



DRAINEX™ RAPID EXCHANGE DRAINAGE CATHETER INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION

DrainEx™ catheters are ethanol-resistant polyurethane general purpose drainage catheters designed for rapid exchange. It is available in multiple sizes. Each catheter has multiple side holes for drainage, suture for pigtail retention, and a jacket for strain relief. Each catheter comes with a cannula for straightening the pigtail and providing support during placement.

INDICATIONS FOR USE

DrainEx™ catheters are designed for percutaneous nephrostomy, cecostomy, and the drainage of abscesses. This device is not indicated for direct contact with the heart, central circulatory system or the central nervous system.

POTENTIAL ADVERSE EVENTS

The following adverse reactions may occur with the use of drainage catheters:

- Polyurethane allergy
- Bronchopleural fistula
- Hemorrhage
- Skin infection
- Catheter dislodgment
- Catheter migration
- Catheter fragmentation
- Empyema

WARNINGS

Exchange or remove this catheter if it becomes malpositioned or occluded.

DO NOT use this catheter to deliver TPN.

DO NOT power inject through this catheter.

CATHETER PLACEMENT PROCEDURE

SELDINGER TECHNIQUE:

1. Inspect package and catheter, to confirm both are pristine.
2. Select the site for catheter insertion.
3. Create sterile field and open package.
4. Prep and drape the site.
5. Perform satisfactory anesthesia.
6. Attach an introducer needle to a syringe.
7. Insert the introducer needle into the fluid collection and aspirate fluid to confirm proper positioning.
8. Remove the syringe from the introducer needle.
9. Insert a guidewire through the introducer needle into the fluid collection.

NOTE: Select a guidewire that is roughly 1½ times the catheter length.

10. Remove the introducer needle over the guidewire and discard it.

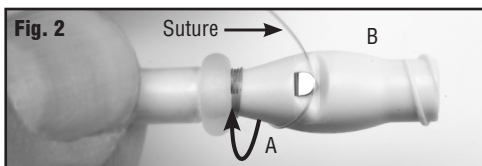
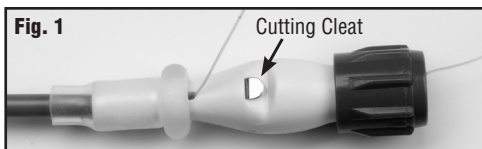
CAUTION: If you must withdraw the guidewire while the needle is in place, remove both as a unit to prevent the needle from damaging the guidewire.

11. While securing guidewire, use appropriate dilator to expand soft tissue track.
12. Open the pigtail of the catheter. Advance the cannula to straighten the pigtail and provide support when advancing the catheter.

NOTE: To ease insertion of the cannula, intermittently straighten the pigtail with your fingers before advancing slightly.

NOTE: To ease insertion of the cannula, intermittently straighten the pigtail with your fingers before advancing slightly.

13. Lock cannula in place.
14. Advance the drainage catheter over the guidewire to the intended location, under imaging guidance.
15. When drainage catheter is in the appropriate position, remove cannula and guidewire to coil the pigtail.
16. Tighten the pigtail by gently pulling the retention suture.
17. Wrap the suture around the hub several times (See Fig. 2, arrow a) and pull the remaining suture under and across the cleat to cut and remove the excess suture (See Fig. 2, arrow B).
18. Secure the suture and cover the cleat with the silicone collar.



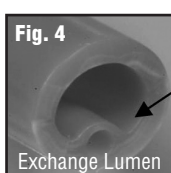
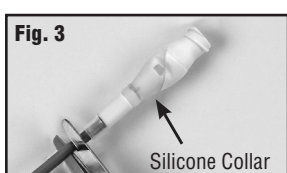
CATHETER REMOVAL

When the physician has determined that the catheter can be removed:

1. Cut catheter 1 cm distal to hub using scissors (See fig. 3). Be aware that the suture is no longer secured to the catheter.
2. Gently withdraw the catheter and confirm full catheter and suture have been removed.
3. Place sterile bandage over catheter removal site.

CATHETER EXCHANGE

1. Create sterile field and open tray.
2. Prep and drape the site.
3. Perform satisfactory anesthesia.
4. Cut old catheter 1 cm distal to hub using scissors (See Fig. 3). Be aware that the suture is no longer secured to the catheter.
5. Advance wire through exchange lumen (See Fig. 4) to required site, under imaging guidance.
6. Gently withdraw old catheter and confirm full catheter and suture have been removed.
7. While stabilizing the wire, advance new catheter to intended location.
8. Slowly withdraw guidewire.
9. Under imaging guidance, pull retention suture to lock the pigtail.
10. Wrap the suture around the hub several times (See Fig. 2, arrow A) and pull the remaining suture into the cutting cleat (See Fig. 1) to make it hold the suture. Cut off the excess suture (See Fig. 2, arrow B).
11. Cover the cleat with the silicone collar. (See Fig. 3)



GUIDEWIRE COMPATIBILITY CHART

Drainage Catheter French Size	Placement Guidewire Size (inch)	Exchange Guidewire Size (inch)
7	0.018	0.018
8	0.018	0.018
11	0.038	0.035
13	0.038	0.035
14	0.038	0.035
16	0.038	0.035
18	0.038	0.035

CAUTIONS

- Federal (USA) law restricts this device to sale by or use under the order of a physician or other properly licensed practitioner.
- r4 sterilizes with ethylene oxide. This product is sterile unless the package is opened or suffered damage.
- Single patient use only.
- Do not re-sterilize this device.

r4 Vascular wrote this Instructions for Use in August 2009. If referencing this document after August 2011, contact r4 Vascular, Inc. to see if additional product information is available. DrainEx™ and “technologies that save” are trademarks or registered trademarks of r4 Vascular, Inc.

r4 Vascular, Inc. warrants to the purchaser of this product that the product will be free from defects in materials and workmanship for a period of one year from the date of purchase. r4 Vascular’s liability under any legal or equitable theory (whether in contract, tort, strict liability or otherwise) will be exclusively limited to repair or replacement of the defective product, or if in r4 Vascular’s opinion repair and replacement would be inadequate or impractical, a refund of the purchase price. This limited warranty does not cover (i) wear and tear from use in accordance with the then current specifications provided by r4 Vascular, (ii) defects resulting from improper storage or handling, (iii) any use of this product not in accordance with the then current specifications provided by r4 Vascular, (iv) attempted re-sterilization or re-use of the catheter, and (v) a catheter that has been altered, modified or repaired by anyone other than r4 Vascular.

TO THE EXTENT PERMITTED UNDER APPLICABLE LAW, THE PRODUCT IS SOLD TO YOU “AS IS” AND THIS LIMITED PRODUCT WARRANTY IS GIVEN IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, AND OF NON-INFRINGEMENT. IN NO EVENT WILL r4 VASCULAR, INC. BE LIABLE TO YOU FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.