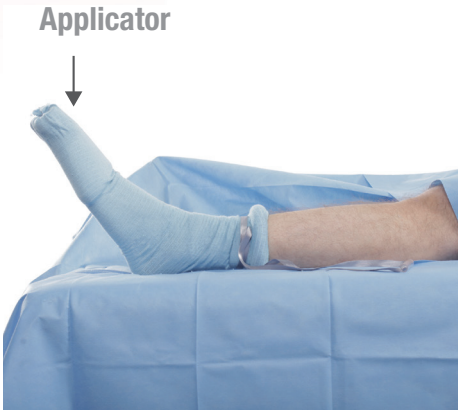
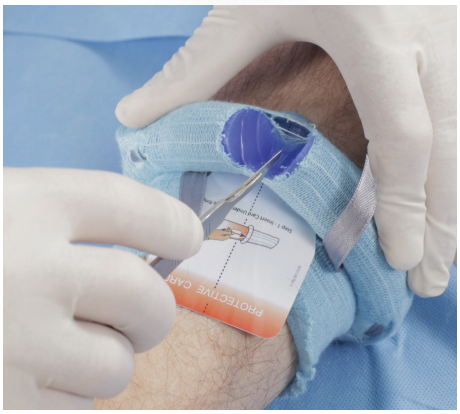
model A by HemaClear

Foot And Ankle Tourniquet





www.HemaClear.com | info@HemaClear.com

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Product Number: PRH-032-MA-01A

HemaClear® Model A™ for Foot & Ankle Surgery
- Instructions for Use

(EN) Read this package insert carefully in its entirety before device application

Indications for Use
HemaClear Model A is indicated for expelling blood from the foot and ankle, occluding arterial flow into it and placing sterile stockinet over the lower leg.

Contraindications
- Do not leave HemaClear on the patient for more than two hours.
- Do not use HemaClear on patients with poor peripheral blood flow, edema or DVT.
- Do not use HemaClear if there are skin lesions (skin disease, paper-thin skin, burns).
- Do not use HemaClear if the limb is infected or with malignancy.

Warnings
- HemaClear should be applied by, or by order of, a physician.
- If the limb is unstable (fracture, dislocation), use axial traction to stabilize it during HemaClear application.
- HemaClear will only occlude arterial blood flow as long as patient's systolic blood pressure does not exceed 160 mmHg.
- The HemaClear Model A can be applied over the lower leg with circumference at the occlusion location ranging between 22 and 32 cm.
- If HemaClear does not stop the blood flow into the limb, it should be removed immediately.

Side Effects
- Temporary (up to 24 hours) discoloration of the skin beneath the HemaClear ring.
- Residual pain at the Occlusion Location - may last up to 7 days (rare).
- Tourniquet failure:
  - ☐ Primary Tourniquet Failure – Incomplete occlusion of arterial inflow right after the HemaClear is applied.
  - ☐ Secondary Tourniquet Failure – Occlusion breach following initial successful occlusion.

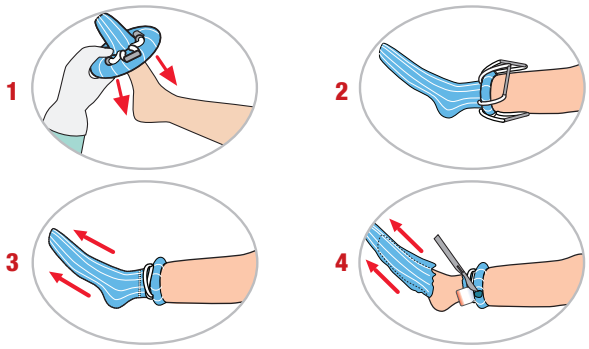
Both failures are uncommon and usually result from the patient's systolic blood pressure exceeding recommended limit for the specific HemaClear model.

Directions for Use
1. Recommended placement location on the lower leg – from 15cm (6'') above the lateral malleolus.
2. Measure the limb circumference at the occlusion location using the measuring tape provided with the product. If the circumference at the desired occlusion location is not within 22-32 cm, use another appropriate model of HemaClear.
3. Verify that the patient's systolic blood pressure does not exceed the device maximal occluding pressure of 160 mmHg.
4. Refer to the Pressure Table for device pressure at skin level.
5. Using sterile technique, open the outer packaging of the device and drop it, inner packaging intact, onto the sterile field. Use sterile technique to remove device from within inner pouch.
6. Keep the protective card for the end of the procedure. The protective card will be used to protect the skin when removing the device at the end of the procedure (see below).
7. If the patient is awake, explain the procedure of application and warn about possible ring pressure discomfort. Sedation and/or analgesia are recommended.
8. Disinfect the lower leg according to the type of procedure performed. Apply the sterile drapes such that they overlap the edge of the disinfected region.
9. Insert the toes into the oval opening of the device applicator, with the handles facing away from the patient. Verify that all the toes are inserted. Grab the handles firmly and pull the handles along the axis of the foot. Use the bottom handle to pull over the heel. Roll device on the lower leg until HemaClear reaches the desired occlusion location.
10. The device will not roll beyond 50 cm (20") from the tips of the toes. If a more proximal position is needed, use an alternative HemaClear model (ex. HemaClear 90).

Note: HemaClear should be positioned within the sterile field on the lower leg and may be placed over the sterile drapes.

11. Once HemaClear is in place the straps can either be wrapped around the limb, distal to the HemaClear ring, or cut away.
12. The HemaClear Model A is constructed with two segments of elastic stockinet. Once the device reaches the occlusion location, the distal sleeve (covering the applicator and toes) can be easily pulled away and removed, or cut to reveal the surgical site. If the stockinet is cut, first apply sterile water or saline, and then cut the stockinet. Wetting the stockinet prior to cutting it minimizes the amount of lint. The surgical site may be covered with a sterile transparent drape if desired.

Start procedure
13. Tourniquet Time begins as soon as the device is in place.
14. When the procedure is over, insert Protective Card under the ring and cut the ring with a scalpel. Use scissors to cut and remove remaining stockinet. Blood flow to the limb will resume. Reactive hyperemia is normal.



HemaClear Foot & Ankle		Distance from Toes [cm]				
		30-34	34-38	38-42	42-46	46-50
Limb Circumference [cm]	22-24	176	167	161		
	24-26	184	177	170	164	
	26-28	191	184	177	170	165
	28-30		190	183	177	171
	30-32			188	182	176

Recommended Storage Conditions
Handle with Care
Humidity < 60% RH
7°C – 28°C 45°F – 83°F
Latex Free
Single Use
Sterilized by EtO
Refer to instructions
Do not use if package is damaged
CE 0482

Contact Information

US Contact:
OHK Medical Devices Inc.
2885 Sanford Ave SW #14751
Grandville, MI 49418, USA
Tel: +1.866.503.1470
Fax: +1.866.430.6132
info@HemaClear.com

International Contact:
OHK Medical Devices Ltd.
PO Box 354
Haifa 31002, Israel
Tel: +972.4.824.2369
Fax: +972.4.834.6753
info@HemaClear.com

European Representative:
MedNet GmbH, Barkstraße 10
Münster 48163, Germany
www.medneteeurope.com
Manufacture by:
OHK Medical Devices
www.HemaClear.com