PreludeSYNC∘**EZ**™

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.
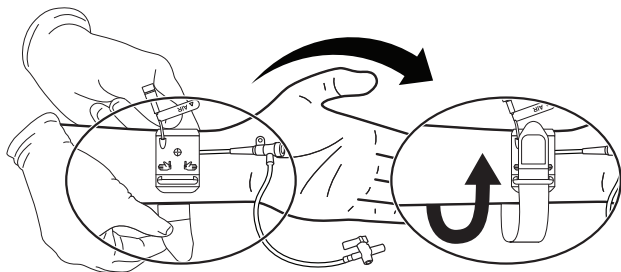
Placement for Radial Artery Use
Figure 1.

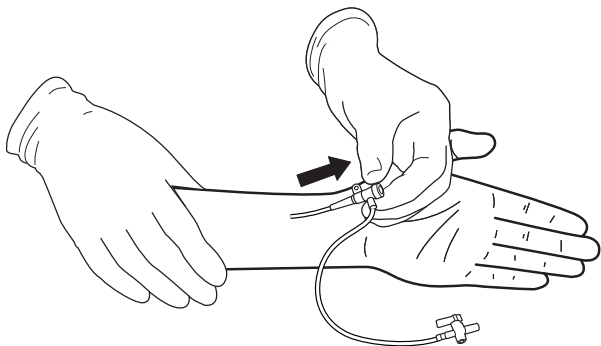2. Aspirate the sheath, then withdraw the sheath approximately one inch (2-3 cm).

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).
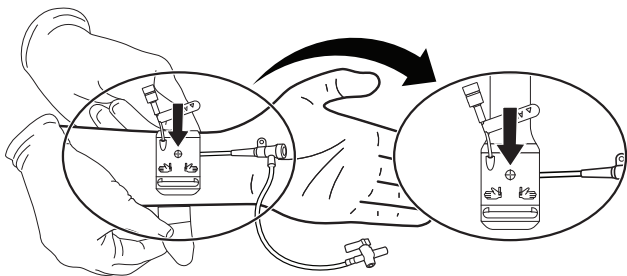

Figure 3.

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.
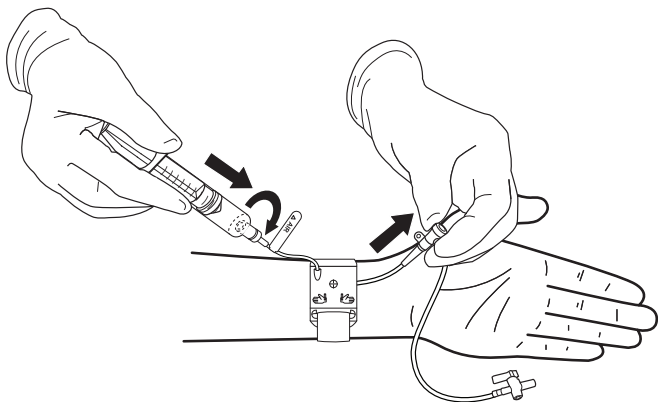
Figure 4.

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.
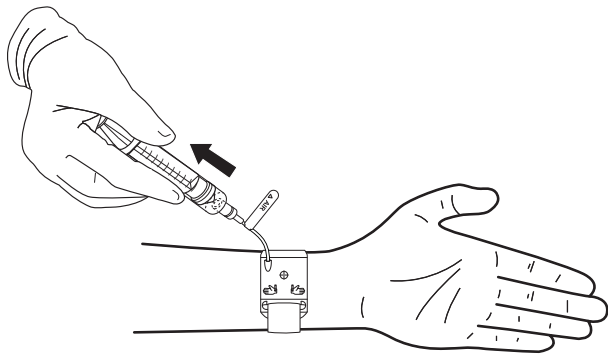
Figure 5.

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.
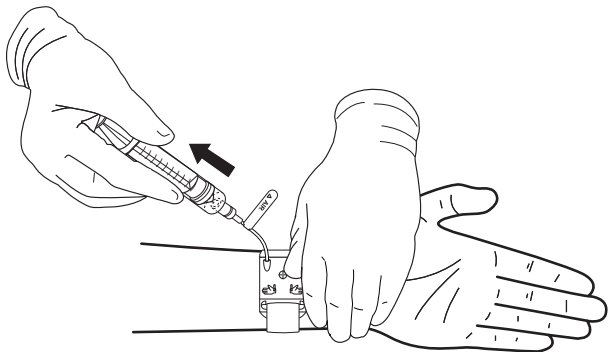
Figure 6.

   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
⊘ (package damaged symbol)	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
② (single use symbol)	Single use
(do not resterilize symbol)	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
EC REP	Authorized Representative in European Community

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