medCOMP®

Valved Peelable Introducer
Instructions For Use

带阀可撕裂穿刺鞘使用说明

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Intended Use:
The Valved Peelable Introducers are intended to obtain central venous access to facilitate catheter insertion into the central venous system.

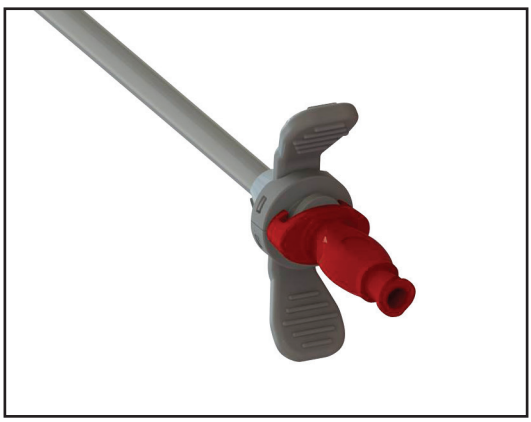
Precautions:
- The Valved Peelable Introducer is designed to reduce blood loss and the risk of air intake but it is not a hemostasis valve.
- It is not intended to create a complete two-way seal nor is it intended for arterial use.
- The valve will substantially reduce air intake. At -12mm Hg vacuum pressure the Valved Peelable Introducer may allow up to 4cc/sec of air to pass through the valve.
- Product is sterile in unopened, undamaged package.
- For single use only. **DO NOT RE-USE.** Re-use may lead to infection or illness/injury.
- Federal (USA) law restricts this device to sale by or on the order of a physician.

Contraindications:
- The Valved Peelable Introducer is not designed for use in the arterial system or as a hemostatic device.

Potential Complications:
- Air Embolism
- Brachial Plexus Injury
- Hematoma Formation
- Hemothorax
- Mediastinal Widening
- Pneumothorax
- Subclavian Artery Puncture
- Subclavian Vein Thrombosis
- Wound Infection

Instructions for Use:

1. Remove the introducer assembly from the package, remove dilator from the sheath and reinsert it into the opposite end. Lock the dilator in place by rotating it ninety degrees clockwise.



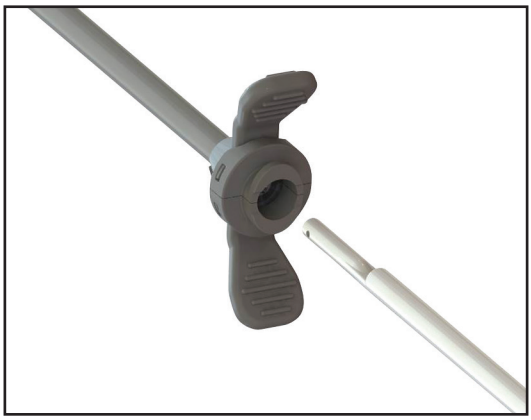
2. After percutaneous access has been achieved, advance the introducer assembly over the guidewire and into the vein.

Caution: DO NOT bend the sheath/dilator during insertion as bending will cause the sheath to prematurely tear. Hold the introducer close to the tip (approximately 3cm from tip) when initially inserting through the skin surface. To progress the introducer towards the vein, regrasp the introducer a few centimeters above the original grasp location and push down on the introducer. Repeat procedure until introducer is inserted to appropriate depth based on patient anatomy and physician's discretion.

3. Remove the dilator and guidewire from the sheath by rotating the dilator ninety degrees counterclockwise to unlock the dilator from the sheath and gently withdraw the dilator and guidewire from the sheath.

Caution: Never leave sheath in place as an indwelling catheter. Damage to the vein will occur.

4. Advance catheter through the valve. To prevent kinking the catheter, it may be necessary to advance in small steps by grasping the catheter close to the sheath.



5. After the catheter has been positioned, crack the sheath handle and valve in half.

6. Remove the sheath from the patient by slowly pulling out of the vessel while simultaneously splitting the sheath by grasping the tabs and pulling them apart (a slight twisting motion may be helpful).

Caution: Do not pull apart the portion of the sheath that remains in the vessel. To avoid vessel damage, pull back the sheath as far as possible and tear the sheath only a few centimeters at a time.

WARRANTY

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预期用途：
带阀可撕裂穿刺鞘适用于建立中心静脉通道便于导管插入中心静脉系统。

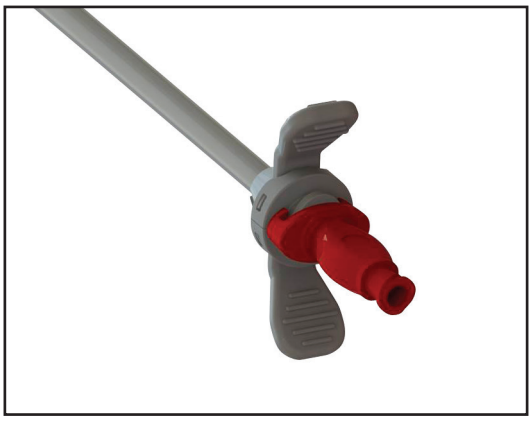
预防措施：
- 带阀可撕裂穿刺鞘可减少失血和空气吸入的风险，但是它不是一个止血阀。
- 它不能产生一个完整的双向密封，也不适用于动脉。
- 这个阀将充分的降低空气吸入。穿刺鞘的-12mm Hg真空压力最大可能允许4ml/s的空气通过这个阀。
- 在未拆封，未破损包装袋内的产品是无菌的。
- 该产品是一次性使用。不要重复使用。重复使用可能导致感染或者疾病/损失。
- 美国联邦法律明令禁止医师销售设备。

禁忌症：
- 带阀可撕裂穿刺鞘不能在动脉系统使用，也不能作为一个止血设备。

潜在并发症：

- 空气栓塞
- 臂丛神经损伤
- 血肿
- 血胸
- 纵膈增宽
- 气胸
- 锁骨下动脉穿刺
- 锁骨下静脉血栓
- 伤口感染

操作说明：
1. 从包装中取出鞘/扩张器结合体，将扩张器从鞘中移出。并且从相反一端重新插入。通过顺时针方向旋转90度将扩张器锁定在位置上。



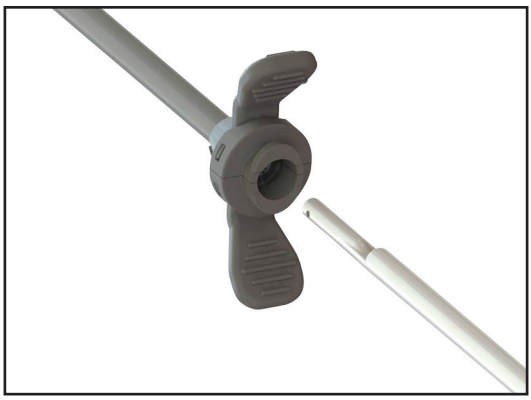
2. 当完成经皮通道后，通过导丝将穿刺鞘/扩张器结合体推进到静脉。

警告：在放置过程中不要弯曲鞘 / 扩张器，因为弯曲会造成鞘过早撕裂。当开始穿刺进入皮肤时，要握住鞘 / 扩张器靠近尖端的部位（距尖端大约3cm）。当鞘 / 扩张器进入静脉时，在原来位置的上方几厘米（大约5cm）处重新握住鞘 / 扩张器并向下推送。基于患者的解剖结构和医生的慎重，重复此过程直至鞘 / 扩张器进入至适当的深度。

3. 通过逆时针方向旋转扩张器90度，将扩张器从穿刺鞘中解锁。将扩张器和导丝从穿刺鞘/扩张器结合体中移走。扩张器和导丝必须轻轻的从鞘中抽出。

警告：不要把鞘当作留置导管。这样做会损伤静脉。

4. 通过阀将导管推进。为了防止导管扭结，需要握紧导管沿着鞘缓慢推进。



5. 当导管到达位置后，将鞘手柄一分为二。

6. 将鞘缓慢从患者血管中拔出，同时抓住可撕裂鞘的两侧快速的将鞘撕开（轻轻的旋转动作可能会有帮助。

警告：还留置在血管内的鞘不要撕裂。为避免血管损伤，请尽可能向回拔出鞘，每次撕裂时只撕开一两公分。

保证书

Medcomp®保证本产品按照适用标准和技术规范制造。患者病情、临床疗法及产品维护可能影响本产品的性能。应该按照使用说明书和处方医师的指示使用本产品。

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特殊储存条件及方法： 应远离极端温度和湿度，储存在+10 - 40℃的环境范围内。
灭菌方式： 环氧乙烷灭菌
生产日期：请见原厂标签
有效期： 请见原厂标签
医疗器械注册证书编号：国械注进20163101245
产品技术要求编号： 国械注进20163101245

产品型号/规格：

SST24S-C	ASPC28-3-C	ASPC2416-3PC-C	RPK-01-C
SST28S-C	ASPC32-3-C	ASPC2816-3PC-C	MR190703-C
SST32S-C	ASPC36-3-C	ASPC3216-3PC-C	MR190803-C
BFL-6-C	ASPC40-3-C	ASPC3616-3PC-C	MR190903-C
BFR-6-C	ASPC55-3-C	ASPC18P-XL-C	MR191003-C
BFS-6-C	ASPC24-3PC-C	ASPC24P-XL-C	MR191103-C
BFL-6S-C	ASPC28-3PC-C	THD155424S-C	MR191203-C
BFR-6S-C	ASPC32-3PC-C	THD155428S-C	MR191303-C
BFS-6S-C	ASPC36-3PC-C	THD155432S-C	MR191403-C
BFR1035KD-A-C	ASPC24-3WO-C	THD155436S-C	MR191503-C
PBF-C	ASPC28-3WO-C	THD155440S-C	MR191603-C
BF11A-C	ASPC32-3WO-C	THD155455S-C	MR191703-C
BF11V-C	ASPC36-3WO-C	THD155624S-C	MC74-C
PBF11A-C	ASPC40-3WO-C	THD155628S-C	MC75-C
PBF11V-C	ASPC55-3WO-C	THD155632S-C	MC76-C
HFS24-C	ASPC24-3PCWO-C	THD155636S-C	MC77-C
HFS28-C	ASPC28-3PCWO-C	THD155624-C	MC78-C
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HFS36PC-C	ASPC4016-3-C	MCVSI16-C	
ASPC24-3-C	ASPC5516-3-C	MCVSI17-C	

编制日期	2022.02.25
修订日期	2022.02.25

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SYMBOL CHART

STERILE EO	STERILIZED WITH ETHYLENE OXIDE
0000-00	DATE OF EXPIRATION YR-MO
	SEE INSTRUCTIONS FOR USE
	SINGLE USE
REF	PRODUCT NUMBER
LOT 000000-0000/00	LOT NUMBER - YR/MO OF MANUFACTURE
LOT 000000-00/00	LOT NUMBER - MO/YR OF MANUFACTURE