

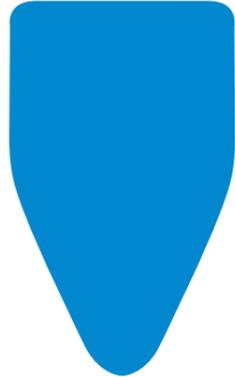
Sterile Exsanguination Tourniquet

User Guide
XXL

www.HemaClear.com

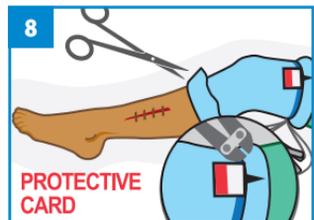
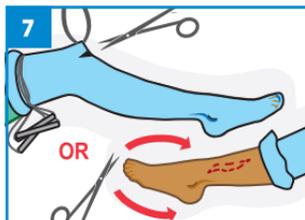
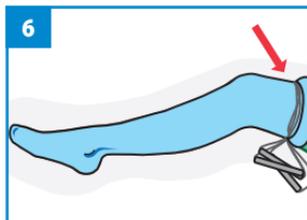
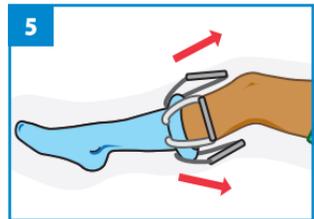
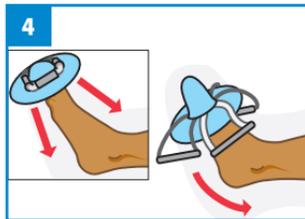
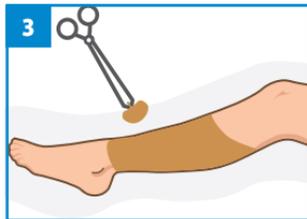
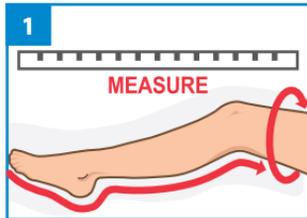
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HemaClear® XXL includes Protective Card and Measuring Tape

HemaClear® - LOWER EXTREMITY

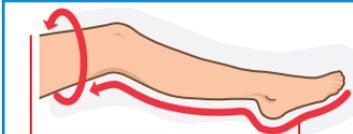


How to Use the HemaClear® Pressure Tables

- Measure the distance between the tips of the toes and the occlusion location.
- Find the column corresponding with the distance in the table on page 6.
- Measure the limb circumference at the occlusion location.
- Find the row corresponding with the limb circumference in the table on page 6.

The intersection of the corresponding column and row presents the pressure exerted by the device to the limb at the skin level on occlusion location.

- Please note that values indicated in the table are within the range of ± 5 mm Hg
- NPd: Non-Physiological Dimensions



HemaClear® MEDIUM RED ≤160 mm Hg PRH-040-RE-01A		Distance from Fingers / Toes (cm)					
		20-30	31-40	41-50	51-60	61-70	71-80
LIMB CIRCUMFERENCE (cm)	24-26	221	218	212	203	194	179
	27-28	230	225	218	209	198	185
	29-30	238	235	227	217	208	191
	31-32	258	252	242	232	221	204
	33-34	265	263	257	246	235	217
	35-36	300	289	277	261	248	229
	37-38	NPd	332	301	283	262	242
	39-40	NPd	361	327	322	305	254

STORAGE CONDITIONS



HemaClear® contains no natural rubber latex.

HemaClear® may be disposed of in accordance with Biological and Medical Waste Disposal procedures.

HemaClear® EXTRA-EXTRA-LARGE (XXL) Turquoise

HemaClear® Skin Pressure, mm Hg

HemaClear® EXTRA EXTRA LARGE (XXL) Turquoise PRH-099-TU01A		Distance from Toes (cm)						
		60-70	71-80	81-90	91-100	101-110	111-120	121-130
LIMB CIRCUMFERENCE (cm)	65-71	274	271	269	266	264	260	256
	72-78	292	286	283	278	276	274	271
	79-85	309	306	302	299	296	293	290
	86-92	326	323	320	317	315	310	308
	93-99	343	340	338	334	331	330	326

HemaClear Size	XXL
Color	Turquoise
Patient's Systolic Blood Pressure Limit	<150 mmHg
Length	<130 cm
Minimum Circumference	65 cm
Maximum Circumference	99 cm

PLEASE READ THIS PACKAGE INSERT CAREFULLY
in Its Entirety Before Using the Device



HemaClear® Instructions for Use

Indications for Use

HemaClear® is indicated for expelling blood from a limb, occluding arterial flow into a limb, and placing a sterile stockinet over a limb.



Contraindications

- Do not use **HemaClear®** on patients with Deep Vein Thrombosis (DVT). See the Wells Score System (next page), for likelihood of DVT.
- Do not use **HemaClear®** if the limb is infected or with malignancy.
- Do not apply **HemaClear®** directly on skin that is fragile or has significant lesions. Use a sterile ace bandage to protect fragile skin before applying **HemaClear®**.
- **Do not leave HemaClear® on a patient's limb for more than 120 minutes.**
- Do not place **HemaClear®** directly over the peroneal nerve (at the proximal tibia and / or distal femur).

DVT Probability: Wells Score System¹

CLINICAL FEATURE	POINTS	PATIENT SCORE
Active cancer (treatment ongoing, within 6 months, or pallative)	1	
Paralysis, paresis or recent plaster immobilization of the lower extremities	1	
Recently bedridden for 3 days or more or major surgery within 12 weeks requiring general or regional anesthesia	1	
Localized tenderness along the distribution of the deep venous system	1	
Entire leg swollen	1	
Calf swelling at least 3 cm larger than asymptomatic side	1	
Pitting edema confined to the symptomatic leg	1	
Collateral superficial veins (non-varicose)	1	
Previously documented DVT	1	
An alternative diagnosis is at least as likely as DVT	-2	
Clinical probability simplified score		
DVT <i>likely</i>	2 or more	
DVT <i>unlikely</i>	1 or less	

¹Wells PS, Anderson DR, Rodger M et al. (2003). Evaluation of D-dimer in the diagnosis of a suspected deep-vein thrombosis. *New England Journal of Medicine* 349: 1227–35.



Warnings

- **HemaClear**[®] should be operated by a physician, or by the order of a physician.
- If the limb is unstable (fracture, dislocation), apply axial traction to stabilize the limb during **HemaClear**[®] application.
- **HemaClear**[®] only occludes arterial blood flow as long as the patient's systolic blood pressure does not exceed the recommended limit, which can be found on page 6.
- **HemaClear**[®] **XXL** can be applied to limbs with circumference (at the occlusion location) ranging between 65 cm and 99 cm.
Do not use HemaClear[®] **XXL** if the circumference at the occlusion location is smaller than 65 cm or greater than 99 cm.
- If **HemaClear**[®] does not stop the blood flow to the limb, it should be removed immediately.



Side Effects

1. **Temporary discoloration of the skin beneath the HemaClear® Ring** (<24 hours).
2. **Residual pain at the occlusion location** - may last up to 7 days (rare).
3. **Tourniquet Failure**
 - **Primary Tourniquet Failure** - Incomplete occlusion of arterial flow from the beginning of the case.
 - **Secondary Tourniquet Failure** - Occlusion breach following initial successful occlusion.

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

Directions for Use

1. Refer to the **Pressure Table** for device pressure at skin level.
2. Using a sterile technique, open the outer envelope of the device and drop it onto the sterile field, with inner envelope intact. Use a sterile technique to remove the device from within the inner envelope. Keep the **Protective Card** for the end of the procedure to protect the skin when the metal spring is cut, in keeping with instructions regarding use of the Protective Card.
3. If the patient is awake, explain the application procedure and warn about possible ring pressure discomfort. Sedation and/or analgesia may be used. Disinfect the limb according to the type of procedure performed. Apply sterile drapes so that they overlap the edge of the disinfected region.

LOWER EXTREMITY: Insert the toes into the orifice of the device with the handles facing away from the patient. Ensure that all the toes are inserted into the circumference of the ring. Position the device on the toes so that one handle is aligned with the bottom (sole) of the foot, and the other handle is aligned with the top of the foot (Pg. 4, Fig. 4). Have two people stand proximately to the patient's foot, so that each can pull two straps. When pulling the device straps proximally on the patient's leg, you are pulling towards your body. Have an assistant stabilize the foot and ankle of the patient (Pg. 4, Image top right). Firmly grab the two plastic handles using the colored straps, and pull the

handles first along the foot and then proximally along the leg. To roll **HemaClear**[®] over the heel, apply more force to the bottom handle, using it as a hinge. Once over the heel, continue pulling on the handles until **HemaClear**[®] reaches the desired occlusion location (Pg. 4, Fig. 6).

Occlusion location: On the groin.

NOTE: **HemaClear**[®] should be placed within the sterile field on the limb over the edge of the sterile drapes.

4. Once **HemaClear**[®] is in place, the colored straps can either be wrapped around the limb, distal to the **HemaClear**[®] ring, or cut off (Pg. 4, Fig. 6).
5. Expose the incision site by pulling the stockinet up, removing it, or cutting a window in the fabric (Pg. 4, Fig. 7).

NOTE: To minimize lint, dampen the fabric with sterile water or saline before cutting it.

6. **Tourniquet Time** begins as soon as the **HemaClear**[®] is in place. Tourniquet Time ends when the **HemaClear**[®] is removed (Pg. 4).
7. When the procedure is over, cut the stockinette to expose the spring. Cut the spring with an orthopedic 3mm wire/pin cutter. Use scissors to cut and remove the remaining stockinet. Blood flow to the limb will resume.

WARRANTY

Subject to the herein restrictions and limitations, Oneg Hakarmel Ltd. (OHK Medical Devices, Inc.) (the “Manufacturer”) hereby warrants to the original purchaser of the HemaClear® product(s) (the “Product”), that the Product shall be free from defects in material and workmanship for the period specified within the Expiration Date printed on the Product packaging, in accordance with the record of the Manufacturer, which shall constitute a prima-facie evidence in that respect. Otherwise the Product is provided AS-IS.

SCOPE OF WARRANTY

This warranty is expressly conditioned on the purchaser's obligation to use and store the Product in accordance with applicable law and the required instructions specified by the Manufacturer, including without limitations with respect to the maintenance and/or use of the Product, (and specifically, using the appropriate size of the Product per each patient, adhering to instructions regarding the Product's shelf life and actual use time on any patient, verifying that the Product shall not expose the respective patient to any health risk per such patient's medical condition, etc.). The above is also subject to the Product being stored and handled per the above, by any distributor or other party which supplied the Product to the purchaser.

The purchaser understands that Manufacturer's instructions may also be updated and published at Manufacturer's website (www.hemaclear.com), and it is the purchaser's responsibility to monitor any such changes.

Purchaser acknowledges receiving such instructions, and without derogating from the provisions herein, the purchaser agrees to be bound by such instructions. If the purchaser does not comply with applicable instructions, then all warranty granted by the Manufacturer shall be void, and the purchaser shall bear the full costs of (a) replacing the Product (including, but not limited to all shipping costs), and (b) any claims brought against it and/or any of its employees, agents, directors, affiliates, etc. relating to its use of the Product, and shall further be required to indemnify the Manufacturer for any such claims.

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Warranty

Subject to the herein restrictions and limitations, OHK hereby warrants You that the Device shall be free from defects in material and workmanship for a period of two (2) years from the manufacturing date of the Device, in accordance with the record of OHK, which shall constitute a prima-facie evidence in that respect.

Scope of Warranty

This warranty is expressly conditioned on Your obligation to use and store the Device in accordance with applicable law and the required instructions specified by OHK, including without limitations with respect to the maintenance and/or use of the Device (and specifically, without derogating from the generality of the foregoing, using the appropriate size of the Product per each patient, adhering to instructions regarding the Device's shelf life and actual use time on any patient, verifying that the Device shall not expose the respective patient to any health risk per such patient's medical condition, etc.). The above is also subject to the Device being stored and handled per the above, by any distributor or other party which supplied the Device to You. You understand that OHK's instructions may also be updated and published at OHK's website, and it is Your responsibility to monitor any such changes.

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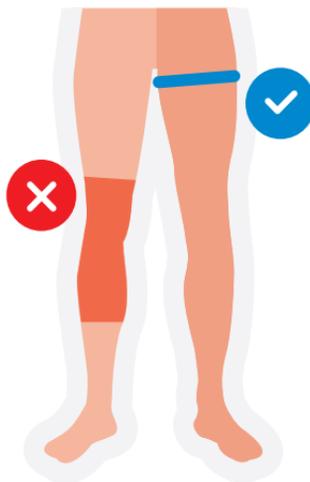
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HemaClear® Placement

NO-HEMACLEAR® ZONE LEG

Peroneal Nerve, Knee,
Calf Muscles -
Soleus/Gastrocnemius



OPTIMAL POSITION - GROIN

As high as possible



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