



TB

Ref. TO4300

R.O.M. Walker

DESCRIPTION

An orthopaedic support light and comfortable to wear, providing an effective stabilization of the ankle joint. The structure is made of technical materials, light and resistant, giving an excellent lateral-medial stability. Easy to wear.

CHARACTERISTICS

- Structure in light and resistant composite material.
- Metal support bars for lateral-medial stabilization.
- Hinges with R.O.M. regulation. Flexion: 0° - 45° by 7,5° step.
- Extension: 0° - 45° by 7,5° step.
- Breathable padding double-coated in polyethylene foam.
- Non-toxic plantar padding.
- Closure belts with Velcro.
- Non-slip rubber sole.

INTENDED USE

Therapeutic and not invasive Medical Devices, capable to correct postural problems or capable to stabilize limbs.

INDICATIONS

Achille's tendon rupture • treatment of malleolar fractures • substitute of plaster cast • post surgery.

APPLICATION *(only for technicians)*

1. Open Velcro straps.
2. Wear the paddings parts on foot and leg.
3. Put the leg inside the shell.
4. Tighten the Velcro straps, starting from the foot ones and then the leg ones. If it's necessary adjust the shape of lateral bars for better comfort.

Tenortho
Get back in action

via Trento e Trieste, 100
20853 Biassono (MB)

Italy



tenortho.com

✉ info@tenortho.com

☎ +39 039 8943960

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POPULATION AND USE LIMITATIONS

Tenortho devices are generally indicated for use on adults over 12 years of age. The product should only be used for the intended purpose (see instruction leaflet, section "Indications"). Some devices that have a range of paediatric sizes or are made to measure can also be used on children from 3 years of age. Caution is recommended and medical advice should be sought before using any devices that may interfere with the maternal womb in pregnant women (collars with sternal-dorsal stabilisers, lumbar belts, corsets, shoulder and hip braces, etc.). Particular attention and careful medical assessment should be paid to the use of braces that may interfere with breathing in patients with pathologies or respiratory difficulties (hyperextensors, corsets, collars, shoulder braces, etc.). The product that includes magnetotherapy (TO1308MG - TENOMAG) should not be used in pregnant women nor in people with implantable devices (pacemakers, defibrillators or fixed implants). Refer to the instructions for use from the manufacturer of the magnetotherapy device.

MAINTENANCE

If possible, remove splints and metal frames before washing. Hand wash in warm water with mild soap; then rinse it with clean water. Dry away from heat sources. Contact your orthopaedic technician in case of problems or worn out parts that need to be replaced. Do not dispose the product in the environment.

PRECAUTIONS FOR USE

The device must not create pressure on any part of the body that is injured or swollen. Consult an orthopaedic technician if there is any doubt about the application. Do not wear the device near open flames.

HEALTH SURVEILLANCE

In the interests of continuous health surveillance to ensure the safest possible use of Tenortho products, please report any severe adverse reactions that occur during the use of the product by sending an email to: ufficiotecnico@tenortho.com

Also report the event to the competent authorities.

WARNINGS

The device must be indicated or prescribed by a Physician and applied by an Orthopaedic Technician, who is the competent figure of reference for both application and information on safe use. The application must be carried out with the utmost care to ensure efficacy, tolerability and correct functioning. Any structural or other modifications must be decided by the Physician and carried out by the Orthopaedic Technician. Personal use of the product is recommended. Direct contact of the device with the skin may cause redness or irritation to very sensitive persons. Do not place the product on injured skin. Contact your doctor immediately in case of intolerability.

DISPOSAL

Do not dispose the product in the environment. Dispose of the product in accordance with the waste laws of your municipality and/or State. The product does not present a risk of contamination.

WARRANTY

Tenortho certifies that the product has been manufactured correctly, that top quality materials have been used, that all the necessary tests have been carried out and that it complies with the standards and laws in force. Tenortho undertakes to remedy any defect, lack of quality or lack of conformity of the Products imputable to itself, occurring within 6 (six) months from the delivery of the Products and communicated promptly and in any case no later than seven days from the discovery of the defect or fault. Tenortho may choose to repair or replace the Products found to be defective. Products replaced or repaired under warranty shall be subject to the same warranty of 6 (six) months from the repair or replacement. Defects of conformity and, therefore, the legal warranty, do not include any defects or damage caused by accidental events or by the User's responsibility (such as, by way of example but not limited to, carelessness, lack of or incorrect cleaning) or by use of the Products that does not comply with their intended use, or by normal wear and tear. Keep packaging, labels and purchase receipt to ensure proper batch traceability.



Hand wash in
warm water



Do not
tumble-dry



Do not iron



Do not bleach



Product compliant with EU Regulation 745/2017 - Issued on 04/2021 - Rev.0
Certified Company: quality system certified according to ISO 9001:2015 and ISO 13485:2016



Manufacturer

REF

Article number

LOT

Lot number



Medical Device