SAFEGUARD®
24cm PRESSURE ASSISTED DEVICE

INSTRUCTIONS FOR USE

Read instructions prior to use. Product not made with natural rubber latex.

DEVICE DESCRIPTION
The SAFEGUARD MAT is a single use disposable device. SAFEGUARD has a clear medical grade polyurethane window and bladder, a clear medical grade PVC flexible fill tube, and a pressure sensitive, self-adhesive peel backing. A luer valve on the end of the fill tube enables a syringe to be connected to inflate the central bladder with air to provide pressure to the puncture site. The SAFEGUARD pressure assisted device has a sterile dressing with a clear window that facilitates visibility of the access site without removal or manipulation of the device.

INDICATIONS
The indications for use for the SAFEGUARD 24cm pressure assisted device are to assist in obtaining and maintaining hemostasis. The device is also indicated in the reduction of active compression time in femoral artery cannulation following diagnostic and interventional procedures with an ACT of 140 seconds or less, using a 6 Fr. and smaller sheath size.

CONTRAINDICATIONS
The adhesive portion of the SAFEGUARD device should not be used over excoriated skin.

CAUTIONS
Do not use in patients with severe coagulopathies. Reuse, reprocess or resterilize the device. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

PRECAUTIONS
• Use proper aseptic techniques while handling product.
• Do not use if package is damaged
• Inspect device prior to use to verify that no damage has occurred during shipping.

POTENTIAL ADVERSE EFFECTS
Possible adverse effects that may result from the use of this device:
• Hematoma
• Local bleeding
• Antero-venous fistula or pseudaneurysm

SAFETY AND EFFECTIVENESS RESULTS
A clinical trial was conducted to evaluate the safety and effectiveness of the SAFEGUARD Manual Assist Technique (MAT) in reducing active compression time compared to historical manual compression data. (Reduced Vascular Complications After Percutaneous Coronary Interventions with a Non-mechanical Suture Device: Results from the Randomized RACE Study, Sanborn, TA)

PRE-HEMOSTASIS, or MANUAL ASSIST TECHNIQUE (MAT)

PLACEMENT OF SAFEGUARD

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.

Note: Placement may require adjustment based on the patient’s anatomy, angle of puncture, and presence or absence of a procedural sheath.

2. Consider the point of maximum pulse, anatomy, angle of puncture, and direction of flow to determine the appropriate SAFEGUARD position and verify.

3. Pull the procedural sheath back approximately 1” (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.

4. Remove the adhesive backing and place the bulb where you would position your fingers to hold manual compression (for example, in femoral artery procedures, typically the point of maximum femoral pulse). Make sure SAFEGUARD is completely adhered to the skin.

5. Attach and completely engage a standard luer lock syringe to inflate the desired volume a maximum volume of 40mL of air into the bulb to apply pressure on the arterial side. Syringe must be completely engaged in the luer to inflate/deflate the bulb. Remove syringe.

Note: Maintain pressure on the plunger while detaching syringe from the SAFEGUARD device. Observe that the desired volume is achieved and maintained.

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

7. Hold manual compression until hemostasis has been achieved. (Approximately 5 minutes)


9. Check distal/proximal pulses to assure flow is maintained.

10. Conform hemostasis by viewing the site through the inflated bulb window.

* Recommendations (MAT only):
Diagnostic patients - minimum 5 minutes
Interventional patients - minimum 10 minutes

11. Per hospital protocol, periodically check the site through the bulb window to assure hemostasis is maintained and the bulb maintains pressure.

12. Deflate bulb every two hours and observe the site. Re-inflate the bulb if necessary.

13. 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: Do not draw negative pressure in the syringe, as this will create a vacuum on the site.

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

POST-HEMOSTASIS TECHNIQUE

1. When hemostasis at the access site has been achieved, apply the SAFEGUARD device with the access site visible on the bulb window of the SAFEGUARD device. Consider the point of maximum pulse, anatomy, angle of puncture and direction of flow to determine the appropriate SAFEGUARD position and verify.

Note: 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.

2. Attach appropriately sized standard luer lock syringe to the valve of the SAFEGUARD device.

Note: Syringe must be completely engaged in the luer to inflate/deflate the bulb.

3. Inflate the bulb of the SAFEGUARD device with air to the desired volume of air (24cm maximum of 40mL) to apply pressure on the anastomotic site and re-release the bulb valve.

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

4. Per hospital protocol, periodically check the site through the bulb window to assure hemostasis is maintained and the bulb maintains pressure.

5. Deflate bulb every two hours and assess the site. Re-inflate the bulb if necessary.

6. 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: Do not draw negative pressure in the syringe, as this will create a vacuum on the site.

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

Maintain sterile field during application.

Keep away from sunlight

Do not Resterilize

Do not Reuse

Do not use if package is damaged

Catalog Number

Lot Number

Use By

Sterilized Using Gamma

Caution: Consult accompanying document

Manufacturer

Authorized Representative

www.merit.com

ID: 010814

400373001/A

Manufacturer: Merit Medical Systems, Inc.

1600 West Merit Parkway, South Jordan, Utah 84095

U.S.A. 1-801-253-1600

U.S.A. Customer Service 1-800-356-3748