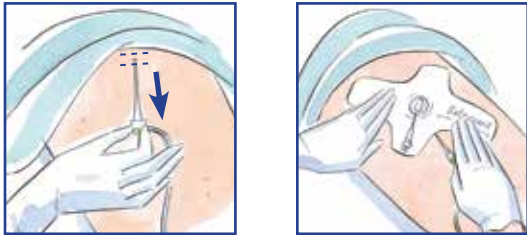


SAFEGUARD®

MANUAL ASSIST TECHNIQUE PATIENT CARE GUIDELINES

Instructions for use

1



- Before adhering SAFEGUARD to the patient, be sure skin is clean and dry. Determine the appropriate angle for SAFEGUARD placement to provide easy access to luer inflate/deflate port and to allow for easy sheath removal.
- Consider the point of maximum pulse, anatomy, angle of puncture and direction of flow to determine the appropriate SAFEGUARD position and verify.
- Pull the procedural sheath back approximately 1 inch (2.5cm), so that when SAFEGUARD is adhered to the skin the sheath hub is outside the area of the SAFEGUARD adhesive.

NOTE: It is recommended that you aspirate the sheath prior to removal to prevent distal embolization from residual clot in sheath.

- Remove the adhesive backing and place the bulb where you would position your fingers to hold manual compression i.e., typically the point of maximum femoral pulse. Make sure SAFEGUARD is completely adhered to the skin.

2



Attach and completely engage a luer lock syringe. Inflate up to a maximum volume of 40cc's of air into the bulb (for SAFEGUARD 12cm use 7cc's) to apply pressure on the arteriotomy site. Syringe must be completely engaged in the luer port to inflate/deflate the bulb. Remove syringe.

NOTE: Maintain pressure on the plunger while detaching syringe from the SAFEGUARD valve. Observe that the desired pressure is achieved and maintained.

3



Remove sheath, then immediately apply manual compression directly over the inflated bulb.

- Hold manual compression until hemostasis has been achieved.* During pressure application the pedal pulses are checked every 2-3 minutes. A diminished pulse is acceptable during brief full-pressure application, but the distal pulses should not be obliterated completely. If the pedal pulse is absent during compression, the pressure over the artery should be slightly decreased periodically to allow distal circulation.

* Recommendations:

- Diagnostic patients - minimum 5 minutes
- Interventional patients - minimum 10 minutes
- Slowly release manual compression.
- Confirm hemostasis by viewing the site through the inflated bulb window and manage the bulb volume and resultant pressure, as per hospital protocol. Continue to check distal/proximal blood flow to assure patency.

4



Deflate the bulb by attaching an appropriately sized luer lock syringe to the valve, engage the valve and slowly depress the bulb allowing the syringe to fill with air. Alternatively, remove plunger from the syringe, attach syringe and allow air to slowly release while gently depressing the bulb.

NOTE: Deflate bulb every two hours to allow for capillary refill and to assess the site. Re-inflate the bulb if necessary. Do not draw negative pressure in the syringe, as this will create a vacuum on the site.

5

Prior to discharge of the patient, remove SAFEGUARD and apply sterile dressing per hospital protocol.

POST CARE INSTRUCTIONS

- SAFEGUARD is sterile and can be used as the patient's sterile dressing.
- Observe puncture site through the clear window and assess site per hospital protocol.
- Check blood flow per hospital policy.
- Ambulate patient per hospital protocol.
- After hemostasis is achieved, verify hemostasis by applying gentle pressure around puncture site.
- In case of bleeding/hematoma apply direct pressure until hemostasis is achieved and notify physician.

**NOTE: SAFEGUARD 24 cm MAXIMUM INFLATION 40 mL
SAFEGUARD 12 cm MAXIMUM INFLATION 7 mL
DEFLATE EVERY 2 HOURS.**

INFLATE: Date _____ Time _____ Initials _____

DEFLATE: Date _____ Time _____ Initials _____

Date _____ Time _____ Initials _____

Date _____ Time _____ Initials _____

Date _____ Time _____ Initials _____

Call 1 800-356-3748 to order SAFEGUARD

For more information, please visit: www.merit.com

Ordering Information:

SAFEGUARD 24cm 82000D (US only)
SAFEGUARD 24cm 82000 (Outside US)
SAFEGUARD 12cm 82050
(10 per box)

Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician. Refer to Instructions for Use for full instructions, current indications, warnings, contraindications, and precautions.

MERITMEDICAL®

Merit Medical Systems, Inc.

1600 West Merit Parkway, South Jordan, Utah 84095 1-801-253-1600

400378001/A ID 111413

