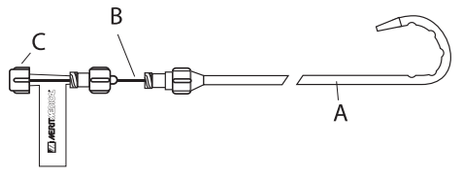
ReSolve®

INSTRUCTIONS FOR USE

PRODUCT NAME
ReSolve® NL (Non-Locking) Drainage Catheter with Hydrophilic Coating

DESCRIPTION OF THE PRODUCT
The ReSolve NL Drainage Catheter with 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 NL Drainage Catheter may be packaged in a pouch with the following components:

One (1) Resolve NL Drainage Catheter with hydrophilic coating (A)
One (1) Metal stiffening cannula (B)
One (1) Trocar stylette (C)



INDICATIONS FOR USE
The ReSolve NL Drainage Catheter with hydrophilic coating is intended for percutaneous drainage of fluid from body cavities.

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

The ReSolve NL Drainage Catheter is contraindicated for intravascular use.

RESTRICTED DEVICE
℞ 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.

PRECAUTIONS
- Read manufacturer's instructions prior to use.
- Contents are sterile (via ethylene oxide) and non-pyrogenic.
- Do not use if packaging is opened, damaged or broken.
- 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.

WARNING: The ReSolve NL Drainage Catheter is not to be used to deliver nutritional supplements.

ADVERSE REACTIONS*
- Septic shock
- Bacteremia
- Hemorrhage
- Superinfection
- Bowel transgression
- Pleural transgression
- Vascular injury
- Pneumothorax
- Skin Infection
- Catheter Occlusion
- Catheter Dislodgement

*Brountzos EN. Quality improvement guidelines for percutaneous nephrostomies.[Internet]. 2006. CIRSE.org. http://cirse.org/files/File/05_qig.pdf. Accessed 04/11/13.
Wallace MJ, et al. Quality improvement guidelines for percutaneous drainage/aspiration of abscess and fluid collections. J Vasc Interv Radiol. 2010;21:431-435.
Ramchandani P, et al. Quality improvement guidelines for percutaneous nephrostomy. J Vasc Interv Radiol. 2003;14:S277-S281.

INSTRUCTIONS FOR USE
PLACEMENT TECHNIQUES OPTION 1:
DIRECT PUNCTURE USING TROCAR STYLET
1. Remove the stiffening cannula and trocar stylette assembly from the ReSolve NL Drainage Catheter.

2. Ensure that the distal portion of the catheter is wet prior to placement.
CAUTION: To maximize the advantages of the hydrophilic coating on the surface of the distal portion of the catheter, wet the catheter prior to use with sterile water or saline. Keep 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. Place the metal stiffening cannula into the catheter and tighten the Luer lock fittings. See Figure 1.

Figure 1

5. 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

6. Place the catheter/cannula/trocar assembly into the fluid collection site using standard insertion technique. Placement should be confirmed with diagnostic imaging.

7. After placement is confirmed, remove the trocar stylette and stiffening cannula.

8. The ReSolve NL Drainage Catheter is now ready to be connected to appropriate drainage bag or tubing.

9. 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
PLACEMENT TECHNIQUES 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.
CAUTION: To maximize the advantages of the hydrophilic coating on the surface of the distal portion of the catheter, wet the catheter prior to use with sterile water or saline. Keep 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. Place the metal stiffening cannula into the catheter and tighten the Luer lock fittings. See Figure 3.

Figure 3

5. Place catheter over appropriate guide wire into the fluid collection site. The catheter accommodates an 0.038" (0.97 mm) wire. See Figure 4.

Figure 4

6. Advance the catheter into the site while holding the guide wire in place. Placement should be confirmed with diagnostic imaging. After placement is confirmed, remove cannula and guide wire.

7. The catheter is now ready to be connected to appropriate drainage bag or tubing.

8. 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 OR REMOVAL

1. Disconnect catheter from drainage tubing or bag.

2. For catheter exchange or if access is to be maintained, advance appropriate guide wire through catheter; use diagnostic imaging to confirm wire placement. Guide wire will maintain access to drainage site, if necessary.

3. Carefully remove the catheter. Proceed with either catheter exchange or skin closure.

Storage Conditions: Do not expose to excessive heat or humidity.

Transportation Conditions: Do not expose to excessive heat or humidity during transportation.

Shelf Life: 3 years.

Body Contact Time: Less than 30 days.

Models:
RNL-6-038J, RNL-6-038S, RNL-8-038J, RNL-8-038S, RNL-10-038J, RNL-10-038S, RNL-12-038J, RNL-12-038S

ELECTRONICALLY GENERATED

MERIT MEDICAL®

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
www.merit.com

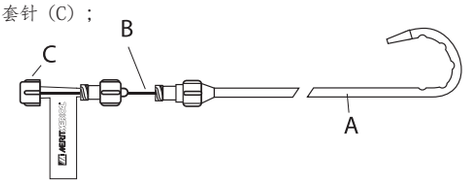
402247009ZHP_001 ID 2023-07-20

ReSolve® Chinese

使 用 说 明

产品名称
一次性使用引流导管包

产品描述
该说明书适用于不带锁通用引流导管。型号规格为RNL-6-038J, RNL-6-038S, RNL-8-038J, RNL-8-038S, RNL-10-038J, RNL-10-038S, RNL-12-038J, RNL-12-038S
不带锁通用引流导管由不带锁引流导管（座：聚碳酸酯，导管轴：80% 聚氨酯95A+20%硫酸钡，亲水涂层：亲水性聚氨酯）、金属套管（座：聚碳酸酯，套管：304不锈钢）、套针（座：聚碳酸酯，套针:304不锈钢）。一次性使用产品，环氧乙烷灭菌。一次性使用引流导管包
可与下列组件共同包装于一个小袋中：
1引流导管（A）
1金属套管（B）；
1套针（C）；



适用范围
该产品主要用于胸膜腔引流、纵膈引流。

禁忌症
一次性使用引流导管包止用于不可使用经皮引流导管之处。
一次性使用引流导管包止用于血管穿刺。

权限设置
℞ Only: 注意：美国（USA）联邦法律规定只有接受过专业培训和/或有使用此装置经历的医生有权限购买或订购此装置。

注意事项：
- 使用前请仔细阅读制造商说明书。
- 装置是无菌的（通过环氧乙烷杀毒灭菌）无热原。
- 若包装已开、损坏或破损，请勿使用。
- 仅用于单个患者。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破坏装置完整性，甚至导致装置故障，这反过来又可能导致病人受伤、患病甚至死亡。重复使用、重复处理或重复灭菌也可能增加装置污染的可能性，从而导致病人感染或交叉感染（包括感染性疾病的相互传播）。装置污染可能病人受伤、患病甚至死亡。
- 插入和维护装置时应遵守该类装置通用的注意事项。由于血源性病原体的风险，医护人员在诊疗过程中应遵守血液和体液相关注意事项。应始终遵循无菌技术。
- 请勿使用过期装置。
- 请将装置存放在阴凉、干燥处。

警告：一次性使用引流导管包不得用于输送营养制剂。

不良反应*：
- 感染性休克
- 菌血症
- 出血
- 二重感染
- 肠道浸润
- 胸膜浸润
- 血管损伤
- 气胸
- 皮肤感染
- 导管闭塞
- 导管移位

*Brountzos EN. Quality improvement guidelines for percutaneous nephrostomies. [Internet]. 2006. CIRSE.org. http://cirse.org/files/File/05_qig.pdf. Accessed 04/11/13.
Wallace MJ, et al. Quality improvement guidelines for percutaneous drainage/aspiration of abscess and fluid collections. J Vasc Interv Radiol. 2010;21:431-435.
Ramchandani P, et al. Quality improvement guidelines for percutaneous nephrostomy. J Vasc Interv Radiol. 2003;14:S277-S281.

使用说明
置入技术 方案1：
使用套管针针芯直接穿刺：
1. 该产品主要用于胸膜腔引流、纵膈引流。

2. 置入之前，保证导管远端部分始终湿润。
注意：为将导管远端表面亲水涂层的作用发挥至最大，使用导管之前，请用无菌蒸馏水或生理盐水润湿导管。在置入过程中保持导管始终湿润。
警告：请勿使用干纱布或任何其他溶液擦拭导管，因为这可能损伤导管涂层。

3. 使用之前请冲洗导管。

4. 将金属套管插入导管，并将鲁尔接头拧紧。详见图1:。

图1

5. 取出套针针芯中的纸垫片。通过金属套管推进套套针针芯，拧紧鲁尔接头。详见图2:。

图2

6. 使用标准的插入技术，固定导管/套管组件，进入液体收集部位。导管的置入应通过诊断成像确认。

7. 导管置入确认后，取出套针针芯和金属套管。

8. 现在,将一次性使用引流导管包引流袋或管路相连接

9. 医生根据每个病人的实际情况，为病人设计具体的冲洗治疗方案。
注意：指导患者或其它医务人员合理使用装置的功能和/或维护。

使用说明
固定技术　方案2：SELDINGER插管技术或导丝交换法
1. 从导管取下金属套管和套针针芯组件。

2. 置入之前，保证导管远端部分始终湿润。
注意：为将导管远端表面亲水涂层的作用发挥至最大，使用导管之前，请用无菌蒸馏水或生理盐水润湿导管。在置入过程中保持导管始终湿润。
警告：请勿使用干纱布或任何其他溶液擦拭导管，因为这可能损伤导管涂层。

3. 使用之前请冲洗导管。

4. 将金属套管插入导管，并将鲁尔接头拧紧。详见图3:。

图3

5. 将导管沿适当的导丝置入液体引流部位。导管可容纳直径为0.038” (0.97 mm)的导丝。详见图4:。

图4

6. 将导丝固定在位，将导管推入目标部位。导管置入应通过诊断成像确认。导管置入确认后，取出金属套管和导丝。

7. 现在,一次性使用引流导管包与引流袋或管路相连接

8. 医生根据每个病人的实际情况，为病人设计具体的冲洗治疗方案。
注意：指导患者或其它医务人员合理使用装置的功能和/或维护。

导管更换或取出
1. 将导管与引流袋或引流管分离断开。

2. 更换导管或维护通路时，用适当的导丝插入导管，并使用影像诊断确认导丝的位置。这样，如果有必要，导丝就可以进入引流部位了。

3. 小心取出导管。最后，进行导管更换操作或者缝合皮肤创口。

储存条件：切勿储存在高温或高湿处

运输条件 运输过程中应不暴露在高温或高湿下

产品有效期 3年

与人体作用时间 小于30天

结构及组成：
产品由不带锁/带锁引流导管系统与导管固定系统构成。不带锁通用引流导管由不带锁引流导管（座：聚碳酸酯，导管轴：80% 聚氨酯95A+20%硫酸钡，亲水涂层：亲水性聚氨酯）、金属套管（座：聚碳酸酯，套管：304不锈钢）、套针（座：聚碳酸酯，套针：304不锈钢）组成。带锁通用引流导管由带锁引流导管（座：聚酯-聚碳酸酯共聚物，导管轴：80% 聚氨酯95A+20%硫酸钡，亲水涂层：亲水性聚氨酯，标记带：铂/氨基甲酸酯 P3，线轴配件：聚酯-聚碳酸酯共聚物+尼龙6）、金属套管（座：聚碳酸酯，套管：304不锈钢）、套针（座：聚碳酸酯，套针：304不锈钢）、可弯曲硬化套管（座：聚碳酸酯，套管：尼龙11）、复位器（聚碳酸酯）、猪尾拉直器（聚丙烯）组成。导管固定装置由胶粘剂贴（Plasto P-1035或3M 9916胶带）、旋转环（聚碳酸酯）、旋转环保护盖（聚丙烯）、固定线（尼龙+有机硅涂层）、固定把手（聚碳酸酯）组成。一次性使用产品，环氧乙烷灭菌。
型号、规格：见附页
生产日期和失效日期：见产品标签
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 Pkwy. South Jordan, UT 84095
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
注册人及生产企业联系方式：1-801-253-1600
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20153142916
说明书编制或修订日期：2023年7月

MERITMEDICAL®

www.merit.com

ELECTRONICALLY GENERATED

Resolve™ 不带锁通用引流导管											
型号	引流导管						金属套管			套针	
	规格	头端	长度(cm)	外径	侧孔	可接受导丝	外径	大小	暴露长度mm	外径	暴露长度
RNL-6-038J	6.5F	J型	20	0.085"	4	0.038” (0.97mm)	0.050"	18 G	218.4	0.038"	9.32"
RNL-6-038S		直型									
RNL-8-038J	8.5F	J型	25	0.1142"	4	0.038” (0.97mm)	0.050"	18 G	266.4	0.038"	11.28"
RNL-8-038S		直型									
RNL-10-038J	10F	J型	25	0.131"	4	0.038” (0.97mm)	0.072"	15 G	266.2	0.038"	11.28"
RNL-10-038S		直型									
RNL-12-038J	12F	J型	25	0.158"	5	0.038” (0.97mm)	0.083"	14 G	264.4	0.038"	11.28"
RNL-12-038S		直型									

ReSolve® 带锁通用引流导管																
StayFix导管固定系统 Revolution导管固定系统																
型号	带锁引流导管								金属套管			套针		可弯曲硬化套管		
	规格	头端	标记带	导管固定系统	可接受导丝	长度 cm	外径	侧孔	外径	大小	暴露长度(mm)	外径	暴露长度	外径	内径	暴露长度
RLC-6-038	6.5F	猪尾	无	无	0.038” (0.97mm)	25	0.085"	7	0.050"	18G	344.2	0.038"	14.25-14.50"	N/A	N/A	N/A
RLC-8-038	8.5F	猪尾	无	无	0.038” (0.97mm)	25	0.112"	8	0.050"	18G	344.2	0.038"	14.22-14.47"	0.056”	0.042"	13.355-13.43"
RLC-10-038	10F	猪尾	无	无	0.038” (0.97mm)	25	0.131”	8	0.072"	15G	343.7	0.038"	14.23-14.48”	0.072"	0.051"	13.33-13.41"
RLC-12-038	12F	猪尾	无	无	0.038” (0.97mm)	25	0.158”	8	0.083"	14G	341.9	0.038"	14.23-14.48"	0.082"	0.063"	13.27-13.34"
RLC-14-038	14F	猪尾	无	无	0.038” (0.97mm)	25	0.184”	9	0.095"	13G	341.4	0.038"	14.24-14.49"	0.095"	0.071"	13.25-13.32"
RLC-8-038MB	8.5F	猪尾	有	无	0.038” (0.97mm)	25	0.112"	8	0.050"	18G	344.2	0.038"	14.22-14.47"	0.056"	0.042"	13.355-13.43"
RLC-10-038MB	10F	猪尾	有	无	0.038” (0.97mm)	25	0.131”	8	0.072"	15G	343.7	0.038"	14.23-14.48”	0.072"	0.051"	13.33-13.41"
RLC-12-038MB	12F	猪尾	有	无	0.038” (0.97mm)	25	0.158”	8	0.083"	14G	341.9	0.038"	14.23-14.48”	0.082"	0.063"	13.27-13.34"
RLC-14-038MB	14F	猪尾	有	无	0.038” (0.97mm)	25	0.184”	9	0.095"	13G	341.4	0.038"	14.24-14.49"	0.095"	0.071"	13.25-13.32"
RLC-6-REV	6.5F	猪尾	无	有 Revolution	0.038” (0.97mm)	25	0.085"	7	0.050"	18G	344.2	0.038"	14.25-14.50”	不适用	不适用	不适用
RLC-8-REV	8.5F	猪尾	无	有 Revolution	0.038” (0.97mm)	25	0.112"	8	0.050"	18G	344.2	0.038"	14.22-14.47”	0.056"	0.042"	13.355-13.43"
RLC-10-REV	10F	猪尾	无	有 Revolution	0.038” (0.97mm)	25	0.131”	8	0.072"	15G	343.7	0.038"	14.23-14.48”	0.072"	0.051"	13.33-13.41"
RLC-12-REV	12F	猪尾	无	有 Revolution	0.038” (0.97mm)	25	0.158”	8	0.083"	14G	341.9	0.038"	14.23-14.48”	0.082"	0.063"	13.27-13.34"
RLC-14-REV	14F	猪尾	无	有 Revolution	0.038” (0.97mm)	25	0.184”	8	0.095"	13G	341.4	0.038"	14.24-14.49"	0.095"	0.071"	13.25-13.32"
RLCMB-8-REV	8.5F	猪尾	有	有 Revolution	0.038” (0.97mm)	25	0.112"	8	0.050"	18G	344.2	0.038"	14.22-14.47"	0.056"	0.042"	13.355-13.43"
RLCMB-10-REV	10F	猪尾	有	有 Revolution	0.038” (0.97mm)	25	0.131”	8	0.072"	15G	343.7	0.038"	14.23-14.48”	0.072"	0.051"	13.33-13.41"
RLCMB-12-REV	12F	猪尾	有	有 Revolution	0.038” (0.97mm)	25	0.158”	8	0.083"	14G	341.9	0.038"	14.23-14.48”	0.082"	0.063"	13.27-13.34"
RLCMB-14-REV	14F	猪尾	有	有 Revolution	0.038” (0.97mm)	25	0.184”	9	0.095"	13G	341.4	0.038"	14.24-14.49”	0.095"	0.071"	13.25-13.32"
RLC-6-SFX	6.5F	猪尾	有	有 StayFix	0.038” (0.97mm)	25	0.085"	7	0.050"	18G	344.2	0.038"	14.25-14.50”	不适用	不适用	不适用
RLC-8-SFX	8.5F	猪尾	有	有 StayFix	0.038” (0.97mm)	25	0.112"	8	0.050"	18G	344.2	0.038"	14.22-14.47"	0.056"	0.042"	13.355-13.43"
RLC-10-SFX	10F	猪尾	有	有 StayFix	0.038” (0.97mm)	25	0.131”	8	0.072"	15G	343.7	0.038"	14.23-14.48”	0.072"	0.051"	13.33-13.41"
RLC-12-SFX	12F	猪尾	有	有 StayFix	0.038” (0.97mm)	25	0.158”	8	0.083"	14G	341.9	0.038"	14.23-14.48”	0.082"	0.063"	13.27-13.34"
RLC-14-SFX	14F	猪尾	有	有 StayFix	0.038” (0.97mm)	25	0.184”	9	0.095"	13G	341.4	0.038"	14.24-14.49”	0.095"	0.071"	13.25-13.32"
RLCMB-8-SFX	8.5F	猪尾	有	有 StayFix	0.038” (0.97mm)	25	0.112"	8	0.050"	18G	344.2	0.038"	14.22-14.47”	0.056"	0.042"	13.355-13.43"
RLCMB-10-SFX	10F	猪尾	有	有 StayFix	0.038” (0.97mm)	25	0.131”	8	343.7	15G	343.7	0.038"	14.23-14.48”	0.072"	0.051"	13.33-13.41"
RLCMB-12-SFX	12F	猪尾	有	有 StayFix	0.038” (0.97mm)	25	0.158”	8	0.083"	14G	341.9	0.038"	14.23-14.48”	0.082"	0.063"	13.27-13.34"
RLCMB-14-SFX	14F	猪尾	有	有 StayFix	0.038” (0.97mm)	25	0.184”	9	0.095"	13G	341.4	0.038"	14.24-14.49”	0.095"	0.071"	13.25-13.32"

ELECTRONICALLY GENERATED