PhD HEMOSTASIS VALVE™

7.3F Hemostasis valve

INSTRUCTIONS FOR USE

DESCRIPTION
The PhD Hemostasis Valve™ has a 0.096" (2.44 mm) inside diameter. This device has two seals that operate independently: the compression seal and the secondary seal. The compression seal can be opened or closed by rotating the cap. Closing of the compression seal allows for pressure injections up to 400 psi and secures the diagnostic/interventional device in position within the vasculature.

The secondary seal is a diaphragm seal that forms around the diagnostic/interventional devices as they move into and out of the vasculature. This seal provides minimal fluid loss without restricting device movement. The secondary seal is open when the cap is pressed down, and closed when the cap is released. An open secondary seal allows air to be purged from the device and allows insertion/withdrawal of diagnostic/interventional devices.

INTENDED USE
The PhD Hemostasis Valve is intended to maintain hemostasis during the introduction/withdrawal and use of diagnostic and interventional devices.

INDICATIONS FOR USE
The PhD Hemostasis Valve is indicated for maintaining a seal around diagnostic/interventional devices with an outside diameter of ≤0.096" (2.44 mm) during interventional procedures.

CONTRAINDICATIONS
None known.

RX Only - Caution: Federal (USA) law restricts this device to sale by or on the order of a physician trained in angiography and percutaneous transluminal coronary angioplasty (PTCA), and/or percutaneous transluminal angioplasty (PTA).

PRECAUTIONS
- Read manufacturer's instructions for the use of catheters, guide wires, and introducers prior to use.
- Inspect the PhD Hemostasis Valve prior to use for any damage. Do not use if packaging is opened, damaged, or broken.
- Follow local guidelines and practices regulating the disposal of the PhD Hemostasis Valve after use.
- Contents are sterile (via ethylene oxide) and non-pyrogenic.

REUSE PRECAUTION STATEMENT
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.

WARNING
- Do not inject any fluid if air bubbles are visible within the PhD Hemostasis Valve.
- To prevent damage to a balloon, it must be completely deflated during advancement/withdrawal through the PhD Hemostasis Valve.
- Failure to depress the cap prior to inserting a guide wire introducer could cause seal damage resulting in leakage and/or particulate embolization.
- Failure to open the secondary seal and compression seal prior to inserting or withdrawing a diagnostic /interventional device could cause damage to the device.
- Care should be taken to avoid over-tightening of the compression seal, as this may compromise the integrity of the diagnostic/interventional device lumen.
- Power injection at pressures greater than 400psi could result in leakage or detachment of components.

INSTRUCTIONS FOR USE:
1. Connect the sideport of the PhD Hemostasis Valve to the manifold assembly. With the compression valve open, flush and fill the assembly with saline. To fill the valve section, ensure the secondary seal is open by pushing down on the cap. Place one finger over the male Luer fitting and continue to fill the assembly until completely purged of air. Gently release the back end cap to engage the secondary seal.
2. Connect the rotating male Luer adapter of the PhD Hemostasis Valve to the guiding catheter. Ensure the connection is airless.
3. To open the PhD Hemostasis Valve for catheter or guide wire insertion, push on the back end cap to open the secondary seal. The PhD Hemostasis Valve is now ready to accept any diagnostic/interventional device.
4. Insert the diagnostic/interventional device through an open secondary seal and an open compression seal.

CAUTION: PhD Hemostasis Valve will be fully open and allow for blood loss when secondary seal is open.

5. Advance the diagnostic/interventional device through an open compression seal. A fluid-tight seal, providing little to no blood loss, will form around the diagnostic or interventional device while not restricting movement of the device.
6. Once the diagnostic/interventional device is in place, if desired, close the compression seal to allow for pressure injections of up to 400 psi and/or secure the diagnostic/interventional device in position.
7. Remove the diagnostic/interventional device through an open compression seal. If resistance is felt, open the secondary seal as well.

Non-pyrogenic. Sterile if package is unopened and undamaged. Made in Ireland

MERIT MEDICAL®

Manufacturer:
Merit Medical Systems, 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

EC REP
Authorized Representative:
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PhD HEMOSTASIS VALVE™

止血阀

使 用 说 明

产品描述：
PhD 止血阀有一个0.096" (2.44 毫米) 的内直径。本装置有两个独立操作的密封单元：压缩密封和二次密封。转动螺帽即可打开或关闭压缩密封单元。关闭压缩密封单元可让压力喷射高达400 psi，并可固定脉管系统内的诊断/介入装置。

二次密封是一种隔膜密封，在诊断/介入装置出入脉管系统时密封装置的外周。这不仅不会限制装置的活动，而且还最大限度降低液体流失。向下按螺帽即可打开二次密封，松开螺帽即可关闭二次密封单元。开启的二次密封单元可清除装置内的空气，有助插入/取出诊断/介入装置。

适用范围
PhD 止血阀旨在用于导入/取出以及使用诊断和介入装置时的止血之用途。

装置说明
PhD 止血阀在介入手术中，可密封外直径≤0.096" (2.44 毫米) 的诊断/介入装置的外周。

型号、规格：
MAP800，MAP801，MAP802，MAP803，MAP804，MAP550，MAP600

禁忌症
未知。

R_X Only – **警告：**（美国）联邦法律规定本装置只能由在血管造影和经皮冠状动脉腔内成形术(PTCA)和/或经皮腔内血管成形术（PTA）训练有素的医生销售或根据医嘱销售。

注意事项
- 使用前阅读厂家有关使用导引导管、导丝和导引器的有关说明。
- 使用PhD 止血阀前检查其是否有损。若包装被开启、受损或破坏，切勿使用。
- 使用后，请参照当地的处置规定和惯例处置PhD 止血阀。
- 产品（经环氧乙烷）消毒，无热原。

严禁再使用警告
仅用于一位患者。切勿再使用、再处理或再消毒。再使用、再处理或再消毒可能影响本装置的结构完整性，从而/或导致装置出现故障，进而导致患者受伤、生病或死亡。再使用、再处理或再消毒也可能导致装置受污染的风险并且/或者导致患者感染或交叉感染，包括但不限于在患者之间传染性疾病的传播。本装置受污染可导致患者受伤、生病或死亡。

警告
- 若PhD 止血阀内有气泡，切勿注射任何液体。
- 为了避免气囊受损，在出入PhD 止血阀时，气囊必须彻底放气。
- 在插入导丝导引器以前若未按压螺帽可致密封失效，从而导致泄漏和/或颗粒栓塞。
- 在插入或取出诊断/介入装置前未开启二次密封和压缩密封单元可致装置受损。
- 应小心，切勿将压缩密封单元拧得过紧，过紧可致诊断/介入装置流明有误。
- 电动注射器的注射压力若大于400psi 可致泄漏或零部件的脱落。

使用说明：
1. 将PhD 止血阀的侧向孔口与管路相接。开启压缩阀，用盐水冲注并灌满管路。为了灌满止血阀，确保摁下螺帽开启二次密封单元。一个手指摁着公螺旋接头，继续灌满管路，直到没有空气为止。小心松开后端帽启动二次密封单元。
2. 将PhD 止血阀的旋转公螺旋接头与导引导管相接。确保连接无空气。
3. 开启PhD 止血阀以插入导引导管或导丝，推后端帽开启二次密封。PhD 止血阀现可接收任何诊断/介入装置。
4. 将诊断/介入装置从开启的二次密封和开启的压缩密封单元中插过。

警告：二次密封单元开启时，PhD 止血阀将完全开通并可致失血。

5. 将诊断/介入装置从开启的压缩密封单元中插过。不透液的密封单元可有助止血，并在不限制诊断或介入装置活动的同时密封装置外周。
6. 一旦置放好诊断/介入装置，若需要，关闭压缩密封单元，以让压力喷射高达400 psi，并/或固定诊断/介入装置。
7. 从开启的压缩密封单元中取出诊断/介入装置。若受阻，也开启二次密封单元。

无热原。包装未启开或受损即无菌。
爱尔兰制造

产品名称：止血阀
结构及组成：该产品由三部分组成：止血阀、导引导丝插入工具（树脂、金属）、转矩器械。该产品经环氧乙烷灭菌，一次性使用，货架有效期3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20173032274
产品技术要求编号：国械注进20173032274
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
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