

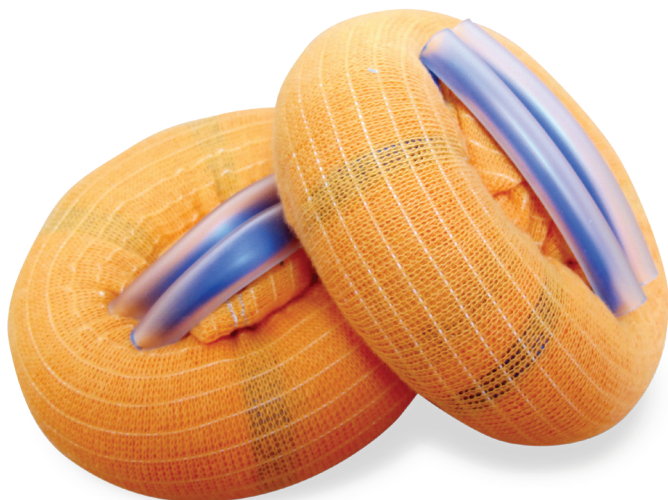
Emergency Auto-Transfusion Tourniquet

User Guide

www.HemaShock.com

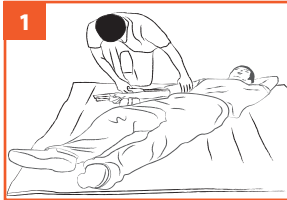
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Emergency Auto-Transfusion Tourniquet (HemaShock®)
Product Includes Labeling Sticker

Instructions for HemaShock® Application



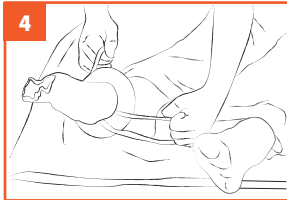
1 Assess patient status.



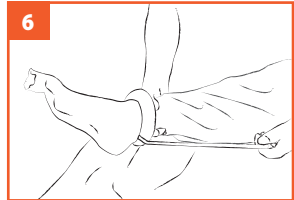
2 Remove patient's shoes.



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



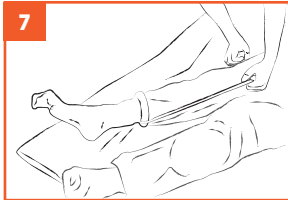
4 Use the handle facing the bottom of the foot to pull **HemaShock®** over the heel.



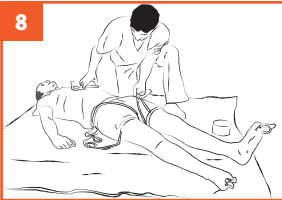
5 Pull both handles in parallel to limb.

6 Pull both handles in parallel to limb.

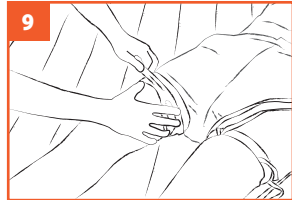
Instructions for HemaShock® Application Cont'd.



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



8 **HemaShock®** is on both legs.



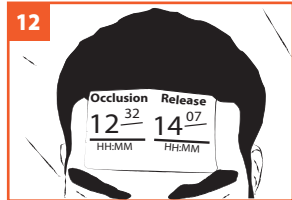
9 Secure straps.
Do not cut the straps, since
they may be needed later.



10



11



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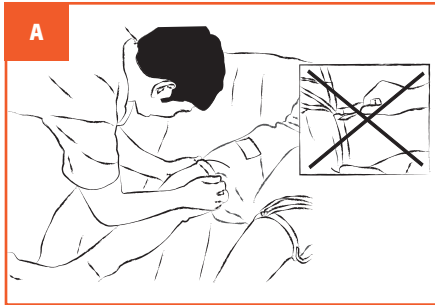
Clearly record the time of **HemaShock®** placement and when it should be removed.
If placed on the legs at different times, record each placement time separately.

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.

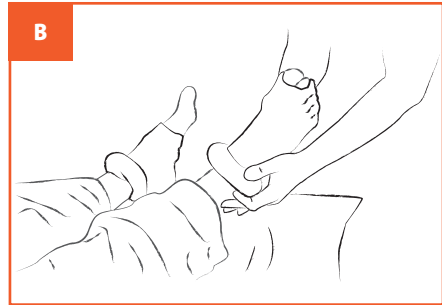
Instructions for HemaShock® Removal



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 gradually.

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



PACKAGE CONTENT

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

REGULATORY CLASSIFICATION FDA LISTED

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PROTECTED BY US AND INTERNATIONAL PATENTS

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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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.

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