



Angiographic Catheters -Including Performa Ultimate™ (all models)

INSTRUCTIONS FOR USE

DESCRIPTION:

Angiographic catheters are single-use, sterile, non-pyrogenic, disposable intravascular catheters.

INDICATIONS:

Angiographic catheters are designed to be used for delivering radiopaque media to selected sites in the vascular system in conjunction with routine diagnostic procedures. Angiographic catheters with marker bands may also be used for anatomical measurements.

CONTRAINDICATIONS:

None known.

WARNING:

- The Impress® angiographic catheter with hydrophilic coating should not be used in the coronary arteries.
- Angiographic catheters are single use.
- Recommended guide wire size: See the individual catheter label.
- Guide wire use has been associated with greater incidence of thrombus formation.

PRECAUTIONS:

- Do not use if package is opened or damaged.
- Do not use after expiration date.
- Do not autoclave.
- Carefully remove the catheters from the package by grasping the hub and slowly withdrawing it from the package.
- If resistance is felt when removing the guidewire from the catheter, remove the guide wire and catheter as a unit to prevent potential damage to the vessel wall.
- Flush all devices entering a blood vessel with sterile heparinized saline or similar isotonic solution before use.
- For catheters containing hydrophilic polymer coating on the distal surface of the catheter, the surface of the distal portion of the catheter must be completely wet to remain lubricated. Proper caution must be taken to wet the catheter prior to and during use.

ADVERSE EVENTS:

Merit Medical angiographic catheters should be used by physicians familiar with percutaneous catheter introduction. Complications which may be associated with the use of angiographic catheters include, but are not limited to, the following.

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|----------------------------------|---------------------------------------|
| • Thrombus formation/emboli | • Air emboli |
| • Hematoma at puncture site | • Arterial wall damage |
| • Plaque dislodgement | • Myocardial infarction |
| • Cardiac arrhythmias | • Infection |
| • Perforation of the vessel wall | • Allergic reaction to contrast media |
| • Vascular occlusion | • Vascular spasm |
| • Stroke and death | |

REUSE PRECAUTION STATEMENT

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, transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

DIRECTIONS FOR USE:

1. A coated guide wire is recommended for use with Merit angiographic catheters.
2. Introduce the catheter into the blood vessel using vascular entry technique of choice.
3. PIGTAIL catheters. Pigtail catheters are fitted with a straightener. It is split for easy removal after the catheter tip is on the guide wire.
- Slide straightener forward until pigtail is straight.
- Place catheter tip on guide wire and remove straightener by pulling on the straightener tab.
4. Marker Band: Anatomical measurement accuracy is $\pm 4\%$.

Storage: Sterile and non-pyrogenic in unopened and undamaged inner package.
Store in a cool dry place.

Shelf Life: The shelf life is established at 3 years from date of sterilization.

Transportation: Do not expose to high temperature or humidity.



Manufacturer: Merit Medical Systems, Inc.
1600 West Merit Parkway, South Jordan, Utah 84095 U.S.A.

Authorized Representative:
Merit Medical Ireland Ltd, Parkmore Business Park West, Galway, Ireland

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血管内造影导管 包括Performa Ultimate™ 造影导管

使用说明

产品描述:

血管内造影导管为一次性使用,灭菌,无热原的血管内导管。

适用范围:

血管内造影导管用于血管内造影, 借助于日常诊断治疗, 将造影剂介质送至血管系统中指定位置。

禁忌症:

未知

警告:

- Impress® 含亲水层血管造影导管不得用于冠状动脉内。
- 血管内造影导管为一次性使用产品。
- 推荐导引导丝大小: 参见导管标签。
- 导引导丝的使用往往伴随着高发生率的血栓形成。

注意事项:

- 包装打开或损坏的情况下,不得使用本品。
- 不得使用过期产品。
- 不要进行高压灭菌。
- 轻轻握住导管头,慢慢将导管从包装中抽出。
- 从导管抽出导引导丝时如遇到阻力,需将导引导丝和导管一同拔出,以防止破坏血管壁。
- 使用导管前,需用消毒肝素盐水或者类似等渗溶液冲洗所有进入血管内的器械。
- 对于远端表面上含亲水聚合物涂层的导管而言, 导管远端部分的表面必须完全湿润, 以维持润滑。使用前和使用时, 必须小心谨慎地将导管弄湿。

副作用:

Merit Medical血管内造影导管只能由熟悉经皮穿刺导管介入技术的医生使用。与血管造影导管相关的并发症包括但不限于以下:

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|-----------|---------|-----------|
| • 血栓形成/栓子 | • 空气栓塞 | • 血管闭塞 |
| • 穿刺部位血肿 | • 动脉壁损伤 | • 中风甚至死亡 |
| • 斑块脱落 | • 心肌梗死 | • 造影剂过敏反应 |
| • 心律失常 | • 感染 | • 血管痉挛 |
| • 血管壁穿孔 | | |

重复使用注意事项声明

仅可用于一名患者。请勿重复使用、重新处理或再次灭菌。重复使用、重新处理或再次灭菌可能会损坏装置的结构完整性和/或导致装置失效,而这有可能因此造成患者损伤、生病或死亡。重复使用、重新处理或再次灭菌也可能构成装置污染风险, 和/或导致患者感染或交叉感染,包括但不限于在患者间传播疾病。装置污染可能导致患者受伤、患病或死亡。

使用指南:

1. 建议带涂层的导引导丝与Merit血管内造影导管一起使用。
2. 采用血管介入技术,将导管引入血管内。
3. 猪尾式导管。猪尾式导管配有拉直器。导管尖装入导引导丝后, 采取分离的方式可轻易取出。
 - 向前滑动拉直器,拉直猪尾式尾端。
 - 将导管尖装入导丝;拉动拉直器环,取出拉直器。
4. 标记带: 解剖学测量的精度: $\pm 4\%$

储存条件: 本品内包装为未打开,无损坏的无菌无热原包装。存储于阴凉干燥处。

产品有效期: 本品从灭菌之日起有效期为3年。

运输条件: 运输过程中不应暴露在高温或高湿下。

型号、规格:

5110381ULT1,5110381ULT2,5110382ULT3,
410038ULT4-T40,4100381ULT4-T40,510038ULT4-T40,5100381ULT4-T40,
410038ULT4-T45,4100381ULT4-T45,510038ULT4-T45,5100381ULT4-T45,
5110381ULT4-T40,5110381ULT4-T45,

产品名称: 血管内造影导管

结构及组成: 该产品由导管座(聚碳酸酯), 导管轴(Pebax), 导管尖端(Pebax), 导管缓冲尖端(Pebax), 应力缓冲套管(Pebax), 编织层(304V不锈钢)制成。一次性使用,环氧乙烷灭菌。

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 Parkway, South Jordan, Utah 84095

生产地址: 14646 Kirby Drive Houston, TX 77047;

Avenida Sor Juana Ines De La Cruz, 19970 Interior B, Edificio 2, Parque Industrial Frontera, Tijuana Baja California, MEXICO 22630

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20153031710

说明书编制或修订日期: 2023年9月



附录A： 型号规格、压力值、粘度值为 4.7cp 条件下流量：

型号、规格	流量（ml/s）	压力值
5110381ULT1	15	600 psi
5110381ULT2	15	600 psi
5110382ULT3	15	600 psi
410038ULT4-T40	11	400 psi
4100381ULT4-T40	10	400 psi
510038ULT4-T40	15	600 psi
5100381ULT4-T40	17	600 psi
5110381ULT4-T40	15	600 psi
410038ULT4-T45	11	400 psi
4100381ULT4-T45	10	400 psi
510038ULT4-T45	15	600 psi
5100381ULT4-T45	17	600 psi
5110381ULT4-T45	15	600 psi