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 with air 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's of air, the 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.

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.

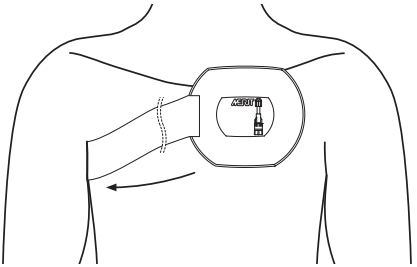
POTENTIAL COMPLICATIONS/RESIDUAL RISKS
Embolism, soft tissue injury, hematoma, local bleeding, local venous thrombosis, nerve damage, pain or numbness, infection, allergic reaction, vasoconstriction and venous fistula or pseudoaneurysm.

INSTRUCTIONS FOR USE

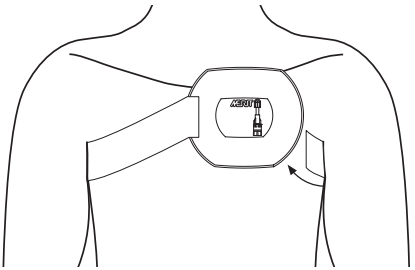
PREPARATION:
1. After closure of surgical site ensure surrounding skin is clean and dry.

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

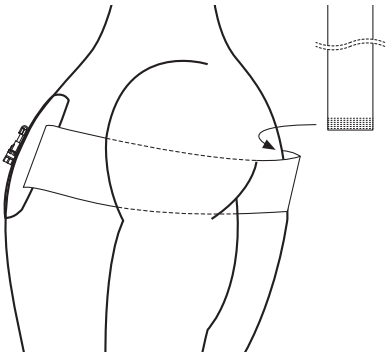
PLACEMENT: ADHESIVE-FREE TYPE
2. Attach printed end of strap to the side of balloon border.
3. Wrap long printed strap around chest of patient under each arm.



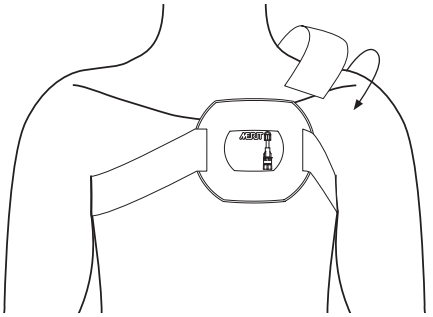
4. Align balloon with desired location of compression and pull strap tight and attach on opposite side.



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



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



7. Trim excess strap material.

APPLYING COMPRESSION

8. Engage syringe with valve by inserting and a half twist.
9. Inflate balloon with up to 60ml of air observing compression of site.
10. Disconnect syringe.
11. Continue to observe site and change air volume as needed up to a total of 120ml of air.
12. 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.
13. If desired, annotate inflation time and volume on device.

REMOVAL

14. When compression is no longer needed, deflate the balloon with syringe and carefully remove adhesive from skin or detach hook and loop bands.

    NOTE: If the SafeGuard FOCUS syringe is not available during air removal or re-injection, the cap on the tubing line may be removed by twisting and a standard luer syringe can be attached.
15. 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.
16. Dispose of SafeGuard FOCUS according to hospital protocol.

℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Caution
	Single Use
	Do Not Re-sterilize
	Do Not Use If Package is Damaged and Consult Instruction for Use
STERILE EO	Sterilized using ethylene oxide
	Keep Dry
REF	Catalog number
LOT	Lot Number
	Keep away from sunlight
	Use by date: YYYY-MM-DD
	Date of Manufacture: YYYY-MM-DD
MD	Medical Device
UDI	Unique Device Identifier
	Single sterile barrier system with protective packaging inside
	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
EC REP	Authorized Representative in European Community
	Manufacturer
LATEX	Latex Free

CE 2797

www.merit.com

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

EC REP **Authorized Representative:**
Merit Medical Ireland Ltd,
Parkmore Business Park West,
Galway, Ireland
EU Customer Service +31 43 358 82 22

406586003_001 ID 2021-09-15