



Next-Generation Limb Support

www.orthoflex.net

ORTHO-FLEX LTD., 12/8 Lincoln St. Haifa, Israel, 34369

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ORTHOFLEX WARRANTY

1. Subject to the terms and conditions stated herein, the manufacturer warrants to the Original Purchaser that under the conditions of normal use and service, Orthoflex splints – OF1 and OF2 and their accessories, will be free from defects in material, workmanship and manufacturing defects. for the lifetime of the product:

In the event that the Original Purchaser experiences a problem with respect to any of the defects set forth in Section 1 above, a new replacement will be provided upon receipt of the original splint and validation of the complaint. The manufacturer reserves the right to require return of the defective splint or accessory(s). This Warranty will be limited to one (1) year start at the date of your purchase.

2. The warranties described above cover only manufacturing defects and do not include defects or damages caused by, or as the result of, any of the following circumstances:
 - a) Improper use of the product or products by the Original Purchaser, his agents, assignees or invitees.
 - b) The improper application or use of the product.
 - c) The occurrence of damage due to the equipment being dropped, intentional abuse, water or fire damage, electricity surges, other external forces or use with equipment not supplied or specified by Orthoflex according to the written instructions in the brochure / manual which is a part of the splint package.
 - d) Any modification or alteration to the product.
 - e) The failure to perform reasonable and necessary maintenance on the product or products.
 - f) The neglect, abuse, improper handling and/or improper storage of the product.
 - g) Exposure of the product to excessive heat and/or cold beyond naturally occurring conditions.
 - h) The application of harmful cleaning solutions or products including, but not limited to, acetone, petroleum products, acids or abrasive compounds.
 - i) The improper removal of any permanent warning or identification labels from the product or products.
 - j) Any inappropriate or unintended use or uses of the product or products.
3. The warranty set forth above is expressly in lieu of all other expressed warranties and of all other obligations or liabilities on the manufacturer's part. The manufacturer neither assumes, nor authorizes any other person to assume for the manufacturer, another liability in connection with the sale of the product. The warranties as described herein are the exclusive remedies for breach. There are no warranties that extend beyond the description on the face of this document.

The manufacturer makes no warranty whatsoever with respect to accessories or parts not supplied by the manufacturer.
4. The warranty cover defects in material, workmanship and manufacturing defect only. The manufacturer's obligation under the warranty is expressly limited to replace of any defective part or component. The manufacturer reserves the right to discontinue the model, models or parts manufactured under this warranty. Any discontinued parts or components may be replaced with an equivalent part at the sole discretion of the manufacturer. The manufacturer is not responsible for any color variation in the replacement part or component. The manufacturer reserves the right to inspect any and all defects in the field.
5. Under no circumstances the manufacturer is not liable for consequential medical damages including, but not limited to, physiological or skin damages.
6. **ELIGIBILITY REQUIREMENTS:** Enforceability of the warranty set forth above is limited to the original individual purchaser.

Any inquiry with respect to the product must be made in writing and include the original purchaser's name, address, telephone numbers, date of purchase, invoice copy , picture of the damaged product , and product information from the product label.

All claims and/or inquiries should be forwarded to the following address: Orthoflex Ltd., 12/8 Lincoln St., Haifa 34369, Israel .Tel: + 972-4-8388778

NON-TRANSFERABILITY: The warranty described above is non-transferable and limited to the Original Individual Purchaser. .

Instructions for use:

- Use of the splint must be according to the instructions given by the treating physician.
- Do not open the packaging with a sharp tool.
- Spread the splint on a flat surface.
- Inflate to full stiffness through the one-way valve by using the pump or other devices. The recommended pressure is 200mm. Hg.
- Increase or decrease inflation according to the degree of stiffness/elasticity required.
- Do not inflate the splint by a compressed air system without using a measuring air pressure control device.
- To protect the skin, cover the limb with a stockinet stocking or upholster the splint with padding; any lesion of the skin must be dressed prior to the application of the splint.
- We do not recommend applying the splint directly to the bare skin.
- Adjust the length of the straps according to the girth of the limb. Now fasten them firmly but comfortably.
- Optional: To restrain movement at the ankle tighten the two oblique side straps attached to the foot piece.
- Optional: To control limb rotation connect the stabilizer to the splint.
- Prior to applying the splint all skin wounds or lesions should be dressed.
- The splint can be washed with water, soap, and the usual antiseptics in use in medical institutions. The wearing of gloves is recommended.
- Do not wash with thinner.
- Allows disinfection with usual disinfection materials such as Chlorehexidine solution.
- Do not wash with alcohol stronger than 70%.
- Do not launder in a washing machine.
- Sterilize the splint by gas when necessary.
- Do not puncture the splint.
- Store at temperatures below 50 degrees Celsius.
- Maximum inflation pressure is 250mm Hg.
- Shelf life 2.0 years before use (when stored as instructed above).
- The splint is intended for personal use.

Warning!

The company takes no responsibility if the splint is not used according to the instructions for use, given above.

Schedules:

Technical Characteristics

1. Material: Woven Nylon covered by polyurethane
2. Air pressure is according to the stiffness required by the treating physician. Commonly used pressures are 200-230 mm. Hg (0.25-0.3 Bar)
3. Loss of air pressure rate is 0-1% per 24 hours.
4. Maximum pressure recommended—250 mmHg (0.33 Bar).
5. Pressure leak is pre-tested at 350 mmHg (0.5 Bar).
6. Temperature range: -15C – +60C.
7. Suited to body surface contact according to international standards.
8. Laundering: use of soaps and antiseptic soap solutions such as chlohexidine scrub. **Do not** use washing machine.
9. Imaging transparency for radiographs, computer tomograms and magnetic resonance imaging.

The cushion: designed to fully protect the heel and foot borders from pressure: at 60 grams per square cm pressure the spongy material loses 10% of its thickness.

10. Strap buckles withstand up to 15 kg of stretch
11. The strap-splint sutures withstand more than 20 kg tension without any material tear.
12. The cloth on the outside of the inner padding cleaves with the Velcro strips inside the splint. It can be removed easily, if necessary.
13. All Velcro strips of the inside the splint, designed to attach to the inner padding, are sewed with double stitch.
14. The pump supplied with the splint builds pressure of approximately 250 mmHg inside the splint, in approximately 60 seconds of pumping.
15. The stabilizer attached to the splint, (found in the pocket in the lower aspect of the sole plate), enables rotational stabilization of the leg when required.
16. The Velcro surfaces on the sole and behind the heel possess a strong snap fit, for the firm attachment of the limb axis stabilizer.

Quality control

Visual check for all splints: This test involves the integrity of sewing integrity and the integrity of the connectors and how they have been installed, and the final stitches of splint fabric, the integrity of the inner padding, etc.

The test includes checking for air leakage at 0.5 bar working pressure, the durability of the connectors, the straps and sewing stitch by force of 15 kg.

Storage instructions:

Long term storage temperatures inside the closed plastic bag packaging: -20°C – +60°C

Storage temperatures for a short time, about 24 hours, in a closed plastic bag packaging, inside a package: -35°C – +65°C