PreludeSYNC•EZ™

English

Radial Compression Device

INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION

The PreludeSYNC EZ™ 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 a large inflatable balloon, and a check valve for easy inflation and deflation with a specialized connection syringe. A clear backer plate provides optimal visualization of the puncture site and ease of placement.

INDICATIONS FOR USE

The PreludeSYNC EZ 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.

CLINICAL BENEFITS

- The PreludeSYNC EZ assists in gaining hemostasis of arterial percutaneous access sites.

WARNINGS

- Prior to inflation of balloon, confirm that air is being injected into the PreludeSYNC EZ and NOT the side port of the sheath or other device.
- Fasten the band securely around the wrist without any slack, but do not overtighten.
- Over-inflation of balloon (above 20mL of air) may cause pain, numbness, artery occlusion, or damage to the device.
- Under-inflation of balloon, 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 PreludeSYNC EZ is in use.

- Do not leave the PreludeSYNC EZ on for an inappropriately long period of time as tissue damage may occur.
- Do not expose the PreludeSYNC EZ 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.
- In the EU - Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the applicable member state.

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

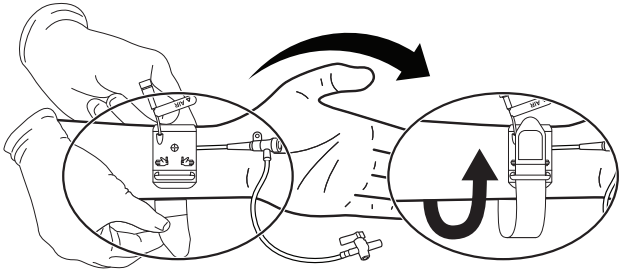
Possible complications that may result from use of this device include, but are not limited to: hematoma, recurrent bleeding, local venous thrombosis, nerve damage, pain or numbness, complex regional pain syndrome, allergic reaction, and artery occlusion.

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 band wraps first around the THUMB side of the wrist.
   - Ulnar artery use: Ensure the band wraps first around the LITTLE FINGER (fifth digit) side of the wrist.
   - Proper placement for radial artery use is illustrated in Figure 1. Indicators showing radial artery placement are also printed on the device as shown in Figure 1.



Placement for Radial Artery Use
Figure 1.

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

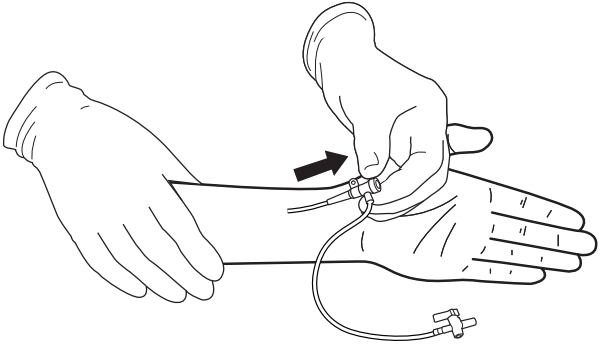


Figure 2.

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).

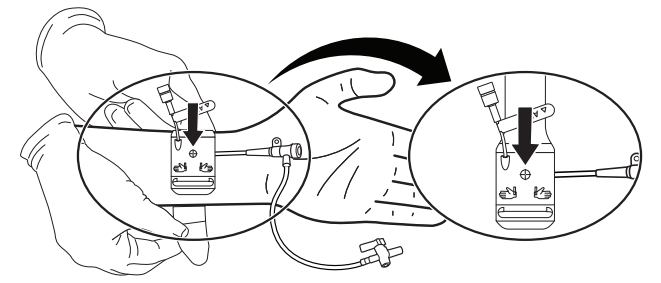


Figure 3.

4. Fasten the band securely around the wrist without any slack, but do not overtighten.
5. Fill the PreludeSYNC syringe (included) with 20mL of air.
   NOTE: Maximum fill volume: 20mL
6. Attach and completely engage the PreludeSYNC syringe to the valve/tubing line labeled "AIR" by inserting the syringe tip into valve and rotating 1/4 turn clockwise.
7. Slowly inflate the balloon with air while simultaneously removing the sheath. Once the sheath is completely removed, continue to inject air into the balloon until bleeding has stopped.

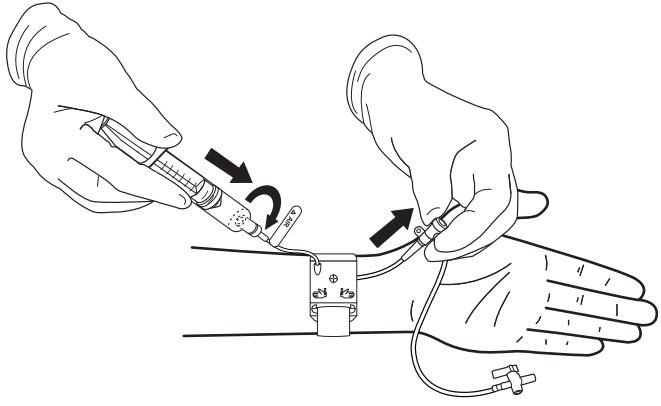


Figure 4.

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

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

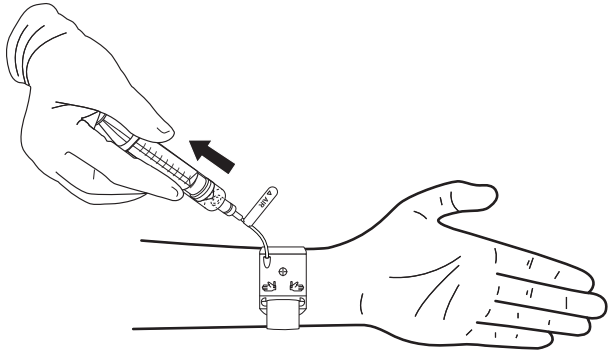


Figure 5.

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 and patent hemostasis is achieved.
10. Per hospital protocol, record the patient's vital signs and ensure adequate distal perfusion is maintained (patent hemostasis). If necessary, adjust air volume in balloon.
    NOTE: Air volume and compression time may differ according to patient's condition, anticoagulant dosage, and size of puncture site.

Device Removal

1. At the recommended device removal time, or in accordance with hospital protocol, withdraw approximately 2mL of air from the PreludeSYNC EZ and observe the access site for bleeding.
   NOTE: Maintain pressure on the syringe plunger to avoid any inadvertent release of air when attaching to the device.

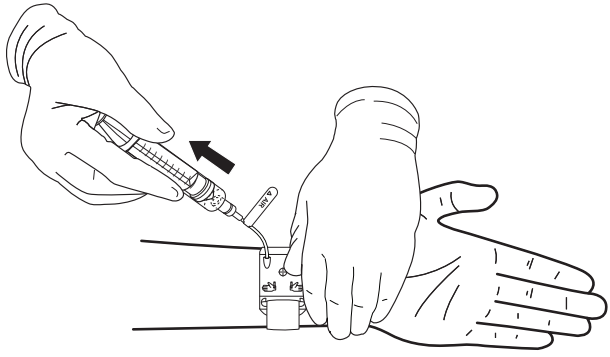


Figure 6.

NOTE: If PreludeSYNC syringe is not available during air removal or re-injection, the cap on the tubing line may be removed by twisting and a standard luer syringe can be attached.
CAUTION: **DO NOT** remove cap while sheath is still in patient.

2. If bleeding is present, inject air until bleeding stops and patent hemostasis is achieved. Wait approximately 30 minutes and repeat step 1 of the device removal instructions, or follow normal hospital protocol.
3. If no bleeding is present, continue to remove approximately 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 PreludeSYNC EZ. Place a sterile dressing over site per hospital protocol. Dispose of the PreludeSYNC EZ according to hospital protocol.

	Caution
	Do not use if package is damaged and consult instruction for use
REF	Catalog number
LOT	Batch code

MD	Medical Device
UDI	Unique Device Identifier
	Single use
	Do not resterilize
	Consult Instructions for Use For electronic copy scan QR code, or go to www.merit.com/ifu and enter IFU ID. For printed copy, call U.S.A. or EU Customer Service
STERILE EO	Sterilized using ethylene oxide
℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Single sterile barrier system
	Use by date: YYYY-MM-DD
	Date of manufacture: YYYY-MM-DD
	Manufacturer

MERIT MEDICAL®

www.merit.com

PreludeSYNC•EZ™

Chinese

Radial Compression Device 桡动脉止血压迫器

使 用 说 明

该说明书适用于EZ-REG、EZ-SML型号。

产品描述

PreludeSYNC EZ™ 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。腕带利用充气球囊实现穿刺部位的可调加压，并具有单向阀，便于通过专用的连接注射器进行充气和放气。透明垫板为穿刺部位提供最佳可视化效果，且便于放置。

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

- 对本加压装置材料过敏的患者。
- 穿刺部位存在感染或其他严重皮肤病的患者。
- 仅与桡动脉插管有关：艾伦试验、桡动脉脉搏异常或者双动脉供血不足的患者。
- 不适用于股动脉压迫。

临床优势

- PreludeSYNC EZ 可帮助实现经皮动脉入路部位止血。

警告

- 在对充气球囊进行充气之前，确认空气已经注入 PreludeSYNC EZ，而非鞘管的侧端口或其他装置。
- 确保腕带牢固地紧固在腕部周围，没有松弛，但也不要拧的太紧。
- 球囊过度充气（超过 20 mL 空气）可能会导致疼痛、麻木、动脉闭塞或装置损坏。
- 若球囊充气不足、腕带未紧扣于腕部造成松弛，可能会削弱装置帮助动脉止血的能力。
- 应监测加压装置远端动脉脉搏，确保动脉未完全闭塞，因为可能会发生动脉损伤或血栓。
- 使用 PreludeSYNC EZ 时，患者不应无人照看。
- 不要将 PreludeSYNC EZ 留置不恰当的过长时间，这可能会造成组织损伤。
- 不要让 PreludeSYNC EZ 暴露于有机溶剂中，这可能会损坏装置。

小心

- 施用时保持在无菌区。
- 本装置应由经过充分此产品培训的临床医生使用。
- 如果包装未打开且未破损，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、患病或死亡。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的传播。装置污染可能会导致患者受伤、患病或死亡。

潜在并发症

可能因使用本装置而产生的潜在并发症包括但不限于：血肿、反复出血、局部静脉血栓形成、神经损伤、疼痛或麻木、复杂的局部疼痛综合征、过敏反应和动脉闭塞。

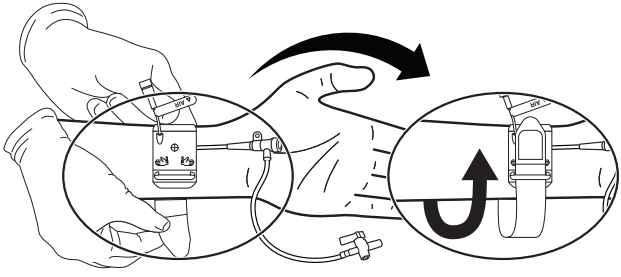
使用说明

装置置入

1. 确保置入部位干净、干燥。

注意：用于以下用途时，需将本装置放置在不同位置：

- 用于桡动脉：确保腕带首先缠在腕部的拇指侧。
- 用于尺动脉：确保腕带首先缠在腕部的小指（第五指）侧。
- 图 1 所示为用于桡动脉时的正确位置。辅助确定桡动脉位置的十字点定位标也印在装置上，如图 1 所示。



用于桡动脉时的位置

图 1.

2. 抽吸鞘管，然后将其抽出约一英寸 (2-3 cm)。

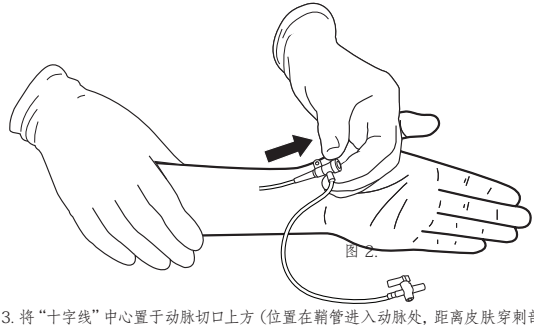


图 2.

3. 将“十字线”中心置于动脉切口上方（位置在鞘管进入动脉处，距离皮肤穿刺部位近心端约 1-2 mm）。

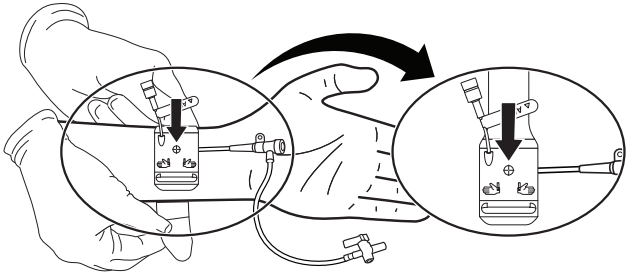


图 3.

4. 将腕带紧扣于腕部，不要有任何松动，但也不要拧得太紧。
5. 用 PreludeSYNC 注射器（内附）吸入 20 mL 空气。
注意：最大充气量：20 mL
6. 通过将注射器尖端插入阀门并顺时针旋转 1/4 圈，将 PreludeSYNC 注射器连接到标有“AIR”（空气）的阀门/管路上并完全接合。
7. 缓慢给球囊充气，同时取下鞘管。一旦完全取下鞘管之后，继续给球囊充气，直至停止出血。

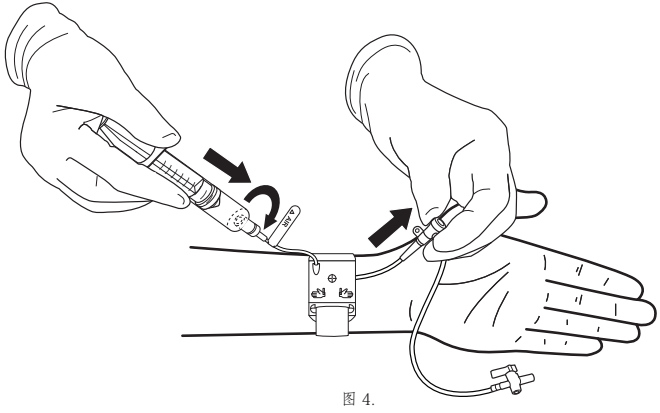


图 4.

注意：在充气的同时，保持注射器推杆压力，以免意外漏气。

8. 缓慢地从球囊中抽出空气，直至从入路部位渗出血液。观察到渗出血液后，重新向球囊中注入最多 4 mL 空气，直至达到止血效果。如果存在出血或血肿，可根据需要注入额外的空气以实现压迫止血。

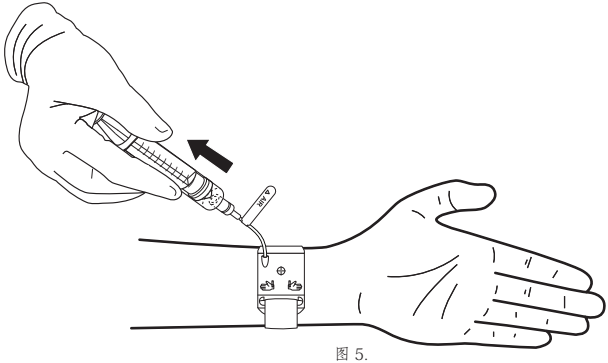


图 5.

9. 取下注射器。

注意：如果在任何时间发现出血，再次充气（不超过最大充气量 20 mL）直至出血停止，实现压迫止血。

10. 根据医院规程，记录患者生命体征，确保维持足够的远端灌注（压迫止血）。如有需要，调节球囊内空气量。

注意：空气量和压迫时间可能因患者病情、抗凝血剂的剂量和穿刺部位的大小而不同。

取下器械

1. 在建议的器械取下时间或按照医院规程，从 PreludeSYNC EZ 中抽出大约 2 mL 空气，并观察入路部位是否出血。

注意：连接到装置时保持注射器推杆压力，以免意外漏气。

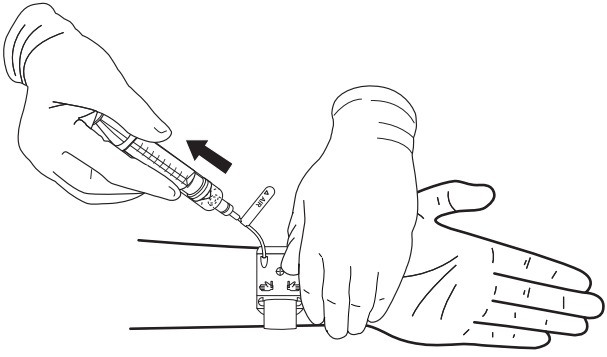


图 6.

注意：如果在排气或重新充气时没有 PreludeSYNC 注射器可供使用，可拧下管线盖，连接一支标准鲁尔接头注射器。
小心：鞘管仍留在患者体内时，不要取下阀门盖。
2. 如有出血，充气直至出血停止，实现压迫止血。等待大约 30 分钟，然后重复装置取下说明的第 1 步，或遵循正常的医院规程。
3. 若无出血，继续每 15 分钟抽出约 2 mL 空气，重复 3 次，或直到压力完全释放。
4. 一旦排出空气，并确认止血之后，小心取下 PreludeSYNC EZ。根据医院规程将无菌敷料敷在穿刺部位。根据医院规程弃置 PreludeSYNC EZ。

	警告
	如包装破损不得使用并查阅使用说明书
REF	产品编号
LOT	批号
MD	医疗器械
UDI	医疗器械唯一标识
	一次性使用
	不得二次灭菌
	查阅使用说明书
STERILE EO	经环氧乙烷灭菌
℞ ONLY	警示：联邦（美国）法律将此器械限制为由医生销售或订购
	单层无菌屏障系统
	失效日期
	生产日期
	制造商

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