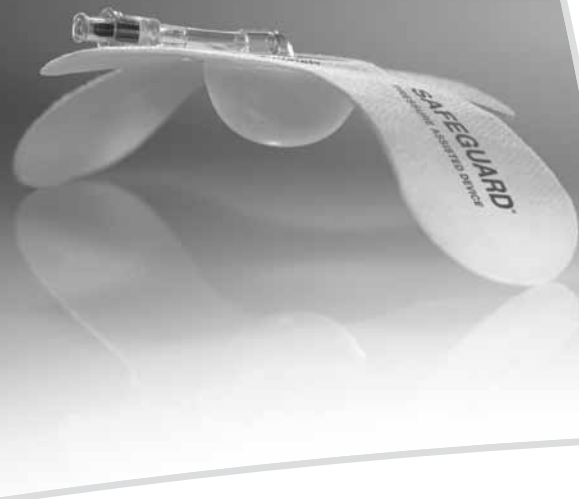


MAQUET
GETINGE GROUP

SAFEGUARD® 24cm
INSTRUCTIONS FOR USE

CARDIOVASCULAR



SAFEGUARD is a trademark of Datascope Corp.

⚠ CAUTION Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

SAFEGUARD® PRESSURE ASSISTED DEVICE • Product contains no latex

PRODUCT STORAGE AND HANDLING REQUIREMENTS

Store in a cool, dry place.

Maintain sterile field during application.



Keep away from sunlight



Do not Resterilize



Do not Reuse

DEVICE DESCRIPTION

The SAFEGUARD 24cm 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 visualization 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

⚠ CAUTION: With over-inflation i.e., above 40cc's of air, the bulb may begin to expand radially and could compromise the adhesive properties of the device.

⚠ CAUTION: Under-inflation of device could compromise the ability of the device to assist in obtaining hemostasis.

WARNING

The SAFEGUARD is designed and validated for single use application only. There is no product validation evidence to support a second use of the product be it sterile or non-sterile and product failure may occur (eg: infection, decreased adhesion to skin, decreased site visibility).

POTENTIAL ADVERSE EFFECTS

Possible adverse effects that may result from the use of this device:

- Hematoma
- Local bleeding
- Arterio-venous fistula or pseudoaneurysm

SAFETY AND EFFECTIVENESS RESULTS

A clinical trial was conducted to evaluate the safety and effectiveness of the SAFEGUARD Manual Assist Technique 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)

	SAFEGUARD MAT N=100	Manual Compression Historical Control N=85
Avg. AC/TTH Manual Compression (minutes)	7.7 ± 3.3	28

	SAFEGUARD MAT N=101		Manual Compression Historical Control N=85	
Major Complications	Diagnostic	Interventional	Diagnostic	Interventional
Access site bleeding requiring transfusion	0	0	0	0
Vascular repair or the need for vascular repair (via surgery, ultrasound-guided intervention, transcatheter embolization, or stent-graft)	0	1	0	2
Any new ipsilateral lower extremity ischemia	0	0	0	0
Surgery for access site related nerve injury	0	0	0	0
Access site-related infection requiring IV antibiotics or extending hospitalization	0	0	0	0

	SAFEGUARD MAT N=101		Manual Compression Historical Control N=85	
	Diagnostic	Interventional	Diagnostic*	Interventional*
Minor Complications				
Access site hematoma >6 cm (after sheath pull)	1	1	-	-
Bleeding requiring > 30 minutes to re-establish hemostasis	0	0	-	-
Non-treated pseudoaneurysm	0	0	-	-
Non-treated arteriovenous (AV) fistula documented by ultrasound	0	0	-	-
Skin excoreation at site of Safeguard after removal of dressing	0	0	-	-
Skin erythema	0	0	-	-
Allergic reaction to adhesive	0	0	-	-
Ipsilateral lower extremity arterial emboli, transient loss of lower extremity pulse, or deep vein thrombosis	0	0	-	-
Access site-related vessel laceration	0	0	-	-
Transient access-site related nerve injury	0	0	-	-
Access site wound dehiscence	0	0	-	-
Localized access site infection treated with intramuscular or oral antibiotics	0	0	-	-

*None Reported

There is no statistical difference in the rate of major complications between the control group and the treated group.

PRE-HEMOSTASIS TECHNIQUE 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, if present.

Note: Placement may require adjustment based on the patient's anatomy, the angle of the puncture site and the 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 inch, if present, 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 i.e., typically the point of maximum femoral pulse. Make sure SAFEGUARD is completely adhered to the skin.

5. Attach and completely engage a luer lock syringe to inflate the desired volume of air into the bulb to apply pressure on the arteriotomy site. Syringe must be completely engaged in the luer to inflate/deflate the bulb. Remove Syringe.

Maximum recommended volume:

SAFEGUARD 24cm: 40cc's of air

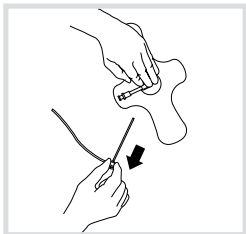
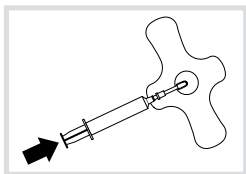
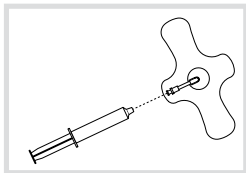
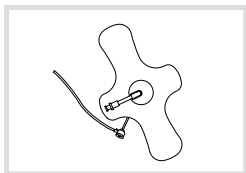
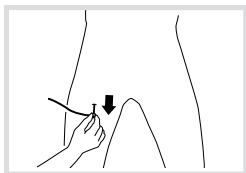
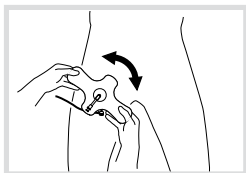
Note: Maintain pressure on the plunger while detaching syringe from the SAFEGUARD valve. Observe that the desired pressure is achieved and maintained.

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

*Recommendations (MAT only):

Diagnostic patients - minimum 5 minutes

Interventional patients - minimum 10 minutes



7. Hold manual compression until hemostasis has been achieved.*
 - Slowly release manual compression.
 - Check distal/proximal blood flow to assure patency.
 - Confirm hemostasis by viewing the site through the inflated bulb window.
8. Per hospital protocol, periodically check the site through the bulb window to confirm hemostasis and to manage the bulb volume and resultant pressure as needed.
9. Deflate bulb every two hours to allow for capillary refill and to assess the site. Re-inflate the bulb if necessary.
10. 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. Or 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.
11. Prior to discharge of the patient, remove SAFEGUARD and apply sterile dressing per hospital protocol.

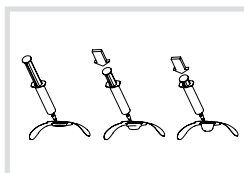
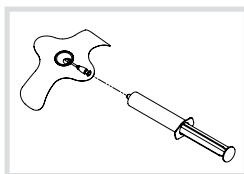
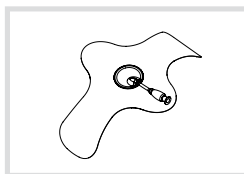
POST-HEMOSTASIS TECHNIQUE

1. When hemostasis at the access site has been achieved, apply the SAFEGUARD device with the access site visible under 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 an appropriately sized 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 40cc's) to apply pressure on the arteriotomy site and remove the syringe. Check distal/proximal pulses to assure flow is maintained.

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. Or 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.

LIMITED WARRANTY

Datascope Corp. warrants that the SAFEGUARD Device is free from defects in workmanship and materials until the expiration date is reached. Datascope Corp. shall not be liable for any incidental, special or consequential loss, damage or expense directly arising from the use of this product. Liability under this warranty and the buyer's exclusive remedy is limited to replacement of the product which, under normal use and services, shall have been found by the Company to have been defective in materials or workmanship. It shall be the buyer's obligation to return any such product to the Company for examination for replacement liability.

No agent, employee, or representative of Datascope Corp. has any authority to bind Datascope Corp. to any affirmation, representation, or warranty concerning its products, and any affirmation, representation, or warranty made by the agent, employee, or representative shall not be enforceable by the buyer.

THIS WARRANTY IS EXPRESSLY IN LIEU OF ANY OTHER EXPRESSED OR IMPLIED WARRANTIES, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS, AND OF ANY OTHER OBLIGATION ON THE PART OF THE SELLER.

Damage to any product or parts through misuse, neglect, accident, or by affixing any non-standard accessory attachments or by any customer modification voids this warranty. Datascope Corp. makes no warranty of their respective manufacturers.

A condition of this warranty is that this equipment or any accessories which are claimed to be defective be returned, when authorized by Datascope, freight prepaid, to Datascope Corp., 15 Law Drive, Fairfield, NJ 07004. Datascope Corp. shall not have any responsibility in the event of loss or damage in transit.

Patents pending.



Keep away from sunlight



Do not Resterilize



Do Not Reuse



Product contains no Latex



Catalogue Number



Batch Code



Use By



Sterilized using Irradiation



Consult Instructions for Use



Manufacturer



Authorized Representative
in the European Community



Caution

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