Finale®

Compression Device

INTENDED USE
The Finale® Compression Device is intended for compression of access site vasculature after catheterization procedures**.**

CONTRAINDICATIONS
The use of the Finale for radial artery compression is contraindicated in patients with an abnormal Allen's test or radial pulse, or insufficient dual arterial supply. The Finale is not intended for femoral artery compression.

CAUTIONS
- Ensure correct placement of the Finale before removing sheath from access site.
- Read instructions prior to use.
- Product is intended for single use only.
- Do not reuse or re-sterilize; do not autoclave.
- Do not use if package is opened or damaged.
- Contents of unopened, undamaged package are
- sterile (via ethylene oxide) and non-pyrogenic.

RX ONLY: CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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.

The Finale should be used by clinicians with adequate training in the use of the device.

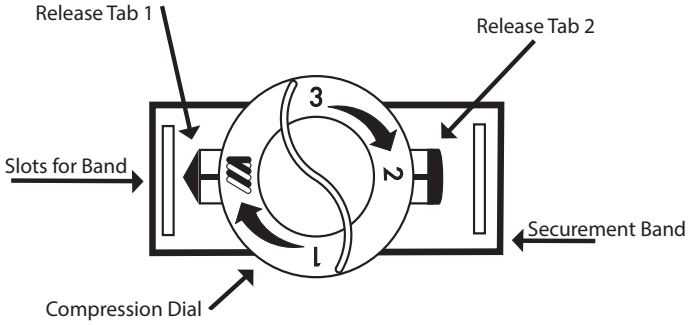
WARNINGS
- Patient should not be left unattended while the Finale is in place
- Ensure correct alignment of the Finale Compression Dial prior to use
- Do not over tighten device
- Do not leave **Finale** on for inappropriately long periods of time as tissue damage may occur
- Arterial pulse distal to the compression plate should be monitored to ensure the artery is not completely occluded as arterial damage and/or thrombosis could occur
- When reducing compression, be sure to grasp dial while pushing in Release Tabs 1 and 2

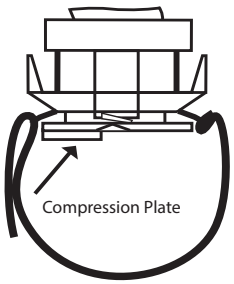
POTENTIAL COMPLICATIONS
Potential complications include, but are not limited to: arterial occlusion, hematoma, hemorrhage, pain, numbness, nerve or tissue damage, and risks normally associated with percutaneous diagnostic and/or interventional procedures. Patient must be monitored for hemostasis; compression pressure should be adjusted according to facility protocol.

PRODUCT DESCRIPTION
(1) Finale Compression Device
(1) Label for compression time

INSTRUCTIONS FOR USE
The following instructions provide technical direction but do not obviate the necessity of formal training in the use of the Finale. The techniques and procedures described do not represent all medically acceptable protocols, nor are they intended as a substitute for the clinician's experience and judgment in treating any specific patient.

1. Remove the sterile Finale from the package.
2. Simultaneously depress Release Tabs 1 and 2 while rotating the compression dial counter-clockwise until the is aligned with Release Tab 1. This ensures correct alignment of the compression dial and plate prior to placement.

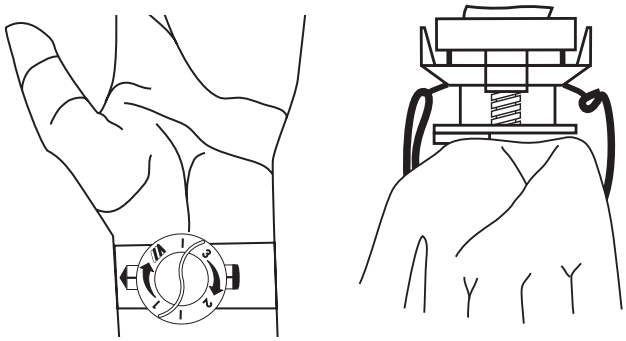




Warning: Ensure correct alignment of the compression dial prior to use.

3. Place device over access site where compression is desired. Loop the VELCRO® brand strap through the slot; attach and tighten appropriately. Do not over tighten strap.

Note – The Finale Compression Device may be used on the right or left arm.



Caution: Ensure correct placement before removing sheath from access site.

4. While slowly removing sheath, rotate compression dial clockwise to achieve hemostatis.

Note - The numbers on the compression dial are for convenience only.

Note - The amount of compression necessary to achieve hemostasis can vary from patient to patient.

Warning – Do not over tighten device.

5. Check for bleeding at access site; if there is bleeding, adjust the compression dial by turning dial clockwise.

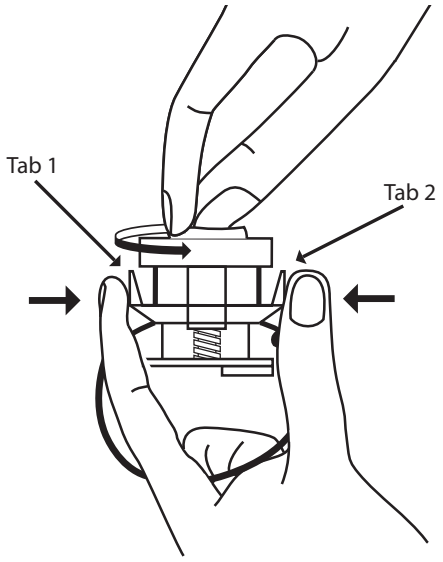
Note – Use minimum amount of pressure necessary to achieve hemostasis.

6. Initial compression should be maintained for approximately 30 minutes. The compression device should be loosened every 15-30 minutes until hemostasis is achieved.

To decrease compression:

Warning - Be sure to grasp dial while pushing Release Tabs 1 and 2

7. Hold the compression dial with one hand, and squeeze Release Tabs 1 and 2 with the other hand. While squeezing Release Tabs, rotate the dial counter-clockwise to desired compression. Release tabs and note the compression level and time on label or chart.



8. Once hemostasis is achieved, remove compression device and discard.

Warning - Patient should not be left unattended while device is in place.

9. Post-procedure care should follow standard facility protocol.

MERITMEDICAL®

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