Merit Pursue™

English

Microcatheter

INSTRUCTIONS FOR USE

DESCRIPTION

The Merit Pursue™ Microcatheter is a microcatheter with a flexible distal region. A hydrophilic coating is applied to the distal 80 cm outer surface. A radiopaque marker is located approximately 0.6 mm proximal to the microcatheter tip to facilitate fluoroscopic visualization. The proximal end of the microcatheter incorporates a standard luer adapter for attachment of accessories.

These may be packaged with the following components:

- Tip straightener
- Male Luer lock syringes

INDICATIONS FOR USE/CLINICAL BENEFITS

The Microcatheter is intended for general intravascular use, including peripheral or coronary vasculature. Once the subselective region has been accessed, the Microcatheter can be used for the controlled and selective infusion of diagnostic, embolic, or therapeutic materials into vessels.

The catheter should not be used in the cerebral vessels.

CONTRAINDICATIONS

There are no known contraindications with the use of this product.

WARNINGS

1. This device is intended to be used only by physicians trained in percutaneous intravascular techniques and procedures.
2. Sterile if package is unopened and undamaged.
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. After use, dispose of product and packaging in accordance with hospital, administrative, and/or local government policy.
5. Do not use a power injector to infuse agents other than contrast media, as the microcatheter may become blocked. The safety setting of injection pressure must not exceed the maximum dynamic injection pressure of 5515 kPa (800 psi). Exceeding injection pressure beyond the maximum injection pressure may cause microcatheter rupture possibly resulting in patient injury. If flow through the microcatheter becomes restricted, do not attempt to clear the microcatheter lumen by infusion. Identify and resolve the cause of the blockage or replace the microcatheter with a new microcatheter before resuming infusion. (See Instructions For Using a Power Injector)
6. Make sure that the guiding catheter does not slip out of the vessel. If the guiding catheter should leave the vessel when the microcatheter and/or the guide wire is moved, this may result in the damage of the microcatheter system.
7. Microcatheter advancement beyond the end of the guide wire may result in vessel trauma.
8. Appropriate anticoagulation therapy should be administered in consideration of the conditions of the patient. Pre-clinical testing shows variable amounts of thrombus formation on the device surface in the absence of anticoagulation.
9. In 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.

PRECAUTIONS

1. **℞ Only** Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
2. Ensure embolic material compatibility with microcatheter prior to use.
3. Always monitor infusion rates when using the microcatheter
4. When injecting contrast for angiography, ensure that the microcatheter is not kinked or occluded.
5. The microcatheter has a lubricious hydrophilic coating on the outside of the catheter. It must be kept hydrated prior to removal from its carrier and during the actual procedure in order to be lubricious. This can be accomplished by attaching the Y-connector to a continuous saline drip.
6. Prior to a procedure, all equipment to be used for the procedure should be carefully examined to verify proper function and integrity.
7. Inspect the microcatheter prior to use for any bends or kinks. Any microcatheter damage may decrease the desired performance characteristics.
8. Exercise care in handling of the microcatheter during a procedure to reduce the possibility of accidental breakage, bending or kinking.
9. When the microcatheter is in the body, it should be manipulated only under fluoroscopy. Do not attempt to move the microcatheter without observing the resultant tip response.
10. Exchange microcatheters frequently during lengthy procedures that require extensive manipulation or multiple guide wire exchanges.
11. Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the microcatheter or guide wire against resistance may result in separation of the microcatheter or guide wire tip, damage to the microcatheter, or vessel perforation.
12. Because the microcatheter may be advanced into narrow subselective vasculature, repeatedly assure that the microcatheter has not been advanced so far as to interfere with its removal.
13. Excessive tightening of a hemostatic valve onto the microcatheter shaft may result in damage to the catheter.
14. Read and follow the manufacturer's IFU for diagnostic, embolic, or therapeutic agents to be used with this microcatheter.
15. Use prior to the "use by" date.
16. Store at controlled room temperature.
17. Remove the stylet from the catheter before removing the catheter from the spiral holder.
18. Syringe accuracy is +/- 5%.

POTENTIAL COMPLICATIONS

Potential complications (in alphabetical order) include, but are not limited to:

- Vessel Dissection
- Embolism
- Hemorrhage
- Infection
- Ischemia
- Vessel Perforation
- Vascular Thrombosis
- Vessel spasm

Table 1: Merit Pursue Compatibility Information

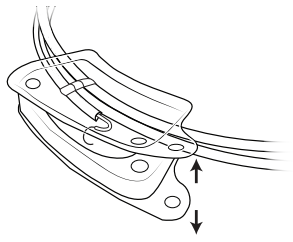
Microcatheter OD	Microcatheter ID	Maximum Guide Wire OD	Minimum Guiding Catheter ID
2.8F / 1.7F	0.016" (0.40 mm)	0.014" (0.36 mm)	0.040" (1.02 mm)
2.9F / 2.0F	0.020" (0.50 mm)	0.018" (0.46 mm)	0.042"(1.07 mm)
Embolics			
Microcatheter OD	**Particles**	**Spherical**	**Maximum Coil Size**
2.8F / 1.7F	≤ 500 µm Emboli	≤ 500 µm Microspheres	0.014" (0.36 mm)
2.9F / 2.0F	≤ 710 µm Emboli	≤ 700 µm Microspheres	0.018" (0.46 mm)
Chemical			
Cisplatin	Cyanoacrylate	DMSO (Dimethyl Sulfoxide)	Doxorubicin
Ethanol	Irinotecan	Lipiodol	

NOTE: Embolic compatibility is for reference only. Read and follow the embolic manufacturers IFU for compatibility.

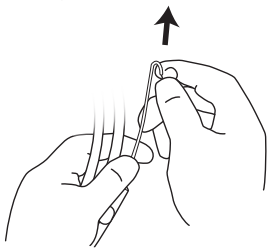
INSTRUCTIONS FOR USE

NOTE: It is recommended that the microcatheter be used with a guiding catheter.

1. Place the appropriate guiding catheter using standard technique. A rotating hemostasis valve may be connected to the guiding catheter luer adapter to continuously flush the guiding catheter with saline.
2. Utilizing sterile technique, carefully open the pouch and remove the microcatheter holder from the packaging.
3. Attach a syringe filled with heparinized saline solution or sterile water to the luer lock fitting of the microcatheter holder.
4. Inject enough solution to wet the microcatheter surface entirely. This will activate the hydrophilic coating on the microcatheter surface. **NOTE:** The surface of the microcatheter may become dry after removal from the holder. Additional wetting with heparinized saline or sterile water will renew the hydrophilic effect.
   NOTE: Steps 5 and 6 are for catheters with a 45˚ or Swan Neck tip shape.
5. Remove the protective cover that covers the tip of the microcatheter.



6. Remove the tip retention stylet from the catheter.
   WARNING: Failure to remove the stylet prior to removing the microcatheter from the microcatheter holder may damage the catheter.



7. Attach a syringe filled with heparinized saline solution or sterile water to the hub of the microcatheter.
8. Inject enough solution to purge any air from the inside of the microcatheter.
9. Remove the microcatheter from the microcatheter holder.
   NOTE: The surface of the microcatheter may become dry after removal from the microcatheter holder. Additional wetting with heparinized saline or sterile water will renew the hydrophilic effect.
10. Upon removal of the microcatheter from the microcatheter holder, inspect the microcatheter to verify there is no damage prior to insertion.
11. If desired, attach a second hemostasis valve with side-arm adapter to the microcatheter. Flush with heparinized saline or sterile water to purge any air.
12. Carefully insert guide wire into the microcatheter and completely close the valve (if used) around the guide wire.
13. Introduce the microcatheter and guide wire assembly into the guiding catheter via the hemostasis valve (if used). If a rotating hemostatic valve is used, tighten the valve around the microcatheter to prevent backflow, but allowing some movement through the valve by the microcatheter.
14. Using fluoroscopy, introduce the microcatheter and guide wire assembly into the vascular system, making sure the guide wire is always ahead of the microcatheter. Advance the guide wire and microcatheter to a selected vascular site by alternatively advancing the guide wire and then tracking the microcatheter over the guide wire. **Note**: To facilitate microcatheter handling, the proximal portion of the microcatheter is uncoated to ensure a non-slip grip.
15. Final positioning is accomplished by short advances of the guide wire and microcatheter until the desired position is achieved and then confirmed by fluoroscopic visualization.
16. Monitor microcatheter placement and position during use.
17. To infuse, completely remove the guide wire from the microcatheter. Connect a syringe with infusate to the microcatheter luer, and infuse as required.

INSTRUCTION FOR USING A POWER INJECTOR WITH THE MICROCATHETER

A power injector can be used to infuse a contrast media through the microcatheter. Observe the warnings and cautions given above. The flow rate depends upon such factors as the viscosity of the contrast media, which varies with the type and temperature of the media, the model and setting of the power injector, and how the injector is connected to the microcatheter. The observed flow rate values indicated below are for reference only.

Table 2: Flow Rates

Merit Pursue Micro-catheter Size Shaft/ Tip	Merit Pursue Micro-cath-eter Usable Length (cm)	Contrast Media	Iodine Content (mg/mL)	Viscosity (cP) at 37°C	MEDRAD Flow Setting Conditions With Linear Rise @ 0.3 Sec		Actual Contrast Delivery mL/Sec with Safety pressure Setting of:	Dead Space (Priming) Volume (mL)
					Flow Rate (mL/Sec)	Volume (mL)	5515 kPa (800 psi)	
2.8F/1.7F	110	ISOVUE (Iopamidol)	300 370	4.7 9.4	6.0 3.0	10 10	3.0 1.5	0.42
	130	ISOVUE (Iopamidol)	300 370	4.7 9.4	6.0 3.0	10 10	2.6 1.3	0.50
	150	ISOVUE (Iopamidol)	300 370	4.7 9.4	6.0 3.0	10 10	2.4 1.2	0.53
2.9F/2.0F	110	ISOVUE (Iopamidol)	300 370	4.7 9.4	6.0 3.0	10 10	4.3 2.4	0.50
	130	ISOVUE (Iopamidol)	300 370	4.7 9.4	6.0 3.0	10 10	3.9 2.0	0.57
	150	ISOVUE (Iopamidol)	300 370	4.7 9.4	6.0 3.0	10 10	3.7 1.9	0.63

REFERENCE DATA

1. Injector used: MEDRAD MARK V
2. Contrast Media temperature: 37°C
3. Injection pressure monitor/ limit setting: 5515 kPa (800 psi)
4. Flow scale: mL/sec
5. Linear rise seconds: 0.3 sec.

Symbol	Description
℞ Only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Use By: YYYY-MM-DD
	Caution: Consult accompanying documents. Read instructions prior to use.
	Date of Manufacture
REF	Catalog Number
LOT	Lot Number
2 STERILIZE	Do Not Re-sterilize
	For electronic copy scan QR code or go to www.merit.com/ifu and enter IFU ID Number. For printed copy, call U.S.A or E.U Customer Service.
	Do not use if package is damaged
	Non-pyrogenic
MAX GUIDE WIRE	Maximum diameter guide wire
	Maximum pressure
STERILE EO	Sterilized using Ethylene Oxide
2	Single use only. Do not Reuse!
	Radiopaque marker
MD	Medical Device
Sterile Package	Sterile Package

MERITMEDICAL®

www.merit.com

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EC REP Authorized Representative:
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Merit Pursue™

Chinese

微导管

使用说明书

产品描述

Merit Pursue™ 微导管是一种具有柔性远端区域的微导管。远端 80 cm 外表面上涂有亲水涂层。不透射线标志位于距微导管头端约 0.6 毫米处，以便于荧光镜检查。微导管的近端包含用于连接配件的标准鲁尔接头。

这些可能与以下组件一起包装：

- 头端矫直器
- 公鲁尔锁注射器

适用范围

微导管用于一般血管内，包括外周血管和冠状动脉血管。选择性插管到位后，微导管可控制性和选择性的将诊断剂、栓塞剂或治疗剂输入血管中。

微导管不得用于脑血管。

禁忌症

本产品目前没有已知的禁忌症。

警告

1. 该器械仅供接受过经皮血管腔内技术与手术培训的医生使用。
2. 如果包装未打开且未破损，则表示已消毒。
3. 本品仅限一位患者使用。请勿重复使用、重复处理或重复消毒。重复使用、重复处理或重复消毒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、患病甚至死亡。重复使用、重复处理或重复消毒还有可能带来设备污染的风险，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、患病甚至死亡。
4. 使用后，请按照医院、行政和/或当地政府政策处置产品和包装。
5. 请勿使用高压注射器输入造影剂以外的药剂，否则微导管可能会被堵塞。注射压力的安全设置不得超过 5515 千帕 (800 psi) 的最大动态注射压力。注射压力超过最大注射压力可能导致微导管破裂，从而使患者受伤。如果流经微导管的流量受限，请勿尝试通过灌注清理微导管。在恢复灌注前，确定并找出堵塞的原因或更换新的微导管。（参见高压注射器使用说明书）
6. 确保导引导管不会滑出血管。如果在微导管和/或导丝移动时导引导管退出血管，可能会损坏微导管系统。
7. 微导管推进超出导丝末端可能损伤血管。
8. 应根据患者的病情进行适当的抗凝治疗。临床前试验表明，在不进行抗凝治疗时，器械表面会形成数量不等的血栓。
9. 在欧盟，任何与器械有关的严重事故都应向制造商及有关成员国的主管当局报告。

注意事项

1. **℞ Only** 警示：联邦（美国）法律将此器械限制为由医生销售或订购。
2. 使用前请确保栓塞剂与微导管之间的兼容性。
3. 在使用微导管时，请随时监控输注速度
4. 为血管造影注射造影剂时，请确保微导管无扭结或堵塞。
5. 微导管的导管外侧具有润滑亲水涂层。在从保护套上取下之前及实际手术过程中必须保持水合，以便润滑。这可通过将 Y 阀连接到持续的生理盐水滴注来实现。
6. 在手术开始前，应仔细检查手术使用的所有设备，确保功能正常及完整。
7. 使用前，请检查微导管是否有任何弯曲或扭结。任何微导管损坏都可能降低预期的性能特征。
8. 在手术过程中，请谨慎操作微导管，以减少意外断裂、弯曲或扭结的可能性。
9. 当微导管在体内时，仅可在透视下操作。在未观察尖端反应结果的情况下，请勿尝试移动微导管。
10. 在需要大量操作或多次更换导丝的长时间手术中，微导管需频繁更换。
11. 如果受到阻力，则在通过透视确定导致阻力的原因之前，不得推动或拉动血管内的器械。不顾阻力而移动微导管或导丝可导致微导管或导丝尖端分离、导管损坏或血管穿孔。
12. 由于微导管可能被推进至狭窄的超选择性血管系统中，因此请再三确保微导管未被推送到过远的位置以免妨碍其退出。
13. 过度拧紧微导管杆身上的止血阀可能损坏导管。
14. 请阅读并遵守制造商的使用说明书，了解与该微导管一起使用的诊断剂、栓塞剂或治疗剂。
15. 请在“使用期限”前使用。
16. 在从螺旋保护套上取下导管之前，请从导管上取下管心针。
17. 注射器准确度为 +/- 5%。

潜在并发症

潜在并发症（按字母顺序排列）包括但不限于：

- 血管夹层
- 栓塞
- 出血
- 感染
- 缺血
- 血管穿孔
- 血栓形成
- 血管痉挛

表 **1**：**Merit Pursue** 兼容性信息

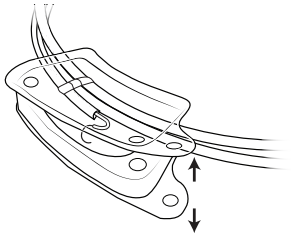
微导管外径	微导管内径	导丝最大外径	导引导管最小内径
2.8F / 1.7F	0.016"（0.40 毫米）	0.014"（0.36 毫米）	0.040"（1.02 毫米）
2.9F / 2.0F	0.020"（0.50 毫米）	0.018"（0.46 毫米）	0.042"（1.07 毫米）
栓塞剂			
微导管外径	颗粒栓塞剂	球形栓塞剂	弹簧圈最大尺寸
2.8F / 1.7F	≤ 500 微米	≤ 500 微米	0.014"（0.36 毫米）
2.9F / 2.0F	≤ 710 微米	≤ 700 微米	0.018"（0.46 毫米）
化学药品			
顺铂	氰丙烯酸酯	DMSO（二甲亚砜）	阿霉素
乙醇	伊立替康	碘油	

注：栓塞剂兼容性仅供参考。对于兼容性，请阅读并遵守栓塞剂制造商使用说明书。

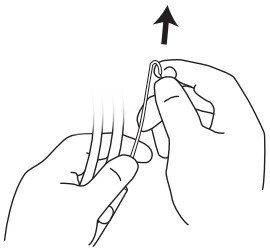
使用说明书

注： 建议微导管与导引导管一起使用。

1. 请使用标准技术放置导引导管。旋转式止血阀可连接导引导管鲁尔接头，以用盐水连续冲洗导引导管。
2. 利用无菌技术，小心地打开袋子，并从包装中取出微导管保护套。
3. 将装有肝素化盐水溶液或无菌水的注射器连接至微导管保护套的鲁尔锁接头上。
4. 注入足够的溶液，以完全润湿微导管表面。这将激活微导管表面上的亲水涂层。
   注：从保护套上取下后，微导管的表面可能会变干。用肝素化盐水或无菌水进行额外润湿，即可重新恢复亲水效果。
   注：步骤 5 和 6 适用于 45° 或 天鹅颈 头型的导管。
5. 取下微导管尖端上的保护盖。



6. 从导管上取下尖端固位管心针。
   警告：在从微导管保护套取下微导管之前，未能取下管心针可能会损坏导管。



7. 将装有肝素化盐水溶液或无菌水的注射器连接至微导管的管座。
8. 注入足够的溶液，以清除微导管内部的任何空气。
9. 从微导管保护套上取下微导管。
   注：从微导管保护套上取下后，微导管的表面可能会变干。用肝素化盐水或无菌水进行额外润湿，即可重新恢复亲水效果。
10. 从微导管保护套上取下微导管后，请在插入前检查微导管，确认没有损坏。
11. 如果需要，请将带有侧臂的第二个止血阀连接至微导管。用肝素化盐水或无菌水冲洗，以清除任何空气。
12. 小心地将导丝插入微导管，并完全关闭导丝周围的阀门（如使用）。
13. 通过止血阀（如使用）将微导管和导丝组合引入导引导管。如果使用旋转式止血阀，则拧紧微导管周围的阀门，以免回流，但允许微导管通过阀门进行移动。

14.使用荧光透视，将微导管和导丝组合引入血管系统，确保导丝始终位于微导管前面。通过交替推进导丝并在导丝上跟踪微导管，将导丝和微导管推进到选定的血管部位。注：为了便于微导管操作，微导管的近端部分无涂层，以确保防滑抓握。

15 最终定位是通过导丝和微导管的短距离推进实现，直到到达目标位置，然后通过荧光透视查看确认。

16. 在使用过程中，请监测微导管的置放和位置。

17. 注射时，请从微导管中完全取下导丝。将装有注入液的注射器连接到微导管鲁尔接头，并根据需要进行注射。

高压注射器与微导管使用说明

高压注射器可通过微导管注射造影剂。请注意以上警告和注意事项。流速取决于造影剂粘度等因素，其随造影剂类型及温度、高压注射器型号及设置以及注射器连接到微导管的方式而变化。以下所示的观察流速值仅供参考。

表 **2**：流速

Merit Pursue 微导管杆身/头端尺寸	**Merit Pursue** 微导管可用长度（厘米）	造影剂	碘含量（毫克/毫升）	**37°C** 下的粘度（厘泊）	**MEDRAD** 流动设置条件，线型增长时间为 **0.3** 秒		安全压力设置下的造影剂实际运送速度：	死腔（预冲）容量（毫升）
					流速（毫升/秒）	流量（毫升）	**5515** 千帕 **(800 psi)**	
2.8F/1.7F	110	ISOVUE（碘帕醇）	300 370	4.7 9.4	6.0 3.0	10 10	3.0 1.5	0.42
	130	ISOVUE（碘帕醇）	300 370	4.7 9.4	6.0 3.0	10 10	2.6 1.3	0.50
	150	ISOVUE（碘帕醇）	300 370	4.7 9.4	6.0 3.0	10 10	2.4 1.2	0.53
2.9F/2.0F	110	ISOVUE（碘帕醇）	300 370	4.7 9.4	6.0 3.0	10 10	4.3 2.4	0.50
	130	ISOVUE（碘帕醇）	300 370	4.7 9.4	6.0 3.0	10 10	3.9 2.0	0.57
	150	ISOVUE（碘帕醇）	300 370	4.7 9.4	6.0 3.0	10 10	3.7 1.9	0.63

参考数据

1. 使用注射器：MEDRAD MARK V
2. 造影剂温度：37°C
3. 注射压力监控器/限制设置：5515 千帕 (800 psi)
4. 流动标度：毫升/秒
5. 线性增长时间：0.3 秒

储存条件：存放于阴凉干燥处。
运输条件：运输期间不要暴露于过高温度或湿度。

产品名称：微导管
结构及组成：微导管主要由管身、导管座、轴衬、矫直器以及注射器组成。
环氧乙烷灭菌，一次性使用，货架有效期3年。
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：1600 West Merit Parkway South Jordan Utah 84095 USA
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：国械注进20213030333
产品技术要求编号：国械注进20213030333
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：2021年8月18日
型号、规格：
28HC17110ST 28HC17110SN
28HC1711045 28HC17130ST
28HC17130SN 28HC1713045
28HC17150ST 28HC17150SN
28HC1715045 29HC20110ST
29HC20110SN 29HC2011045
29HC20130ST 29HC20130SN
29HC2013045 29HC20150ST
29HC20150SN 29HC2015045

标志	说明
℞ Only	警示：联邦（美国）法律将此器械限制为由医生销售或订购。
	失效日期
	警告
	生产日期
REF	产品编号
LOT	批号
2 STERILIZE	不得二次灭菌
	查阅使用说明
	如包装破损切勿使用
	无热原
MAX GUIDE WIRE	导丝最大直径
	最大压力
STERILE EO	经环氧乙烷灭菌
2	不得二次使用
	不透射线标志
MD	医疗器械
无菌包装	无菌包装

MERIT MEDICAL®

www.merit.com

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1600 West Merit Parkway South Jordan Utah 84095 USA
1-801-253-1600
美国客户服务 1-800-356-3748

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