Instructions for use

TTCool-pad MD

TARGET TEMPERATURE COOLING PAD - Medical Device

Version 2.4 2026-04-01 EN

Cooling mat for stationary and mobile use for medical temperature control

A product of the

we care energy

Everynear GmbH
www.everynear.eu
Friedrichstr. 56, 2500 Baden, Austria

Room for notes:

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1. Indications and indications

The TTCool-pad surface cooling system is a non-active, skin-friendly, non-invasive surface cooling system designed to reduce the temperature of the body or regions of the body.

TTCool-pad is used to lower the body temperature in order to achieve a desired target temperature of the entire body (target temperature management), fever reduction, achievement of normothermia or therapeutic hypothermia, if this therapy is medically indicated.

Use in fever, after cardiac arrest and successful resuscitation, myocardial infarction, stroke, sepsis and traumatic brain injury.

TTCool-pad is also used for the local treatment of swelling after injuries with an intact skin surface. Pain relief, cooling in the event of dislocations, tissue injuries and whenever local or total cooling is medically desired.

In patients weighing less than 35 kg, TTCool-pad must not be used for therapeutic hypothermia treatment or reduction of body temperature below the range of normothermia.

2. Contraindications

If the patient's clinical picture recommends the production of normothermia, a holistic or local reduction of body or tissue temperature or therapeutic hypothermia, no contraindications are known.

Do not use in areas of open skin injuries, wounds, burns, other skin diseases and pressure ulcers.

3. Side effects

Surface cooling leads to temporary reversible redness of the skin surface in the areas of the 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.

4. Application

Depending on the area of application and the desired target temperature, one or more TT-Cool-pad pads with the adhesive layer are glued to the area of the patient's body to be cooled.

For **local cooling** , a TTCool 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, near the area to be cooled.

For **fever reduction, target temperature management or for the purposes of therapeutic hypothermia,** the compresses can be applied to the patient in a non-specific manner. The facial area, genital area and the area of female nipples as well as hands in the finger area and feet in the toe area are to be excluded from the sticker.

To establish a body temperature of 33°C, an average of 2 individual pads (= 1 packaging unit) per 10 kg body weight are required.

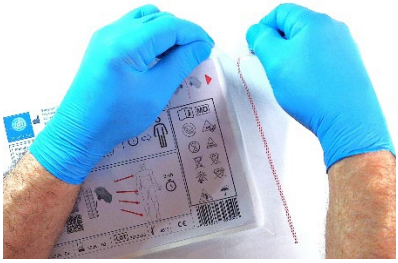
The number of pads actually required depends on the desired target temperature, body weight and the specific energy balance of the patient. In the case of large-scale, not only local

cooling, it must always be ensured that the temperature of the body is monitored with suitable measuring instruments that reliably record the core temperature.

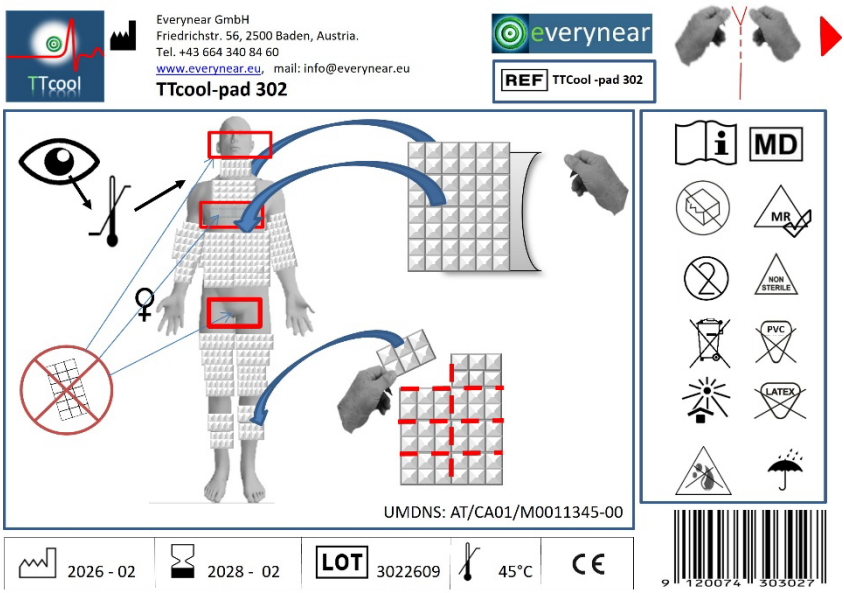
Application Flow:

1) The frozen pads are removed from the cooling container and checked for suitable cooling temperature by pressure test. All cooling elements must be hard. (Thermal indicators are blue).

2) Tear open the outer packaging (hard shell) at the marked points and remove the pad.



Each packaging unit contains a quick start guide = label.



3) Peel off the masking film and apply the TTCool-pad locally or over a large area to the body with the adhesive layer, depending on the indication. To prevent condensation, the PAD must be glued to the body immediately after the cover film has been removed.

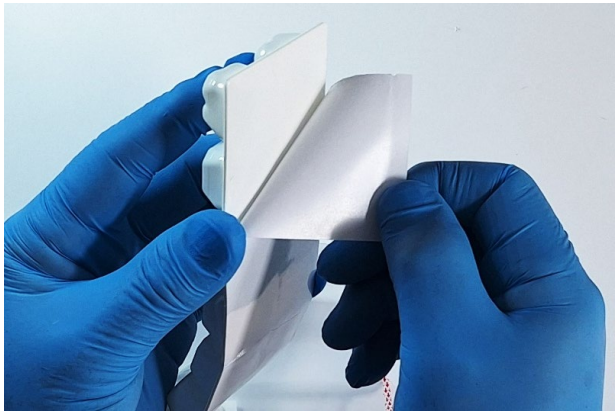


Figure : Removing the cover film

4) The pad can be divided as needed for the use of small surface areas by simply tearing at the intended perforation points.

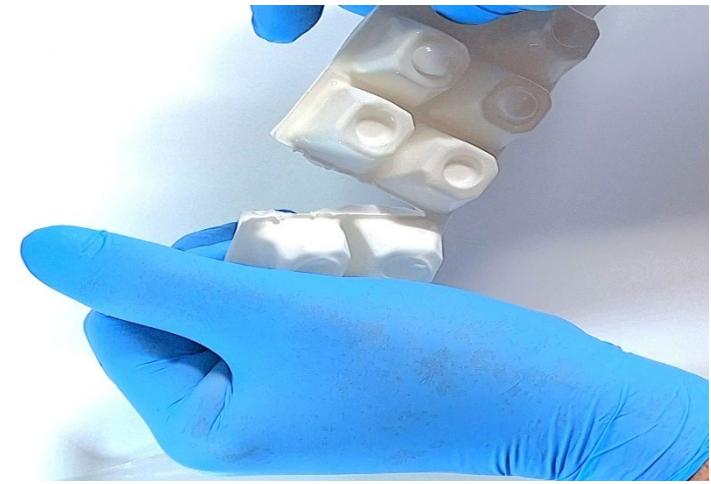


Figure: Demolition of small units

Figure: maximum division of a pad unit

Body surfaces on strongly curved body surfaces can be damaged by separating individual parts and also tearing the pads at the lines provided for this purpose (perforation)

Figure: Attaching individual parts in strongly curved areas

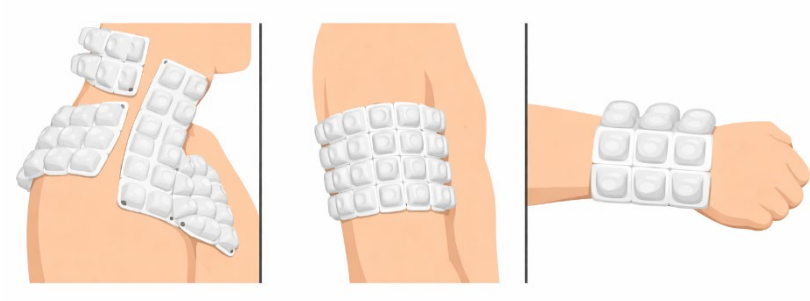


Figure: Attaching individual parts in strongly curved areas

Figure: Attaching individual parts in the arm area.

Figure: Attachment of individual parts in the wrist area

5) Once the target temperature has been reached, the pad must be removed immediately. In the case of large-area rapid cooling, it is possible to run the cooling even after the pads have been removed, so earlier removal of the cooling pads may be necessary.

6) If the target temperature has not yet been reached, but the cooling capacity of the mat has been used up (all temperature indicators red), the TTCool pad must be removed and another one must be applied if further cooling is required.

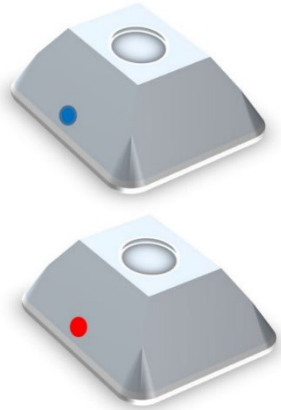


Figure Temperature Indicators
Top: Cooling capacity available – blue

bottom: cooling capacity used up – red

5. Warnings and precautions

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

a) TTCool-pad should only be used under the supervision of qualified medical personnel.

b) The number of cooling pads used must be specifically adapted to the desired target temperature and the patient. Body weight, metabolism and ambient temperature influence the speed of cooling.

c) Temperature measurement with a method suitable for the respective application is mandatory for temperature reduction treatments. Unless it is indicated for other medical reasons, temperature measurement can be omitted in the case of small-area, local cooling where there is no risk of lowering the entire body temperature.

d) In the case of large-scale application of TTCool-pad for the purposes of therapeutic hypothermia or intensive

normothermia, the measurement must be carried out with a reliable measurement method that records the patient's core temperature.

e) In the case of therapeutic hypothermia, if necessary, the muscle tremors can be prevented with medication under the responsibility of the qualified medical staff.

f) 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.

g) 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.

h) TTCool-pad must not be applied in the genital area, in the area of the nipples (papilla mammae) and in the field of vision.

i) TTCool-pad is a non-sterile disposable 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.

j) When using TTCool-pad at the same time as other cooling methods, the responsibility is solely at the discretion of the user and not at the expense of Everynear. Especially when using cold infusions, the sustainability of surface cooling in the tissue must be taken into account.

k) Its use in pregnant patients is not permitted. This does not apply to local cooling in peripheral areas, provided that the patient's body temperature does not fall below the range of normothermia as a result of the local application.

l) Due to the intensive cooling of the body tissue, fast cooling methods such as the TTCool-pad can lead to a further drop in the core body temperature even after the cooling pads have been removed. Therefore, in the case of large-scale cooling for therapeutic hypothermia purposes and a rapid temperature drop of over 3°C per hour, it is recommended to carefully remove the cooling pads from the patient's skin immediately about 0.5°C before reaching the target temperature.

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

n) 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.

o) In order to avoid leakage of the coolant and thus the reduction of the performance of the TTCool-pad, the use of objects that could damage the shell of the heat sinks must 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. A defibrillation-disrupting effect can also be avoided by simply drying it.

6. Liability

The documentation of each treatment is the responsibility of the user. In accordance with the relevant regulations on patient safety, he is obliged to document the typical parameters of the treatment. These include medical history, medication, target temperature, initial temperature and temperature profile. The number and batch number of the pads used must also be documented. In the event of insufficient documentation by the end user, all liability for Everynear will be extinguished.

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.

7. 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

8. Product name

Order number: TTCool-pad - 302

9. 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. A dimensionally stable shell ensures the solidification of the water coolant in combination with the elastic cover in a special form. In order 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.

A hard shell ensures dimensional stability before and during the freezing phase. Each individual cooling element is separately encapsulated and shrink-wrapped, so that the cooling pad can be separated at any point. By separating the individual cooling elements without connecting to a filling channel, a lowering of the coolant is avoided when stored vertically. In the event of mechanical damage to a cooling element, only the toxic and 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.

Depending on the surface of the applied cooling pad, it can be used for the purpose of producing normothermia (36 - 37°C) or for achieving and maintaining the core body temperature of therapeutic hypothermia (32 - 34°C).

TTCool-pad can be used without an external power supply and can therefore be used in both rescue services and clinics.

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 inserted during angiography without affecting the 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.).

10. Dimensions and cooling capacity

Packaging unit (PU)	2 pads each
Package Size:	160 x 220 x 30 mm
Pad size	156 x 207 x 15 mm
Cooling area per VPE	207 x 312 x 15 mm = 0.064m²
Therapy pack	10 PU
Cooling surface	0.64 m²
Storage size incl. outer box	300 x 255 x 221 mm
Number of cooling elements per package	96 cooling elements Can be separated by perforation into units of 2 x 3 cooling elements each
Weight Without packaging:	500 g per packaging unit 250 g per pad 5000g per therapy 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
Order description	TTCool – pad 302 TTCool – pad 320 (= 10 PU TTcool-pad302 in outer box)
EAN	9120074303027
Barcode	
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

*Heating/cooling pads intended only to release stored thermal energy are not active devices because they do not act by conversion of energy. However, heating/cooling pads which act by chemical action (e.g. endothermic or

exothermic reaction) are active devices as they are converting chemical energy into heat energy and or vice versa.

11. Materials used

TTCool-pad is supplied in a hard shell, which is used for dimensional stability and transport before and during the freezing phase. The hard shell is designed as a blister and can be opened quickly for use.

Material of hard shell:
The shell of the cooling elements and the cooling pad is made of thermoplastic polyurethane (TPU) and is latex, PVC and phthalic acid ester free. The adhesive layer to establish good contact with 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 2 pads. Several pads are combined into sets.

12. 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 3 years after the date of delivery (see expiration date) if stored correctly.

13. Preparation of the TTCool pad

Before use, TTCool pads should be frozen in a freezer suitable for processing until all cooling pads are frozen throughout and have a temperature of -10°C +/- 1°C.

Suitable cooling units have a reliable thermostat that maintains a largely constant temperature of -10°C +/- 1°C in the cooling unit.

The change of the setting value on the cooling unit must not be possible by unauthorised third parties without technical aids

PREPARATION TIME: approx. 48 hours of cooling in a controlled cooling unit. If several pads are inserted at the same time, the performance of the cooling device must be taken into account. The preparation time may be extended accordingly.

For preparation, the pads must be removed from the cardboard outer packaging. Freezing in the cardboard overpackaging is possible, but longer processing times must then be planned.

The plastic cover should only be removed immediately at the time of application!

14. Temperature indicator

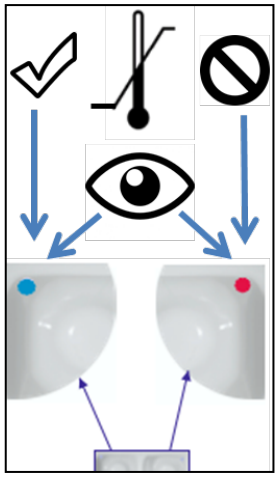
For easy orientation about the approximate temperature of the cold rooms, the cooling pad is provided with several thermochromic markings on each individual cooling pad. These markings change color depending on the temperature and serve as an easy orientation during cooling to determine whether the cooling capacity of the individual cold rooms has already been used up.

ATTENTION: The temperature indicators are not an indicator of whether the cooling pads are sufficiently prepared!

Color of Temperature Indicator:

Dark blue = cold
Red = warm approximately room temperature (contents of the cold room thawed)

During the treatment , the temperature indicators change from dark blue to red at different times. The temperature increase in the individual cold rooms and thus the color change depends on the heat output of the underlying body surface and the ambient temperature. Areas with a good blood supply can therefore be exhausted in their capacity much earlier than peripheral areas.



ATTENTION: The cooling pad must always be removed when the target temperature is reached!

All indicators red means that the cooling capacity of the cooling pad is exhausted and no further power is being absorbed. If all temperature indicators are red and the contents of the cold rooms are liquid throughout (pressure test), the cooling pad must be removed. In any case, the cooling pad must also be removed before the target temperature is reached.

ATTENTION: The coloured temperature indicators are only used as a non-binding orientation about the temperature of the cooling pad itself. Under no circumstances should the patient's temperature or the patient's temperature development be derived from the colour of the temperature indicators. The coloured temperature indication is not a medical measuring instrument and may not be used for measurement purposes.

15. Mobile use

Maintaining operational readiness for mobile use: TTCool-pad 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.

16. Manufacturer information

Everynear GmbH

Phone: +43 (0)664 340 84 60
E-mail: info@everynear.eu
Web: **www.everynear.eu**
Product name: TTcool-pad - 302
Where to buy: see website

Company Headquarters
Friedrichstr. 56,
2500 Baden,
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.

Development and production in Europe (Austria)