Prelude®

English

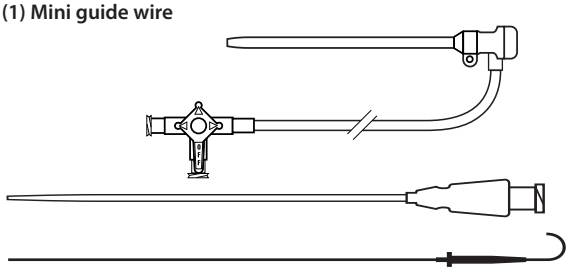
Prelude Sheath Introducer

INSTRUCTIONS FOR USE

Product Description

The Merit Prelude™ Sheath Introducer consists of the following components. These components may be packaged in a single pouch or may be packaged separately.

One (1) Sheath Introducer
One (1) Vessel Dilator
One (1) Mini guide wire



INTENDED USE: The Merit Prelude Sheath Introducer is intended to provide access and facilitate the pe r cutaneous introduction of various devices into veins and/or arteries while maintaining hemostasis for a variety of diagnostic and therapeutic procedures.

WARNINGS:
- Do not advance the introducer and/or guide wire if resistance is met.
- Do not leave the introducer in place for extended periods of time without a catheter or an obturator to support the cannula wall.
- Do not use device with a power injector.

CAUTIONS
- Read instructions prior to use.
- RX Only
- Store in a cool dry place.
- This device is intended for single use only. Do not reuse or resterilize.

POTENTIAL Complications:
Potential complications include, but are not limited to: Air embolism, Infection, Hematoma, Bleeding, Perforation or laceration of the vessel wall, Thrombus formation, Pseudo aneurysm formation, guide wire embolization, vessel spasm, Risks normally associated with percutaneous diagnostic and/or interventional procedures.

Instructions for Use
1. Identify the insertion site and prepare the site using proper aseptic technique and local anesthesia as required.
2. Remove the Prelude Sheath Introducer components from package using proper aseptic technique.
3. Flush all components with saline or suitable isotonic solution. After flushing side port, turn stopcock to off position to maintain flush in side port and prevent bleed back upon insertion into the vessel.
4. Insert vessel dilator into Prelude Sheath Introducer through hemostasis valve and snap into place. Dilator must be securely snapped into place to avoid damage to the vessel.
5. Insert appropriate access needle into vessel. While holding the access needle, place the flexible end or J end of the guide wire through access needle into vessel. Note — Refer to product labeling for the guide wire size that is compatible with the system components.
   Warning: Do not advance the guide wire if resistance is met. Determine the cause of resistance before proceeding.
6. Hold guide wire in place and remove access needle. Hold pressure at the site until the introducer/dilator assembly is placed.
   Warning: If a needle with a metal cannula is used, do not withdraw the guide wire after it has been inserted because it may damage the guide wire.
7. Insert the introducer/dilator assembly over the guide wire into the vessel. Using a rotating motion, advance the introducer/dilator assembly through the tissue into the vessel. Grasp the assembly close to the skin as it is being placed into the vessel to avoid buckling.
8. After introducer/dilator assembly has been placed into vessel, detach the dilator from the introducer by bending the dilator hub down slightly (this will un-snap the dilator hub from the introducer cap). While holding the sheath, carefully remove the dilator and guide wire togethe r , leaving the sheath introducer in the vessel.
9. Aspirate from the side port extension to remove any potential air. After aspiration, flush the side port with a suitable solution. Stopcock should be turned off to maintain flush in side port.
10. Insert selected device(s) (wires, catheters, etc.) into Prelude Sheath Introducer. Note: Hold the sheath in place when inserting, positioning, or removing the devices. Always exchange or remove devices slowly through the sheath.
11. To temporarily suture the sheath in place, use the rotating suture ring.
12. REMOVAL:
    - The sheath may be removed when clinically indicated. Compression on the vessel, above the puncture site, should be started as the sheath is slowly removed. Note: Collected fibrin at the tip of the sheath may be aspirated via the side arm tubing prior to removal of the sheath. Discard the sheath appropriately.
    - If the sheath is to be left in place, an obturator of appropriate size should be placed into sheath. After the sheath is flushed, place the obturator through the sheath and snap into place. A suitable solution should be flushed through the side arm after obturator is placed. Note: An obturator that is one French size smaller than the sheath introducer should be used to allow flushing, infusion and pressure monitoring. When clinically indicated, the sheath and obturator may be removed (see above).

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EC REP

Merit Medical Ireland Ltd, Parkmore Business Park West, Galway, Ireland

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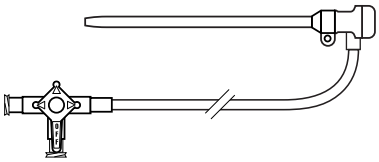
Prelude®
导管鞘器械

使 用 说 明

产品描述
PRELUDE 导管鞘器械包含以下组件。
这些组件可包装在一个小袋内。

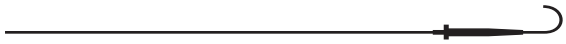
一 (1) 个导管鞘
一 (1) 个血管扩张器
一 (1) 根迷你导丝
一 些套件中还包括穿刺针

导管鞘



血管扩张器

迷你导丝



适用范围：用于提供各种装置进入静脉和／或动脉的通道，方便经皮引导，同时对诊断和治疗程序维持止血。

警告：
• 遭到阻力时不要强推导管鞘和／或导丝。
• 不要在无导管或填塞器支撑管壁的情况下将导管鞘长时间留在原位。
• 不要通过高压注射器使用装置。

警示：
• 使用之前请阅读使用说明。
• 仅凭处方销售
• 储存在凉爽、干燥的地方。
• 本装置仅供一次性使用。请勿重复使用或重新消毒

不得重复使用的警示：
本产品仅为单个病人使用。不得重复使用、重复加工或重复灭菌。重复使用、重复加工或重复灭菌可能危及产品结构的完善性和/或导致器械失效，从而导致病人受伤，生病或死亡。重复使用、重复加工或重复灭菌也可能产生污染产品的风险和/或导致病人感染或交叉感染，包括（但不限于）：病人之间传染性疾病传播。被污染的产品可能导致病人受伤，生病或死亡。

潜在并发症：
潜在并发症包括但不限于：气栓、感染、血肿、流血、血管壁穿孔或撕裂、血栓形成、假性动脉瘤形成、导丝栓塞、血管痉挛、一般与经皮诊断和／或介入程序有关的风险。

使用说明
1. 确定插入部位，并采用恰当的无菌技术和局部麻醉（如需要）对该部位进行预处理。
2. 采用恰当的无菌技术将 PRELUDE 导管鞘组件从包装中取出。
3. 使用盐溶液或适当的等渗溶液冲洗所有组件。冲洗侧接口后，转动活塞至关闭位置，以维持在侧端口冲洗并防止插入血管后血液回流。
4. 将血管扩张器通过止血阀插入 PRELUDE 导管鞘内，并卡入位。扩张器必须安全地卡入位，以避免损坏血管。
5. 插入适当的穿刺针至血管内。保持穿刺针的同时，穿过穿刺针将导丝柔韧的一端或 J 型端置入血管内。注意一请参阅产品标签查看导丝尺寸是否与系统组件相符。
警告：遇到阻力时不要强推导丝。
确定产生阻力的原因后再继续。
6. 保持导丝在原位并移除穿刺针。在该部位施以一定压力，直至放好导管鞘／扩张器组件。警告：如果使用带金属套管的针头，则在插入导丝后不要收回导丝，因为这样可能会损坏导丝。
7. 通过导丝将导管鞘／扩张器组件插入至血管内。通过旋转运动，将导管鞘／扩张器组件穿过组织旋入血管内。在组件置入血管内时，抓紧靠近皮肤的组件部位以免变形。
8. 导管鞘／扩张器组件置入血管内后，轻轻地弯下扩张器接阀（这样会使扩张器接阀从导管鞘帽上脱离卡位），将扩张器从导管鞘上分离。握住鞘的同时，小心地将扩张器和导丝一起移除，使导管鞘留在血管内。
9. 从侧接口延伸部分抽吸任何潜在的空气。抽吸后，使用适当的溶液冲洗侧接口。活塞应关闭以维持在侧接口冲洗。
10. 插入选择的装置（导丝、导管等）至 PRELUDE 导管鞘内。注意：在插入、放置或移除装置时，使鞘保留在原位。始终缓慢地通过鞘更换或移除装置。
11. 如要暂时将鞘缝合到位，请使用旋转缝合环。
12. 移除：

• 可按临床指示移除鞘。缓慢移除鞘后，应立即在穿刺部位上压紧血管。注意：在鞘的顶端处收集的纤维蛋白可在移除鞘之前，通过侧臂管吸出。妥善地丢弃鞘。
• 如果鞘要留在原位，应在鞘内放入适当尺寸的填塞器。冲洗鞘后，将填塞器穿过鞘并卡入位。放入填塞器后，通过侧臂使用适当的溶液冲洗。注意：应使用比导管鞘小一个法国尺寸的填塞器，以方便冲洗、输注和压力监测。鞘和填塞器可按临床指示移除（参见上文）。

储存条件：存储于通风干燥处。

运输条件：运输过程中应不暴露在高温或高湿下。

有效期：3年。

生产日期和失效日期：见产品标签。

未开封且未损坏的包装内含物无菌、无热原。

使用一次后销毁。

经环氧乙烷灭菌。

警示：请查阅随附文件。

产品名称：导管鞘器械

型号、规格：请见附页。

结构及组成：

本产品由导管鞘、扩张器、导丝组成，含或不含穿刺针。产品经环氧乙烷灭菌，一次性使用。货架有效期3年。

注册证编号：国械注进20213030434
产品技术要求编号：国械注进20213030434
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
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注册人及生产企业住所：1600 West Merit Parkway, South Jordan, Utah 84095 USA
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说明书编制或修订日期：2021年11月8日。

MERIT MEDICAL®

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授权代表: Merit Medical Ireland Ltd, Parkmore Business Park West, Galway, Ireland

附页

型号、规格列表

PSI-4F-11-035	PSI-5F-11-035-18G
PSI-5F-11-035	PSI-5F-11-038-18G
PSI-5F-11-038	PSI-6F-11-035-18G
PSI-6F-11-035	PSI-6F-11-038-18G
PSI-6F-11-038	PSI-7F-11-035-18G
PSI-7F-11-035	PSI-8F-11-035-18G
PSI-7F-11-038	PSI-4F-7-018
PSI-8F-11-035	PSI-5F-7-018
PSI-8F-11-038	PSI-6F-7-018
PSI-4F-23-035	PSI-4F-11-018
PSI-5F-23-035	PSI-5F-11-018
PSI-5F-23-038	PSI-6F-11-018
PSI-6F-23-035	PSI-4F-7-025
PSI-6F-23-038	PSI-5F-7-025
PSI-7F-23-035	PSI-6F-7-025
PSI-7F-23-038	PSI-4F-11-025
PSI-8F-23-035	PSI-5F-11-025
PSI-8F-23-038	PSI-6F-11-025

- 列表结束 -