USER INSTRUCTIONS

HALLUXSAN®

HALLUX VALGUS BRACE

albrecht©
FUNKTIONELLE REHABILITATION

Contents

1. Introduction

1.1. Foreword

Hallux valgus is the medical term for a deformity where the big toe sits at an angle to the second toe.

The ball of the big toe ball protrudes, often becoming the site of painful inflammation. Dynamic tension applied in the opposite direction countervails this development. Pain is alleviated.

The halluxsan brace can be used in both conservative and post-operative treatment.

The halluxsan® brace should be worn without shoes for several hours while resting or at night.

1.2. Customer information

For your own safety please read through these User Instructions carefully and accurately before using the brace. The instructions, notes and procedures must be read and understood thoroughly in order to benefit from the correct operation and use of the device. If anything in the User Instructions is not clear, or any instructions, operating procedures or safety information is not fully understandable, please contact the appropriate specialist retailer or albrecht GmbH directly, before you use the brace. This particularly applies to the safety instructions.

1.3. Mode of operation

The halluxsan® functions according to the CDS®-principle and has been designed to treat hallux valgus (bunion). The brace applies a dynamic low load prolonged stretch to stimulate growth in the contracted tissue and reduce pain. **The adjustable redression range protects the tissue of painful overstretching.**

1.4. Application

The brace must only be used for the orthotic treatment of the hallux valgus.

Conservative treatment:

- Moderate hallux valgus with a mild to moderate deformity (deviation of the toe).
- Onset of pain at the base joint of the big toe with irritation of the bursa (apply ice pack before treatment).
- Relapse after surgery (if the toe starts to force itself outwards again).
- Preventive treatment if there is a family predisposition to hallux valgus.
- Swelling of the bursa.

Pre-operative use in surgery preparation.

Post-operative treatment:

- Use only when the wound has stabilized and once the stitches have been removed.
- The brace should not cause any pressure points or severe pain.

1.5. Scope of delivery

The halluxsan® brace is supplied to you ready for use with the appropriate product labeling, for the side of the foot you ordered, together with user instructions. It is packed in a protective carton.

Please check the contents for completeness.

1.6. Declaration of conformity

The albrecht GmbH company, as the manufacturer solely responsible, declares that the halluxsan® brace conforms to the Regulation (EU) 2017/745 concerning medical devices.

1.7. Features

- Therapy in the physiological position of the big toe
- Pain reduction
- Individual adjustment of the tension spring without tools
- Individual adjustment of the straps
- Easy handling and high wearing comfort
- Available in four colours

1.8. Indications

The physician will prescribe the fitting based on his or her diagnostic findings.

Generally, the use is indicated in:

- Conservative treatment of moderate cases of hallux valgus as well as preventive treatment
- Pre-surgical treatment in order to prepare the soft tissue for surgery
- Post-surgical treatment in order to stabilize the surgery result

The brace **MUST NOT** be worn in the event of soft tissue problems, problems with wound healing, infections, etc. The doctor should be consulted for any indications not listed above.

For all other indications a physician must be consulted.

1.9. Contraindications

The brace is only intended for use in contact with intact skin.

1.10. Safety Instructions

The optimal effect of the brace is only achieved when used correctly.

- The brace must only be used in the intact, complete and mechanically undamaged condition and with complete and intact cushioning and walers. This must be verified by the user before each usage.
- Opening or removing one or more belts, as well as excessive loosening of the waler when using the brace leads to a reduction of the therapeutic effect of the brace and may lead to injury.
- The brace must not be worn over open wounds.
- The skin should be free of oils, grease, gels or other debris, to prevent reactions with the skin or the structure of the material.
- The orthosis should fit firmly but not too tight, so as not to restrict the blood circulation and adversely affect nerve and lymph vessels. Excessive compression is therefore to be avoided.
- Combination with other products is currently not provided for or is to be agreed with the manufacturer in writing.
- The brace is not intended for single use, but is intended for multiple use by a single person.
- The product as delivered is not sterile.
- Contact your physician immediately in the event of an allergic reaction.
- Please note that cushioned sections can heat up under direct sunlight. Protect the orthosis from direct sunlight if necessary.
- Currently there is no test for flammability. Exercise caution when using the orthosis in the direct vicinity of open flames such as lighters and cigarettes.

1.11. Warranty

We assume the warranty for the brace for a period of 3 months. The brace is a medical rehabilitation device and must not be used for any purpose other than the intended, as described in the User Instructions. Changes to the brace or other applications require the written consent of the albrecht GMBH. If this is not obtained, the manufacturer may not honor the guarantee. If you are using single joints or other components, these should be used as intended. If changes or modifications (e.g. additional mounting holes) are made to the individual parts or components, the manufacturer's warranty no longer applies. The removal of or damage to the QM seal will also void the warranty.

1.12. Transfer of the brace

The brace is not intended for single use, but rather is intended for multiple use by a single person. We do not recommend transfer to other users. Should this be desired however, please ensure to pass on the care and cleaning instructions and have the brace checked by an authorized specialist dealer for safe and proper operation.

1.13. Disposal

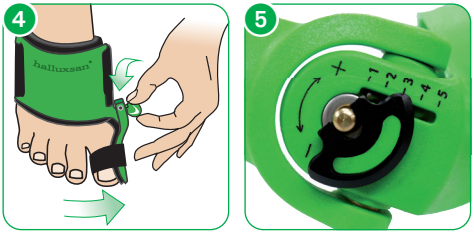
The brace contains recyclable materials without toxic or other harmful substances or other environmentally hazardous substances. Provided it is not contaminated with infectious germs, the brace can be deposited in the normal waste disposal. To be sure, consult your specialist orthopaedics dealer.

2. Individual adjustments

The footpiece and the toe support can be individually adjusted by a specialist, by way of thermoplastic forming.

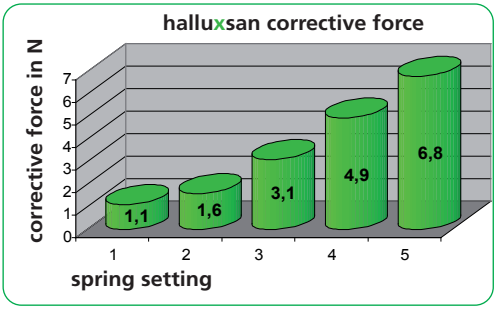
1. Attach the halluxsan® brace with its footpiece and its toe support (Fig.1) to your foot. Please take care, that the joint axis of the brace lies behind the hallux metacarpophalangeal joint. Pressure must not be exerted on the ball of the foot.
2. Adjust the length of the foot strap (Fig.2)
3. and the length of the toe strap (Fig.3).
   Ensure correct and painfree positioning.
   When attaching and taking off the brace, the straps do not have to be pulled out of their lugs, in order to obtain the intended belt guide (direction of tension).

4. The corrective force applied is increased by turning the tension ring towards +.
   The corrective force applied is reduced by turning the tension ring towards -.
5. The scale from 1 to 5 shows the corrective force set.



The brace should only be attached or taken off when it is in an untensioned condition.

The adjustment of spring tension may only be carried out after consulting the attending physician.



Hand wash at 30°C

Do not bleach

Do not iron

Do not dry-clean

Do not tumble dry

3. Cleaning, maintenance and disinfection

The orthosis is designed to be maintenance-free. To ensure proper operation over the period of treatment the orthosis should be cleaned regularly (at least every 3 months) or as required, according to the following instructions.

3.1. Care

- The product as delivered is not sterile and is not suitable for sterilization.
- Do not use harsh or abrasive cleaners.
- All fabrics can be washed by hand at 30°C using water and a mild detergent and/or disinfectant.
- Not machine washable.
- The halluxsan® can be dried in the open air.
- In the case of more severe soiling, a replacement set of textile parts is available.
- Wipe down surfaces with a cloth soaked with disinfectant.
- Wet completely, and do not wipe off.
- Spray inaccessible surfaces.
- When spraying ensure complete wetting.
- A mild alcohol-based disinfectant is recommended.

Ask your physician or pharmacist when selecting a disinfectant, and follow the instructions given by the disinfectant manufacturer. The Robert Koch list of approved disinfectants can be found at http://www.rki.de.

4. Technical data

Description	Material
toe strap	PA velour
shell strap	48% PA, 43% PES, 9% elastothane
padding	PU foam material

5. Size chart and article numbers

Art.-No.: left foot	Art.-No.: right foot	Colour
940A-L	940A-R	green
940AS-L	940AS-R	black
940AP-L	940AP-R	pink
940AG-L	940AG-R	grey

Optionally available in pairs: suitable socks in black	
EU shoe size	Art.-No.: Sock for right and and left foot
35 - 38	70001
39 - 42	70002
43 - 46	70003

6. Choice of size

The halluxsan® brace is available in a single size for either the right or the left foot as shown in the table below.

Duty to report

Due to regional legal regulations, you are required to immediately report any serious incident involving the use of this medical device to the manufacturer and the responsible authorities. Please find our contact details on the back of this brochure.

PATENTS: DE 10 2008 049 854

VERSION: EN 12.2022

MD

Medical device

Manufacturer

albrecht GmbH
CHIEMSEESTRASSE 81
D-83233 BERNAU AM CHIEMSEE
T +49 (0)8051 96129-0
F +49 (0)8051 96129-30

INFO@ALBRECHTGMBH.COM
WWW.ALBRECHTGMBH.COM

Made in Germany
Hergestellt in Deutschland

TÜVRheinland ZERTIFIZIERT
Management System EN ISO 13485:2016
www.tuv.com ID 0000046096