English

ReSolve MINI™

Locking Drainage Catheter

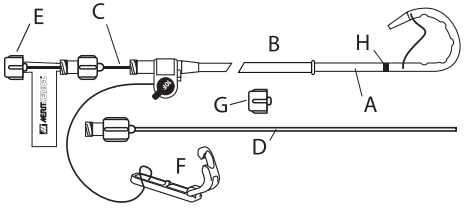
INSTRUCTIONS FOR USE

PRODUCT NAME
ReSolve Mini™ Locking Drainage Catheter

DESCRIPTION OF THE PRODUCT
The ReSolve Mini Locking Drainage Catheter with locking pigtail and hydrophilic coating is a radiopaque catheter with multiple side holes used for percutaneous drainage. The components of the catheter allow for introduction and placement using a trocar stylette or over-the-wire method.

The ReSolve Mini Locking Drainage Catheter may be packaged with the following components:

- One (1) ReSolve Mini Locking Drainage Catheter with locking pigtail (A), hydrophilic coating and pigtail straightener (B)
- One (1) Metal stiffening cannula (C)
- One (1) Flexible stiffening cannula (D)
- One (1) Trocar stylette (E)
- One (1) Repositioning Tool (F)
- One (1) Dead end cap (G)
- One (1) Marker band (H)



INDICATIONS FOR USE
The ReSolve Mini Locking Drainage Catheter with locking pigtail and hydrophilic coating is intended for percutaneous drainage of fluid from body cavities.

CLINICAL BENEFITS
Percutaneous drainage of fluid from body cavities.

CONTRAINDICATIONS
The ReSolve Mini Locking Drainage Catheter is contraindicated for use where percutaneous drainage catheterization is unacceptable.

The ReSolve Mini Locking Drainage Catheter is contraindicated for intravascular use.

MRI INFORMATION

MR CONDITIONAL
The ReSolve Mini Locking Drainage Catheter is MR Conditional

Non-clinical testing has demonstrated that the ReSolve Mini Locking Drainage Catheter is MR Conditional. This device can be scanned safely in a patient, immediately after placement under the following conditions:

- Static Magnetic Field of 3 Tesla or less
- Maximum spatial gradient magnetic field of 4,000 gauss/cm (40 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg in the First Level Controlled Operating Mode of operation for the MR system

MRI-RELATED HEATING
Under the scan conditions defined above, the ReSolve Mini Locking Drainage Catheter is expected to produce a maximum temperature rise of 2.3°C after 15 minutes of continuous scanning.

ARTIFACT INFORMATION
The maximum artifact size as seen on the gradient echo pulse sequence at 3-Tesla extends approximately 2-mm relative to the size of the shape of the ReSolve Mini Locking Drainage Catheter.

The safety of the initial placement system including the metal stiffening cannula has not been evaluated in the MR environment, and therefore, these components should not be used within the MR environment.

PRECAUTIONS

- Read manufacturer's instructions prior to use.
- Contents of unopened, undamaged package are sterile.
- 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.
- Follow universal precautions when inserting and maintaining this device.
- Due to the risk of bloodborne pathogens, healthcare professionals should always use standard blood and body fluid precautions in the care of all patients.
- Sterile technique should always be followed.
- Do not use after expiration date.
- Store in a cool, dry place.

WARNINGS

- The ReSolve Mini Locking Drainage Catheter is not to be used to deliver nutritional supplements.

℞ Only Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician trained and/or experienced in the use of this device.

ADVERSE REACTIONS

- Septic shock
- Bacteremia
- Hemorrhage
- Superinfection
- Bowel transgression
- Pleural transgression
- Vascular injury
- Catheter dislodgement
- Catheter occlusion

INSTRUCTIONS FOR USE OPTION 1:

DIRECT PLACEMENT USING TROCAR STYLET

1. Remove the stiffening cannula and trocar stylette assembly from catheter.
2. Wet the distal portion of the ReSolve Mini Locking Drainage catheter prior to use with sterile water or saline. Keep the distal portion of the catheter wet during placement.
   WARNING: DO NOT wipe catheter with dry gauze or any solvents because it may damage the catheter coating.
3. Flush catheter prior to use.
4. Ensure suture locking mechanism is in the proximal position.

5. Slide pigtail straightener along distal portion of catheter to straighten curve prior to placing metal stiffening cannula into the catheter. Place the metal stiffening cannula into the catheter and tighten the Luer lock fittings. See Figure 1.

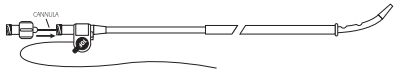


Figure 1

Caution: To prevent catheter damage fully seat cannula in the catheter tip before removing the paper spacer and inserting the trocar stylette.

6. Remove the paper spacer from the trocar stylette. Advance the trocar stylette through the metal stiffening cannula and tighten the Luer lock fittings. See Figure 2.

Figure 2

7. Remove pigtail straightener from catheter prior to insertion.
8. Place the catheter/cannula/trocar assembly into the fluid collection site using standard insertion technique.

   Note: Placement should be confirmed with diagnostic imaging.
9. After placement is confirmed, remove the trocar stylette and stiffening cannula.
10. To engage the suture locking mechanism: Pull the suture until desired pigtail is formed. Rotate the suture locking mechanism distally to hold the suture in place. See Figure 3.

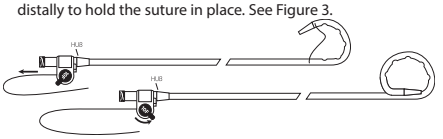


Figure 3

Note: If the catheter needs to be repositioned, unlock the suture locking mechanism by rotating the arm proximally to the point of resistance.

Precaution: When unlocking, do not rotate the suture locking mechanism beyond the point of resistance. Rotating the suture locking mechanism beyond the point of resistance will not release the suture to allow the pigtail to straighten upon removal.

11. Once placement is confirmed, and the suture locking mechanism has been rotated to the most distal position, press the suture locking mechanism into the hub to secure it. The suture locking mechanism is now locked into position. See Figure 4.

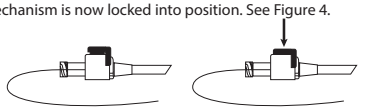


Figure 4

12. The ReSolve Mini Locking Drainage Catheter is now ready to be connected to appropriate drainage bag, tubing or dead end cap.

    WARNING: If using alcohol to clean the catheter hub, allow sufficient time for alcohol to dry before connecting the drainage tubing or dead end cap.

    WARNING: DO NOT over tighten the connection between the drainage catheter and drainage 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.

INSTRUCTIONS FOR USE OPTION 2:

SELDINGER ENTRY TECHNIQUE OR GUIDE WIRE EXCHANGE

1. Remove the stiffening cannula and trocar stylette assembly from catheter.
2. Ensure that the distal portion of the catheter is wet prior to placement. Wet the distal portion of the ReSolve Mini Locking Drainage catheter prior to use with sterile water or saline. Keep the distal portion of the catheter wet during placement.

   WARNING: DO NOT wipe catheter with dry gauze or any solvents because it may damage the catheter coating.
3. Flush catheter prior to use.
4. Ensure suture locking mechanism is in the proximal position.

5. Slide pigtail straightener along distal portion of catheter to straighten curve prior to placing the stiffening cannula into the catheter. Place the stiffening cannula into the catheter and tighten the luer lock fittings. See Figure 5.

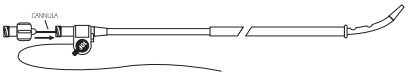


Figure 5

6. Remove pigtail straightener from catheter prior to insertion.
7. Place catheter/cannula assembly over appropriate guide wire and advance into the fluid collection site. The catheter accommodates a 0.038" (0.97 mm) wire. See Figure 6.

   Note: Placement should be confirmed with diagnostic imaging.

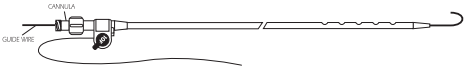


Figure 6

8. After placement is confirmed, remove the stiffening cannula and guide wire.
9. To engage the suture locking mechanism: Pull the suture until desired pigtail is formed. Rotate the suture locking mechanism distally to hold the suture in place. See Figure 7.

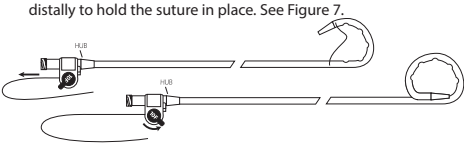


Figure 7

Note: If the catheter needs to be repositioned, unlock the suture locking mechanism by rotating the arm proximally to the point of resistance.

Precaution: When unlocking, do not rotate the suture locking mechanism beyond the point of resistance. Rotating the suture locking mechanism beyond the point of resistance will not release the suture to allow the pigtail to straighten upon removal.

10. Once placement is confirmed, and the suture locking mechanism has been rotated to the most distal position, press the suture locking mechanism into the hub to secure it. The suture locking mechanism is now locked into position. See Figure 8.

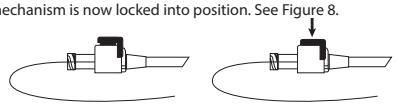


Figure 8

11. The ReSolve Mini Locking Drainage Catheter is now ready to be connected to appropriate drainage bag, tubing or dead end cap.

    WARNING: If using alcohol to clean the catheter hub, allow sufficient time for alcohol to dry before connecting the drainage tubing or dead end cap.

    WARNING: DO NOT over tighten the connection between the drainage catheter and drainage tubing or dead end cap.

    Note: A flush regimen should be designed for the circumstances of each patient and the protocol of the physician.

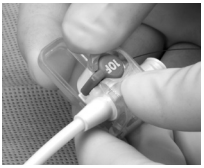
    Note: Instruct patient or other healthcare personnel in appropriate device function and/ or maintenance.

CATHETER EXCHANGE, REPOSITIONING OR REMOVAL

1. Disconnect catheter from drainage bag, tubing or dead end cap.
2. To release the pigtail loop choose one of the following options:

Option 1:

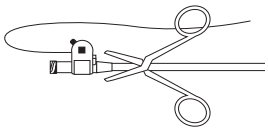
- Using the Repositioning Tool align the opening of the round section of the Repositioning Tool in line with the handle of the suture locking mechanism.
- Bring the flat back of the Repositioning Tool around the catheter hub.
- Gently squeeze together.
- Remove the Repositioning Tool and rotate the suture locking mechanism to the most proximal position.



Precaution: Do not rotate the suture locking mechanism beyond the point of resistance. Rotating the suture locking mechanism beyond the point of resistance will not release the suture to allow the pigtail to straighten upon removal.

Option 2:

For exchange or removal only, cut the hub off the drainage catheter and sever suture. This will release the suture and the pigtail loop.
WARNING: The suture will no longer be secured to the catheter. Take care to remove both the suture and catheter.



3. For catheter exchange or if access is to be maintained, advance appropriate guide wire through catheter; using diagnostic imaging to confirm guide wire placement. Guide wire will maintain access to drainage site. To ease guide wire placement, a stiffening cannula may be used

   WARNING: When long-term use is indicated, it is recommended that indwelling time not exceed 90 days. The ReSolve Mini Locking Drainage Catheter should be evaluated by a physician on or before 90 days post placement.
4. Carefully remove the ReSolve Mini Locking Drainage Catheter. Proceed with either catheter exchange or skin closure.
5. Dispose of explanted catheter following standard blood and body fluid precautions per applicable hospital protocols.

ATTENTION ATTENDING PHYSICIAN: IF PATIENT WILL NOT BE FOLLOWED UP BY YOU, IT IS RECOMMENDED THAT THE "INSTRUCTIONS FOR USE" OR THE SECTION ON HOW TO REMOVE THE CATHETER BE ATTACHED TO THE PATIENT'S CHART.

℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Caution: Consult accompanying documents.
	Single use.
STERILIZE	Do not resterilize
	Non-pyrogenic
	Do not use if package is damaged
STERILE EO	Sterilized using ethylene oxide
	Maximum diameter guide wire
REF	Catalog number
LOT	Batch code
MR	MR Conditional
	Date of Manufacture: YYYY-MM-DD
	Use by date: YYYY-MM-DD
	Consult Instructions for Use
MD	Medical Device
Sterile Package	Sterile Package

In the EU, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the applicable Member State.

CE 2797

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