator™ Dilator
- 14 - 16 F Dualator™ Dilator
- (2) End caps
- Insertion stylet
- Tunneler

Product and Packaging Are Not Made with Natural Rubber Latex

_____

REPRESENTATIVE NAME

_____

CONTACT PHONE NO.

_____

PHYSICIAN'S NAME

_____

PHYSICIAN'S SIGNATURE

Decathlon™ Long-Term Hemodialysis Catheter

Indications for Use: The Decathlon™ DF long-term hemodialysis catheter is 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.

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

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.[1,2] · 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 Decathlon® DF 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 Decathlon® DF 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 Rib[4], 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

Warnings: · 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 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.[3] · 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.

Please consult product labels and package inserts for indications, contraindications, hazards, warnings, cautions and instructions for use.

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