



Sterile Exsanguination Tourniquet

User Guide

[www.HemaClear.com](http://www.HemaClear.com)

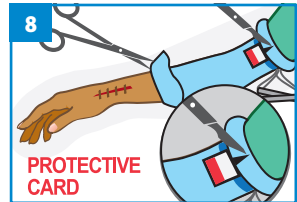
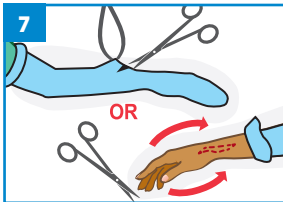
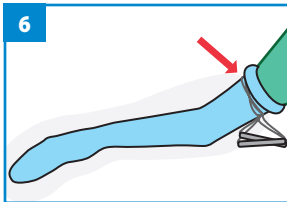
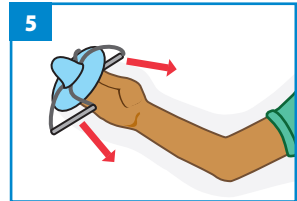
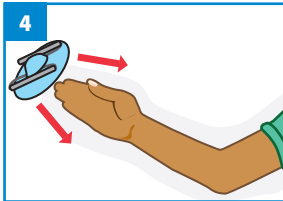
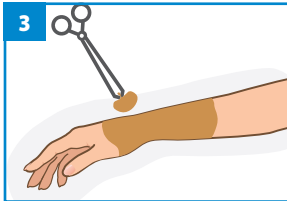
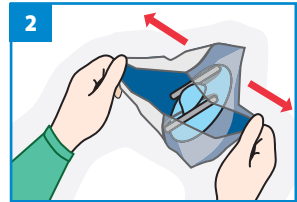
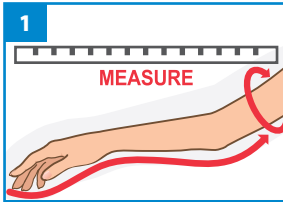
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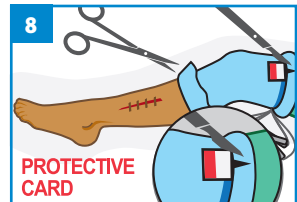
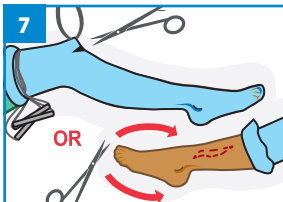
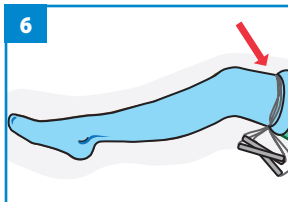
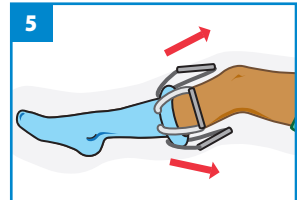
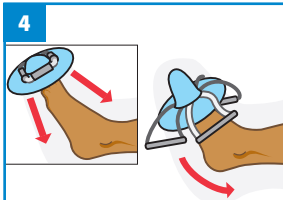
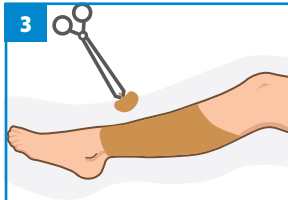
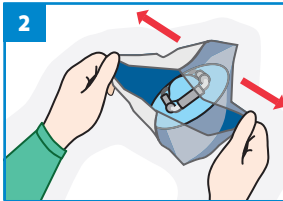
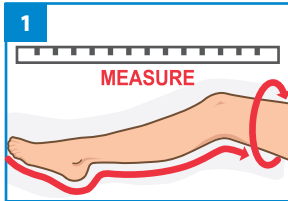


HemaClear® Products including Protective Card and Measuring Tape

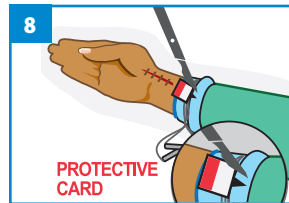
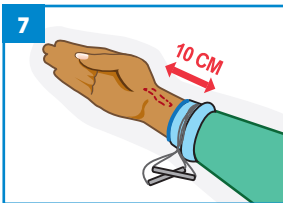
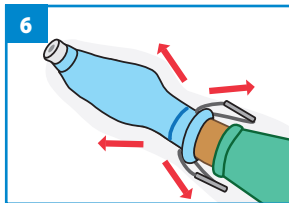
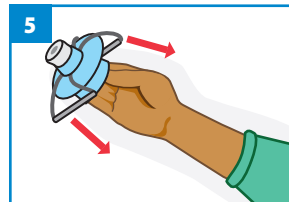
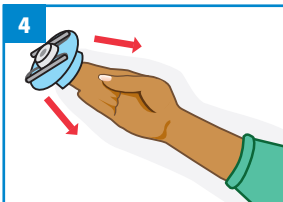
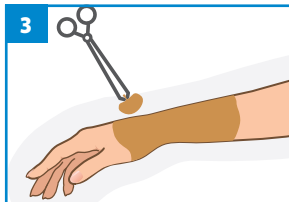
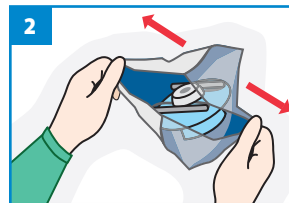
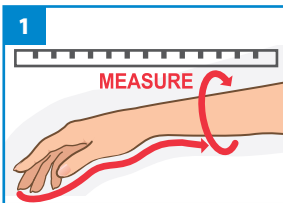
## HemaClear® - UPPER EXTREMITY



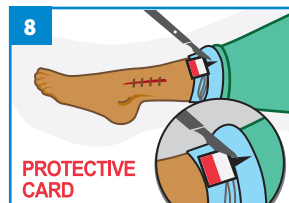
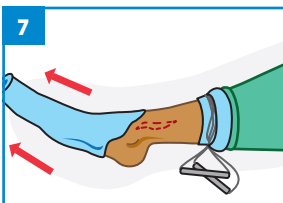
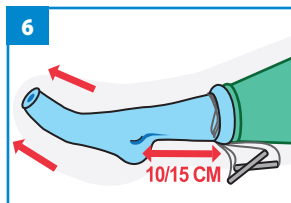
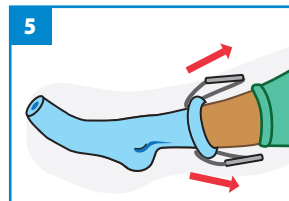
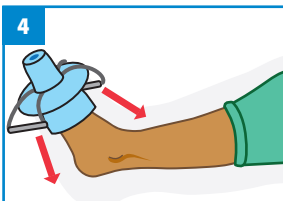
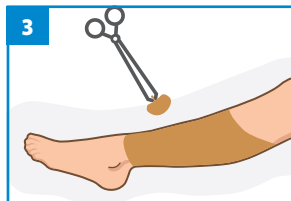
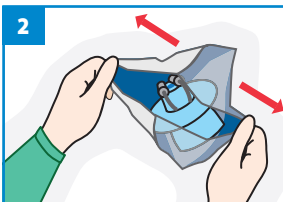
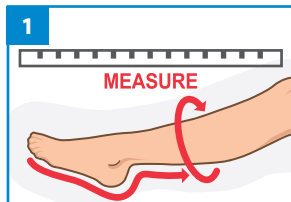
## HemaClear® - LOWER EXTREMITY



## HemaClear® Model F™ for Hand & Wrist Procedures



## HemaClear® Model A™ for Foot & Ankle Procedures



## HemaClear® SELECTION GUIDE

HemaClear® Size	Small	Medium			Large			X-Large
Color	Pink	Green	Red	Yellow	Blue	Orange	Brown	Black & White
Patient's Systolic Blood Pressure Limit	<130 mm Hg	<130 mm Hg	<160 mm Hg	<190 mm Hg	<130 mm Hg	<160 mm Hg	<190 mm Hg	<160 mm Hg
Length	<50 cm	<80 cm			<95 cm	<110 cm		<120 cm
Circumference	14-28 cm	24-40 cm			30-55 cm			50-85 cm

HemaClear® Size	Model F™	Model A™
Color	White	Silver
Systolic Blood Pressure	<160 mm Hg	<160 mm Hg
Distance	<40 cm	<50 cm
Circumference	14-34 cm	22-32 cm

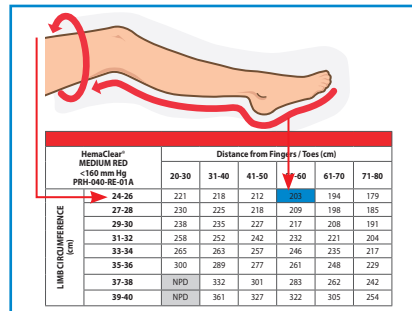


## How to Use the HemaClear® Pressure Tables

- Identify the Model to be used (e.g. **HemaClear®** Extra-Large - Black & White).
- Choose the Table section that matches the Model chosen.
- Measure the distance between the tips of the fingers/toes and the occlusion location.
- Find the column corresponding with the distance.
- Measure the limb circumference at the occlusion location.
- Find the row corresponding with the limb circumference.

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

- Please note that values indicated in the table are within the range of  $\pm 5$  mm Hg
- NPD: Non-Physiological Dimensions



## STORAGE CONDITIONS



Handle with Care



7°-28°C | 45°-83°F



Humidity <60% RH



Latex Free



Single Use



Sterilized by EtO

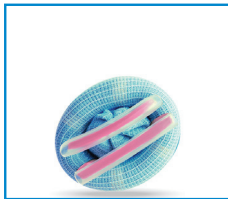
*HemaClear® contains no natural rubber latex.*

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

# HemaClear® SMALL PINK

HemaClear® Skin Pressure, mm Hg

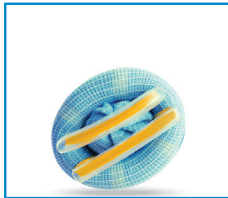
HemaClear® SMALL PINK < 130 mm Hg PRH-028-PI-01A		Distance from Fingers / Toes (cm)							
		10-15	16-20	21-25	26-30	31-35	36-40	41-45	46-50
LIMB CIRCUMFERENCE (cm)	14-16	181	173	168	162	157	151	147	142
	17-18	195	189	184	178	173	169	164	160
	19-20	207	202	197	192	188	184	177	174
	21-22	217	212	207	204	198	194	187	183
	23-24	225	220	216	211	207	202	197	193
	25-26	233	229	224	219	217	209	204	201
	27-28	241	235	230	226	221	216	213	209



# HemaClear® MEDIUM YELLOW

HemaClear® Skin Pressure, mm Hg

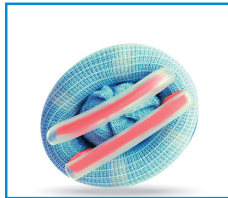
HemaClear® MEDIUM YELLOW <190 mm Hg PRH-040-YE-01A		Distance from Fingers / Toes (cm)					
		20-30	31-40	41-50	51-60	61-70	71-80
LIMB CIRCUMFERENCE (cm)	24-26	231	224	216	208	199	190
	27-28	233	228	222	215	206	196
	29-30	251	242	232	222	214	202
	31-32	270	260	248	236	229	214
	33-34	283	274	265	249	244	226
	35-36	325	304	288	263	259	238
	37-38	NPD	333	314	288	274	249
	39-40	NPD	368	344	339	311	261



# HemaClear® MEDIUM RED

HemaClear® Skin Pressure, mm Hg

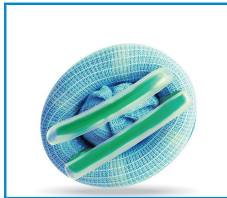
HemaClear® MEDIUM RED							
HemaClear® MEDIUM RED <160 mm Hg PRH-040-RE-01A		Distance from Fingers / Toes (cm)					
		20-30	31-40	41-50	51-60	61-70	71-80
LIMB CIRCUMFERENCE (cm)	24-26	221	218	212	203	194	179
	27-28	230	225	218	209	198	185
	29-30	238	235	227	217	208	191
	31-32	258	252	242	232	221	204
	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



# HemaClear® MEDIUM GREEN

HemaClear® Skin Pressure, mm Hg

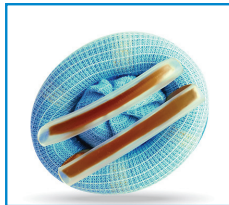
HemaClear® MEDIUM GREEN <130 mm Hg PRH-040-GR-01A		Distance from Fingers / Toes (cm)					
		20-30	31-40	41-50	51-60	61-70	71-80
LIMB CIRCUMFERENCE (cm)	24-26	217	213	203	195	179	162
	27-28	220	217	209	202	187	169
	29-30	232	228	218	210	193	175
	31-32	249	244	233	224	207	188
	33-34	260	253	248	239	221	200
	35-36	287	279	268	253	235	213
	37-38	NPD	324	292	273	238	226
	39-40	NPD	358	318	293	254	239



# HemaClear® LARGE BROWN

HemaClear® Skin Pressure, mm Hg

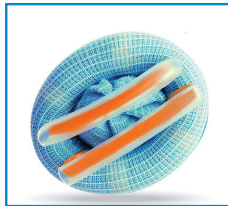
HemaClear® LARGE BROWN <190 mm Hg PRH-060-BR-01A		Distance from Fingers / Toes (cm)						
		40-50	51-60	61-70	71-80	81-90	91-100	101-110
LIMB CIRCUMFERENCE (cm)	30-32	310	301	296	281	276	264	257
	33-36	362	355	346	337	332	320	311
	37-40	387	379	370	363	354	344	337
	41-44	NPD	429	407	389	376	367	363
	45-48	NPD	NPD	436	412	395	389	384
	49-52	NPD	NPD	NPD	425	409	406	400
	53-55	NPD	NPD	NPD	432	422	418	413



# HemaClear® LARGE ORANGE

HemaClear® Skin Pressure, mm Hg

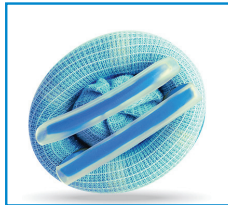
HemaClear® LARGE ORANGE <160 mm Hg PRH-060-OR-01A		Distance from Fingers / Toes (cm)						
		40-50	51-60	61-70	71-80	81-90	91-100	101-110
LIMB CIRCUMFERENCE (cm)	30-32	281	276	264	257	250	236	229
	33-36	341	332	320	311	306	285	281
	37-40	365	355	344	337	326	307	302
	41-44	NPD	423	390	363	346	328	324
	45-48	NPD	NPD	413	372	352	335	324
	49-52	NPD	NPD	NPD	387	357	341	324
	53-55	NPD	NPD	NPD	415	365	349	346



# HemaClear® LARGE BLUE

HemaClear® Skin Pressure, mm Hg

HemaClear® LARGE BLUE <130 mm Hg PRH-060-BL-01A		Distance from Fingers / Toes (cm)					
		40-50	51-60	61-70	71-80	81-90	91-95
LIMB CIRCUMFERENCE (cm)	30-32	264	257	250	236	229	216
	33-36	326	311	306	285	281	261
	37-40	363	342	326	307	302	293
	41-44	NPD	371	348	328	324	324
	45-48	NPD	NPD	357	335	324	326
	49-52	NPD	NPD	NPD	341	329	328
	53-55	NPD	NPD	NPD	347	341	335

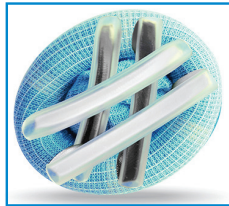




# HemaClear® EXTRA-LARGE BLACK & WHITE

HemaClear® Skin Pressure, mm Hg

HemaClear® EXTRA LARGE BLACK & WHITE <160 mm Hg PRH-090-BW-01A		Distance from Toes (cm)					
		60-70	71-80	81-90	91-100	101-110	111-120
LIMB CIRCUMFERENCE (cm)	50-54	300	296	292	289	285	281
	55-60	315	311	307	304	300	296
	61-66	327	323	320	316	313	310
	67-72	337	333	330	326	323	320
	73-78	345	342	338	335	331	328
	79-85	352	349	346	342	339	336



# HemaClear® Model F™

HemaClear® Skin Pressure, mm Hg

HemaClear® MODEL F™ (Forearm) <160 mm Hg PRH-035-FA-01A		Distance from Fingers (cm)		
		25-30	31-35	36-40
LIMB CIRCUMFERENCE (cm)	14-18	204	197	192
	19-22	236	231	227
	23-26	257	254	247
	27-30	276	270	264
	31-34	295	286	281



# HemaClear® Model A™

HemaClear® Skin Pressure, mm Hg

HemaClear® MODEL A™ (Foot & Ankle) <160 mm Hg PRH-032-MA-01A		Distance from Toes (cm)				
		30-34	35-38	39-42	43-46	47-50
LIMB CIRCUMFERENCE (cm)	22-24	176	167	161	NPD	NPD
	25-26	184	177	170	164	NPD
	27-28	191	184	177	170	165
	29-30	NPD	190	183	177	171
	31-32	NPD	NPD	188	182	176



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 poor peripheral blood flow, edema, or 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 ulnar nerve (at the elbow) or the peroneal nerve (at the proximal tibia).

## DVT Probability: Wells Score System<sup>1</sup>

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	
<b>Clinical probability simplified score</b>		
<i>DVT likely</i>	2 or more	
<i>DVT unlikely</i>	1 or less	

<sup>1</sup>Wells 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**<sup>®</sup> 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**<sup>®</sup> application.
- **HemaClear**<sup>®</sup> only occludes arterial blood flow as long as the patient's systolic blood pressure does not exceed the recommended limit. Please refer to the **Selection Guide** for the specific limit of a patient's systolic blood pressure for each Model.
- **HemaClear**<sup>®</sup> devices can be applied to limbs with a circumference (at the occlusion location) ranging between 14 cm and 85 cm.  
**Do not use HemaClear**<sup>®</sup> if the circumference at the occlusion location is smaller than 14 cm or greater than 85 cm. Please refer to the **Selection Guide** for specific circumference range of each Model.
- If **HemaClear**<sup>®</sup> does not stop the blood flow to a 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. Measure the limb circumference at the occlusion location using the **Measuring Tape** provided, which is color coded according to circumference, in order to select the correct **HemaClear®** Model (Small, Medium, Large, Extra-Large). Verify that the circumference corresponds to the device range according to the **Selection Guide**.
  - For upper extremity procedures, the occlusion location should be 10 cm above the wrist for hand procedures, or mid upper arm (or higher) for forearm, elbow, and distal humerus procedures.
  - For lower extremity procedures, the occlusion location should be 5-15 cm above the lateral malleolus (below the calf muscles) for foot procedures. For ankle, lower leg, knee, or distal femur procedures, **HemaClear®** should be placed on the upper thigh near the groin.
2. Measure the distance from the tips of the fingers/toes to the occlusion location. Verify that the distance does not exceed the device maximal length according to the **Selection Guide**.
3. Verify that the patient's systolic blood pressure does not exceed the limit specified in the **Selection Guide** for the selected **HemaClear®** Model.
4. Refer to the appropriate color coded **Pressure Table** for device pressure at skin level.
5. 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 silicone ring is cut, in keeping with instructions regarding use of the Protective Card.

6. 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.

**UPPER EXTREMITY:** Insert fingertips into the orifice of the device with the handles facing away from the patient (Pg. 4, Fig. 4). Ensure that all fingers are inserted into the circumference of the ring (Pg. 4, Fig. 5). Have an assistant stabilize the hand by holding it from the palm side (Pg. 4, Image top left). Firmly grab the two plastic handles using the colored straps, and pull the handles proximally along the arm to the desired occlusion location (Pg. 4, Fig. 5).

**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. 5, Fig. 4). Stand proximally to the patient's foot, so that 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 for the patient (Pg. 5, 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**<sup>®</sup> 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**<sup>®</sup> reaches the desired occlusion location (Pg. 5, Fig. 5).

**Occlusion locations:** A) On the calf (5-15 cm above the medial malleolus, below the calf muscle) or B) On the thigh (at or above the mid-thigh).

NOTE: **HemaClear**<sup>®</sup> should be placed within the sterile field on the limb over the edge of the sterile drapes.

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

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

9. **Tourniquet Time** begins as soon as the **HemaClear**<sup>®</sup> is in place. Tourniquet Time ends when the **HemaClear**<sup>®</sup> is removed (Pg. 5, Fig. 8).
10. When the procedure is over, insert the **Protective Card** under the ring from its distal side by pulling one of the straps and cut the ring with a scalpel. Use scissors to cut and remove the remaining stockinet. Blood flow to the limb will resume.

## HemaClear® Model F™ for Hand & Wrist Procedures

For **HemaClear® Model F™** please follow the general Directions for Use as specified above, including the following:

1. If the circumference of the forearm at the desired occlusion location is less than 14 cm, use a stockinet to build up the forearm circumference to 14-16 cm. If the circumference at the desired occlusion location is not within the 14-34 cm range, use another appropriate **HemaClear® Model**.
  2. Insert the finger tips into the oval opening of the device application cup with the handles facing away from the patient. Verify that all fingers are inserted. Grab the handles firmly and pull them proximally towards the patient, along the forearm. The device will roll smoothly up the hand and the forearm.
  3. The recommended placement location on the forearm is 10 cm (4") proximal to the wrist.
  4. 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 it is decided to cut the stockinet, apply sterile water or saline, before cutting the stockinet. The surgical site may be covered with a sterile transparent drape if desired.
- NOTE: Wetting the stockinet prior to cutting minimizes the amount of free fabric fragments.

## HemaClear® Model A™ for Foot & Ankle Procedures

For **HemaClear® Model A™** please follow the general Directions for Use as specified above, including the following:

1. The recommended placement location on the lower leg is from 5-15 cm (2-6") above the lateral malleolus.
2. If the circumference at the desired occlusion location is not within 22-32 cm, use another appropriate **HemaClear®** Model.
3. If the patient's foot is larger than 29 cm (shoe size 14 or larger USA, or 47 or larger in Europe) use **HemaClear®** Large (Orange or Brown) at the same lower leg location specified for **Model A™**.
4. Insert the tips of the toes into the oval opening of the device application cup with the handles facing away from the patient. Verify that all toes are inserted. Grab the handles firmly and pull them proximally towards the patient, along the axis of the foot. Use the bottom handle to pull **HemaClear®** over the heel. Roll the device on the lower leg until it reaches the desired occlusion location.
5. The device will not roll beyond 50 cm (20") from the tips of the toes. If a more proximal position is required, use an alternative **HemaClear®** Model (**HemaClear®** Large or **HemaClear®** Extra-Large).
6. The **HemaClear® Model-A™** is constructed with two segments of elastic stockinet.

Once the device reaches the desired 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 it is decided to cut the stockinet, apply sterile water or saline before cutting the stockinet. The surgical site may be covered with a sterile transparent drape if desired.

NOTE: Wetting the stockinet prior to cutting minimizes the amount of free fabric fragments.

# 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](http://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.

THIS WARRANTY APPLIES ONLY TO THE ORIGINAL PURCHASER OF THE PRODUCT. EXCEPT FOR THE LIMITED WARRANTY STATED ABOVE, ALL WARRANTIES, STATUTORY, EXPRESS, OR IMPLIED, WITH RESPECT TO ANY PRODUCT, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE HEREBY DISCLAIMED. THE REMEDIES SET FORTH HEREIN UNDER THE LIMITED LIABILITY SECTION ARE EXCLUSIVE. NO COURSE OF DEALING AND NO

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## LIMITED LIABILITY

Manufacturer's sole obligations and the purchaser's exclusive remedies with respect to goods determined by Manufacturer to be defective, shall be limited to the replacement or refund of the purchase price, at Manufacturer's sole discretion, unless an option to select from such alternatives has been expressly granted to the purchaser (the "Option").

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# END USER LICENSE AGREEMENT

## **Important information - Please read carefully:**

This End User License Agreement ("EULA") is the legal agreement between you and Oneg Hakarmel Ltd. ("OHK") for your use of OHK's proprietary medical device and any applicable documentation or application ("Device" and/or the "Product"), including the package itself. By using the Device, You ("You" shall mean any medical staff or relevant personnel that make use of the Device, or that purchased it for them) acknowledge that You have read this EULA and agree to be bound by its terms and conditions. We recommend that You keep a copy of this license agreement for Your records.

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Subject to Your compliance with the terms and conditions set forth herein, OHK hereby grants You a personal, non-exclusive, non-transferable, non-sublicensable, revocable, limited license to use the Device solely in accordance with this EULA and the user's guide ("User's Guide").

### **Restrictions on Use**

You shall not: (i) copy, modify, translate, reverse engineer, decompile, disassemble, or create derivative works based on the Device; (ii) repurpose the Device in any way or shape or use it more than once; (iii) share or permit any other person to use the Device, rent, lease or transfer distribute, sell it or otherwise take any action herein prohibited or allow or abide others to; (iv) delete or modify any attributions, legal notices or other proprietary designations or labels on the Device. Any such forbidden uses shall immediately and automatically terminate Your license to use the Device, without derogating from any other remedies available to OHK at law or in equity.

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You acknowledge and agree that the Device, including any versions, revisions, corrections, modifications, enhancements, parts and/or upgrades thereto, accompanying materials, and any material such as the package or documents attached to it are owned by OHK, and are protected under Intellectual Property laws such as copyright, trademarks, patents, and



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### **Compliance with Laws & Export Controls**

You undertake to use the Device in accordance with all applicable laws. Without derogating from the foregoing and from any other terms herein, You agree to comply with all applicable export laws (including U.S. export laws) and restrictions and regulations of any relevant agency or authority, and agree that You will not export, allow the export or re-export, or otherwise use the Device in violation of any applicable restrictions, laws or regulations.

### **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.

You acknowledge receiving such instructions, and without derogating from the provisions herein, You agree to be bound by such instructions. If You do not comply with the applicable instructions, then all warranty granted by OHK shall be void, and the You shall bear the full costs of (a) replacing the Device (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 Device, and shall be further required to indemnify OHK for any such claims.

THIS WARRANTY APPLIES ONLY TO YOU. EXCEPT FOR THE LIMITED WARRANTY STATED ABOVE, ALL WARRANTIES, STATUTORY CLAIMS, WHETHER EXPRESSED OR IMPLIED, WITH RESPECT TO ANY DEVICE, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE HEREBY DISCLAIMED. THE REMEDIES SET FORTH HEREIN UNDER THE LIMITED LIABILITY SECTION ARE EXCLUSIVE. NO COURSE OF DEALING AND ANY DEVICE DESCRIPTION OR SPECIFICATION SHALL BE DEEMED A WARRANTY. NO INDIVIDUAL IS AUTHORIZED TO GIVE ANY OTHER WARRANTY ON BEHALF OF OHK.

You may not redistribute the Device, any such redistribution shall annul this warranty and make it void. OHK disclaims any warranty in case of redistribution and/or any use not by You.

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All remedies are expressly conditioned upon Your compliance with the obligations herein, and without limitations, to comply with the provisions of the maintenance and usage instructions for the applicable Device. If You fails to comply with these provisions, You shall bear the full cost of any service, including but not limited to replacement and return, without derogating from any other remedy that OHK may be entitled to herein and/or applicable law, and in such case You shall also bear all the liability for any claims arising from the use of the Device, and indemnify OHK accordingly.

OHK SHALL NOT BE LIABLE TO YOU OR ANY OTHER PERSON FOR ANY INDIRECT, INCIDENTAL, PUNITIVE AND/OR CONSEQUENTIAL DAMAGES WHATSOEVER, INCLUDING BUT NOT LIMITED TO INJURIES (INCLUDING DEATH), LOSS OF PROFITS, EXPENSES, AND/OR DAMAGES ARISING OUT OF BREACH OF THIS WARRANTY BY PURCHASE AND/OR NEGLIGENT USAGE OF THE PRODUCT.

### **Final Agreement**

OHK'S WARRANTY HEREIN IS EXCLUSIVE, AND SETS FORTH ALL OF OHK'S RESPONSIBILITIES WITH REGARD TO THE PRODUCT. OHK DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED.

This warranty is the complete, final and exclusive agreement between OHK and You with respect to the Device and any and all warranties and representations. The laws of the state of Delaware shall govern this limited warranty, without reference to its conflicts of law provisions. The competent courts of Delaware shall have sole and exclusive jurisdiction over any matter arising hereof.

# HemaClear® Placement

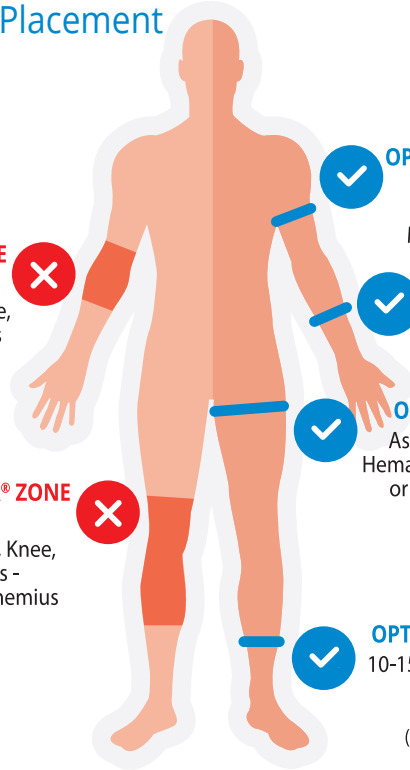
## NO-HEMACLEAR® ZONE ARM

Ulnar Nerve, Radial Nerve,  
Elbow, Forearm Muscles



## NO-HEMACLEAR® ZONE LEG

Peroneal Nerve, Knee,  
Calf Muscles -  
Soleus/Gastrocnemius



## OPTIMAL POSITION - UPPER ARM

Bottom of Deltoid Muscle  
HemaClear®  
Medium Yellow or Large Orange



## OPTIMAL POSITION - FOREARM

10 cm Above the Wrist  
Distal to Forearm Muscles  
HemaClear® Model F™



## OPTIMAL POSITION - THIGH

As Close to the Groin as Possible  
HemaClear® Extra-Large Black & White  
or Large Orange or Large Brown



## OPTIMAL POSITION - LOWER LEG

10-15 cm Above the Lateral Malleolus  
HemaClear® Model A™  
or Large Orange  
(patient shoe size ≥ US14 / EU27)





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