PreludeSYNC™

Radial Compression Device

INSTRUCTIONS FOR USE

使用说明

MERITMEDICAL®

PreludeSYNC™

English

Radial Compression Device

INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION

The Prelude Sync™ Radial Compression Device is a sterile, single use disposable device used to assist in gaining and maintaining hemostasis of the radial and ulnar artery following catheterization procedures. It has a soft wristband with a secure hook and loop fastener. The band delivers adjustable compression of the puncture site with an inflatable bulb, and a check valve for easy inflation and deflation with a syringe. A clear curved backer plate provides optimal visualization of the puncture site and ease of placement.

INDICATIONS FOR USE

The Prelude Sync is a compression device used to assist in gaining hemostasis of arterial percutaneous access sites.

CONTRAINDICATIONS

- Patients hypersensitive to the materials of the compression device.
- Patients with infection or other serious skin diseases at the site of puncture.
- Pertaining to radial artery catheterization only: patients with an abnormal Allens test, radial pulse, or insufficient dual artery supply.
- Not indicated for femoral artery compression.

WARNINGS

- Prior to inflation of bulb, confirm that air is being injected into the Prelude Sync and NOT the side port of the sheath or other device.
- Ensure the band is fastened securely around the wrist without slack.
- Over-inflation of bulb (above 20mL of air) may cause pain, numbness, artery occlusion, or damage to the device.
- Under-inflation of bulb, or failure to secure band without slack around the wrist, may compromise the ability of the device to assist hemostasis of the artery.
- Arterial pulse distal to the compression device should be monitored to ensure the artery is not completely occluded as arterial damage or thrombosis may occur.
- Patients should not be left unattended while the Prelude Sync is in use.
- Do not leave the Prelude Sync on for an inappropriately long period of time as tissue damage may occur.
- Do not expose the Prelude Sync to organic solvents, as they may cause damage to the device.

CAUTIONS

- Maintain sterile field during application.
- This device should be used by clinicians with adequate training in the use of the device.
- Sterile if package is unopened and undamaged.

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.

POTENTIAL COMPLICATIONS

Possible complications that may result from use of this device include, but are not limited to: hematoma, recurrent bleeding, local venous thrombosis, nerve damage, pain or numbness, complex regional pain syndrome, allergic reaction, and artery occlusion.

INSTRUCTIONS FOR USE

Device Placement

1. Ensure site is clean and dry.
   NOTE: This device needs to be positioned differently for the following uses:
   - Radial artery use: Ensure the CURVED section of the clear plate is on the THUMB side of the wrist.
   - Ulnar artery use: Ensure the CURVED section of the clear plate is on the LITTLE FINGER (fifth digit) side of the wrist.

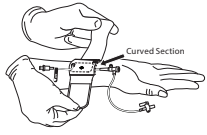

Figure 1.

2. Aspirate the sheath, then withdraw the sheath approximately one inch (2-3 cm).

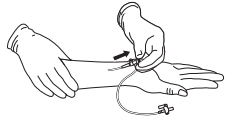

Figure 2.

3. Place the center of the "crosshairs" over the arteriotomy (location where the sheath entered the artery, approximately 1-2mm proximal to the skin puncture site).

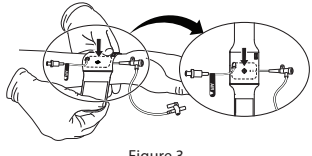

Figure 3.

4. Fasten the band securely around the wrist without any slack, but do not overtighten.

5. Fill the Prelude Sync syringe (included) with 20mL of air.
   NOTE: Nominal air inflation: 15mL
   Maximum fill volume: 20mL
6. Attach and completely engage the Prelude Sync syringe to the tubing line labeled "AIR".
7. Slowly inflate the bulb with air while simultaneously removing the sheath. Once the sheath is completely removed, continue to inject air into the bulb until bleeding has stopped.

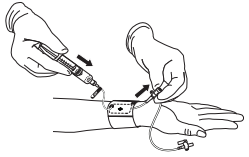

Figure 4.

NOTE: While inflating, maintain pressure on the syringe plunger to avoid any inadvertent release of air.

8. Slowly withdraw air from the bulb until there is oozing from the access site. Once oozing is observed, re-inject up to 4mLs of air into the bulb until hemostasis is achieved. If bleeding or hematoma are present, additional air may be injected as needed to achieve patent hemostasis.

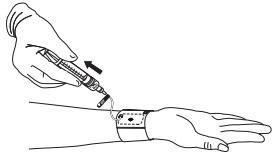

Figure 5.

9. Remove syringe.
   NOTE: If bleeding is observed at any time, inject additional air (not exceeding the max fill volume of 20mL) until bleeding stops.
10. Optional tubing clip: You may snap the loose tubing into the clip to secure it to the device.
11. Per hospital protocol, record the patient's vital signs and ensure adequate distal perfusion is maintained (patent hemostasis). If necessary, adjust air volume in bulb.
    NOTE: Air volume and compression time may differ according to patient's condition, anticoagulant dosage, and size of puncture site.
12. Optional device/chart stickers are included to facilitate recording the time of inflation and mLs, as well as the time of deflation and mLs removed.

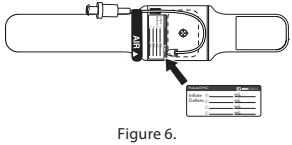

Figure 6.

Device Removal

1. At the recommended device removal time, withdraw 2mL of air from the Prelude Sync and observe the access site for bleeding.

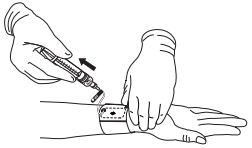

Figure 7.

2. If bleeding is present, inject air until bleeding stops. Wait 30 min. and repeat step 1. of the device removal instructions.
3. If no bleeding is present, continue to remove 2mL of air every 15 minutes x3, or until pressure is fully released.
4. Once the air is removed and hemostasis is confirmed, carefully remove the Prelude Sync. Place a sterile dressing per hospital protocol.

℞ Only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Consult accompanying documents. Read instructions prior to use.
 Single Use	Single use.
	Do not use if package is damaged.
STERILE EO	Sterilized using ethylene oxide.
REF	Catalog Number
LOT	Lot Number
	Used By

PreludeSYNC™

Radial Compression Device

桡动脉止血压迫器

使用说明

该说明书适用于SRB24AC、SRB24MED、SRB29AC、SRB29MED、SRB20AC型号。

产品描述

Prelude Sync™ 桡动脉止血压迫器是无菌一次性装置，用于帮助实现和维持导管插入术后的桡动脉与尺动脉的止血。本装置具有柔软的腕带，该腕带带有牢固的环形扣件。该带利用充气球囊实现穿刺部位的可调加压，并具有单向阀以便于用注射器加气和放气。透明的弯曲垫板提供穿刺部位的最佳可视化，并且便于放置。

最长使用时间不超过24小时。

适用范围

桡动脉止血压迫器是一种加压装置，用于帮助实现动脉经皮穿刺部位的止血。

禁忌症

- 对加压装置的材料过敏的患者禁用。
- 在穿刺部位有感染或其它严重皮肤疾病的患者禁用。
- 与桡动脉导管插入有关的：艾伦试验、桡动脉的脉搏异常或双动脉供血不足的患者。
- 不用于股动脉加压。

警告

- 在对充气球囊进行充气之前，确认空气已经注入 Prelude Sync 而非鞘管的侧端口或其他装置。
- 确保该带牢固地紧固在腕部周围，没有松弛。
- 对充气球囊过度充气（超过 20mL 空气）可能会导致痛疼、麻木、动脉阻塞或装置受损。
- 充气球囊充气不足或者没有围绕腕部牢固地紧固该带，可能会损害装置辅助动脉止血的能力。
- 应当监控加压装置远侧的动脉脉搏，确保动脉不完全堵塞，因为可能会发生动脉损伤或血栓。
- 在使用 Prelude Sync 时，必须留有人照看患者。
- 请勿长时间不正当使用Prelude Sync，这样可能造成组织受伤。
- 请勿让 Prelude Sync 接触有机溶剂，因为有机溶剂可能导致装置受损。

小心

- 在应用期间保持消毒区。
- 本装置应当由经过装置使用的充分培训的临床医生来使用。
- 如果包装未打开或未破损，则为无菌状态。

防止重复使用声明

本品仅限一位患者使用。请勿重复使用、重复处理或重复灭菌。重复使用、重复处理或重复灭菌可能会破坏该装置的结构完整性，并且/或者导致装置故障，进而可能导致患者受伤、患病甚至死亡。重复使用、重复处理或重复灭菌还有可能带来装置污染的风险，并且/或者导致患者受到感染或交叉感染，包括但不限于传染病在患者之间传播。装置污染可能会导致患者受伤、患病甚至死亡。

潜在并发症

使用本装置可能导致的并发症包括但不限于：血肿、再出血、局部静脉血栓、神经损伤、疼痛或麻木、疼痛综合征、过敏反应以及动脉阻塞。

使用说明

装置放置

1. 确保部位清洁并且干燥。

   注意：对于以下用途，需要以不同方式定位本装置：

   - 用于桡动脉：确保透明板的弯曲部分位于手腕的拇指侧。
   - 用于尺动脉：确保透明板的弯曲部分位于手腕的小拇指（第五根手指）侧。

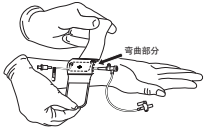

图 1.

2. 对鞘管内进行回抽，然后抽出鞘管大约一英寸 (2cm-3cm)。

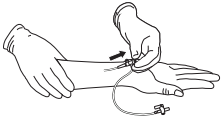

图 2.

3. 将“十字准线”的中心置于动脉穿刺部位（鞘管进入动脉的部位，大约在皮肤穿刺部位近端1-2mm 1mm-2mm）。

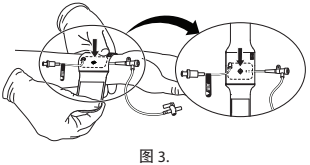

图 3.

4. 将腕带牢固地紧固在手腕上不要过松，但也不要过紧。
5. 向 Prelude Sync 注射器（内附）加入 20mL 空气。

   注意：标准充气量：15mL

   最大充气量：20mL
6. 将 Prelude Sync 注射器连接至标记有“AIR”的管道。

7. 用空气缓慢地给充气球囊充气，同时取下鞘管。一旦完全取下鞘管，继续向注入空气，直至出血停止。

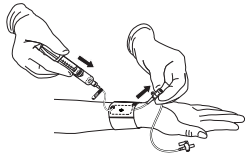

图 4.

注意：在充气时，保持注射器推杆上的压力，避免由于疏忽而释放空气。

8. 从充气球囊缓慢抽出空气，直至出现来自穿刺部位的渗出。一旦观察到渗出，则重新注入最多 4mL 充气球囊气到球中，直至实现止血。如果存在出血或血肿，可根据需要注入额外空气以实现患者止血。

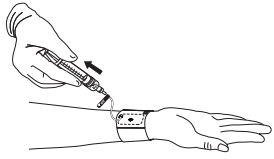

图 5.

9. 移除注射器。

   注意：如果在任何时间观察到出血，则注入额外空气（不超过 20mL 的最大加注量）直至出血停止。

10. 可选的卡扣夹：您可将松动的充气管路放入卡扣夹里，将其固定到装置上。
11. 根据医院规定，记录患者的生命体征并确保维持足够远端灌注（专利止血）。如果必要，请调节充气球囊中的空气量。

    注意：空气量和加压时间可根据患者的状况、抗凝剂用量以及穿刺部位大小而有所不同。

12. 内附可选的装置/图表贴纸，以便于记录充气时间和毫升数，以及放气时间和抽走的毫升数。

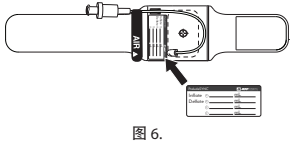

图 6.

装置移除

1. 在建议的装置移除时间，从 Prelude Sync 抽出 2mL 空气，并观察穿刺部位是否出血。

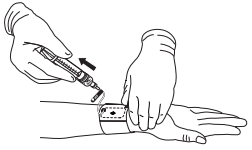

图 7.

2. 如果存在出血，则注入空气，直至出血停止。等待 30 分钟，然后重复装置移除说明的步骤 1。
3. 如果不存在出血，继续每隔 15 分钟抽出 2mL 空气 3 次，或者直至压力完全释放。
4. 去除空气并确认止血后，即可小心移除 Prelude Sync。根据医院规定放置消毒敷料。

Rx Only	警示：联邦（美国）法律将此器械限制为由医生销售或订购。
	警告。
	一次性使用
	如包装破损不得使用并查阅使用说明书
STERILE EO	经环氧乙烷灭菌
REF	产品编号
LOT	批号
	失效日期

产品名称：桡动脉止血压迫器
型号、规格：SRB24AC、SRB24MED、SRB29AC、SRB29MED、SRB20AC, EZ-REG, EZ-SML
结构及组成：产品主要由压迫止血器和注射器组成。采用环氧乙烷灭菌。
注册证编号：国械注进20192140562
产品技术要求编号：国械注进20192140562
有效期：3年
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 USA
注册人及生产企业联系方式：1-801-253-1600

生产地址：

型号	生产地址
SRB24AC	Avenida Sor Juana Inés de la Cruz 19970 interior B, Edificio 2 Parque Industrial Frontera Tijuana, Baja California C.P. 22630 Mexico
SRB24MED	
SRB29AC	
SRB29MED	
SRB20AC	1600 West Merit Parkway South Jordan Utah 84095 USA
EZ-REG	Avenida Sor Juana Inés de la Cruz 19970 interior B, Edificio 2 Parque Industrial Frontera Tijuana, Baja California C.P. 22630 Mexico 1600 West Merit Parkway South Jordan Utah 84095 USA
EZ-SML	

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
生产日期和失效日期：见产品标签
说明书编制或修订日期：2025年1月

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