

Nephrostomy Catheter

INSTRUCTIONS FOR USE

DESCRIPTION

The ReSolve CirQ™ Nephrostomy Catheter is a radiopaque nephrostomy catheter designed to be placed in a loop to help prevent inadvertent catheter withdrawal. The ReSolve CirQ may be packaged with the following components:

- Y-connector with locking collars
- FastBreak™ Breakaway Connector connectors with varying connection strengths

INDICATIONS FOR USE

The ReSolve CirQ Nephrostomy Catheter is intended for percutaneous nephrostomy drainage.

CONTRAINDICATIONS

- The ReSolve CirQ Nephrostomy Catheter is contraindicated for use where percutaneous drainage catheterization is unacceptable.
- The ReSolve CirQ Nephrostomy Catheter is contraindicated for intravascular use.

WARNINGS

- The ReSolve CirQ Nephrostomy Catheter is not to be used to deliver nutritional supplements.
- The ReSolve CirQ Nephrostomy Catheter is not to be used in the biliary system.
- The primary and secondary tracts should not be in the same calyx.

PRECAUTIONS

1. **RX ONLY: Caution:** Federal law (U.S.A.) restricts this device to sale by or on the order of a physician trained and/or experienced in the use of this device.
2. Read manufacturer's instructions prior to use.
3. For single patient use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure, which in turn may result in patient injury, illness, or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.
4. Do not use after expiration date.
5. Periodic evaluation is advised; catheter must not remain indwelling more than three months.

INSTRUCTIONS FOR USE

To replace an existing nephrostomy catheter with a ReSolve CirQ

1. Opacify the renal pelvis and calyces via nephrostogram.
2. Using standard technique, make a secondary tract (new tract created for CirQ), far enough from the primary tract (existing nephrostomy tract) to prevent the catheter from kinking in the renal pelvis (Fig.1)
3. Place a guide wire into the renal pelvis through the secondary tract long enough to place the catheter over.
4. Dilate tracts as necessary.
5. Remove the nephrostomy tube in the primary tract while maintaining access.
6. Consider using an appropriate sized sheath for placing the ReSolve CirQ.
7. Using standard methods, capture the guide wire in the secondary tract via the primary tract. (Fig. 2)
8. Withdraw the guide wire through the primary tract creating a loop to thread the catheter over. (Fig. 3)
9. Wet the distal portion of the ReSolve CirQ catheter prior to use with sterile water or saline. Keep the distal portion of the catheter wet during placement.
Note: Step 9 is only for catheters with hydrophilic coating.
WARNING: DO NOT wipe catheter with dry gauze or any solvents because it may damage the catheter coating.
10. Place the catheter over the guide wire using the secondary tract. (Fig. 4)
NOTE: Ensure all of the drainage holes are within the renal pelvis.
11. Remove the guide wire through one end of the catheter.
12. Occlude one end of the catheter and perform a nephrostogram to confirm proper positioning.
13. If the catheter is not in the appropriate position, re-insert the guide wire and reposition the catheter and repeat steps 8 -10.
14. When proper positioning is confirmed, cut the shaft of the catheter with a square cut, to the correct length.
NOTE: The tapered end of the catheter must be cut prior to connecting to the Y-connector. (Fig. 5)
15. Fasten the ends of the catheter to the Y-connector by pushing the catheter over the barb until the catheter end is past the collar crease (Fig. 6)
16. Connect the desired FastBreak Breakaway Connector to the Y-connector. (Fig. 7)
17. Connect the appropriate drainage bag, tubing or dead end cap to the FastBreak Breakaway Connector.
WARNING: DO NOT over tighten the connection between the FastBreak Breakaway Connector and drainage bag, tubing or dead end cap.
Note: A flush regimen should be designed for the circumstances of each patient and the protocol of the physician.
Note: Instruct patient or other healthcare personnel in appropriate device function and/ or maintenance.

To Exchange an existing ReSolve CirQ Nephrostomy Catheter

1. Clean the catheter using standard technique.
2. Cut both sides of the catheter leaving enough catheter length to hold the catheter from the primary and secondary tracts. (Fig. 8)
3. Thread a guide wire through the catheter.
NOTE: Some difficulty may be experienced negotiating the guide wire past the drainage holes of the catheter in the renal pelvis.
4. Remove the catheter over the guide wire ensuring the guide wire continues to exit both tracts. (Fig. 3)
5. Consider using an appropriate sized sheath for placing the ReSolve CirQ.
6. Wet the distal portion of the ReSolve CirQ catheter prior to use with sterile water or saline. Keep the distal portion of the catheter wet during placement.
Note: Step 6 is only for catheters with hydrophilic coating.
WARNING: DO NOT wipe catheter with dry gauze or any solvents because it may damage the catheter coating.
7. Place a new catheter over the guide wire into appropriate position. (Fig. 4)
8. Remove the guide wire through one end of the catheter.
9. Occlude one end of the catheter and perform a nephrostogram to confirm proper positioning.

10. If the catheter is not in the appropriate position, re-insert the guide wire and reposition the catheter and repeat steps 5 -7.
11. When proper positioning is confirmed, cut the shaft of the catheter with a square cut, to the correct length.
NOTE: The tapered end of the catheter must be cut prior to connecting to the Y-connector. (Fig. 5)
12. Fasten the ends of the catheter to the Y-connector by pushing the catheter over the barb until the catheter end is past the collar crease (Fig. 6)
13. Connect the desired FastBreak Breakaway Connector to the Y-connector. (Fig. 7)
14. Connect the appropriate drainage bag, tubing or dead end cap to the FastBreak Breakaway Connector.
WARNING: DO NOT over tighten the connection between the FastBreak Breakaway Connector and drainage bag, tubing or dead end cap.
Note: A flush regimen should be designed for the circumstances of each patient and the protocol of the physician.
Note: Instruct patient or other healthcare personnel in appropriate device function and/ or maintenance.

To place a ReSolve CirQ Nephrostomy Catheter without prior catheter in place

1. Gain primary tract access into a lower pole calyx using standard technique. (Fig. 9)
2. Opacify the renal pelvis and calyces via nephrostogram.
3. Using standard technique, make a secondary tract, far enough from the primary tract to prevent the catheter from kinking in the renal pelvis (Fig.10)
4. Place a guide wire into the renal pelvis through the secondary tract long enough to place the catheter over.
5. Dilate catheter tracts as necessary.
6. Consider using an appropriate sized sheath for placing the ReSolve CirQ
7. Using standard methods, capture the guide wire in the secondary tract via the primary tract. (Fig. 2)
8. Withdraw the guide wire through the primary tract creating a loop to thread the catheter over. (Fig. 3)
9. Wet the distal portion of the ReSolve CirQ catheter prior to use with sterile water or saline. Keep the distal portion of the catheter wet during placement.
Note: Step 9 is only for catheters with hydrophilic coating.
WARNING: DO NOT wipe catheter with dry gauze or any solvents because it may damage the catheter coating.
10. Place the catheter over the guide wire using the secondary tract. (Fig. 4)
NOTE: Ensure all of the drainage holes are within the renal pelvis.
11. Remove the guide wire through one end of the catheter.
12. Occlude one end of the catheter and perform a nephrostogram to confirm proper positioning.
13. If the catheter is not in the appropriate position, re-insert the guide wire and reposition the catheter and repeat steps 8 -10.
14. When proper positioning is confirmed, cut the shaft of the catheter with a square cut, to the correct length.
NOTE: The tapered end of the catheter must be cut prior to connecting to the Y-connector. (Fig. 5)
15. Fasten the ends of the catheter to the Y-connector by pushing the catheter over the barb until the catheter end is past the collar crease (Fig. 6)
16. Connect the desired FastBreak Breakaway Connector to the Y-connector. (Fig. 7)
17. Connect the appropriate drainage bag, tubing or dead end cap to the FastBreak Breakaway Connector.
WARNING: DO NOT over tighten the connection between the FastBreak Breakaway Connector and drainage bag, tubing or dead end cap.
Note: A flush regimen should be designed for the circumstances of each patient and the protocol of the physician.
Note: Instruct patient or other healthcare personnel in appropriate device function and/ or maintenance.

RX ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Caution: Consult accompanying documents.
	Do not use if package is damaged
	Non-pyrogenic
	Maximum diameter guide wire
STERILE EO	Sterilized using Ethylene Oxide



www.merit.com



Manufacturer:
Merit Medical Systems, Inc.
1600 West Merit Parkway, South Jordan, Utah 84095 U.S.A.
1-801-253-1600
U.S.A Customer Service 1-800-356-3748



Authorized Representative:
Merit Medical Ireland Ltd, Parkmore Business Park West, Galway, Ireland
EC Customer Service +31 43 3588222



FIGURE 1

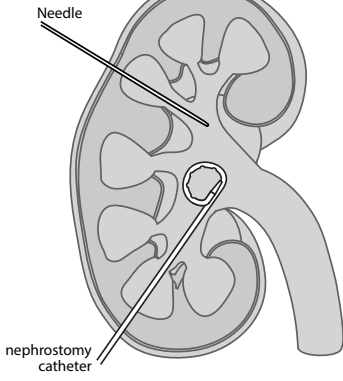


FIGURE 2

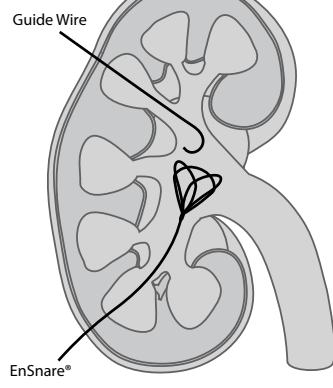


FIGURE 3

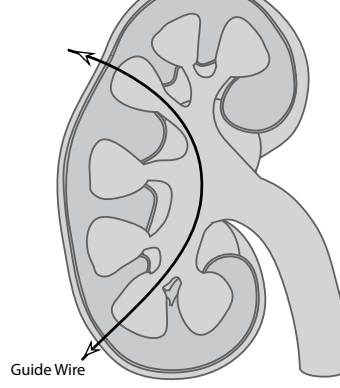


FIGURE 4

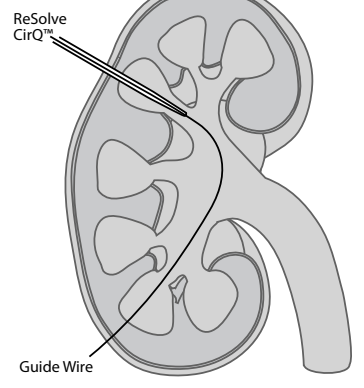


FIGURE 5

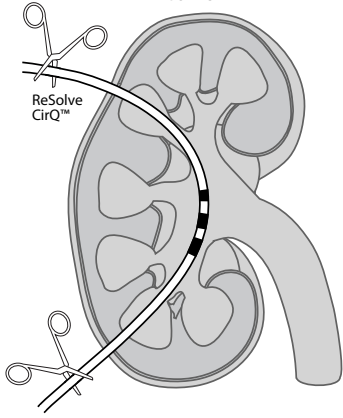


FIGURE 6

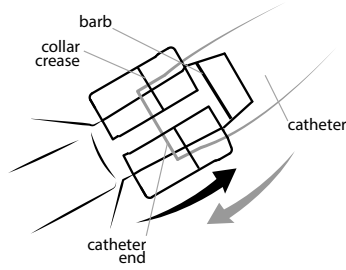


FIGURE 7

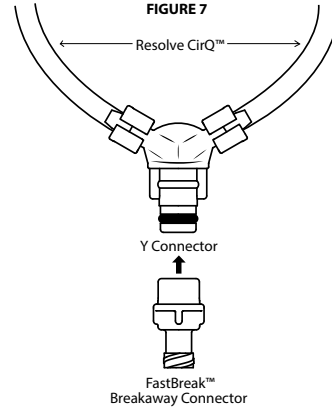


FIGURE 8

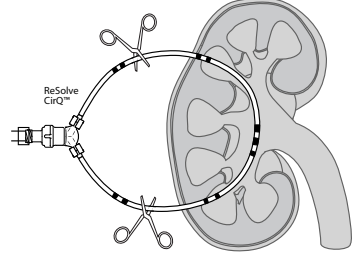


FIGURE 9

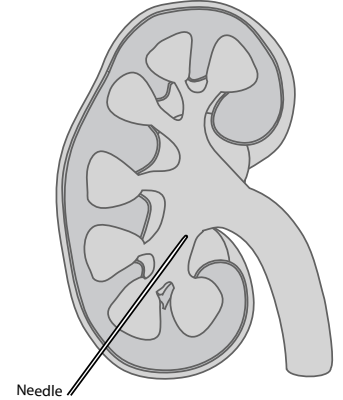


FIGURE 10

