Instructions for use

TTcool-ortho MD

TARGET TEMPERATURE COOLING PAD - Medical Device

Version 1.1 2026-03-29EN

Cooling mat for orthopaedic use

A product of the

everynear

we care energy

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Room for notes:

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1. Indications

The TTcool-ortho surface cooling system is a non-active, skin-friendly, non-invasive surface cooling system for temperature reduction of individual areas of the body especially for the field of orthopaedics.

TTcool-ortho is also used for the local treatment of swelling after injuries with an intact skin surface. Pain relief, cooling in case of dislocations, tissue injuries and whenever local cooling is medically desired.

Note: For use in the emergency medical field for therapeutic hypothermia treatment or reduction of body temperature below the range of normothermia, TTcool-ortho should not be used, but preferably TTcool-pad, which has thermal indicators for temperature monitoring of the pad.

2. Contraindications

The device may not be used in areas of open skin injuries, wounds, burns or other skin diseases, unless cooling application is indicated.

3. Side effects

In contrast to classic cool pads, TTcool-ortho can also be applied directly to the skin for longer periods of time if properly processed.

Surface cooling with TTcool-ortho leads to temporary, reversible redness of the skin surface in the areas of application, which usually disappears a few minutes after the end of the treatment. No permanent skin damage was observed.

In isolated cases, 1st and 2nd degree frostbite occurred in extensively cooled patients with poor skin perfusion, which healed without scarring.

Unforeseen side effects, malfunctions and quality defects must be reported to the manufacturer immediately to the contact details listed in the Contact section.

1. Preparation of the TTCool pad

Before use, TTcool-ortho pads must be removed from the transport box and frozen in the sealed plastic sleeve in a freezer suitable for processing until all cooling pads are continuously frozen and have a temperature of minus 18° to minus 8°C. Depending on the number of pads inserted at the same time and the cooling capacity of the freezer, this may take about 24 hours, or longer.

Suitable refrigeration units have a reliable thermostat that maintains a temperature in the temperature range mentioned above.

Super freezer buttons or other technical devices on freezers must not be activated for the reprocessing of TTcool-ortho!

It must not be possible to change the setting value on the cooling unit by unauthorised third parties without technical aids.

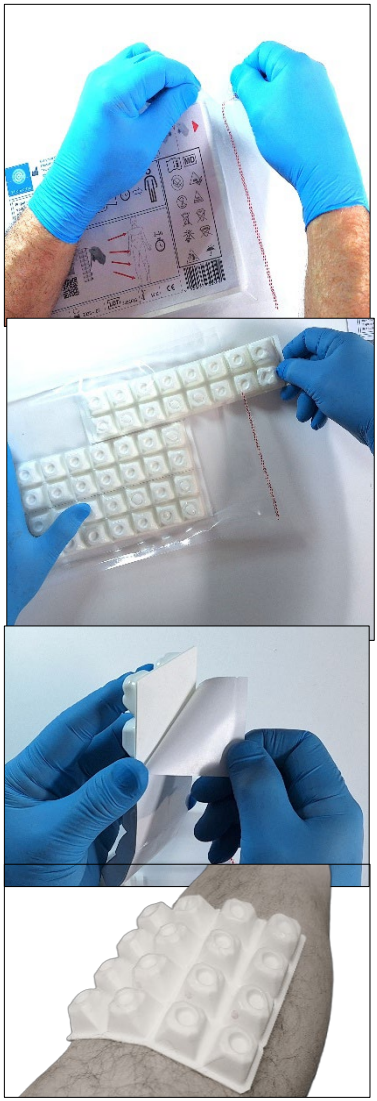
2. Application

The frozen pads are removed from the cooling container (freezer or similar) and checked for suitable cooling temperature by pressure test. All cooling elements should be hard (frozen).

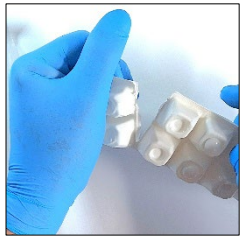
The plastic sleeve is opened at the notch provided for this purpose in the packaging. This is marked by a red line.

depending on the area of application, one or more TTcool-ortho pads are removed from the packaging. The remaining parts can be put back in the freezer in the plastic sleeve.

After removing the protective layer, a TTcool-ortho pad is applied to the area of the body to be cooled, if this is not possible for reasons of skin injury, surgical wounds or the like, TTcool-ortho should be applied near the area to be cooled. Alternatively, TTCool-ortho can also be applied to wound dressing, but the adhesive effect and cooling effect may be reduced depending on the thickness and material of the dressing.



For further adjustment, the pads can be divided additional at the perforations. The perforations are recognizable by the notches on the edge.



The facial area, genital area and the area of female nipples are to be excluded from the sticker.

Each packaging unit contains a quick start guide = label. This user manual can be accessed via the printed QR code.

To avoid condensation water on the adhesive layer, the TTcool-ortho pads should be applied to the body or bandage as soon as possible after the cover film has been removed.

3. Warnings and precautions

The user is responsible for the correct use of TTcool-ortho. The instructions for use and the following warnings must be observed.

a) TTcool-ortho is not intended for large-area cooling of more than approx. 30 x 30 cm. Cooling with larger areas should only be carried out with a TTcool-pad and only under the supervision of qualified medical personnel, as this can influence the overall body temperature.

b) Cooling for patients with low body weight and children under 30 kg should only be carried out with very small cooling pads of no more than 10 x 5 cm.

c) Before using TTCool-pad, the patient's skin condition should be checked. Use in areas of broken skin, open wounds, skin diseases and burns, pressure ulcers or the like is not permitted.

d) In patients who have an increased risk of pressure- or cold-related skin damage due to a pre-existing condition, poor tissue circulation, diabetes, vascular diseases, malnutrition, the use of steroids or blood pressure-increasing medication, the use of pressure-relieving pads is recommended to avoid skin irritation.

e) TTcool-ortho must not be applied in the genital area, in the area of the nipples (papilla mammae) and in the field of vision.

f) TTCool-ortho is a non-sterile single-use product. After use, it must be treated as bandages due to the risk of contamination with bacteria or viruses and disposed of in accordance with the relevant regulations.

g) After the cooling pads have thawed completely, they must be removed from the patient as soon as possible.

h) Skin areas to which cooling pads are to be applied must not be treated with skin creams, ointments, alcoholic or

other antibacterial liquids or gels before and during application, as these both reduce adhesion and thus heat conduction and also pose the risk of skin damage due to chemical reactions under the adhesive layer.

i) In order to avoid leakage of the coolant and thus the reduction of the performance of the TTcool-ortho overlay, the use of objects that could damage the shell of the heat sinks should be avoided. Should damage nevertheless occur, there is no danger to patients or nursing staff, as the ingredient, pure water without additives, is non-toxic and has no contaminating effect.

4. Liability

The documentation of each treatment is the responsibility of the user.

Everynear's liability for product performance and patient safety applies only to those cases in which the rules of the instructions for use have been followed, the warnings have been observed and the precautions have been fully observed.

Everynear also assumes no liability in those cases in which modifications have been made to the product and the product has not been prepared in accordance with the instructions for use. Likewise, no liability is assumed for damage caused by errors in storage, exceeding the expiration date, multiple use or other improper use.

5. Symbols used

	Follow the instructions for use		MR compatible
	No open packaging Use		non-sterile
	Single-use product		Free of PVC
	Batch number		Free of latex
	Use by no later than		Store in a dry place
	Protect from sunlight		Avoid condensation: apply immediately
	Do not dispose of with household waste		Date of manufacture
	Order number		Manufacturer
	CE marking		Maximum storage and transport temperature

6. Product name

Order name: TTcool-ortho
The delivery is in an overpackaging of 20 units each

7. Registration number in the Österr. Register for Medical Devices

AT/CA01/M0023425-02 Code 10-932

8. System Overview

TTCool-pad is a surface cooling system that can be easily adapted to the body. It uses cooling elements combined into a cooling pad, the contents of which are brought into a frozen state by cooling in a freezer. To ensure good heat transfer between the patient and the medical device, the cooling pad is applied to the patient's intact skin with the help of a medical adhesive film during application. The energy sink stored in the cooling elements extracts energy from the environment and thus from the patient through the phase transition from solid to liquid form. Due to the special, internationally patented shape of the individual cooling elements, liquid that is produced inside the heat sink during phase transformation is displaced from the contact surface facing the patient. This avoids an insulating liquid layer between the patient, and the solid energy storage system and the high cooling capacity is kept largely constant throughout the entire application period. Due to the patented design, no admixture to improve thermal conductivity is required despite the high cooling capacity and heat transfer.

Each individual cooling element is separately encapsulated and shrink-wrapped, so that the cooling pad can be separated at any point. The separation of the individual cooling elements prevents the coolant from lowering when stored vertically. In the event of mechanical damage to a cooling element, only the completely

harmless contents of a single element can escape. There is no contamination of the patient and no danger to the ability to defibrillate in the event of fluid leakage.

TTCool-pad is permeable to X-rays, CT and can also be used in MRI because it contains no metallic parts. The cooling pad can be used without affecting an imaging diagnosis.

TTCool-pad is a single-use product and must be disposed of after use in accordance with the disposal regulations for bacterially or virally contaminated disposable materials (bandages, etc.).

9. Dimensions and cooling capacity

Packaging unit (PU)	1 pad divided in the package
Package Size:	160 x 220 x 15 mm
Pad size	156 x 207 x 15 mm
Cooling area per VPE	207 x 312 x 15 mm = 0.064m²
Delivery unit	20 PU
Storage size incl. outer box	300 x 255 x 221 mm
Number of cooling elements per package	48 cooling elements Can be separated by perforation into units of min. 2 x 2 cooling elements each
Weight Without packaging:	250 g per PU, 5000g per delivery unit
Maximum cooling capacity when pre-cooled to -9 °C	Approx. 101 kJ per pad Approx. 200 kJ per packaging unit Approx. 2000 kJ per therapy pack = 20 pads
Product description VPE	TTcool-ortho
Order name delivery unit	TTcool-ortho 20 (= 20 PU TTcool-ortho in outer box)
EAN Packaging Unit	9 120074 303041
EAN Delivery Unit (20PU)	9 120074 303058
Medical device class and CE marking	Medical device class I CE marking under the manufacturer's own responsibility according to guideline MEDDEV 2. 4/1 Rev. 9 June 2010*

10. Materials used

The shell of the cooling elements and the cooling pad are made of thermoplastic polyurethane (TPU) and are free of latex, PVC and phthalic acid esters. The adhesive layer for establishing contact between the cooling elements and the patient is formed by a medically approved adhesive film. The adhesive film meets all dermatological requirements and is well tolerated by the skin even when used for several hours.

The heat sink itself is formed by pure water without admixtures. The high cooling capacity and good heat transfer are achieved by the special patented shape of the heat sinks, which prevents the formation of a heat-insulating water film between the heat sink and the patient, thereby ensuring continuous high heat transfer throughout the cooling period.

Performance data: The smallest packaging unit of the product consists of 1 pad. Several pads are combined into sets.

11. Service life and storage

Storage must be carried out in a dry, light-protected place with a temperature not exceeding 40°C. Short-term exceedances of the storage temperature of up to 5°C have no influence on the quality of the product, but can reduce the shelf life. The shelf life is at least 2 years after the date of delivery (see expiration date) if stored properly.

12. Mobile use

Maintaining operational readiness for mobile use: TTcool-ortho must be stored in suitable freezers before use. For mobile use, especially in the rescue services, pre-prepared cooling pads can be stored in suitable transport containers with good thermal insulation. Depending on the design of these transport systems, they are ready for use for up to 24 hours.

13. Manufacturer information

Manufacturer: everynear GmbH

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Web: **www.everynear.eu**
Product name: TTcool-ortho
Where to buy: see website

Headquarter:
Friedrichstr. 56,
2500 Baden,
Austria

Country of production:
Austria

Imprint:
UID: ATU65207723
Commercial Register No.: 333734k
Commercial Register Court: Wiener Neustadt Regional Court

Chamber memberships:

Chamber of Commerce, www.wko.at
Specialist Group: Medical Technology, Mechatronics
Access to professional regulations under ww.ris.bka.gv.at

The product is protected by international patents.