English

SAFEGUARD FOCUS™
COMPRESSION DEVICE

INSTRUCTIONS FOR USE

DESCRIPTION
The SAFEGUARD FOCUS™ Compression Device is a sterile, single use disposable device. The SAFEGUARD FOCUS has a sterile dressing with a clear window over the compression balloon that facilitates visibility of the access site without removal or manipulation of the device. A valve on the end of the flexible fill tube enables the included syringe with adapted connector to be connected to inflate the balloon to provide pressure to the desired site. The SafeGuard FOCUS comes in a pressure-sensitive self-adhesive version and an adhesive-free version with hook and loop straps.

INDICATIONS FOR USE
The SAFEGUARD FOCUS dressing provides compression over closed surgical sites (to and including pacemaker and ICD pockets) in the immediate post-operative period.

CONTRAINDICATIONS
- The adhesive portion of the SAFEGUARD device should not be used over damaged skin.
- Not indicated for femoral artery compression.

CLINCAL BENEFITS
The SAFEGUARD FOCUS assists in providing compression to closed surgical sites in the immediate post-operative period.

PRECAUTIONS
- This device should be used by clinicians with adequate training in the use of the device.
- 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.

WARNINGS
- Do not leave the SafeGuard FOCUS on for an inappropriately long period of time as tissue damage may occur.
- Do not expose the SafeGuard FOCUS to organic solvents, as they may cause damage to the device.
- Over-inflation above 120 mL of air, or above 60 mL of Cooling Solution, balloon may burst, detach or compromise the adhesive or fastening properties of the device.
- Do not attempt to reposition adhesive. Adhesive only sticks properly on first application.
- Balloon should be partially deflated at periodic intervals.
- Do not reuse saline remaining in basin after saline is drawn into SafeGuard FOCUS Cool Syringe.

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.

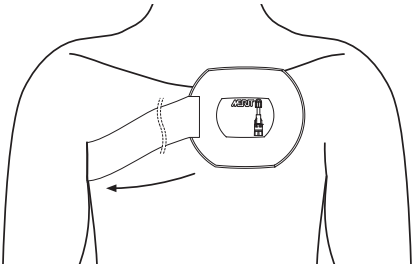
POTENTIAL COMPLICATIONS/RESIDUAL RISKS
Embolism, soft tissue injury, hematoma, local bleeding, local venous thrombosis, nerve damage, pain or numbness, infection, allergic reaction, vasoconstriction and venous fistula or pseudoaneurysm.

INSTRUCTIONS FOR USE

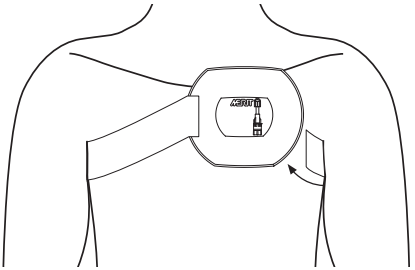
PREPARATION:
1. After closure of surgical site ensure surrounding skin is clean and dry.

PLACEMENT: ADHESIVE TYPE
1. Remove backing material from adhesive.
2. Align balloon with desired location of compression.
3. Apply adhesive to surrounding skin.

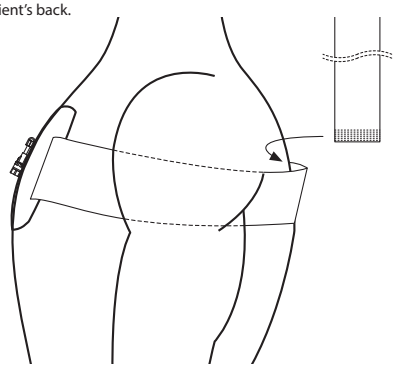
PLACEMENT: ADHESIVE-FREE TYPE
1. Attach printed end of strap to the side of balloon border.
2. Wrap long printed strap around chest of patient under each arm.



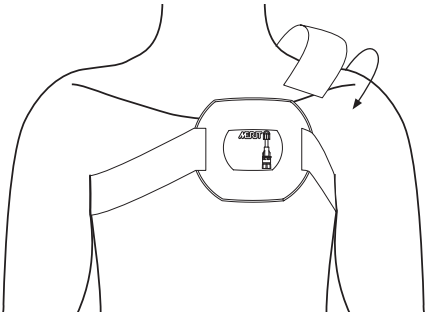
3. Align balloon with desired location of compression and pull strap tight and attach on opposite side.



4. Attach short strap to the underside of the long strap on the patient's back.



5. Bring short strap over shoulder and attach to top of balloon border ensuring balloon is maintained over desired compression area.



6. Trim excess strap material.

APPLYING COMPRESSION (AIR)

1. Engage syringe with valve by inserting and a half twist.
2. Inflate balloon with up to 60ml of air observing compression of site.
3. Disconnect syringe.
4. Continue to observe site and change air volume as needed up to a total of 120ml of air.
5. Device can be inflated past the immediate post-operative period with no more than 30mL, for up to a TOTAL inflation time of 24 hours.
6. If desired, annotate inflation time and volume on device.

APPLYING COMPRESSION (FOCUS COOL)

1. Remove the cap from the syringe.
2. Draw saline into the syringe to the 60 mL marker.
3. Replace the cap onto the syringe tip, and shake the syringe vigorously for approximately 10 seconds, ensuring the syringe becomes cold to the touch.
4. Remove syringe cap again and draw additional saline into syringe, purging air as needed, until 60 mL of mixed solution is loaded into syringe.
5. Shake syringe gently to mix solution.
6. Engage syringe tip with valve by inserting and a half twist.
7. Inject contents of the syringe into balloon, inflating to desired volume.
8. Disconnect syringe.
9. Discard basin & remaining saline. DO NOT REUSE REMAINING SALINE.
10. Continue to observe site and change volume as needed, while ensuring volume does not exceed 60 mL of solution.
11. Device can be inflated past the immediate post-operative period with no more than 30mL, for up to a TOTAL inflation time of 24 hours.
12. If desired, annotate inflation time and volume on device.

REMOVAL

1. When compression is no longer needed, deflate the balloon with syringe and carefully remove adhesive from skin or detach hook and loop bands. For partial deflation with SafeGuard FOCUS Cool, dispose of removed solution via normal hospital protocol.

   NOTE: If the SafeGuard FOCUS syringe is not available when withdrawing contents of balloon or re-injection, the cap on the tubing line may be removed by twisting and a standard luer syringe can be attached.
2. Once adhesive is removed from skin do not attempt place back on patient. If compression is still needed after removal a new device should be used.
3. Dispose of SafeGuard FOCUS according to hospital protocol.

	Caution
	Do Not Use If Package is Damaged and Consult Instruction for Use
REF	Catalog number
LOT	Batch code
MD	Medical Device
UDI	Unique Device Identifier
	Single use
	Do not resterilize
	Consult Instructions for Use For electronic copy scan QR code, or go to www.merit.com/ifu and enter IFU ID. For printed copy, call U.S.A. or EU Customer Service
STERILE EO	Sterilized using ethylene oxide
℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Single sterile barrier system with protective packaging inside
	Use by date: YYYY-MM-DD
	Date of Manufacture: YYYY-MM-DD
	Manufacturer
	Keep away from sunlight
	Keep dry
	No Latex

www.merit.com

Manufacturer:
Merit Medical Systems, Inc.
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South Jordan, Utah 84095 U.S.A.
1-801-253-1600
U.S.A Customer Service 1-800-356-3748

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