EN

GENUTONIC

Ref. TO3121

Open knee brace with articulated hinges and flexion-extension control (short)

DESCRIPTION
Innovative medical-orthopaedic support. The frame made with calibrated breathable elastic fabric ensures the stabilization of the joint. Easy to wear, with a great fitting, it does not have any seam in the popliteal fossa ensuring an excellent comfort. The frame is made of combined C6Tex with carbon fiber: antistatic, breathable, thermoregulatory, bacteriostatic, hypoallergenic, it reduces the concentration of lactic acid, improving blood flow and cellular oxygenation. The frontal opening eases its application.

CHARACTERISTICS
- C6Tex fabric, elastic and 100% breathable.
- Inside is made with a velvet effect for a better comfort.
- No seams in the popliteal fossa.
- Frontal opening.
- Easy closure system.
- No tie-effect.
- Posterior elastic bands for a better stabilization. Polycentric stays with adjustment of flexion-extension from 0° to 90° (flexion: 0°-15°-30°, 45°-60°-75°-90°; extension: 15°-30°-45°; immobilization 0°-15°-30°-45°).
- Length: 35 cm.

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

INDICATIONS
Sprained knee trauma • patellar chondromalacia associated with ligament laxity • latero/medial stabilization • prevention of sprain trauma • arthrosic instability • helpful in the treatment of arthrosic inoperable knee.

APPLICATION
Inside the package there are limiting pins recognizable by letters **E (extension), F (flexion), I (immobilization)** to be used for adjusting the hinge. Each of them is marked with two dots that indicate in which slot of the joint they have to be inserted, vertically for the flexion block and horizontal for the extension block. Insert the extension limiting pin in the front of the polycentric joint; the limiting element will magnetically be locked inside the slot. If you need to block the knee flexion, insert a flexion limiter into the back of the polycentric joint. The third limiter pin indicates the pin for immobilizing the hinge. To completely immobilize the hinge, first insert the extension pin and then the immobilization pin; make sure that the degrees shown on the two pins are the same. For removal, proceed first with the immobilization pin and then with the extension pin. The insertion of the pins in their respective sites is done manually, forcing their insertion. The removal of the pin can be done using the special key, inserting the pointed part into the slot of the joint and, acting as a lever, allowing the removal of the pin (any pointed tool can also be used).

1. Open the 4 frontal flaps.
2. Wear the knee brace closing first the two internal Velcro, taking care to put the rubber logo upwards and placing the patella into the central opening.
3. Close others external flaps.
4. If necessary, adjust the flexion-extension angle or the shape of the aluminum rods (only for specialized technicians and taking care not to alter the rotation axis of the joint).

MADE IN ITALY

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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.

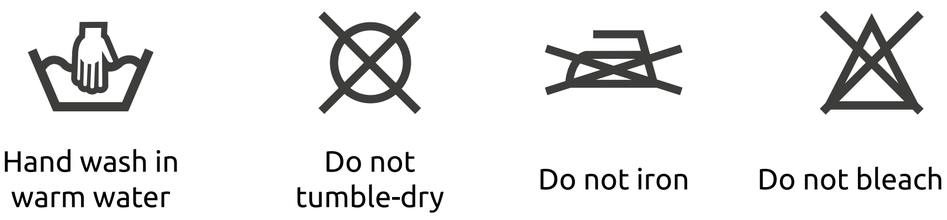
PRECAUTIONS FOR USE
The device must not create pressure on any part of the body that is injured or swollen. Consult an orthopaedic technician if there is any doubt about the application. Do not wear the device near open flames.

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