PreludeSYNC DISTAL™

Radial Compression Device

INSTRUCTIONS FOR USE

MERIT MEDICAL®

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English

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PRODUCT DESCRIPTION

The PreludeSYNC DISTAL™ Radial Compression Device is a sterile, single use disposable device used to assist in gaining and maintaining hemostasis of the radial artery following catheterization procedures. It has a soft wristband and thumb saddle strap with secure hook and loop fasteners. The band delivers adjustable compression of the puncture site with an inflatable balloon, 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 PreludeSYNC DISTAL 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.
- Not indicated for femoral artery compression.
- Patients with an abnormal Allens test, radial pulse, or insufficient dual artery supply.

WARNINGS

- Prior to inflation of balloon, confirm that air is being injected into the PreludeSYNC DISTAL and NOT the side port of the sheath or other device.
- Ensure the band is fastened tightly around the wrist and hand without slack.
- Prolonged over-inflation of balloon may cause pain, numbness, artery occlusion, nerve damage or damage to the device.
- Under-inflation of balloon, or failure to secure band without slack around the wrist and hand, may compromise the ability of the device to assist hemostasis of the artery, resulting in bleeding, and/or hematoma.
- 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 DISTAL is in use.
- Do not leave the PreludeSYNC DISTAL on for an inappropriately long period of time as tissue damage, or arterial occlusion may occur.
- Do not expose the PreludeSYNC DISTAL 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.
2. For left hand placements use catalog code SDRB-REG-LT. For right hand placements use catalog code SDRB-REG-RT.
3. For a large patient wrist/hand, you may add the extension band (included) prior to placing the PreludeSYNC DISTAL (**FIGURE 1**).

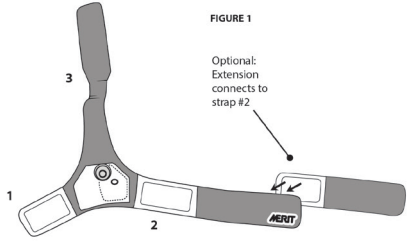

FIGURE 1

4. Aspirate the sheath, then withdraw the sheath approximately one inch (2-3 cm).
5. Place the band on the hand/wrist with band #1 on the little finger side, band #2 on the thumb side, and band #3 facing up toward the thumb (**FIGURE 2**).

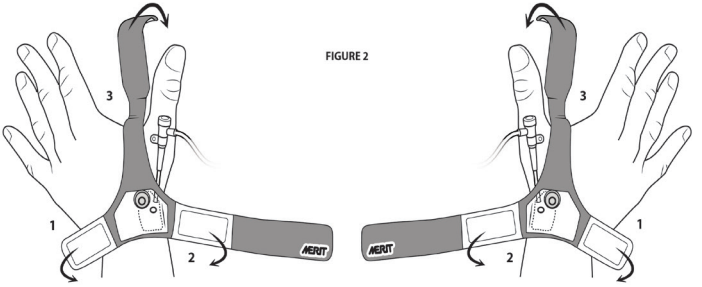

FIGURE 2

Left Hand Device *Right Hand Device*

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

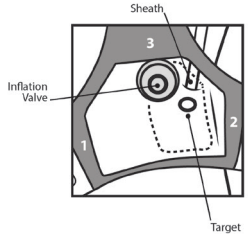

FIGURE 3

Target 1 - 2mm proximal to the skin puncture site

7. Fasten band #1 and #2 tightly around the wrist, then wrap band #3 around the saddle of the thumb without any slack (**FIGURE 4**).
   NOTE: If the sheath is in the way of securing band section #3, then band section #3 may be secured after removal of sheath.

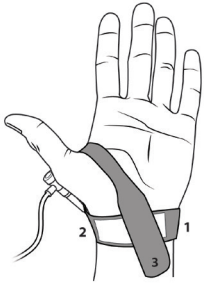

FIGURE 4

Fasten band securely around the wrist

8. Fill the syringe (included) with 10mL of air.
   NOTE: Maximum balloon fill volume: 10mL
9. Engage the syringe into the valve on the top of the device by inserting the syringe tip into the valve and rotating ¼ turn clockwise.
10. 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.
    NOTE: While inflating, maintain pressure on syringe plunger to avoid any inadvertent release of air.
11. Adjust air volume in balloon to achieve hemostasis. If bleeding or hematoma are present, additional air may be injected until bleeding stops.
12. Remove the syringe.
    NOTE: The patient should be able to move their hand/wrist freely without any bleeding. If desired, ask the patient to move their hand and wrist and check the site for any bleeding. If bleeding is observed, inject additional air (not exceeding the max fill volume of 10mL) until bleeding stops.
    NOTE: If bleeding is observed at any time, inject additional air (not exceeding the max fill volume of 10mL) until bleeding stops.
    NOTE: Keep included syringe accessible for device deflation and removal.

13. Per hospital protocol, record the patient's vital signs and ensure adequate distal perfusion is maintained. 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 Deflation and Removal

1. If desired, all air may be removed slowly at the appropriate amount of time to achieve complete hemostasis; or, a small amount of air (such as 1-2 mL) may be removed from the balloon periodically based on the hospital's preferred clinical technique/hospital protocol to aid in maintaining hemostasis.
NOTE: If PreludeSYNC DISTAL syringe is not available during air removal or re-injection, the cap on the valve 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. Upon reaching complete hemostasis, slowly withdraw remaining air from the PreludeSYNC DISTAL and observe the access site for bleeding.
NOTE: Complete hemostasis time may differ according to patient's condition, anticoagulant dosage, and size of puncture site.
3. If bleeding is present, inject air until bleeding stops. Wait sufficient time and repeat the device deflation and removal instructions.
4. Once the air is removed and hemostasis is confirmed, carefully remove the PreludeSYNC DISTAL.
5. Place a sterile dressing per hospital protocol.

Rx ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.		Caution: Consult accompanying documents. Read instructions prior to use.
2	Single use.	2	Do not re-sterilize
	Do not use if package is damaged.	STERILE EO	Sterilized using ethylene oxide.
L	Left hand device	R	Right hand device
MD	Medical Device	Sterile Package	Sterile Package
	For electronic copy scan QR code or go to www.merit.com/ifu and enter IFU ID Number. For printed copy, call U.S.A or E.U Customer Service.		

CE 2797

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