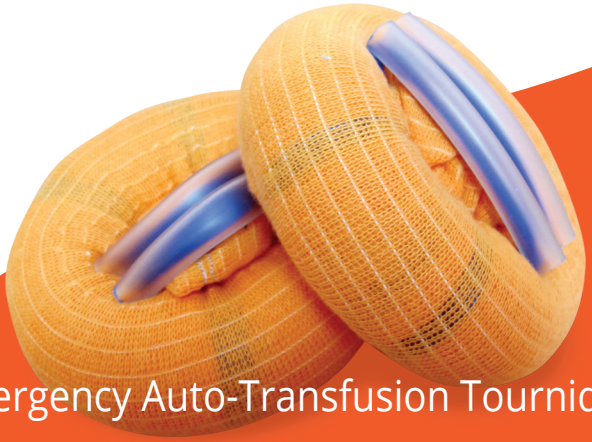
HemaShock®

Emergency Auto Transfusion



Emergency Auto-Transfusion Tourniquet

User Guide

www.HemaShock.com

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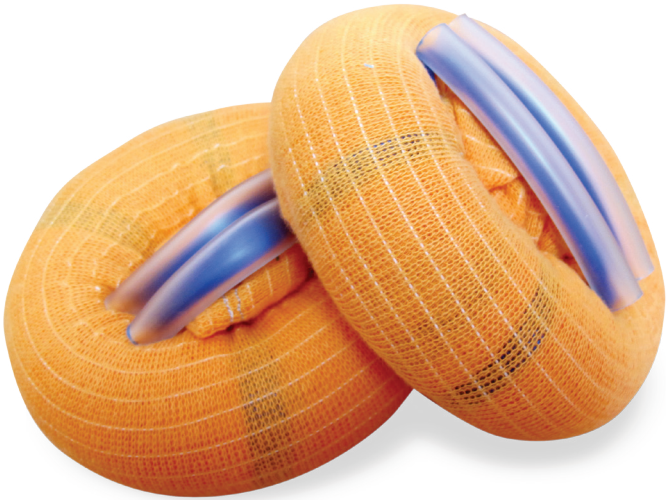
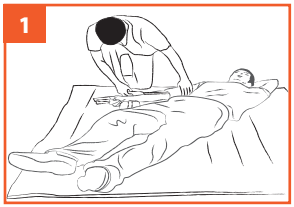
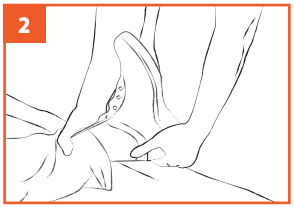


Emergency Auto-Transfusion Tourniquet (HemaShock®)
Product Includes Labeling Sticker

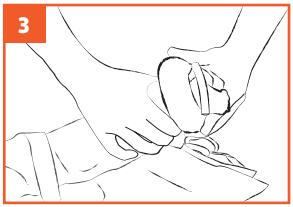
Instructions for **HemaShock®** Application



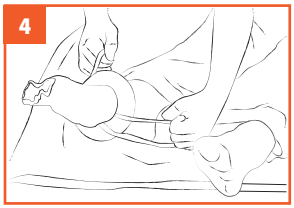
Assess patient status.



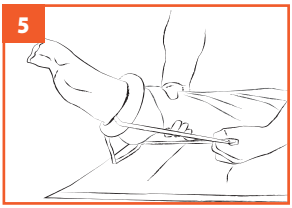
Remove patient's shoes.

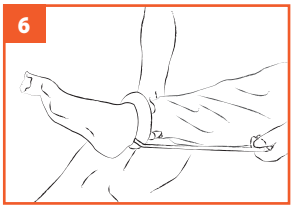


Place **HemaShock®** on **all toes**, handles facing away from patient.



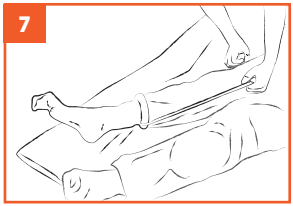
Use the handle facing the bottom of the foot to pull **HemaShock®** over the heel.



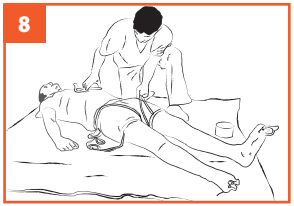


Pull both handles in parallel to limb.

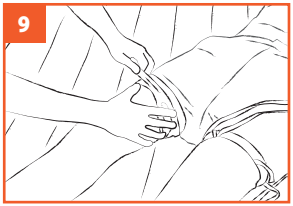
Instructions for **HemaShock**® Application Cont'd.



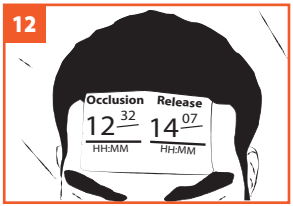
Pull **HemaShock**® up one leg.
If indicated, apply a second **HemaShock**®.



HemaShock® is on both legs.

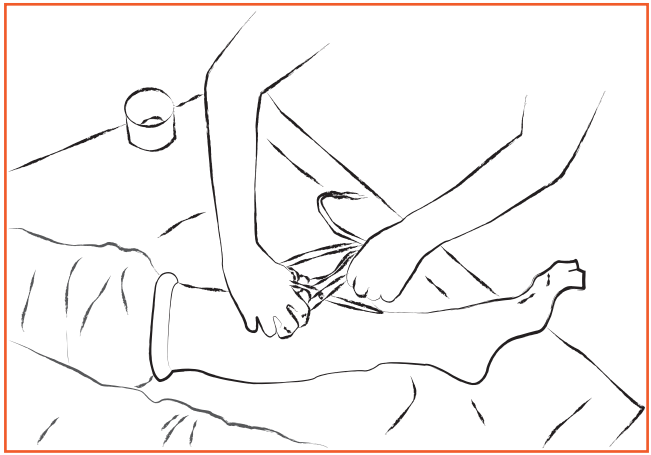


Secure straps.
Do not cut the straps, since they may be needed later.



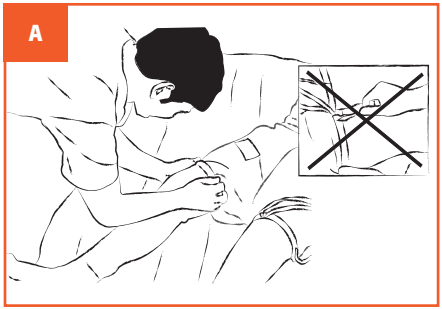
Clearly record the time of **HemaShock**® placement and when it should be removed.
If placed on the legs at different times, record each placement time separately.

Instructions for **HemaShock**® Application Cont'd.



Once **HemaShock**® is on the patient, the sleeve can be perforated or cut to examine and treat injuries. Occlusion (tourniquet) is created only by the ring.

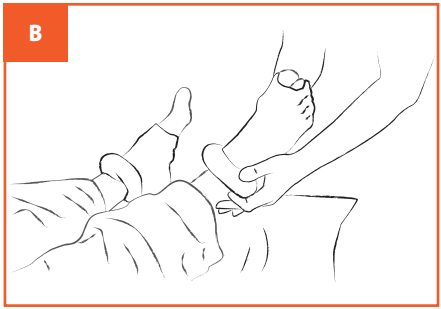
Instructions for **HemaShock**® Removal



Roll down to knee.
Assess hemodynamic parameters.

Roll down to mid-calf.
Assess hemodynamic parameters.

Roll down to ankle.
Assess hemodynamic parameters.



Remove carefully by pulling over the heel.

DO NOT CUT RING.

ONLY REMOVE **HemaShock**® AT DEFINITIVE CARE,
UNDER CONTROLLED CLINICAL SUPERVISION.

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

Intended Use

HemaShock® is indicated for shifting blood from the limbs to central circulation and blocking its reentry in patients who need it.

Contraindications

Do not use **HemaShock®** on patients with Deep Vein Thrombosis (DVT).

HemaShock® Introduction

Device Description

HemaShock® by Oneg HaKarmel Ltd. (OHK) is comprised of an elastic ring wrapped by a stockinet; when applied, **HemaShock®** rolls up a patient's limb to squeeze blood out of it into the central circulation and acts as a tourniquet to completely block blood return to the limb. **HemaShock®** induces auto-transfusion: displacement of 500ml of fresh blood from each leg into the patients' core. In parallel, limb perfusion is blocked and demand of the limited cardiac output is decreased.

HemaShock® is simple, self-contained, applied within ~30 seconds by a single health-care provider in the field or during transport.

HemaShock® is used alongside other resuscitation protocols and does not delay transport.

Safety

- **Do not leave the HemaShock® on a limb for over 2 hours**.
- Single patient use. Do not attempt to reuse to avoid product malfunction and risk of cross-contamination.
- Remove grandually.

HemaShock® Instructions for Use

Application

1. Assess patient status. Determine if **HemaShock®** is indicated.
2. Remove patient's shoes.
3. Place **HemaShock®** over the toes, directing the handles to face away from patient. Make sure to include all toes.
4. Place handles towards knee and thigh, pull both handles in parallel to the limb axes and roll the **HemaShock®** to mid or upper thigh.
   Note: Pulling is easier than pushing.
5. Wrap straps around the thigh to Secure **HemaShock®** in place. Do not cut straps as it might be needed to adjust **HemaShock®** height or for removal.
6. Clearly and visibly record time of **HemaShock®** placement on the labeling sticker. Clearly and visibly record the time of mandatory removal.
   *Note: Forehead sticker prevents overlooking **HemaShock®** during transport.*

HemaShock® Instructions for Use Cont'd.

Removal

ONLY REMOVE HemaShock® STEPWISE, ONCE THE PATIENT IS IN DEFINITIVE CARE AND WHILE MONITORING HEMODYNAMIC PARAMETERS!

Always remove **HemaShock®** gradually. **Never cut the ring**. remove each **HemaShock®** separately.

1. Assess patients' condition. If blood pressure is >100mmHg, consider removing **HemaShock®**.
2. Roll **HemaShock®** gradually down one leg up to knee level, by using the palms of your hands.
3. Assess patient. If hemodynamically stable, roll down **HemaShock®** up to mid-calf.
4. Assess patient. If hemodynamically stable, roll down to ankle level.
5. Assess patient. If hemodynamically stable, remove **HemaShock®** carefully by pulling it over the heel.
6. Repeat removal with second **HemaShock®**.
7. Record time of **HemaShock®** removal.

⚠ Warnings

- **HemaShock®** is to be used by or on the order of a physician.
- The time of applying **HemaShock®** on each limb must be marked clearly and visibly.
- The time when **HemaShock®** removal should commence must be marked clearly and visibly on each limb.
- **HemaShock®** is not sterile. Do not use in sterile field, or directly on an open wound. If there is an open wound in limb, cover with a sterile dressing prior to use.
- When applying on an unstable limb due to fracture or dislocation, apply axial traction while applying.
- Do not apply **HemaShock®** on a limb that has deep vein thrombosis (DVT). Application may dislodge a thrombus that will move to the pulmonary circulation causing severe pulmonary embolism. Signs of DVT: Unilateral swollen, discolored, edematous and tender limb.
- **HemaShock®** is not indicated for a patient in whom blood volume expansion is not recommended (e.g. pulmonary edema, cardiogenic shock). It should be used cautiously in such cases.
- Applying **HemaShock®** to an awake and conscious patient is not needed.

- Do not leave **HemaShock®** on a limb for more than 120 minutes. Ischemic injury to nerves and muscles may result.
- Do not cut the ring to remove **HemaShock®**. It should be removed stepwise and gradually. Patient's blood pressure should be measured at each step while taking measures to ensure hemodynamic stability. Removal should be done in a medically controlled environment and under the supervision of a physician to avoid inadvertent hemodynamic collapse of the patient.
- If the patient's systolic blood pressure exceeds 130 mmHg, blood may escape under the ring and it will become a venous occlude. **HemaShock®** should be lowered if the patient's blood pressure rises above 110 mmHg and is hemodynamically stable.
- The **HemaShock®** ring will occlude arterial blood flow even on the ankle, if the patient's blood pressure is low.

⚠ Adverse Effects

1. Temporary discoloration of the skin beneath the **HemaShock®** ring (<24 hours).
2. Residual pain at the occlusion location (may last up to 7 days, rare).

General Information

STORAGE CONDITIONS


Handle with Care


0°-45°C | 32°-113°F


Humidity <15-90% RH

Latex Free


Single Use

PACKAGE CONTENT

Each package contains two devices and a labeling sticker to indicate occlusion and removal time.

REGULATORY CLASSIFICATION CE FDA LISTED

HemaShock® contains no natural rubber latex.
HemaShock® may be disposed of in accordance with Biological and Medical Waste Disposal procedures.

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.

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

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LIMITED LIABILITY

Manufacture'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").

MANUFACTURER SHALL NOT BE LIABLE TO PURCHASER 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 PURCHASER AND/OR NEGLIGENT USAGE OF THE PRODUCT.

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

FINAL AGREEMENT

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This warranty is the complete, final and exclusive agreement between Manufacturer and the purchaser with respect to the Product and any and all warranties and representations. The laws of the State of Israel shall govern this Limited Warranty, without reference to its conflicts of law provisions. The competent Courts of Haifa, Israel shall have sole and exclusive jurisdiction over any matter arising hereof and/or relating to the use of the Product.

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").

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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.

Title and Ownership

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 treaties. You further acknowledge and agree that all right, title, and interest in and to the Device, including associated

intellectual property rights (including, without limitation, any patents- registered or pending, copyrights, trade secrets, trademarks, etc.), evidenced by or embodied in and/or attached/connected/related to the Device, are and shall remain owned solely by OHK. This EULA does not convey to You any interest in or to the Device, but only a limited, revocable right of use in accordance with the terms of this EULA and the User's Guide. Nothing in this EULA constitutes a waiver of OHK's intellectual property rights under any law.

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 Israeli and 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.

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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.

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HemaShock®
Emergency Auto Transfusion

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