

Model F



by HemaClear

Hand Surgery Made Easy



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CE & FDA Cleared

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Product Number: PRH-035-FA-01A

HemaClear® Model-F - Instructions for Use



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

Indications for Use

HemaClear® Model-F is indicated for expelling blood from a forearm, occluding arterial flow into it and placing sterile stockinet over the forearm.

Contraindications

- Do not leave HemaClear® on patient's forearm for more than two hours.
- Do not use HemaClear® on patients with poor peripheral blood flow, edema or DVT.
- Do not use HemaClear® if forearm has significant skin lesions (skin disease, paper-thin skin, burns).
- Do not use HemaClear® if forearm is infected or with malignancy.

Warnings

- HemaClear® should be applied by, or by order of, a physician.
- If the forearm is unstable (fracture, dislocation), use axial traction to stabilize the forearm during HemaClear® application.
- HemaClear® will only occlude arterial blood flow as long as patient's systolic blood pressure does not exceed 160 mmHg.
- HemaClear® device can be applied over a forearm with circumference at the Occlusion Location ranging between 14 cm and 34 cm.
- If HemaClear® does not stop the blood flow into the forearm, 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. Measure the Forearm Circumference at the Occlusion Location using the measuring tape provided. If the circumference at the forearm is less than 14 cm, use stockinet to build up the forearm circumference to 14-16 cm. If the circumference at the desired occlusion location is not within 14-34 cm, use another appropriate model of HemaClear®.
2. Recommended placement location on the forearm – from 10 cm (4") proximal to the wrist, to 10 cm (4") distal to the elbow.
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 casing of the device and drop it, inner casing intact, onto the sterile field. Use sterile technique to remove device from within inner casing. Protective Card will be used to protect the skin when removing the device at the end of the procedure (see below).
6. If the patient is awake, explain the procedure of application and warn about possible ring pressure discomfort. Sedation and/or analgesia may be used.

7. Disinfect the forearm according to the type of procedure performed. Apply the sterile drapes such that they overlap the edge of the disinfected region.

8. Insert the tips of the fingers into the oval opening of the device application cup, with the handles facing away from the patient. Insure that all fingers are inserted. Grab the handles firmly and pull the handles proximally towards the patient along the forearm. The device will roll up the hand and the forearm smoothly.

9. Continue pulling on the handles until HemaClear® reaches the Occlusion Location.

Note: HemaClear® should be placed within the sterile field on the forearm. HemaClear® may be placed over the sterile drapes.

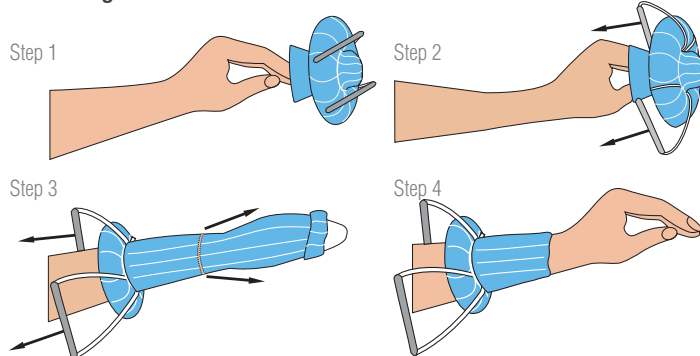
10. Once HemaClear® is in place the straps can either be wrapped around the forearm, distal to the HemaClear® ring, or cut away.

11. The HemaClear® Model-F is constructed with two segments of elastic stockinet. Once the device reaches the occlusion location, the distal sleeve (covering the fingers) can be easily pulled away and removed, or cut to reveal the surgical site. If chosen to cut the stockinet, apply first 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

12. Tourniquet Time begins as soon as the device is in place.

13. 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 arm will resume.



HemaClear® Forearm Pressure Table [mmHg]		Distance from Fingers [cm]		
		25-30	30-35	35-40
Limb Circumference [cm]	14-18	204	197	192
	18-22	236	231	227
	22-26	257	254	247
	26-30	276	270	264
	30-34	295	286	281

Handle with Care

Humidity < 60% RH

7°C – 28°C 45°F – 83°F

Latex Free

Single Use

Sterilized by EtO

Do not use if package is damaged

CE 0482

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