



Varomed

Das Original mit dem V

Gebrauchsanweisung

Instructions for use • Notice d'utilisation • Návod k použití
Instrucciones de uso • Istruzioni per l'uso
Инструкция по использованию



Ihr Produkt
Your product

Artikelname
Product name: _____

Artikelnummer
Article number: _____

Kaufdatum
Purchase date: _____

Verkäufer
Supplier: _____



Stempel/Stamp



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Dear customer,

Thank you for choosing Varomed shoes!

You now own a high-quality medical product that can help you live your life more comfortably. Before you wear them for the first time, please read the care and usage information so that you can enjoy your shoes for a long time to come.

1. General information

Varomed shoes are available for different uses and are offered in the following four product groups:



DIABETIC

Diabetic shoes with the base UDI-DI:
4040261diabetikerGY



THERAPY/BANDAGE

Therapy shoes with the base UDI-DI:
4040261therapieUE



STRETCH

Stretch shoes with the base UDI-DI:
4040261stretchF4



PROPHYLACTIC

Prophylactic shoes with the base UDI-DI:
4040261prophylaxeM3

These product group designations at the various product levels allow you to recognise exactly which part of the usage instructions, in addition to the general information, is important for the use of your specific product. You can find the designation on the product itself, on the shoe box, and in the catalogue.

1.1 Symbols

In this section, we explain the symbols used in our usage instructions and their meaning:



Attention



No water



Manufacturer



Max. temperature



Protect from sunlight



Protect from moisture



Repeated use by one patient only

1.2 General purpose

All shoes from the product groups mentioned above are intended for indoor and outdoor continuous use of less than 24 hours daily. More specifics can be found in the intended purposes of the individual product groups.

1.3 General product description

Our products are made of the following materials and have the following characteristics:

- Shafts with upper materials such as leather, imitation leather, textiles, or a combination of these materials
- Linings made of wool, cotton, polyamide or a combination of these materials
- Wide, stable sole surfaces for a firm grip, made of EVA/PU/TPU
- Heel cap for a good heel fit (only in closed models, except for 60882 and 60420, which are slip-ons)
- Simple, easy-to-use fasteners allow the models to be easily put on and taken off (except for shoes that are lace-up only)

- Suitable for use with insoles - adjustments should be made by trained specialists/orthopaedic shoe technicians only
- Soles can be reworked - by trained specialists/orthopaedic shoe technicians only in compliance with occupational safety regulations - the product is considered a custom-made device within the meaning of Regulation (EU) 2017/745 Art. 2,3.
- A variety of widths for optimal adjustment to the individual shape of the foot, to the extent that this is possible with ready-made shoes.

1.4 General contraindications

A contraindication exists when the type of foot deformity no longer permits wearing of or treatment with a ready-made shoe.

2. Safety information

Serious incidents occurring in connection with the product must be reported to the manufacturer and the responsible authorities in the member state in which the patient resides.

Please keep the label that comes on the shoe box for the product. It contains important information providing tracing data that is necessary if you need to file a complaint.

2.1 Safety information classification

Please note the following categories of safety notices.



DANGER

Important information about a possible dangerous situation that will lead to death or irreversible injuries if not avoided.



WARNING

Important information about a possible dangerous situation that will lead to reversible injuries requiring medical attention if not avoided.



CAUTION

Important information about a possible dangerous situation that will lead to minor injuries not requiring medical attention if not avoided.

NOTICE

Important information about a possible situation that will lead to product damage if not avoided.

2.2 All information for your safety



DANGER

Non-compliance with the following information can lead to irreversible adverse health effects, including death.

When the product is used as intended, risks leading to death or irreversible injuries have not been known to occur. However, particular risks exist for the diabetic foot (see page 15).



WARNING

Non-compliance with the following information can lead to reversible adverse health effects and medical treatment.

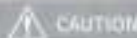
- Wearing footwear on the wrong foot or wearing footwear that fits poorly or is unsuitable or not correctly closed can cause health problems such as blood flow cut-off, poor circulation, and pinching. It also increases the risk of skin irritation/open sores and of tripping and falling.
Have your orthopaedic shoe technician or trained specialists adjust your Varomed shoes and explain their correct use.
- Wearing insoles on the wrong foot or wearing the wrong insoles or none at all can cause skin irritation, pinching, and pain.
Use only the insoles supplied or insoles that have been specially adjusted by your orthopaedic shoe technician, and ensure that they are seated correctly.
- Foreign objects, folds in the interior, or deformed spots can lead to injuries, skin irritation and pinching. Wear the shoes only if you have checked them for the problems listed above and rectified any issues. Otherwise, contact your orthopaedic shoe technician.
- Even with the utmost care, wearing the shoes can lead to skin irritation and open sores.
After wearing the shoes, check your feet for problem areas, using a hand mirror if necessary.
- During wear, pain, swelling, pinching, unusual reactions, or tingling with unclear causes can occur. In these cases, stop wearing the shoes and consult your doctor or orthopaedic shoe technician.

- Changes due to adjustments and adaptations can lead to health problems and physical strain if not performed properly.
Adjustments must be performed by qualified specialists such as your orthopaedic shoe technician.

- If the shoes are worn by more than one person, infections, including mycosis, can be transmitted. Use the shoes only for your own personal needs and, for hygienic reasons, do not lend them to anyone else.



Repeated wear by one patient only



CAUTION

Non-compliance with the following information can lead to minor injuries that do not necessarily require medical attention.

- Substances from the lining material can be absorbed through the skin or open sores on the foot. Always wear the shoes from the diabetic, stretch and prophylactic product groups with socks that are not wrinkled. This is not always possible for therapy shoes due to wrappings/bandages.
- Worn-out soles, fasteners that no longer close, cracks or tears in the material can compromise the safety of the product and lead to health problems. Check your shoes for signs of wear and have them repaired in good time by qualified specialists or your orthopaedic shoe technician.

NOTICE

Non-compliance with the following information can lead to damage to the product.

- Fasteners that are not sufficiently opened when the shoes are put on and taken off can lead to deformations and cracks or tears in the material due to shoe overstretching.
When putting on and taking off the shoes, always open all fasteners and use a shoe horn if possible.
- The shoes are not intended for use in water (in the shower, for example) and, as with all shoes, there is a risk of slipping on ice, snow, and slippery and wet surfaces.
Use the shoes for their intended purpose and have your orthopaedic shoe technician give you a comprehensive consultation.



Do not use in water

3. Cleaning and care information

- 1) Check your shoes for signs of wear during care and have your orthopaedic shoe technician or a qualified specialist repair them if necessary.
- 2) After wearing your shoes, remove dust and slight dirt with a damp cloth.
- 3) If your shoes become wet, stuff them with absorbent paper or a dish towel and let them dry completely. Drying them on a direct heat source such as a radiator or in direct sunlight is not recommended, since it can cause the leather to harden or the colour to change. Wearing damp shoes can lead to fungal infections.

4) After drying them, rub or spray your shoes with a suitable care product. Follow the instructions provided by the care product manufacturer.

- Remove salt stains with a solution of equal parts vinegar and water.
- If the lining is dirty, clean it with a soft brush and a soap solution. Remove the soap residue with a cloth and water and let the shoes dry as described above.
- You can treat the shoes with a commercially available disinfectant. Follow the manufacturer's instructions.
- Therapy shoes with terrycloth lining can be washed in the washing machine at 30°C using the delicates cycle. Let them dry as described above.

4. Storage information



Do not store above 40°C



Direct sunlight may cause colour changes and accelerated aging



Protect the shoe box from moisture

5. Technical data

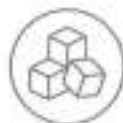
You can find the technical data for your product in the information for the product group or on the packaging label.

6. Disposal

Dispose of the product and the packaging in compliance with the legal regulations applicable in the country in which you live.

7. Guarantee

A guarantee can be provided only within the legal guarantee period and if the product has been used and cared for as intended. As the manufacturer, we assume no liability for the consequences of improper use.



Diabetic shoes
with the base UDI-DI: 4040261diabetikerGV

Purpose:

Our diabetic shoes are intended for users with diabetes mellitus type I or II with diabetic foot syndrome and no significant foot deformities and therefore offer special protection.

The shoes can also be used prophylactically. They have enough volume and a sufficient shaft height to accommodate a diabetic footbed.

Indications:

- **DFS = diabetic foot syndrome**
(Diabetic polyneuropathy with distinct neuropathy and distinct angiopathy = nerve damage + poor circulation)

- Associated with existing or healed ulcers or other mechanical irritations that lead to regional pressure points

Additional contraindication:

Cases in which a customized orthopaedic shoe is necessary due to the physiological shape of the foot



Unnoticed open sores can lead to irreversible health problems.

The diabetic foot, which is susceptible to injuries, tends to heal slowly from wounds which in an extreme case can lead to amputation. This is of particular concern if the shoes are worn without the soft cushioning diabetic insoles.

Always wear the shoes with your soft cushioning diabetic insoles and check your feet for problem areas after wear. If necessary, consult your orthopaedic shoemaker or doctor.



Therapy shoes
with the base UDI-DI: 4040261therapieUE

Purpose:

Our therapy and lymph shoes are intended for users who require a wound dressing, a bandage, and/or a special footbed. They are therefore suitable for post-

operative treatment or compression therapy. Velcro fasteners with a large gripping area ensure infinite width regulation in addition to a secure hold and easy handling so patients with limited mobility can use the shoes more easily. They protect the feet and are intended to help maintain or improve mobility as much as possible.

Indications:

- Bandages/swelling due to lymphatic and/or vascular disorders of the feet
- Postoperative or other wounds including those treated with elastic, possibly padded bandages, with an extended healing process allowing at least partial weight to be placed on the foot while walking, including outside
- Hormonal or systemic illness tending to cause swollen legs, ankles and/or feet
- For deformities, swelling and inflammation

Additional contraindication:

Gait disorders which could cause the two shoes' Velcro fasteners to become entangled if they have been improperly fastened (models 60460 Meran XXL and 60910 Meran)



WARNING

Allergic reactions and toxic substance absorption through the skin

Despite the use of tested materials, direct skin contact can lead to allergic reactions and toxic substance absorption through the skin.

Avoid direct skin contact and wear therapy shoes only with socks, a wrapping, or an appropriate wound dressing and bandage.

NOTICE

Only products that are labelled as washable can be washed in the washing machine at 30 °C using the delicates cycle. For hygienic reasons, such products are particularly favourable for wound treatment.



Stretch shoes with the base UDI-DI: 4040261stretchF4

Purpose:

Stretch shoes are intended for users who, due to their illness, suffer from increasing and decreasing swelling in the feet/ankles or more or less distinct deformities. The goal is to prevent pressure points and mechanical impairments that result from shoes being too tight. Sometimes the following indications are also accompanied by a reduced manual gripping ability; many models are therefore equipped with adjustable Velcro fasteners with large gripping areas and/or eyelets for easy handling. Stretch shoes are intended to help relieve foot pain and thereby promote natural movement in order to reduce awkward postures assumed to ease pain and damage caused by such postures.

Indications:

- **Deformities/malpositions** and/or inflammation caused by gout, rheumatoid arthritis, osteoarthritis or other degenerative diseases
- **Systemic disorders** (lymphatic, vascular, hormonal, etc.) that cause foot swelling to increase and decrease over the course of the day
- **Hallux valgus, Hallux rigidus, hammer toes, claw toes**

Additional contraindications:

Besides the contraindications mentioned in section 1.4 "General contraindications" none are known.

NOTICE

Only products that are labelled as washable can be washed in the washing machine at 30 °C using the delicates cycle. For hygienic reasons, such products are particularly favourable for wound treatment.



Prophylactic shoes
with the base UDI-DI: 4040261prophylaxeM3

Purpose:

Our prophylactic shoes are intended for users whose feet are particularly sensitive and require protection.

Illnesses can cause sensitivity disorders and pressure sensitivity. The lining of the prophylactic shoes absorbs moisture and is almost completely seamless, minimising friction. These shoes are therefore also intended for diabetics who have not yet shown signs of diabetic foot syndrome.

Indications:

- **Diabetes**, as long as there are no signs of diabetic foot syndrome (DFS)
- **Diabetes with slight foot deformities** that require, for example, insoles to be worn, but without diabetic foot syndrome – suitability is based on the judgement of the responsible doctor and the specialist providing the product
- **Poor circulation**, as long as diabetic foot syndrome can be ruled out as the cause
- **Polyneuropathy with mild symptoms**, as long as diabetic foot syndrome can be ruled out as the cause
- **Slight foot deformities**
- **Pressure sensitivity** with or without associated inflammation

Additional contraindication:

The use of prophylactic shoes is not indicated in the case of diabetic foot syndrome. For more information, read the "Diabetic shoes" section.

**Warning**

Progressive worsening of the illness
Your illness may worsen over time, necessitating a different foot treatment.
Visit your doctor regularly (at least once a year) to have your feet checked.



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