PreludeSYNC EVO™

English

Radial Compression Device

INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION

The PreludeSYNC EVO™ 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 curved backer plate provides optimal visualization of the puncture site and ease of placement.

INDICATIONS FOR USE

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

WARNINGS

- Prior to inflation of balloon, confirm that air is being injected into the PreludeSYNC EVO 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 balloon (above 30mL 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 EVO is in use.
- Do not leave the PreludeSYNC EVO on for an inappropriately long period of time as tissue damage may occur.
- Do not expose the PreludeSYNC EVO 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 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.

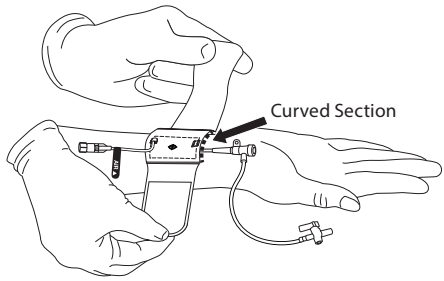

Figure 1.

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

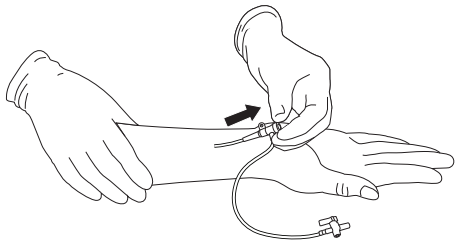

Figure 2.

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).

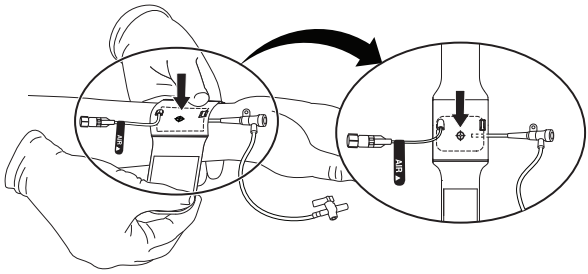

Figure 3.

4. Fasten the band securely around the wrist without any slack, but do not overtighten.
5. Fill the PreludeSYNC EVO syringe (included) with 20mL of air.
   NOTE: Nominal air inflation: 15mL
   Maximum fill volume: 30mL
6. Attach and completely engage the PreludeSYNC EVO 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.

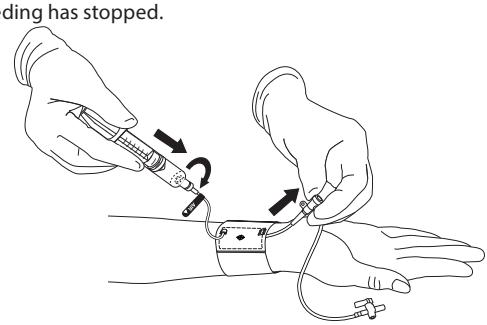

Figure 4.

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.

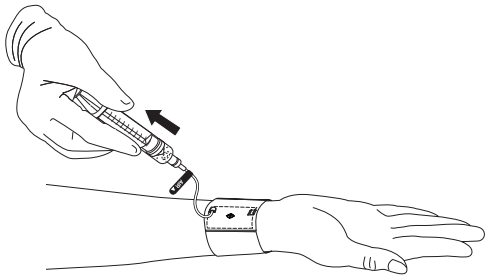

Figure 5.

9. Remove syringe.
   NOTE: If bleeding is observed at any time, inject additional air (not exceeding the max fill volume of 30mL) until bleeding stops and patent hemostasis is achieved.
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 balloon.
    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.

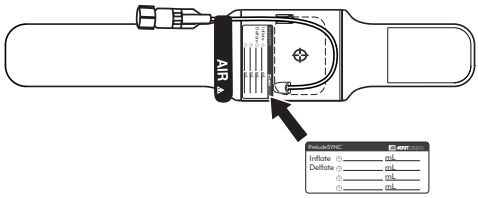

Figure 6.

Device Removal

1. At the recommended device removal time, or in accordance with hospital protocol, withdraw approximately 2mL of air from the PreludeSYNC EVO 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.

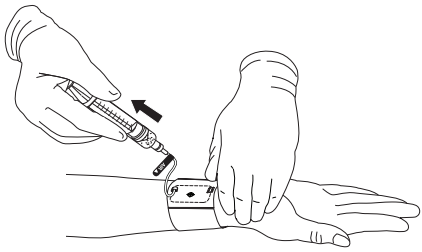

Figure 7.

NOTE: If PreludeSYNC EVO 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 EVO. Place a sterile dressing over site per hospital protocol. Dispose of the PreludeSYNC EVO according to hospital protocol.

Rx 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.
	Do not use if package is damaged.
STERILE EO	Sterilized using ethylene oxide.
REF	Catalog Number
LOT	Lot Number
	Use By: YYYY-MM-DD
	Do Not Re-sterilize
	Date of Manufacture: YYYY-MM-DD
MD	Medical Device
Sterile Package	Sterile Package

CE 2797

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