FAQ US Territories
EMCOOLS Flex.Pad/Flex.Pad Small

Indication and field of application

1. What is mild therapeutic hypothermia?

Mild therapeutic hypothermia is a medical treatment that lowers a patient's body temperature to 32°C – 34°C / 89.6°F – 93.2°F, which reduces the risk of neurological damage following a period of insufficient blood flow either locally (stroke / myocardial infarction) or throughout the whole body (cardiac arrest).

2. What are the indications for use of the EMCOOLS cooling system?

Temperature reduction in adult patients where clinically indicated, e.g. in hyperthermic patients.[1]

3. Why do we need to start cooling in the pre-hospital setting?

Pre-hospital treatment, immediately after successful resuscitation has its unquestionable benefits (European Resuscitation Council Guidelines for Resuscitation 2010, Guidelines of the American Heart Association 2010) and might increase the chances of survival by 24% and the neurological outcome by 41%.[2] Various studies like the post-hoc secondary data analysis of Sendelbach et al. highlight the benefits of early cooling as well.[3]

4. How can we start cooling in the pre-hospital setting?

The EMCOOLS cooling system provides a safe and effective cooling method for rapid induction of therapeutic hypothermia in the pre-hospital setting. The cooling pads are non-invasive, take only 2 minutes to apply to the patient's body and do not require any external power supply during use. Hence, the portable design of the EMCOOLS cooling technology allows for the cooling therapy to be started immediately after ROSC and followed through to intensive care.

5. How can we cool in the in-hospital setting?

The EMCOOLS cooling system allows for patients to be treated immediately after hospital admission / in-hospital cardiac arrest. It is characterized by full patient access and mobility during hypothermia treatment as no external power supply, tubes and cables are needed. The cooling pads are non-invasive and take only 2 minutes to apply to the patient's body. EMCOOLS Flex.Pad is transparent and safe for X-Ray, CT and MRI.

6. Are there any contraindications for using the EMCOOLS cooling system?

There are no known contraindications for the use of a temperature reduction system. The EMCOOLS Flex.Pad must not be used in case of skin diseases, inflammation, burns or skin injuries. Reversible, temporary skin reactions may occur in very rare cases i.e. in patients with hypersensitive skin. (For detailed information please refer to the Instructions for Use).

Product description and performance

7. How can the Flex.Pad provide such a high cooling capacity?

The EMCOOLS Flex.Pad contains HypoCarbon®, a patented technology that is characterized by outstanding cooling rates of up to 3.3°C / 5.94°F per hour. The heat absorption potential of HypoCarbon® is 15 times higher than that of ice and 58 times higher than that of water.[4]

8. Is there a risk to the user, patient or any third party if individual components of the Flex.Pad leak?

HypoCarbon® is non-toxic and does not constitute a safety hazard or danger to the environment. There is no risk to the user, patient or third parties if it is released due to a mechanical damage to the outside material. In case of leakage the substance can be easily cleaned with soapy water.

9. Do individual product components of EMCOOLS Flex.Pad represent a risk to the user, patient or any third party?

All EMCOOLS products and product packaging that come into direct contact with the patient are latex and PVC free. Furthermore we can certify that all EMCOOLS products and product packaging are phthalates-free which means that they do not contain any hazardous plasticizers such as DEHP, DBP, BBP

and DIBP. As a result EMCOOLS products represent no danger / risk to the user, patient, third parties or the environment.

10. Does the adhesive on the back of the Flex.Pad cause skin irritation or skin injury?

The back of the Flex.Pad consists of a medical adhesive film suitable for medical products with direct skin contact such as operating sheets and bandages. The adhesive film is skin-friendly and dermatologically tested to be suitable for medical products.

The medical adhesive film on the reverse of the Flex.Pad guarantees optimum skin contact during application and use. At the same time it has been designed to show little resistance during removal. This ensures a skin-friendly, soft and easy removal of Flex.Pads after use.

In patients with hypersensitive skin, reversible reddening (hyperaemia) may occur in some rare cases after removing the EMCOOLS Flex.Pad. The skin reddening is temporary and reversible (up to 24 hours after the cooling therapy) and does not cause permanent skin injury. This reversible reddening may be caused due to the cooling temperature during the hypothermia treatment. The medical adhesive film does not create reddening of the skin. Permanent skin injury has not been observed in any case when compliance with the instructions for use is assured.

11. What is the ideal temperature for storing Flex.Pads?

Before use, EMCOOLS Flex.Pad must be placed and precooled in a freezer at –8°C to –11°C / 12.2°F to 17.6°F until the color indicator label has turned blue.

12. How do I know if Flex.Pad is ready to use?

The color indicator on the product packaging indicates if Flex.Pads are ready for use and have been stored at the correct temperature.

At room temperature (when unchilled) the color indicator displayed on the product packaging is **GRAY**. When precooled at correct temperature the color indicator displayed on the product packaging turns **BLUE** and Flex.Pads are ready to use. If the color indicator turns **BLACK** the Flex.Pads have been stored at a temperature much colder than needed and are not ready for use. In such case please check and adjust the freezer temperature according to the instructions for use (-8°C to -11°C / 12.2°F to 17.6°F).

13. How can I ensure that Flex.Pads are at correct temperature and ready for use in the pre-hospital setting?

For pre-hospital application Flex.Pad can be stored in one of the suitable mobile cooling units: the EMCOOLS Box for emergency vehicles or the products of the EMCOOLS Six.Pack Family suitable for both air rescue and ambulances. Both mobile cooling units keep Flex.Pads at correct temperature and ready for use over a period of 12 to 24 hours with no need for external power supply.

Cooling therapy

14. How many Flex.Pads do I need to cool one patient?

To obtain the full cooling capacity of 3.3°C / 5.94°F per hour it is recommended to apply one Flex.Pad (2 single pads) per 20 kg bodyweight.

15. Where do I apply Flex.Pads?

For initial cooling Flex.Pads are applied on dry skin on chest, abdomen, back and thighs. If required one additional Flex.Pad is applied on chest and abdomen during maintenance cooling.

16. Can I use EMCOOLS Flex.Pads during defibrillation?

EMCOOLS Flex.Pads can be used during defibrillation with automated external defibrillators. Place the defibrillator pads directly onto the patient's skin as instructed by the AED manufacturer and place the EMCOOLS Flex.Pads on top as instructed above covering the core body surface area.[5]

17. How do I measure the patient's temperature during the treatment?

The EMCOOLS Flex.Pad can be used with all commercially available medical monitoring systems and all medical temperature probes. However, EMCOOLS recommends esophageal or tracheal temperature measurements as it closely correlates with core body temperature.

18. How do I rewarm the patient after the cooling therapy?

After the maintenance cooling process is completed all patients are required to be rewarmed to normothermia (36°C/96.8°F) at the rate of 0.2°C – 0.5°C / 0.36°F – 0.9°F per hour. The use of controlled passive rewarming proves

safe and effective as highlighted in several publications.[4,6,7] Cover the patient with a heating blanket to initiate the controlled passive rewarming process. Passive rewarming will proceed at 0.2°C – 0.5°C / 0.36°F – 0.9°F per hour.

19. Do patients shiver when treated with Flex.Pad?

Naturally all humans have a shivering threshold. Cooling therapies which reduce the core body temperature may cause shivering in patients. The attending physician is responsible for proactive management of shivering where applicable. The first randomized clinical trials of therapeutic hypothermia after cardiac arrest (HACA Study Group, Hachimi-Idrissi and Bernard in 2001 and 2002) use Midazolam and/or Fentanyl for sedation and analgesia and Pancuronium or Vecuronium for relaxation. Please refer to published mild hypothermia cooling protocols for further details on shivering management.[6,8,9]

20. Can I re-use the Flex.Pads?

The EMCOOLS Flex.Pad is a disposable product. It is non-sterile and designed for single patient use only. For hygienic reasons, disposal is required after application. EMCOOLS Flex.Pads must be disposed of with contaminated medical waste.

Order and service

21. Where can I purchase the EMCOOLS cooling system?

The EMCOOLS products can be purchased directly from our distribution partners. Please refer to the "Distribution Network" section on our website for further details.

http://emcools.com/en/sales.aspx or http://emcools.com/de/vertrieb.aspx

22. How much does one Flex.Pad cost?

Flex.Pad is delivered in packaging units of 2 single pads. For information on prices please contact the respective distribution partner in your country (please see 21.).

23. Who do I contact if I need further information and support?

If you require any further information or support do not hesitate to contact the EMCOOLS Team on emcools-office@emcools.com

REFERENCES

1 - Source: The indication for use is valid for the US market

2 - Source: The Hypothermia after Cardiac Arrest Study Group: Mild Therapeutic Hypothermia to improve outcome after Cardiac Arrest, The New England Journal of Medicine, February, 2002.

3 - Source: Sendelbach, S., et al., Effects of variation in temperature management on cerebral performance category scores in patients who received therapeutic hypothermia post cardiac arrest, Resuscitation 83, 2012.

4- Source: Uray, T., et al., on behalf of the Vienna Hypothermia after Cardiac Arrest (HACA) Study Group. Out-of-hospital surface cooling to induce mild therapeutic hypothermia in human cardiac arrest: A feasibility trial, Resuscitation Journal, 2008.

5 - Source: Vienna Ambulance Service. Data on file at EMCOOLS.

6 - Source: The Hypothermia after Cardiac Arrest Study Group. Mild Therapeutic Hypothermia to improve the neurologic outcome after Cardiac Arrest, The New England Journal of Medicine, February 2002.

7 - Source: Kory P. et al, A rapid safe and low-cost technique for the induction of mild therapeutic hypothermia in post-cardiac arrest patients, Resuscitation 2011.

8 - Source: Bernard SA, Gray TW, Buist MD, et al. Treatment of comatose survivors of out-of-hospital cardiac arrest with induced hypothermia. N Engl J Med 2002.

9 - Source: Hachimi-Idrissi S, Corne L, Ebinger G, Michotte Y, Huyghens L. Mild hypothermia induced by a helmet device: a clinical feasibility study. Resuscitation 2001.