English

ReSolve MINI™

Locking Drainage Catheter

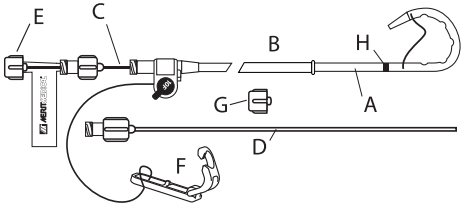
INSTRUCTIONS FOR USE

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.

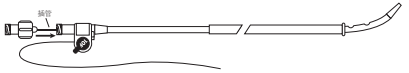


Figure 1

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.

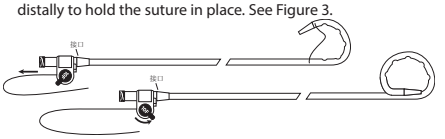


Figure 3

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.

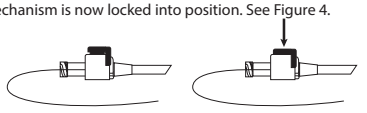


Figure 4

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.

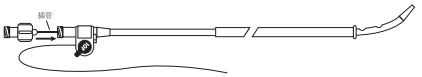


Figure 5

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.

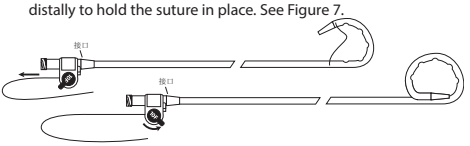


Figure 7

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.

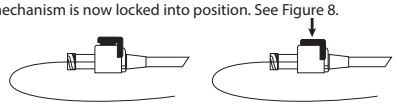


Figure 8

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.

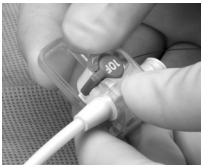
    Note: Instruct patient or other healthcare personnel in appropriate device function and/ or maintenance.

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:

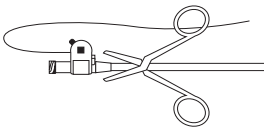
- Using the Repositioning Tool align the opening of the round section of the Repositioning Tool in line with the handle of the suture locking mechanism.
- Bring the flat back of the Repositioning Tool around the catheter hub.
- Gently squeeze together.
- Remove the Repositioning Tool and rotate the suture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

MERIT MEDICAL® www.merit.com

ReSolve MINI™

Chinese

一次性使用引流导管

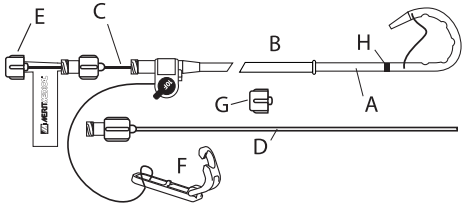
使用说明

产品名称
一次性使用引流导管

产品说明
ReSolve Mini 一次性使用引流导管，具有可以锁定的猪尾管及亲水涂层，X射线下可以显影的管身上有多个引流侧孔，可用于经皮穿刺引流术。利用该引流导管的组件，可实施经套管针的一步法穿刺引流或经导丝的两步法穿刺引流。

ReSolve Mini 一次性使用引流导管的包装中可能包含以下组件：
- 一根 (1) ReSolve Mini 锁定引流导管，带锁定尾管 (A)、亲水涂层和尾管校直器 (B)
- 一根 (1) 金属硬化套管 (C)
- 一根 (1) 可弯曲硬化套管 (D)
- 一根 (1) 套针 (E)
- 一件 (1) 复位器 (F)

一只 (1) 封堵帽 (G)
一根 (1) 标记带 (H)



适用范围
一次性使用引流导管可用于胸腔和腹腔内积液的经皮穿刺引流。

临床优势
体腔内液体的经皮引流。

禁忌症
切忌在不宜接受经皮引流插管术的情况下使用 ReSolve Mini 锁定引流导管。

切忌在血管内使用 ReSolve Mini 锁定引流导管。

MRI 信息

MR 特定条件下安全
ReSolve Mini 锁定引流导管在 MR 特定条件下安全

非临床检测显示：ReSolve Mini 锁定引流导管在 MR 特定条件下安全。在以下条件下放置后，可以安全扫描患者体内的此设备：
- 3 特斯拉或以下的静态磁场
- 最大空间梯度为 4,000 高斯/cm (40 T/m) 的磁场
- MR 系统报告的最大值，在 MR 系统的第一级受控运行模式下的全身平均比吸收率 (SAR) 为 4 W/kg

MRI 相关发热
在上述规定的扫描条件下，ReSolve Mini 锁定引流导管的温度预计在连续扫描 15 分钟后最高上升 2.3° C。

MR

伪影信息
与 ReSolve Mini 锁定引流导管的尺寸和形状相比，在 3 特斯拉下的梯度回波脉冲序列上看到的最大伪影尺寸大约增加 2 mm。

并未在 MR 环境中评估过初始放置系统（包括金属强化插管）的安全性，因此，不应在 MR 环境中使用这些组件。

注意事项
- 使用前请阅读制造商的说明书。
- 未开封、未受损的包装内物品处于无菌状态。
- 本品仅限一位患者使用。请勿重复使用、重复处理或重复灭菌。重复使用、重复处理或重复灭菌可能会破坏该设备的结构完整性，并且/或者导致设备故障，进而可能导致患者受伤、患病或死亡。重复使用、重复处理或重复灭菌还有可能带来器械污染的风险，并且/或者导致患者受到感染或交叉感染，包括但不限于传染病在患者之间传播。设备污染可能会导致患者受伤、患病或死亡。
- 在插入和维护此设备时应遵循通用的预防措施。
- 由于存在血液病原体风险，医疗专业人员在对所有患者进行护理期间应始终采取标准的血液和体液预防措施。
- 应始终采用无菌技术操作。
- 切勿在过期之后使用。
- 阴凉干燥处保存。

警告
- ReSolve Mini 锁定引流导管不得用于输注营养补充剂。

℞ ONLY 警示：联邦（美国）法律将此器械限制为由医生销售或订购。

不良反应
- 感染性休克
- 菌血症
- 出血
- 重复感染
- 肠道穿透
- 胸膜穿透
- 血管受伤
- 导管移位
- 导管闭塞

使用说明 - 方案 1：

使用套管针直接放置
1. 从导管上移除硬化套管和套针组件。
2. 在使用之前，用无菌水或盐水将 ReSolve Mini 锁定引流导管的远端部分浸湿。在放置期间，使导管的远端部分保持湿润。
   警告：切勿使用干纱布或任何溶剂擦拭导管，否则，可能会破坏导管上的涂层。
3. 在使用前，冲洗导管。
4. 确保缝线锁定装置在近端位置。

5. 在将金属硬化套管放入导管之前，将猪尾管矫直器延导管移至远端以拉直猪尾部分。将金属硬化套管放入导管，然后拧紧鲁尔锁接头。参见图 1。

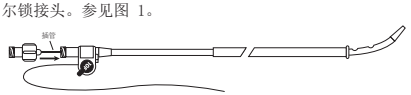


图 1

注意：为了防止导管损坏，将套管完全放入导管尖端后再取下间隔纸片和插入套管针。

6. 移除套管针上的间隔纸片。向前推动套管针，使之穿过金属硬化套管，然后拧紧鲁尔锁接头。参见图 2。

图 2

7. 在插入之前，移除导管上的猪尾矫直器
8. 使用标准的插入技术，将导管/套管/套管针组件放入积液部位。

   注：应通过诊断成像来确认放置情况。
9. 在确认放置情况之后，移除套管针和硬化套管。
10. 要锁定缝线锁定装置：拉动缝线直至形成所需猪尾管。向远端旋转缝线锁定装置，将缝线固定到位。参见图 3。

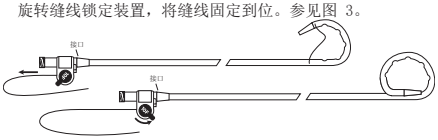


图 3

注：如果需要调整导管的位置，请向近端旋转把手，直至到达阻力点，以解开缝线锁定装置。

注意事项：在解锁时，切勿将缝线锁定装置转到阻力点外。如果旋转缝线锁定机构时超过了阻力点，将无法释放缝线，尾管将不能在移除时校直。

11. 在确认放置情况并且缝线锁定装置已旋转到离身体最远的位置之后，将缝线锁定装置压入接口内，以将其固定。缝线锁定装置此时即已锁定到位。参见图 4。

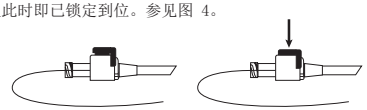


图 4

12. ReSolve Mini 锁定引流导管现在已准备就绪，可以连接到相应的引流袋、管路或封堵帽。

    警告：如果使用酒精来清洁导管接口，则应等待足够长的时间以使酒精晾干，然后才能连接引流管路或封堵帽。

    警告：切勿将引流导管与引流管路或封堵帽之间的连接拧得过紧。

    注：冲洗方案应当根据每位患者的具体情况和医生的治疗方案进行设计。

    注：应就相应的设备功能和/或维护对患者或其他医疗工作人员进行说明。

使用说明 - 方案 2：

塞尔丁格置入法或导丝更换

1. 从导管上移除硬化套管和套针组件。
2. 在放置前，确保导管的远端部分处于湿润状态。在使用之前，用无菌水或盐水将 ReSolve Mini 锁定引流导管的远端部分浸湿。在放置期间，使导管的远端部分保持湿润。

   警告：切勿使用干纱布或任何溶剂擦拭导管，否则，可能会破坏导管上的涂层。
3. 在使用前，冲洗导管。
4. 确保缝线锁定装置在近端位置。

5. 在将金属硬化套管放入导管之前，将猪尾矫直器沿导管移至远端以拉直猪尾部分。将金属硬化套管放入导管，然后拧紧鲁尔锁接头。参见图 5。

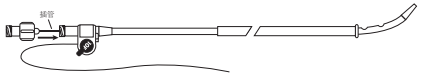


图 5

6. 在插入之前，移除导管上的猪尾矫直器。
7. 将导管/套管组件套在相应的导丝上，向前推进到积液部位内。导管内可容纳直径为 0.97 mm（0.038 英寸）的导线。参见图 6。

   注：应通过诊断成像来确认放置情况。

图 6

8. 在确认放置情况后，移除硬化套管和导丝。
9. 锁定缝线锁定装置拉动缝线直至形成所需猪尾管。向远端旋转缝线锁定装置，将缝线固定到位。参见图 7。

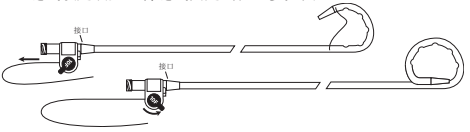


图 7

注：如果需要调整导管的位置，请向近端旋转把手，直至到达阻力点，以解开缝线锁定装置。

注意事项：在解锁时，切勿将缝线锁定装置转到阻力点外。如果旋转缝线锁定装置时超过了阻力点，将无法释放缝线，尾管将不能在移除时校直。

10. 在确认放置情况并且缝线锁定装置已旋转到离身体最远的位置之后，将缝线锁定装置压入接口内，以将其固定。缝线锁定装置此时即已锁定到位。参见图 8。

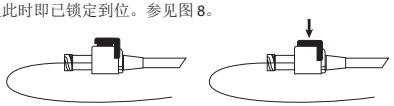


图 8

11. ReSolve Mini 锁定引流导管现在已准备就绪，可以连接到相应的引流袋、管路或封堵帽。

    警告：如果使用酒精来清洁导管接口，则应等待足够长的时间以使酒精晾干，然后才能连接引流管路或封堵帽。

    警告：切勿将引流导管与引流管路或封堵帽之间的连接拧得过紧。

    注：冲洗方案应当根据每位患者的具体情况和医生的治疗方案进行设计。

    注：应就相应的设备功能和/或维护对患者或其他医疗工作人员进行说明。

导管更换、位置调整或移除

1. 将导管与引流袋、管路或封堵帽断开。
2. 为了释放尾管环路，请选择以下方案之一：

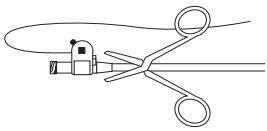
方案 1：

- 使用复位器，将该工具的圆形部分的开口与缝线锁定装置的把手对齐。
- 使复位器的平底部分套住导管接口。
- 将它们轻轻地挤压在一起。
- 移除复位器，将缝线锁定装置旋转到最近端位置。

注意事项：切勿将缝线锁定装置转到阻力点外。如果旋转缝线锁定装置时超过了阻力点，将无法释放缝线，猪尾管将不能在移除时校直。

方案 2：

（仅限更换或移除）将接口从引流导管上移除，并割断缝线。这将释放缝线和尾管环路。
警告：缝线将不再固定到导管。请小心移除缝线和导管。



3. 如需更换导管或将保持通路，将适用的导丝推过导管；采用诊断成像确认导丝放置情况。导丝将用于保持通向引流部位的穿刺口。为了更方便地放置导丝，可以使用硬化套管
   警告：如果需要长期使用，建议留置时间不超过 90 天。
4. 移除 ReSolve Mini 锁定引流导管时应小心操作。随后应更换导管或缝合皮肤。
5. 根据适用的医院方案和标准血液和体液注意事项处置取出的导管。

请主治医生注意：如果您不对患者进行持续监护，则建议将此“使用说明”或有关如何移除导管的部分附在患者的病历后。

产品名称：一次性使用引流导管
型号、规格：RML17-6-038MB, RML17-7-038MB, RML17-8-038MB, RML17-10-038MB, RML17-12-038MB, RML17-14-038MB, RML27-6-038MB, RML27-7-038MB, RML27-8-038MB, RML27-10-038MB, RML27-12-038MB, RML27-14-038MB, RML42-6-038MB, RML42-7-038MB, RML42-8-038MB, RML42-10-038MB, RML42-12-038MB, RML42-14-038MB
结构及组成：该产品由锁定引流导管（导管轴：聚氨酯，导管管身涂有亲水性涂层）、金属硬化套管（不锈钢）、可弯曲硬化套管（聚丙烯）、套针（不锈钢）、复位器（聚碳酸酯）、缝线锁定装置（聚酯-聚碳酸酯共聚物）、分离式接头（聚碳酸酯和聚酯混合物）、猪尾矫直器（聚丙烯）组成。一次性使用产品，环氧乙烷灭菌。
注册人及生产企业名称：美国麦瑞通医疗设备有限公司Merit Medical Systems, Inc.
注册人及生产企业住所：1600 West Merit Parkway South Jordan Utah 84095 USA
注册人及生产企业联系方式：1-801-253-1600
生产地址：14646 Kirby Drive Houston, Texas 77047 USA; Avenida Sor Juana Inés de la Cruz 19970 interior B, Edificio 2 Parque Industrial Frontera Tijuana, Baja California C.P. 22630 Mexico
中国境内代理人及售后服务单位名称：麦瑞通医疗器械（北京）有限公司
中国境内代理人及售后服务单位住所： 北京市朝阳区东大桥路9号楼2单元801室内B01, B02及B03单元
中国境内代理人及售后服务单位电话：010-85610788
中国境内代理人及售后服务单位传真：010-85616981
注册证编号/产品技术要求编号：国械注进20242140643
有效期：3年
生产日期和失效日期：见产品标签
说明书编制或修订日期：2024年12月

℞ ONLY	警示：联邦（美国）法律将此器械限制为由医生销售或订购。
	警告
	一次性使用
	不得二次灭菌
	无热原
	如包装破损不得使用并查阅使用说明书
STERILE EO	经环氧乙烷灭菌
	最大直径导丝
REF	产品编号
LOT	批号
	MR 特定条件下安全
	生产日期
	失效日期
	查阅使用说明书
MD	医疗器械
Sterile Package	无菌包装