

"I have been using HemaClear for 2 years at the Brigham and have found it offers a significant clinical advantage over the pneumatic tourniquet, mainly because it's so thin that it gives much more working room above the elbow in a bloodless field.

It is safe and reliable."

Dr. George Dyer, Brigham & Woman's Hospital

Q & A

How does HemaClear® work?

HemaClear is a sterile, single use only surgical tourniquet that gives the surgeon a much larger surgical field with greater visibility, enhancing surgical performance and outcomes. Simply place HemaClear® over the patient's fingers or toes, hold the handles and pull proximally. The silicone ring inside HemaClear® rolls up the limb while the stockinette sleeve covers it. The pressure from the ring exsanguinates the limb as it is applied and blocks blood flow at the occlusion site.

How long can HemaClear® remain on the limb?

HemaClear® can remain on the limb for up to 120 minutes. HemaClear® follows the same AORN guidelines as pneumatic tourniquets.

What do I do if the procedure is over 2 hours?

For procedures that last longer than 2 hours, remove the HemaClear® surgical tourniquet and after the reperfusion period, apply a new sterile unit.

How much pressure does HemaClear® exert?

The pressure exerted by the HemaClear® sterile surgical tourniquet is comparable to pneumatic tourniquets at approximately 200-250 mm Hg for upper limbs and 300-350 mm Hg for lower limbs.

The exact pressure depends on the model used, limb circumference at the occlusion site, and the distance from the fingers or toes. Pressure tables are available in the instructions for use.

Who is HemaClear®?

HemaClear is a medical device development, manufacturing, and sales company based in Israel.

Our R&D and manufacturing facilities are in the city of Haifa.

Contraindications

Do not leave HemaClear® on the patient's limb for more than 120 minutes.

Do not use HemaClear® on patients with poor peripheral blood flow, edema or DVT.

Do not place HemaClear® directly over the ulnar nerve (at the elbow) or peroneal nerve (at proximal tibia).

Do not use HemaClear® if the limb has significant skin lesions (skin disease, burns).

Do not use HemaClear® if the limb is infected or malignant.

Product Family	Product Number	Product Description	Suitable for patient's Systolic Blood Pressure	Suitable for patient's limb circumference
HemaClear®/28	PRH-028-PI-01 A/C	HemaClear®/28 - Pink	< 130 [mmHg]	14 – 28 [cm]
HemaClear®/40	PRH-040-GR-01 A/C	HemaClear®/40 - Green	< 130 [mmHg]	24 – 40 [cm]
	PRH-040-RE-01 A/C	HemaClear®/40 - Red	< 160 [mmHg]	24 – 40 [cm]
	PRH-040-YE-01 A/C	HemaClear®/40 - Yellow	< 190 [mmHg]	24 – 40 [cm]
HemaClear®/60	PRH-060-BL-01 A/C	HemaClear®/60 - Blue	< 130 [mmHg]	30 – 55 [cm]
	PRH-060-OR-01 A/C	HemaClear®/60 - Orange	< 160 [mmHg]	30 – 55 [cm]
	PRH-060-BR-01 A/C	HemaClear®/60 - Brown	< 190 [mmHg]	30 – 55 [cm]
HemaClear®/90	PRH-090-BW-01 A/C	HemaClear®/90 - B&W	< 160 [mmHg]	50 – 85 [cm]

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HemaClear®
It Just Fits Better



**The All-In-One, Sterile,
Exsanguinating Tourniquet.
Improving Clinical Performance.
Saving Time in the
Operating Theater.**

"The HemaClear technique is unparalleled."

Dr. David Helfet, Chief of Orthopedic Trauma
Hospital for Special Surgery, New York



The ALL-IN-ONE Sterile Surgical Tourniquet

“Superior exsanguination and easier to use over Esmarch and pneumatic cuffs. Everytime.”

Dr. Jesse Jupiter, Director
MGH Orthopedic Hand Service, Boston

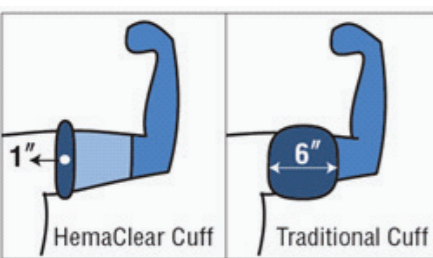
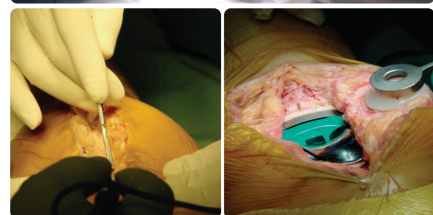
Superior exsanguination: The rolling action of the occlusive silicone ring pushes 95% of the standing blood out of the surgical field, as opposed to 69% with the Esmarch bandage. ^{1 & 2}

Creates a sterile field: HemaClear® is a sterile, single use tourniquet that eliminates the need for contaminated reusable cuffs, thus reducing infection rates. ^{3 & 4}

Increases the surgical field: At 1" wide, the narrow profile enables a wider and sterile field.

Simple and cost-effective: The easy application reduces preparation time and eliminates the need for tourniquet machines, contaminated reusable cuffs and Esmarch bandages.

HemaClear® is used worldwide: HemaClear® is FDA and CE approved. More than 20 published studies demonstrate the safety, reliability and clinical superiority of HemaClear®.



HemaClear® Outperforms Pneumatic Cuffs

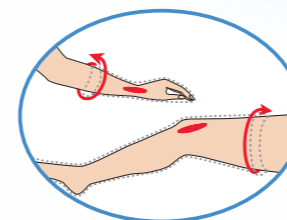
	HemaClear®	Pneumatic Cuffs
SET-UP TIME ⁵	< 1 minute	15 minutes
EASE OF USE	Just grab and pull	Multiple OR personnel, complicated equipment
SAFETY	Sterility reduces infection rates; Low incidence of complications	Non-sterile, risk of infection, higher risk of complications
FOOTPRINT	Requires no OR large capital equipment	Multiple device
COST	A single disposable expense, no maintenance fees	Disposable equipment plus extra OR time

References

- 1) Blond L, Madsen JL. Exsanguination of the upper limb in healthy young volunteers. J Bone Joint Surg Br. 2002;84-B:489-491.
- 2) Blond L, Madsen JL. Exsanguination of the limbs in elderly volunteers. Int Orthop. 2003;27:114-116.
- 3) Thompson SM et al. The effect of sterile versus non-sterile tourniquets on microbiological colonisation in lower limb surgery. St Peter's Hospital, Chertsey, UK Ann R Coll Surg Engl 2011; 93: 589-590 doi 10.1308/147870811X13137608455334. Accepted 21 August 2011.
- 4) Gottlieb T et al. Reusable tourniquets. An underestimated means for patient transfer of multi-resistant bacteria. BMC Proceedings 2011 5(Suppl 6):P38.
- 5) Boiko M, Roffman M. Evaluation of a novel tourniquet device for bloodless surgery of the hand. J Hand Surg [Br]. 2004;29B:185-187.

HemaClear® in 3 Easy Steps

1 Measure



Find the right size
Match the size with the circumference



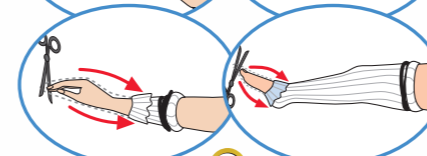
2 Apply



Roll HemaClear® over fingers or toes



Pull handles, stopping where you would normally position the bottom of the tourniquet

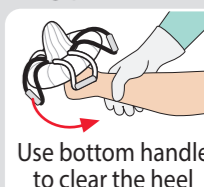


Cut the Trim: expose surgical field and then cut the straps

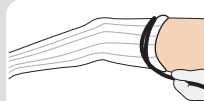


Tourniquet Up: Record tourniquet start time

Tips for leg placement

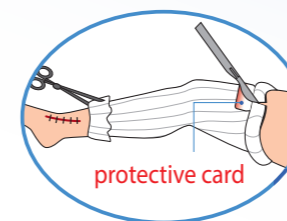


Use bottom handle to clear the heel



Cinch the straps to keep them tight

3 Remove



Cut off when done: for safety, always place the **protective card** between the stockinet and tourniquet



Tourniquet Down: Record total tourniquet time

Model F



by HemaClear

Hand Surgery Made Easy



www.HemaClear.com

CE & FDA Cleared

Protected by U.S. and International Patents (US 7854748)

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.

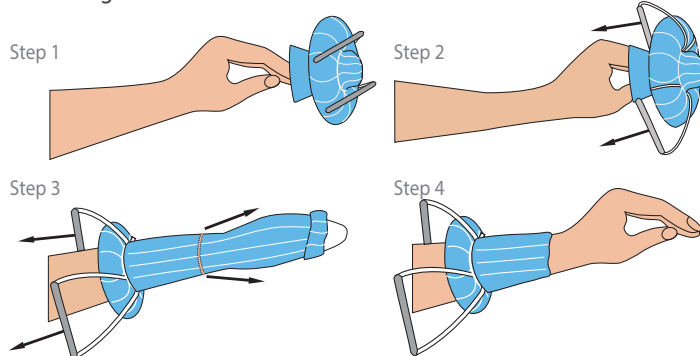
10. Once HemaClear® is in place the straps can either be wrapped around the forearm, distal to the HemaClear® ring, or cut away.

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

70C – 280C 450F – 830F

Latex Free

Single Use

Sterilized by EtO

Do not use if package is damaged

CE 0482

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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 a 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

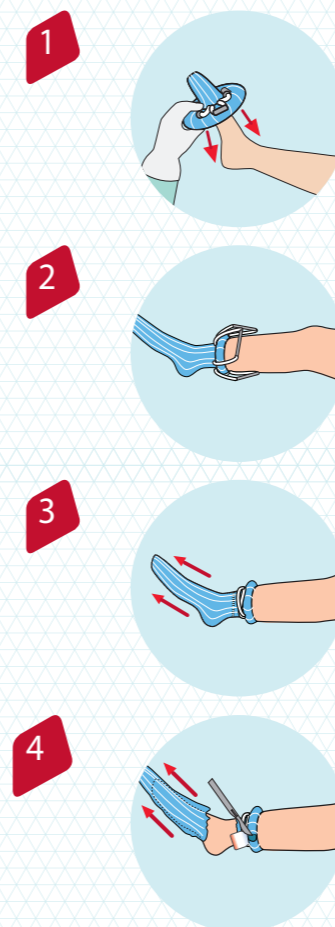
- Temporary (up to 24 hours) discoloration of the skin beneath the HemaClear® ring.
 - Residual pain at the Occlusion Location - may last up to 7 days (rare).
 - Tourniquet failure:
 - Primary Tourniquet Failure – Incomplete occlusion of arterial inflow right after the HemaClear is applied.
 - Secondary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

- Recommended placement location on the lower leg – from 15cm (6") above the lateral malleolus.
 - 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®.
 - Verify that the patient's systolic blood pressure does not exceed the device maximal occluding pressure of 160 mmHg.
 - Refer to the Pressure Table for device pressure at skin level.
 - 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.
 - 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.
 - If the patient is awake, explain the procedure of application and warn about possible ring pressure discomfort. Sedation and/or analgesia are recommended.
 - 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.
 - 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.
 - 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.
- Once HemaClear® is in place the straps can either be wrapped around the limb, distal to the HemaClear® ring, or cut away.
 - 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

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



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

Product Number: PRH-032-MA-01A

Recommended Storage Conditions

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

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