EN

AGILOMB LUMBAR

Ref. TO1104 Lumbar musculoskeletal corset

DESCRIPTION
The latest generation of orthopaedic medical support, unique in its category. The innovative design, the structure made of C6Tex fabric with carbon fiber (Tenortho exclusive), elastic and 100% breathable, this corset guarantees an excellent fit and at the same time stability to the spine. The elastic straps are especially designed to ensure easy and controlled traction, making the corset necessary when controlling minor pathologies referred to lumbar area. Easy to wear, excellent fitting, it ensures correct back support providing well-being and comfort during daily activities.

CHARACTERISTICS
- Combined C6Tex, antistatic (the special fiber absorb and disperse the electric charges).
- Breathable and thermoregulator, bacteriostatic and hypoallergenic, it helps the blood flow and the cellular oxygenation minimizing the concentration of lactic acid.
- Frontal Velcro fastening system. Elastic back straps in order to have a tailored pressure. The lumbar area is supported by adjustable stays inside the corset. The abdominal area is supported by oblique spiral stays.
- Anterior height: 23 cm, posterior 33 cm.

INTENDED USE
Therapeutic and not invasive Medical Devices, capable to correct postural problems.

INDICATIONS
Lumbar sciatica • lower back pain • mild trauma of lumbar -lumbosacral area • discopathy • spondyloarthrosis • paravertebral muscular contractures • lumbar vertebral collapse.

APPLICATION
Don't wear the brace directly on the skin.

1. Open the corset completely, keeping the loop for thumb upwards.
2. Frontal side made of 5 Velcro (1 bigger for abdominal, 4 obliques smaller for lateral sides).
3. Adjust the Velcro straps first, fixing them on the lateral oblique ones.
4. Wear the corset and close the "large abdominal Velcro" just enough to stabilize it properly.
5. Take the Velcro straps and pull them until you reach the large abdominal one and fast them in the central area.
6. First, hook the upper Velcro straps, then the lower ones.
7. For proper positioning, make sure that the back and bottom edge of the corset is positioned at half of the gluteus.

MADE IN ITALY

tenortho
Get back in action

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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.

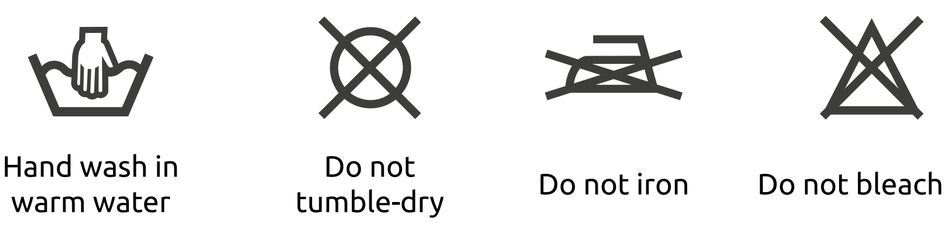
PRECAUTIONS FOR USE
The device must not create pressure on any part of the body that is injured or swollen. Consult an orthopaedic technician if there is any doubt about the application. Do not wear the device near open flames.

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.



CE 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 | MD Medical Device