

Instructions for use



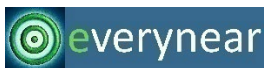
TTCool-pad MD

TARGET TEMPERATURE COOLING PAD - Medical Device

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Cooling pad for in-patient and mobile usage for medical
Temperature control.

Product of



we care energy

Everynear GmbH
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Notes:

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1. Indications and areas of application

The surface cooling system TTCool-pad is a non-active, skin-compatible, non-invasive surface cooling system for the temperature reduction of the body or regions of the body.

TTCool-pad is dedicated to the reduction of the body temperature (target temperature management), fever reduction, induction of normothermia or therapeutic hypothermia, if this therapy is medically indicated. It can be used to reduce the temperature of the body as a whole or in local areas.

The above-mentioned therapeutic goals may be indicated in patients with fever, after cardiac arrest and successful resuscitation, myocardial infarction, stroke, sepsis, and traumatic brain injury.

TTCool-pad also serves for the local treatment of swellings after injuries with intact skin surface, luxation, tissue injury as well as for pain alleviation, and whenever local or whole-body cooling is indicated.

For patients with a body weight of less than 35 kg, TTCool-pad may not be used for therapeutic hypothermia treatment or reduction of the body temperature below normothermia.

2. Contraindications

Provided the clinical picture of the patient recommends induction of normothermia the complete or partial reduction in body temperature, tissue temperature or therapeutic hypothermia, no contraindications are known.

The device must not be applied to areas of open skin injuries, chronic wounds, combustions, to areas affected by dermatologic disease or decubitus.

3. Side effects

Surface cooling leads to temporary reversible red coloring of the skin surface in the areas of application, which generally disappears after a few minutes when treatment has finished. Sustained skin damage was not observed.

Rarely patients with weak skin perfusion reacted with frostbites of first or second degree without permanent damage.

Unexpected side effects, malfunctioning or lack of quality, are to be announced to the manufacturer via the contact section to the stated contact data immediately.

4. Application

According to local or general cooling needs and target temperature, parts of one, or several, TTCool-pads should be placed with the adhesive layer directly onto the body area of the patient that is to be cooled, or distributed over the trunk, neck and limbs, if the whole body should be cooled.

For local cooling, the TTCool-pad should be placed on the specific body area to be cooled. If this is not possible due to skin injury, operation wounds or similar, the pad should be placed as close as possible to the specific area that is to be cooled.

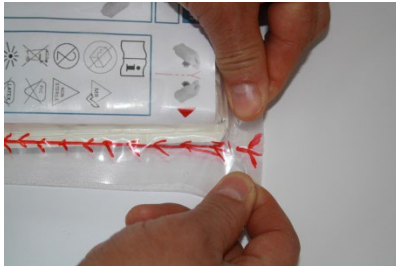
For fever reduction, temperature management (target temperature management), or purposes of therapeutic hypothermia, the pads can be distributed over the trunk, neck and limbs. Face, genitalia, the area around the female nipples as well as hands and feet, must be avoided.

To reach a target body core temperature of 33°C in average 2 single pads per 10kg body mass are needed.

The number of pads is dependent on target temperature, body weight and specific energy balance in the patient. If used to cool the whole body below normothermia, it must be guaranteed by all means, that the core body temperature is measured with suitable and accurate devices.

Usage:

- 1) After taking the deep-frozen pads out of the cooling device (freezer) check if all parts are frozen (hard).
- 2) Open the cover package along the red dotted line and remove the hard cover.



Every package includes a short instruction:

Sample

Everyyear GmbH
Friedrichstr. 56, 2500 Baden, Austria.
Tel. +43 664 340 84 60
www.everyyear.eu, mail: info@everyyear.eu
TTcool – pad 302

everyyear

REF TTcool -pad 302

UMDNS: AT/CA01/M0011345-00

XXXX - XX XXXX - XX LOT XXXXXXX 45°C CE

9 120074 303027

3) Remove the cover foil and place the TTcool-pad with its adhesive side according to indication locally or distributed over the trunk, neck and limbs. To avoid condensation of the adhesive layer, the pad **MUST** be stuck immediately after removal of the foil.



Image: Removing the foil layer from the adhesive layer.

4) If needed, the pad can be split for the use on small surface areas simply by separation at the intended perforation.

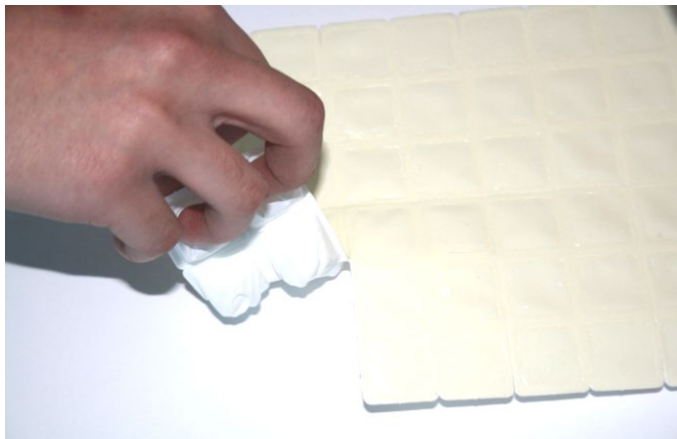


Image: Splitting the pad into smaller sections



Image: Maximal separation

Bent body parts can be covered by separating parts along the lines intended for it (perforation).



Image: Separation of the pads into smaller units for small bent body areas



Image: Separation of the pads into smaller units for small bent body areas



Image: Attachment of separate units on arm

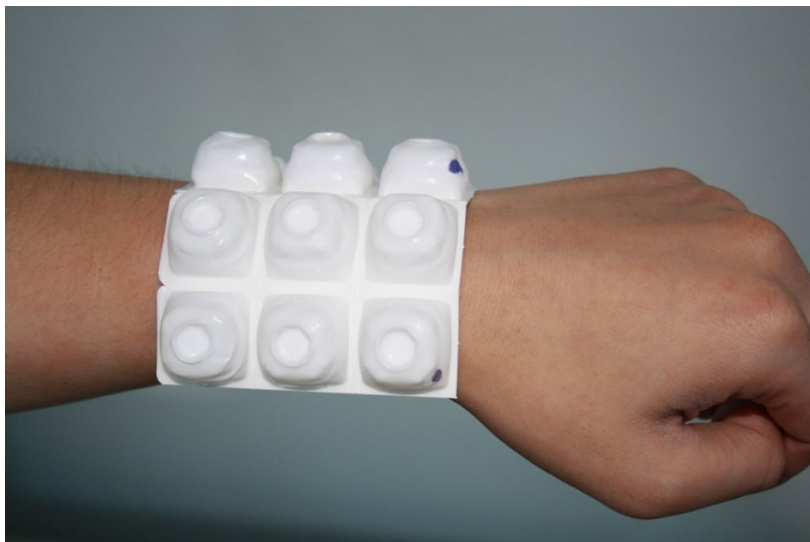


Image: Fixing separated units in the area of the wrist

5) When target temperature is reached, the pad must be removed immediately. If large areas of surface are cooled, an overrun after removing the pads may occur, so earlier removal of the cooling pads may be required.

6) If target temperature is not reached, however, the cooling effect of the pad has stopped, and the TTCool-pad is to be replaced by a frozen pad.

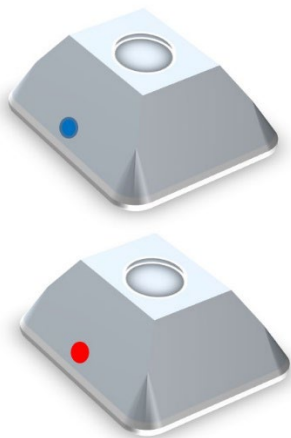


Image: temperature indicators;

still cooling (blue) /
cooling capacity used up (red)

5. Warnings and precautionary measures

The user is responsible for the correct use of TTCool-pad. The user manual, as well as the following warning indications, are to be adhered to:

- a) TTCool-pad may only be used under supervision of qualified medical staff.
- b) The number of applied cooling pads must be adapted to target temperature as well as the patient's body weight, metabolic rate and environmental temperature affecting the cooling speed.
- c) Accurate temperature measurement using suitable methods before respective application and by means of reaching target temperature must be used. Temperature management is not required if indicated for other medical reasons, such as if cooling is only used locally with a low number of pads.
- d) By using TTCool-pad for therapeutic hypothermia or intense normothermia the patient's core body temperature must be measured by means of reliable methods.
- e) Trembling or shivering of the muscles occurring during the use of TTCool-pad may be reduced by means of medication under the supervision of qualified medical staff.
- f) Before using TTCool-pad, skin conditions must be checked carefully. TTCool-pad must not be applied directly on broken skin (eg. skin diseases, burnt skin, open wounds or damaged skin).
- g) Patients with poor tissue perfusion and poor skin integrity due to diabetes, peripheral vascular disease, poor nutritional status, steroid use or high doses of vasopressor therapy have a higher risk of skin damage by pressure and/or cold. If warranted, use pressure relieving or pressure reducing devices under the patient's body to protect them from skin injury.

- h) TTCool-pad must not be applied to the genital region, in the area of female breast tissue (Papilla mammae) and the face.
- i) TTCool-pad is a non-sterile product for single use only. After application it must be considered contaminated and disposed of according to local policies.
- j) For simultaneous application of TTCool-pad with other cooling methods, the responsibility lies exclusively with the user and is not the responsibility of Everynear. Particularly with using cold infusion, durability of surface cooling of the tissue has to be considered.
- k) TTCool-pad must not be used on pregnant women.
- l) By intensive cooling of the body with methods such as the TTCool-pad, further dropping in body temperature may occur also after removing the pads. Hence, in the case of extensive cooling (i.e. induction of therapeutic hypothermia) and rapid temperature reduction (approx. 3° C per hour) it is recommended to carefully remove all pads once a temperature 0.5° C above target temperature has been reached.
- m) After thawing, the cooling pads are to be removed as soon as possible.
- n) Skin areas where the cooling pads are to be attached, may not be treated with skin creams, ointments, alcohol or other antibacterial liquids or gels before or during treatment.
- o) In order to avoid leakage of coolants thus reducing efficacy of TTCool-pad, avoid handling objects on or near the pad that could damage it. In the event of a leakage, the components pose no hazard to patients or staff once. The pad's ingredients consist solely of pure water without any additives, hence, there are no contaminating effects.

Furthermore, the risk of disturbance of defibrillation, cardioversion, cardiac pacing and monitoring can be avoided simply by drying the affected areas.



















6. Liability

The documentation of every treatment lies within the responsibility of the user. To ensure good medical practice, it is compulsory to document the parameters of the treatment. This includes, but is not limited to history, indication, medication, aimed target temperature, number of pads applied, achieved temperature and changes in temperature. With failure to document adequately, every liability of Everynear expires.

The liability of Everynear for product performance and patient's safety is considered only under circumstances where strict adherence to the instructions for use was maintained if the entire warnings have been considered and all the precautionary measures were taken.

Everynear does not provide liability under circumstances where modifications in the product were carried out and preparations did not take place according to the operation instructions. Furthermore, no liability for losses or damage is taken that are due to mistakes with storage, usage after expiration date, repeated use or any other inappropriate application.

7. Applied symbols

	Pay attention to suitable operating instruction		MR
	No open packaging use		No steril
	Single use product		Free of PVC
	Charge number		Free from latex
	Use no later than		Dry storage
	Protect against sunlight		Avoid condensation: Raise immediately
	Do not dispose Of in household trash		Production date
	Part Number		Manufacturer
	CE		Maximum storage temperature

8. Product designation

TTCool-pad Part number: TTCool-pad 302

9. System overview

TTCool-pad is a surface cooling system that is adaptable to the body. The cool pad consists of cooling elements and is prepared by cooling in a freezer. A form-stable cover in connection with a special-formed elastic cover protects the coolant water from solidification. This preventing the water from melting and producing an isolating water film between the pad and the patient's body. Heat transfer between patient and medicine is increased with a medical adhesive film on intact skin of the patient. The (physical seen negative) energy stored in the cool pads reduces over duration of the treatment as the coolant changes form solid to liquid through surrounding heat and the patient's own energy. The special patented form of the pads and its separate layers, allow cool energy stored in the pads to be transferred to the patient's body. Thus, an isolating liquid layer between the pad and body can be avoided and the high cooling performance is kept on a constant level during the entire treatment. The patented design of the device allows for a high transfer rate without need for catalysts to improve heat conductivity.

Each individual pad is separately encapsulated and sealed by the cooling cover which can be split at any position. Content of the cooling device is non-toxic.

TTCool-pad can be used to induce normothermia (36 – 37° C), or to achieve a core body temperature of therapeutic hypothermia (32 - 34° C). Temperature can be managed by using a different number of pads to cover different skin portion.


TTCool-pad is to be used without an external power supply and can thus be used, depending on the indication, for outpatients, in

prehospital emergency medicine, during patient transfer and in hospitals.

TTCool-pad is transparent to x-rays, is suitable for CT and can also be used for MRI's since it contains no metallic parts. The cooling pad can be used without affecting the diagnostic imaging during angiography.

TTCool-pad is a disposable product and, after usage, must be disposed of in accordance with disposal regulations for bacterial or viral contaminated disposable materials (bandages etc.)

10. Dimensions and cooling capacity

Package unit	2 Pads per package unit
Package size:	160 x 220 x 30 mm
Pads size	156 x 195 x 15 mm Package surface for cooling 195 x 312 x 15 mm = 0,608m ²
Number of cooling Elements	96 cooling elements At Perforation separable in units 2 x 3 cooling elements
Weight Without package:	500g per package unit 250g per pad
Max cooling rate with Precooling on -9°C	about. 101 kJ each Pad about. 201 kJ each packing unit = 2 Pads about. 2000 kJ each therapypackage = 20 Pads
Order designation	TTCool – pad 302 TTCool – pad 320 (package of 20 pads = (10 package units TTcool- pad 302)
EAN	9120074303027
Barcode	 9 120074 303027
Medical product class und CE labeling	Med Device Class I According to MEDDEV 3.1.4/1 Rev. 9 June 2010 Ref. Ares(2015)2068632 - 18/05/2015

Heating/cooling pads intended only to release stored thermal energy are not active devices because they do not act by conversion of energy..

<https://ec.europa.eu/docsroom/documents/10337/attachments/1/translations>

11. Material used

TTCool-pad is supplied with a hard shell to support form stability and transportation before and during freezing. The hard shell is implemented as a blister and can be opened quickly before application.

Material of the hard shell:

The cover of the cool pads and the cooling imprint are formed from thermoplastic polyurethane (TPU) and is free from latex, PVC and phthalate ester. The adhesive layer for producing good skin contact is formed by a medically adhesive film. This adhesive film corresponds with all dermatological demands and is well skin-compatible even with application of several hours.

The cooling body itself is formed with pure water and without admixtures. The high cooling performance and its good heat transmission are reached by the special patented form of the cooling body, which prevents development of a thermal isolated water film between the TTCool-pad and the patient, thereby guaranteeing a continuously high heat transfer during the entire period of cooling.

Performance data: The smallest packaging unity of the product consists of 1 pad. Several pads are summarized into a set.

12. Lifespan and storage

The device must be stored in a dry place that is protected against light and at a temperature below 40° C. Short term exposure to temperature that exceeds the warehouse temperature by 5° C have no influence on the quality of the product; however, this may

reduce shelf life. Stored correctly, shelf life amounts up to 3 years after delivery date – see expiration date.

13. Preparation of the TTCool-pad

To prepare the TTCool-pads for application, TTCool-pads are to be frozen in a freezer, specifically suitable for the preparation of all cooling pads until all pads are frozen to a temperature of minus 10°C +/- 1°C for a minimum of 48 hours.

Suitable freezers are freezers which can be adjusted to a temperature of minus 10°C +/- 1°C by use of a reliable thermostat and temperature preset cannot be reset to a different temperature without technical tools.

Preparation time: 48 hours. When several sets of pads are stored at the same time limited power of the cooling device may result in longer preparation time.

Carton packing must be removed before putting the pads into the freezer. All other packing must be kept directly until the time of usage.

14. Temperature indicator

For easy orientation regarding the approximate temperature of the cool cells, the cool pad is provided with several thermochromic points on each separate pad. These marks change in color according to their temperature and serve for simple orientation of the device warming during procedure it displays when the cooling effects of a specific cool cell has been used up.

ATTENTION: The temperature indicators are not to be used as indication of freezing during preparation of the device.

Colors of the temperature indicators:

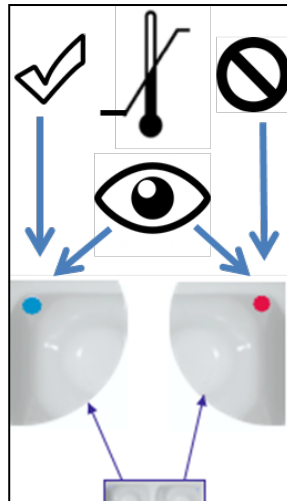
Dark blue = cold

Red = warm, about surrounding temperature (content of cool cell has thawed)

During treatment the indicators will change from dark blue to red.

ATTENTION: The pads must be removed in any case when reaching target body temperature!

If all indicators show up red, the cooling effects of the TTCool-pad is exhausted. If all temperature indicators are red and the content the cool pad is fluid, the pad must be removed. In any case the cool pad must also be removed before target temperature is reached.



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ATTENTION: The color temperature indicators serve as a non-committal orientation for the temperature of the cool pad only. In no case must the patient's temperature or temperature development be derived from the color of the

temperature indicators. The color temperature indicator is not a medical monitoring device and may not be used for measuring purposes.

15. Mobile application

Maintenance of readiness for the duty of the mobile application: Before application TTCool-pads must be kept in suitable deep cooling devices. For mobile applications, e.g. in emergencies in the field or during patient transfer, pads that have already been cooled can be transported in a suitable transport container.

16. Manufacturer

Everynear GmbH

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Email: info@everynear.eu

Web: www.everynear.eu

Product designation: TTcoolpad – 302,
TTcool-320 (10 x TTcool 302)

Distributors – see Website

Headquarters

Friedrichstrasse 56

2500 Baden,

Austria



Impressum

VAT: ATU65207723

Company No.: 333734k

Commercial register: Landesgericht Wiener Neustadt

National and international Patents available