

# Insoles

Custom fabrication

Instructions for use (patient)



# Table of Contents

- 1 Foreword ..... 3**
- 2 Product description ..... 3**
- 3 Safety ..... 3**
  - 3.1 Explanation of warning symbols .....3**
  - 3.2 General safety instructions .....3**
- 4 Areas of Application and Usage Restrictions ..... 4**
- 5 Handling ..... 4**
  - Sensomotoric insoles .....5
  - 5.1 Inserting the insoles .....5**
  - 5.2 Putting shoes on and taking them off .....6**
    - Putting on .....6
    - Taking off .....6
  - 5.3 Selecting shoes .....6**
    - General requirements .....6
    - Special requirements .....6
- 6 Cleaning ..... 6**
- 7 Disposal ..... 7**
- 8 CE Conformity ..... 7**
  - 9.1 Information on your device .....8**
- The service life of your device shall be reviewed at your review appointments. ....8

# 1 Foreword

## INFORMATION

Last update: 17-05-2021

- ← Please read this document carefully before using the product.
- ← Follow the safety instructions to avoid injuries and damage to the product.
- ← Have yourself instructed by qualified personnel in the proper and safe use of the product.
- ← Please keep this document in a safe place.

This document contains important information on the handling of the customised orthopaedic device that Ottobock has fabricated for you. If you have any questions or problems, please consult your certified orthotist.

## 2 Product description

You have received customised insoles from Ottobock. The insoles were custom made for you to make it easier to stand and walk or to meet other medical requirements. Each insole forms a functional unit with the shoe it is worn in. The type of insole used depends on the indication.

## 3 Safety

### 3.1 Explanation of warning symbols



Warning regarding possible risks of accident or injury.

### 3.2 General safety instructions



Non-compliance with general safety instructions

Risk of injury and risk of product damage

- The device may be used only by the person it was made for.
- Use the device only for the indication described with the stated restrictions.
- Observe the instructions for the indication and use of the device.
- Check the device for damage if it has been subjected to excessive wear or exposed to impermissible environmental conditions.
- Do not continue to use a damaged device and contact your certified orthotist.
- Keep the device away from open flames, embers and other sources of heat.
- Check the areas of skin that come into contact with the device before every use.
- Use the device only on healthy skin.
- Observe the instructions for cleaning and care.
- Observe the inspection intervals (see page 7).

## 4 Areas of Application and Usage Restrictions

Your orthosis is an orthopaedic appliance that makes it possible or easier for you to stand and walk, or fulfils other specific requirements relevant to your condition. The Ottobock team adapted the orthosis to the loads expected at the time of fitting. If your activity level increases in the course of use, adjustments may be required. Changes will also have to be made if your physical condition worsens and more support from the orthosis is needed.

Please consult your doctor regarding the daily duration of use and potential therapeutic measures (e.g. occupational therapy or physical therapy) to improve your performance. First-time users in particular are at first unaccustomed to wearing an orthosis and have to learn how to handle their orthosis. Applying and removing, sitting, standing and walking must be practised. Ways to handle a potential fall must also be explained. Your doctor, physiotherapist or orthotist can provide you with additional advice on orthosis training.

In general, you should not experience too much discomfort when wearing your orthosis. Excessive pressure can cause complications, e.g. pressure sores or joint problems. If you have any questions or concerns about your orthosis, please do not hesitate to contact your orthotist.

Your insoles are orthopaedic devices for use in suitable shoes.

- Your insoles have special requirements for the shoes worn with them (see page 5). Observe these requirements every time you buy new shoes. Contact your certified orthotist for support when you buy shoes in a new size.
- The capacity to withstand loads was coordinated to the expected load at the time of fitting. Excessive loading can lead to material fatigue or destruction of the device.
- Use the device in water only if it is intended for such use.
- Do not expose the device to temperatures above **50 °C**.
- Do not allow the device to come into contact with agents, ointments or lotions containing oil or fat, harsh cleaning agents or solvents.

## 5 Handling

- Discuss the daily duration of use of the device with your doctor.
- The effect of the device can be supported with physiotherapy. Discuss which exercises can be useful for you with your doctor or physiotherapist.
- Let persistent pressure points be checked by your certified orthotist.
- If you have impaired sensation in your feet, check your feet several times a day for changes in the skin to prevent pressure points. A mirror can facilitate this check.
- Contact your certified orthotist if you have any allergic reactions to the material of the device.
- Do not allow the device to come into contact with injured skin.

### Breaking in your insoles

You need to break in your insoles gradually by building up on wear time, from 30 mins on day one, and increasing by 30 mins a day over a two week period.

It could take up to one month to get used to your new insoles.

## **Sensomotoric insoles**

The following information is relevant only if you have received sensomotoric insoles from Ottobock. Sensomotoric insoles affect muscle tone and coordination by providing specific sensory information. This can reduce or correct posture and balance problems and less than optimal movement patterns. Due to the unaccustomed surface of the insole, it may take 3 to 5 days to get used to sensomotoric insoles. If you feel that the insoles are still uncomfortable after this time, please contact your certified orthotist to make additional fine adjustments.

### **5.1 Inserting the insoles**

1. Remove the inner soles of your shoes before using the insoles for the first time.
2. Remove any foot supports that may be glued in before using the insoles for the first time. The foot supports would prevent correct placement of the insoles.
3. Insert the insoles in your shoes as marked (L=left, R=right). The heel shells of the insoles must be placed up against the back of the heel.

## 5.2 Putting shoes on and taking them off

### Putting on

1. Open the shoes far enough that you can put them on easily without curling up your toes.
2. Put the shoes on.
3. Close your shoes so they fit snugly without exerting pressure on your feet.

### Taking off

1. Open your shoes far enough that you can take them off easily and take them off.
2. Remove the insoles from the shoes and follow the directions for cleaning and care (see page 5).
3. Check your feet for pressure points or other injuries.

## 5.3 Selecting shoes

Your insoles function only in conjunction with suitable shoes. Your certified orthotist has made your insoles for use with a suitable pair of shoes that you brought to the fitting.

Please observe the following information for purchasing new shoes that must be suitable for insoles.

### General requirements

The shoes must have sufficient volume to accommodate your feet with the insoles. A removable insole helps increase the volume. The volume of the shoes should be adjustable (for example with shoe laces or hook and loop closures) to ensure a good fit.

The heel counter must be high enough to prevent the heel from slipping out of the shoe.

Your insoles were made for the effective heel height of the shoes you brought to the fitting (see page 7). When buying new shoes, be sure that they have the same effective heel height. If you have any more questions about this, please talk to your certified orthotist.

### Special requirements

**Custom-made shoes:** Some insoles have special requirements that only custom-made shoes can meet. Consult your certified orthotist in such a case.

**Safety shoes:** The use of orthopaedic insoles in safety shoes is allowed only if the insoles were made specifically for this purpose and are approved. Please talk to your certified orthotist if you want to use your insoles in safety shoes.

## 6 Cleaning

1. Take your insoles out of your shoes after every use and air them in a dry location. **NOTICE! Do not place your insoles on a heater to dry. This can lead to damage to the material and changes of the fit.**
2. Wipe soiled insoles with a damp cloth to clean them.
3. If your insoles have come in contact with body secretions (e.g. if you have open blisters), disinfect them with an alcohol-free, colourless disinfectant.

## **7 Disposal**

In accordance with our activities to protect the environment and also in your best interest, we offer you the option of returning your device to an Ottobock fitting centre for disposal.

## **8 CE Conformity**

Your custom-fabricated product is a risk class I medical device , manufactured in accordance with Regulation (EU) 2017/245 on Medical Devices. The product does not bear the CE mark as it is a custom fabrication.

## 9 Appendix

### 9.1 Information on your device

Name of the customer:

---

Number of the device:

---

#### Properties of your insoles

Corrective



Supportive (to optimise statics and gait pattern)



Embedding

Compensation for length



Sensomotoric



Your device was fabricated for a specific effective heel height. The effective heel height is the difference between the thickness of the sole at the heel (a) and at the forefoot (b).



Effective heel height of your device [mm]:

Material with skin contact: \_\_\_\_\_

\_\_\_\_\_

Ottobock team recommends that your device is reviewed every 12 months unless otherwise indicated.

**The service life of your device shall be reviewed at your review appointments.**

Quarterly

(and if the shoe size changes)



Annually

(and if the shoe size changes)



Semi-annually

(and if the shoe size changes)



When needed





**Ottobock Ireland**

Cappagh Orthopaedic Hospital, Finglas, Dublin 11, D11 KV07, Ireland

T +353 (1) 8348970, F +353 (1) 8348113

[Ireland@ottobock.com](mailto:Ireland@ottobock.com)

[www.ottobock.ie](http://www.ottobock.ie)

**Ottobock Cork**

St Mary's Health Campus, Block 4, Gurrabraher, Cork, T23 FFX9, Ireland

T +353 (21) 4301110

[cork@ottobock.com](mailto:cork@ottobock.com)

[www.ottobock.ie](http://www.ottobock.ie)



