HeartSpan®

Transseptal Needles

Transseptal Needle and Stylet Set

Directions for Use

Read instructions for use in its entirety prior to use.

Single use only disposable medical device.

Rx Only: Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Device Description
The transseptal needle kit consists of an outer needle cannula and an inner stylet. The needle is comprised of flexible thin walled tubing with an ergonomic hub and stopcock attached to the proximal end. The stylet consists of a solid wire that when inserted in the needle protrudes beyond the distal tip of the cannula.

Indications for Use
The transseptal needle is used in conjunction with a transseptal catheter and/or introducer to create the puncture in the atrial septum to allow left heart catheterization procedure to occur through the right atrium.

Contraindications
- Left atrial thrombus or tumor
- Dilated aortic root
- Continual anticoagulation
- Inability to lie flat
- Substantial deformity of the spine or chest
- Marked atrial enlargement
- Distorted anatomy due to congenital heart disease
- Previous intra-septum patch

Warnings
- For single 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. This single-use product is not designed or validated to be reused. Reuse may cause a risk of cross-contamination, affect the measurement accuracy, system performance, or cause a malfunction as a result of the product being physically damaged due to cleaning, disinfection, re-sterilization, or reuse.
- Only those physicians who specialize in the practice of invasive cardiology techniques should use this device. The device should be restricted for use by those specialists trained to perform transseptal procedures.
- Maintain continuous pressure monitoring and repeated biplane fluoroscopy during positioning.
- Caution should be used in patients with small left atrium, to avoid left atrial wall puncture.
- The transseptal needle should never be advanced until the catheter is positioned correctly on the atrial septum.
- Always ensure that the transseptal needle has clearly entered the left atrial cavity by confirming distinct left atrial pressure and fluoroscopy of the needle tip before advancing the dilator, sheath or catheter.
- Do not remove a dilator, sheath or catheter that has been inadvertently advanced into the pericardial space until the patient is in surgery.
- Do not reuse this device. The device must be discarded after one use using acceptable medical practices and applicable local, state and federal laws and regulations.
- Follow instructions accompanying the transseptal introducers.

Precautions
- Store in a cool, dark and dry place.
- Inspect all components prior to use.
- If resistance is met while advancing or withdrawing the introducer or guidewire, fluoroscopy should be used to determine the cause.
- Prior to use, ensure the appropriate catheter is being used with the transseptal needle.

Adverse Events
In addition to the complications associated with any cardiac catheterization, the following could occur during a transseptal catheterization:
- Inferior vena cava puncture
- Aorta puncture
- Atrial free wall puncture
- Coronary sinus puncture
- Arterial embolism from thrombus at the puncture site
- Tamponade
- Residual atrial septal defects
- Atrial arrhythmia

Directions for Use
1. To determine the size and location of the left atrial septum, it may be helpful to perform right side angiography.
2. Thoroughly flush the transseptal needle.
3. Inspect all components prior to use for integrity and appropriateness for the particular procedure.
4. The transseptal needle/stylet set is advanced through the transseptal catheter and/or introducer until the tip of the needle is just within the catheter. Note: Ensure the transseptal needle is free to twist and/or rotate without resistance, as it is advanced to this position.
5. Retract the stylet prior to puncturing the interatrial septum.
6. The tip of the transseptal needle is positioned against the interatrial septum.
7. The transseptal needle is advanced through the septum into the left atrium once the correct location is confirmed using fluoroscopy (preferably biplane).
8. The successful puncture into the left atrium is confirmed by observing a left atrial pressure tracing. If an incorrect pressure tracing is observed, a small amount of contrast media is injected to identify the positioning.
9. The transseptal catheter is advanced over the transseptal needle into the left atrium.
10. The transseptal needle is slowly removed.

Shelf Life: 3 years.

STERILE EO	Contents non-pyrogenic and sterilized using ethylene oxide
	Do not resterilize
	Single use only / Do not reuse
	Manufacturer
	Manufacturing date
LOT	Lot number
	Expiration date
#	Number of
	Do not use if packaging is damaged!
REF	Catalog number
	Caution, read intructions for use prior to use
UPN	Product number
	Proximal gage
	Distal gage
	Store in a cool, dark and dry place

MERIT MEDICAL®

Manufacturer:
Merit Medical System, Inc.
1600 West Merit Parkway South Jordan, Utah 84095 U.S.A.
1-801-253-1600 U.S.A
Customer Service 1-800-356-3748

www.merit.com

HeartSpan®
Transseptal Needles

房间隔穿刺针

使用说明

使用前请完整阅读使用说明。

仅供单个患者使用的一次性医疗器械。

警告：美国联邦法律要求本器械仅凭医嘱销售。

产品描述
房间隔穿刺针由针套，座/手柄，旋塞阀，管芯针和管芯针帽组成。材料：304不锈钢，聚碳酸酯和高密度聚乙烯。

适用范围
房间隔穿刺针用于在心房间隔上造成原发性穿孔，以使导管鞘和/或导管从心脏右侧穿过间隔到达心脏左侧。

禁忌症
- 左心房血栓或肿瘤
- 主动脉根部扩张
- 持续抗凝治疗
- 患者不能平躺
- 脊柱或胸廓严重畸形
- 心房显著增大
- 先天性心脏病导致的扭曲性解剖结构
- 术后间隔修补

警告
- 仅限一次性使用。不能重复使用、再加工或灭菌。重复使用、再加工或重复灭菌可能会危害器械的结构完整性，导致器械运转不良，对患者造成伤害、致病或死亡。该一次性使用产品未设计或验证用于重复使用。重复使用可能会导致交叉感染、影响测量准确性、器械性能或因清洁、灭菌、重复灭菌或重复使用导致物理损坏而造成故障的风险。
- 只有那些专门从事有创心血管技术操作的医生才能使用此器械。该器械仅限于训练有素的专家进行房间隔穿刺术。
- 定位时应持续监测压力，并重复进行双平面X射线透视。
- 用于左心房小的患者时应小心，以避免刺穿左心房壁。
- 导管在房间隔正确定位后，才能向前推进房间隔穿刺针。
- 推进扩张器、鞘管或导管前，请务必通过监测左心房压力和X射线透视确保房间隔穿刺针明确进入左心房腔内。
- 请勿取出意外进入心包腔的扩张器、鞘管或导管，除非对患者进行外科手术。
- 请勿重复使用此装置。必须根据可接受的医疗规范和适用的本地、州和联邦法律和法规对经一次性使用的器械进行处置。
- 请遵照房间隔穿刺鞘随附的说明书。

注意事项
- 产品应贮存在通气良好，无腐蚀性气体的室内。
- 使用前请检查所有组件。
- 如果在推进或退出鞘或导丝时遇到阻力，应当进行X射线透视以确定原因。
- 使用房间隔穿刺针前，请确保使用恰当的鞘管。

不良事件
除了与任何心导管插入术相关的并发症外，在室间隔穿刺插入导管术中，可能会发生以下情况：
- 穿破下腔静脉
- 穿破主动脉
- 穿破心房游离壁
- 穿破冠状窦
- 穿刺部位血栓造成动脉栓塞
- 心包填塞
- 遗留房间隔缺损
- 房性心律失常

使用说明
1. 进行右侧血管造影可能会有助于测量左心房间隔的大小和位置。
2. 彻底冲洗房间隔穿刺针。
3. 使用前检查所有部件的完整性和进行是否适用于特定操作。
4. 将房间隔穿刺针/管芯针推进房间隔穿刺鞘，直至针尖刚好到达鞘管前端。注意:请确保房间隔穿刺针在推进到此位置时可以自由扭曲和/或无阻力旋转。
5. 房间隔穿刺前缩回管芯针。
6. 调整房间隔穿刺针尖端正对房间隔。
7. 一旦使用X射线透视（最好为双平面）确认正确定位后，推进房间隔穿刺针穿刺房间隔进入左心房。
8. 通过观察左心房压力监测值确认成功穿刺进入左心房。如果观察到不正确的压力监测值，将注射少量造影剂，以确定位置。
9. 沿房间隔穿刺针推送房间隔穿刺导鞘进入左心房。
10. 缓慢退出房间隔穿刺针。

结构及组成
房间隔穿刺针由套管针，座/手柄，旋塞阀，管芯针和管芯针帽组成。材料：304不锈钢，聚碳酸酯和高密度聚乙烯。环氧乙烷灭菌，一次性使用，货架有效期三年。

生产日期和失效日期：见产品标签。
有效期：3年
注册证编号：国械注进20193031836
产品技术要求编号：国械注进20193031836
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 Pkwy South Jordan, UT 84095
生产地址：14646 Kirby Drive Houston, Texas, 77047 USA；Avenida Sor Juana Inés de la Cruz 19970 interior B, Edificio 2 Parque Industrial Frontera Tijuana, Baja California C.P. 22630 Mexico;

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： 2023年7月
型号规格：
FND-019-00 FND-019-01 FND-019-02
FND-019-03 FND-019-04 FND-019-05
FND-019-06

STERILE EO	不含致热原并经环氧乙烷灭菌
	请勿重复灭菌
	仅限一次性使用/请勿重复使用
	制造商
	制造日期
LOT	批号
	失效日期
#	数量
	如果包装打开或损坏则禁止使用
REF	订购编号
	警告，使用前请阅读说明书
UPN	产品编号
	近端
	远端
	产品应贮存在通气良好，无腐蚀性气体的室内