



MINI ACCESS KIT

INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION

The Merit MAK (Mini Access Kit) utilizes a small coaxial introducer with dilator and guide wire for placement of larger diameter guide wires into the vasculature system when a small needle stick is preferred.

The Merit MAK consists of the following components. These components may be packaged in a single pouch or may be packaged separately.

- One (1) 4F or 5F coaxial introducer/dilator pair or 4F or 5F coaxial introducer/stiffened dilator pair
- One (1) 21 gauge introducer needle or 21 gauge echo enhanced introducer needle
- One (1) 0.018" (0.46mm) guide wire

INTENDED USE

The Merit MAK is intended for percutaneous placement of a 0.035" (0.89mm) or 0.038" (0.97mm) guide wire into the vascular system.

WARNINGS

Withdrawal, pull back, or manipulation of the guide wire distal tip through the needle tip may result in breakage or embolization.

Do not advance the guide wire if resistance is met.

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 risks normally associated with percutaneous diagnostic and/or interventional procedures.

Other complications include, but are not limited to:

- Air embolism
- Infection
- Hematoma
- Bleeding
- Thrombus formation
- Pseudo aneurysm formation
- Guide wire embolization
- Perforation or laceration of the vessel wall

INSTRUCTIONS FOR USE

1. Identify the insertion site and prepare the site using proper aseptic technique and local anesthesia as required.
2. Insert the 21 gauge introducer needle using standard technique.
3. Carefully advance the flexible end of the 0.018" (0.46mm) guide wire through needle. Advance the guide wire as far as appropriate. Verify correct positioning.
WARNING: Do not advance guide wire if resistance is met.
4. Remove needle while maintaining the 0.018" (0.46mm) guide wire in position.
WARNING: Withdrawal, pull back, or manipulation of the guide wire distal tip through the needle tip may result in breakage or embolization. To avoid guide wire damage during manipulation, remove the introducer needle and proceed to step 5.
5. Insert the coaxial introducer/dilator pair over the 0.018" (0.46mm) guide wire and advance to the desired position.
6. Remove dilator and 0.018" (0.46mm) guide wire leaving the introducer in position.
NOTE: Place a finger over the hub of the introducer to minimize blood loss and risk of air aspiration.
7. Insert 0.035" (0.89mm) or 0.038" (0.97mm) guide wire through introducer.
8. Remove introducer, leaving 0.035" (0.89mm) or 0.038" (0.97mm) guide wire in place.

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.



www.merit.com

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

使用说明

产品描述:

MERIT MAK (迷你型导管鞘套装) 是在使用小型穿刺针更合适时, 利用带有扩张器和导丝的小同轴导管鞘将直径较大的导丝放入血管包含型号、规格: MAK5F-10、MAK5F-15、MAK501、MAK501N、MAK501N-15、MAK505、MAK501-E、MAK501N-E、MAK505-E、MAK501-PED、MAK501N-PED、MAK401、MAK405、MAK401N、MAK401-E、MAK401N-E、MAK405-E、MAK401-PED、MAK401N-PED、S-MAK5F-10、S-MAK5F-15、S-MAK501、S-MAK501N、S-MAK501N-15、S-MAK505、S-MAK401、S-MAK401N、S-MAK405

MERIT MAK 由以下组件组成。这些组件可能为一个套件包装也可能单独包装。

- 一个 4F 或 5F 同轴导管鞘/扩张器对 或 4F 或 5F 同轴导管鞘/加强扩张器对
- 一个 直径为21G的穿刺针或直径为 21G的回型穿刺针
- 一条 0.018英寸 (0.46毫米) 导丝

适用范围: 该产品协助经皮穿刺装置插入至静脉和/或动脉。

警告

通过穿刺针尖取出、回拉或操作导丝末端可能会造成破裂或栓塞。

如果遇到阻力, 请勿推进导丝。

注意

- 使用之前请阅读使用说明
 - 仅凭处方销售
 - 在阴凉干燥处存放
 - 该器械仅适用于一次性使用。
- 请勿重复使用或重复灭菌。

潜在并发症

潜在并发症通常包括与经皮诊断和/或介入手术相关的风险。

其他潜在并发症包括, 但不限于:

- 空气栓塞
- 感染
- 血肿
- 出血
- 血栓形成
- 假性动脉瘤形成
- 导丝栓塞
- 血管壁穿孔或裂伤

使用说明

- 根据要求确定插入部位并使用正确的无菌技术和局部麻醉准备穿刺部位。
- 使用标准技术插入 直径为21G的穿刺针。
- 小心地将直径为 0.018 英寸 (0.46 毫米) 的导丝的柔性端通过穿刺针推进。尽可能向前推动导丝到适当的位置。确认正确的定位。

警告: 如果遇到阻力, 请勿推进导丝。

- 取出穿刺针, 同时保持 0.018 英寸 (0.46 毫米) 导丝在原地。

警告: 通过穿刺针尖取出、回拉或操作导丝末端可能会造成破裂或栓塞。为了避免在操作期间损坏导丝, 取出引导器针然后进行第 5 步。

- 沿着0.018英寸 (0.46毫米) 导丝插入同轴导管鞘/扩张器对, 并推进到预期位置。
- 取出扩张器和 0.018 英寸 (0.46 毫米) 导丝, 将导管鞘留在原地。
注: 将手指放在导管鞘的导管头上, 以尽量减少失血和吸入空气的风险。
- 经导管鞘插入 0.035英寸 (0.89毫米) 或 0.038英寸 (0.97毫米) 导丝。
- 取出导管鞘, 将 0.035英寸 (0.89毫米) 或 0.038英寸 (0.97毫米) 导丝留在原地。

产品名称: 导管鞘器械

型号、规格: 见附页

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

注册人及生产企业联系方式: 1-801-253-1600

说明书编制或修订日期: 2024年2月

生产地址: 1600 West Merit Parkway, South Jordan, Utah84095(此地址适用于除MAK&SMAK外的 Prelude型号); Avenida Sor Juana Ines De La Cruz, 19970 InteriorB, Edificio 2, Parque Industrial Frontera, Tijuana, Baja California, MEXICO22630 (此地址适用于MAK&SMAK型号)

储存条件

应贮存在相对湿度不大于80%, 温度应经过控制的室温环境。

运输条件

运输过程中应不暴露在高温或高湿处
如包装破损切勿使用

结构及组成：该产品由Prelude导管鞘套装、PreludePRO导管鞘套装、Prelude ACT导管鞘套装、带标记带Prelude PRO导管鞘套装、带标记带Prelude导管鞘套装、带穿刺针Prelude导管鞘套装、带穿刺针PreludePRO导管鞘套装、Prelude迷你套装、Prelude短导管鞘套装、MAK迷你套装、S-MAK迷你套装组成。组件包括导管鞘、扩张器、导丝和穿刺针。环氧乙烷灭菌，一次性使用。货架有效期3年。

灭菌方式：环氧乙烷灭菌

生产日期和失效日期：见产品标签

有效期：3年

注册证编号/产品技术要求编号：国械注进20153032590

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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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

型号、规格附页

PSI-4F-11	PRO-6F-11-038	PSI-7F-23MT	PSS-6F-4-018MT
PSI-4F-11-035	PRO-7F-11	PSI-7F-23-035MT	PSS-7F-4-018MT
PSI-5F-11	PRO-7F-11-035	PSI-7F-23-038MT	PSS-8F-4-018MT
PSI-5F-11-035	PRO-7F-11-038	PSI-8F-23MT	MAK5F-10
PSI-5F-11-038	PRO-8F-11	PSI-8F-23-035MT	MAK5F-15
PSI-6F-11	PRO-8F-11-035	PSI-8F-23-038MT	MAK501
PSI-6F-11-035	PRO-8F-11-038	PSI-5F-11-035-18G	MAK501N
PSI-6F-11-038	PSI-4F-11ACT	PSI-5F-11-038-18G	MAK501N-15
PSI-7F-11	PSI-4F-11-035ACT	PSI-6F-11-035-18G	MAK505
PSI-7F-11-035	PSI-5F-11ACT	PSI-6F-11-038-18G	MAK501-E
PSI-7F-11-038	PSI-6F-11ACT	PSI-7F-11-035-18G	MAK501N-E
PSI-8F-11	PSI-7F-11ACT	PSI-8F-11-035-18G	MAK505-E
PSI-8F-11-035	PSI-8F-11ACT	PRO-5F-11-038-18G	MAK501-PED
PSI-8F-11-038	PRO-4F-11MT	PRO-6F-11-038-18G	MAK501N-PED
PSI-4F-23	PRO-4F-11-035MT	PSI-4F-7-018	MAK401
PSI-4F-23-035	PRO-5F-11MT	PSI-5F-7-018	MAK405
PSI-5F-23	PRO-5F-11-035MT	PSI-6F-7-018	MAK401N
PSI-5F-23-035	PRO-5F-11-038MT	PSI-4F-11-018	MAK401-E
PSI-5F-23-038	PRO-6F-11MT	PSI-5F-11-018	MAK401N-E
PSI-6F-23	PRO-6F-11-035MT	PSI-6F-11-018	MAK405-E
PSI-6F-23-035	PRO-6F-11-038MT	PSI-4F-7-025	MAK401-PED
PSI-6F-23-038	PRO-7F-11MT	PSI-5F-7-025	MAK401N-PED
PSI-7F-23	PRO-7F-11-035MT	PSI-6F-7-025	S-MAK5F-10
PSI-7F-23-035	PRO-7F-11-038MT	PSI-4F-11-025	S-MAK5F-15
PSI-7F-23-038	PRO-8F-11MT	PSI-5F-11-025	S-MAK501
PSI-8F-23	PRO-8F-11-035MT	PSI-6F-11-025	S-MAK501N
PSI-8F-23-035	PRO-8F-11-038MT	PSS-5F-4MT	S-MAK501N-15
PSI-8F-23-038	PSI-4F-23MT	PSS-5F-4-038MT	S-MAK505
PRO-4F-11	PSI-4F-23-035MT	PSS-6F-4MT	S-MAK401
PRO-4F-11-035	PSI-5F-23MT	PSS-6F-4-038MT	S-MAK401N
PRO-5F-11	PSI-5F-23-035MT	PSS-7F-4MT	S-MAK405
PRO-5F-11-035	PSI-5F-23-038MT	PSS-7F-4-038MT	3339-21
PRO-5F-11-038	PSI-6F-23MT	PSS-8F-4MT	3339-31
PRO-6F-11	PSI-6F-23-035MT	PSS-8F-4-038MT	3339-41
PRO-6F-11-035	PSI-6F-23-038MT	PSS-5F-4-018MT	3339-51