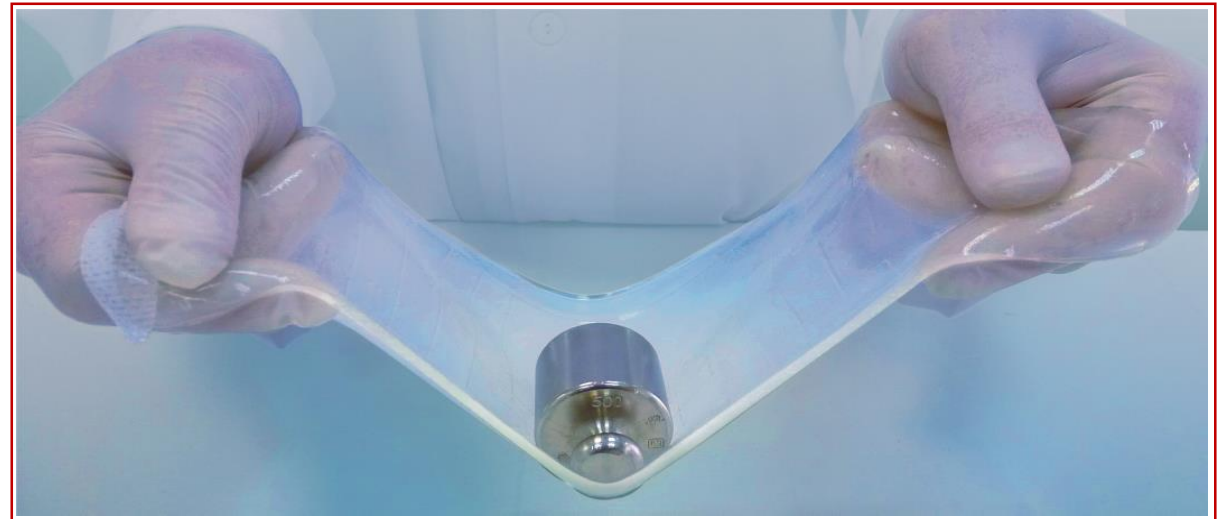
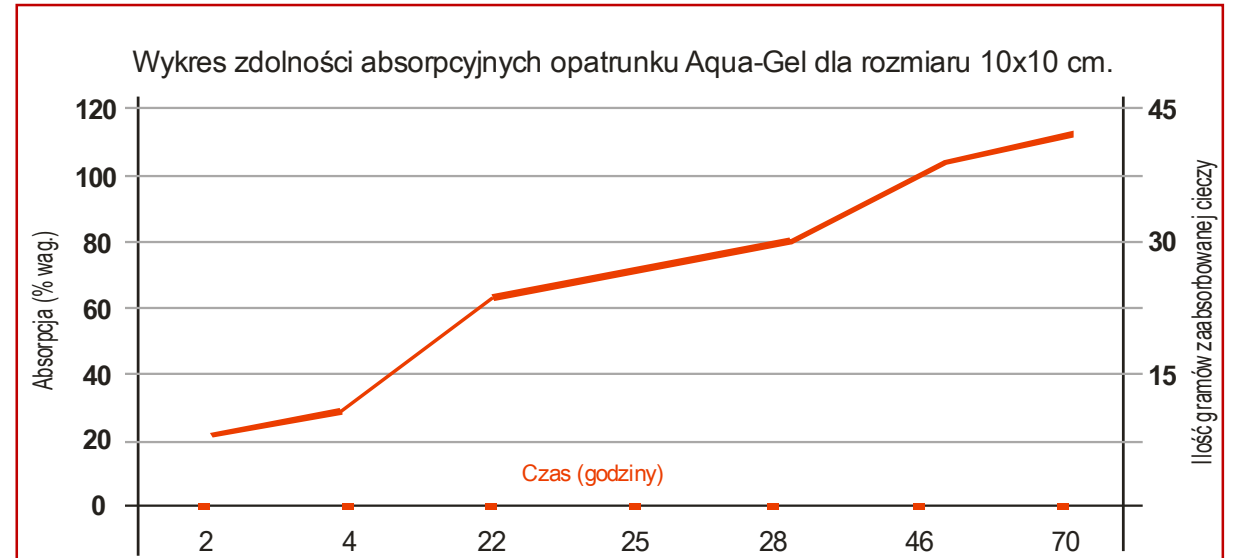




HYDROGEL DRESSINGS IN
EMERGENCY MEDICINE

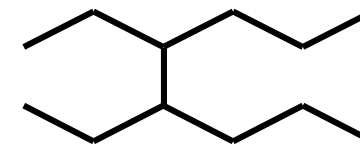
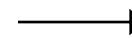
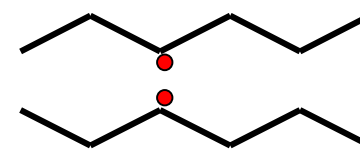
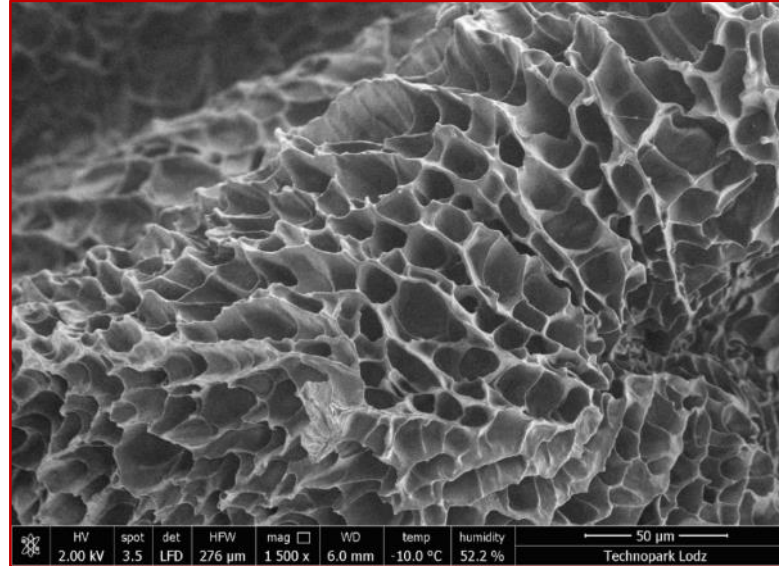
HYDROGELS AS POLYMER BIOMATERIALS

- Hydrogels are usually defined as systems with at least two components, in which one component is a hydrophilic polymer, whereas the other component is water. A chemical hydrogel is insoluble in water due to its chains being linked into a spatial network.
- The ability to absorb liquids without permanent loss of shape and mechanical properties is a very important hydrogel property, also found in many natural organs, such as: muscles, tendons, cartilages, intestines. Sorption of water by hydrogels is caused by their hydration and the presence of capillary areas.
- Sufficient mechanical strength

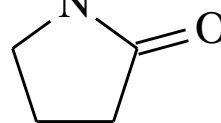
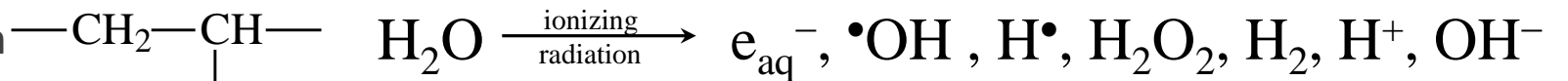


INNOVATIVE TECHNOLOGY

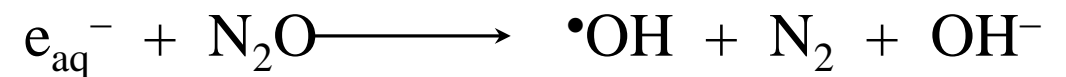
- developed at the Lodz University of Technology
- an aqueous composition of natural and synthetic polymers: povidone, polyethylene glycol and agar
- polymerization and radiation sterilization
- Radiation engineering - as a result of radiation absorption, permanent chemical bonds are formed between separate polymer chains.
- Possibility of initiating a reaction without the need to introduce chemical initiators into the system.



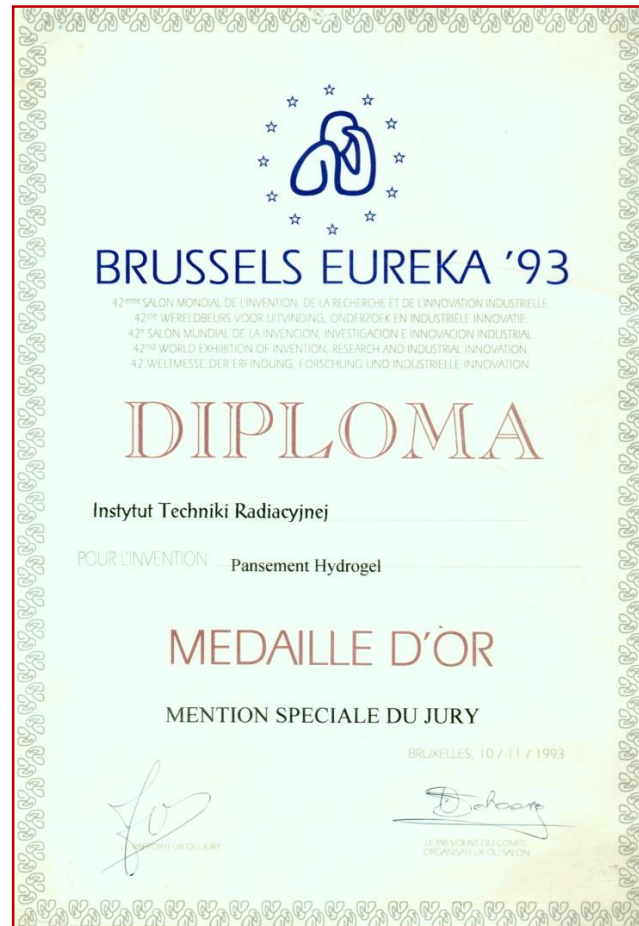
Electron beam cross-linking



Polyvinylpyrrolidone

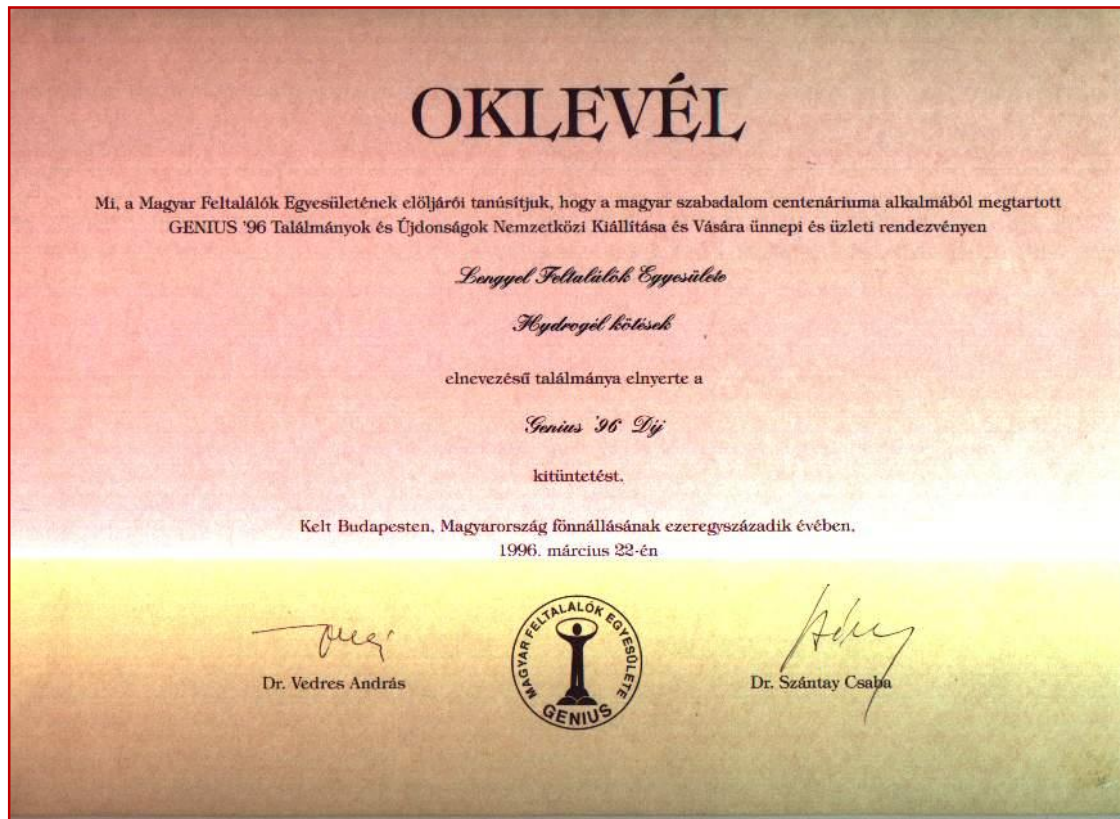


AWARDS AND DISTINCTIONS



The technology of production of hydrogel dressing was awarded on International Exhibition of Innovation EUREKA in 1993.

AWARDS AND DISTINCTIONS



In 1996 the technology was awarded again on Technical Exhibition GENIUS, in Budapest.

AWARDS AND DISTINCTIONS



First Degree Award, "Leader of State Security" Gala
organized by the National Security Bureau



AWARDS AND DISTINCTIONS



The main distinction in the category of
"Emergency and Action-Supporting
Equipment" during the EDURA 2014 Fair.



MADE IN POLAND

The only manufacturer of specialty
hydrogel dressings in Poland

We have 25 years of experience



CERTIFICATES CONFIRMING COMPLIANCE WITH INTERNATIONAL PRODUCTION REQUIREMENTS



CERTYFIKAT WE / EC CERTIFICATE

zgodny z 93/42/EWG Załącznik II (p. 4) / acc. 93/42/EEC Annex II (p. 4)

Niniejszym zaświadcza się, że firma / This certifies, that the company

KIKGEL Sp. z o.o.
ul. Marii Curie-Skłodowskiej 7,
PL / 97-225 Ujazd

dla kategorii wyrobów sterylnych klasy IIb / for the product category class IIb in sterile condition
(Lista wyrobów patrz załącznik 1 / List of products see annex 1)

Sterylnie opatrunki hydrożelowe.
Sterile hydrogel dressings.

Właściciel systemu zapewnienia jakości w projektowaniu, produkcji i kontroli jakości wyznaczonych wyrobów zgodnie z wymaganiami Załącznika II (z wyjątkiem sekcji 4) dyrektywy 93/42/EWG. Dodatkowo, przy zmianie CE musi zostać nadany nowy numer certyfikacji przy jednoczesnym powiadomieniu właściwych organów, za co jest odpowiedzialny system zapewnienia jakości zgodny z wymaganiami dyrektywy (jego nadawcą może być jednostka notyfikowana zgodnie z Załącznikiem II, rozdział 5. Certyfikat nie może być przeniesiony pod żadnym warunkiem).

has established a quality system for design, production and final testing acc. to the requirements of Annex II (excluding section 4) of the directive 93/42/EEC. Additional to the CE marking the notification number of the notified body has to be affixed. The validity of this certificate is based on the maintenance of the quality system in accordance with the requirements of the directive and its surveillance by the Notified Body according Annex II section 5. The certificate may not be transferred under any circumstances.

Nr rej. / Reg.-No. TNP/MD/0228/4680/2018 Ważny od / Valid from 11-07-2018
Raport nr / Report No.: PL4680/2018-05 Ważny do / Valid until 10-07-2021


Piotr Bielecki
Jednostka Certyfikująca Wyroby Medyczne /
Certification body for medical devices
Katowice 31-08-2018
Jednostka notyfikowana Numer identyfikacyjny 2274
Notified Body ID No. 2274

TÜV NORD Polska Sp. z o.o. ☎ +48 32 786 46 46, Fax +48 32 786 46 01
ul. Mickiewicza 26 40-085 Katowice www.tuv-nord.pl, biuro@tuv-nord.pl

Dopuszczają się kopowania certyfikatu tylko w niezmienionej postaci. / Copies of this certificate only without changes.



CERTIFICATE

Management system as per
PN-EN ISO 13485:2016-04
Medical devices - Quality management systems - Requirements for regulatory purposes

In accordance with TÜV NORD Polska Sp. z o.o. procedures, it is hereby certified that:

KIKGEL Sp. z o.o.
ul. Marii Curie-Skłodowskiej 7,
PL / 97-225 Ujazd

applies a management system in line with the above standard for the following scope:

**Design, manufacturing and sale of sterile hydrogel dressings
and sterile hydrogel standoff pads for USG.**

Regardless of the fact that TÜV NORD Polska Sp. z o.o. is a notified body No. 2274 in the area of medical devices, this Certificate is not a Certificate of Conformity within the meaning of Directive 93/42/EEC and is not a basis for CE marking.

Certificate Registration No. AC090 MD/1706/4680/2018 Valid from 11-07-2018
Audit Report No. PL4680/2018 Valid until 10-07-2021
Initial certification: 01-03-2007


Manager of Certification Body
TÜV NORD Polska Sp. z o.o. Katowice 31-08-2018

This certification was conducted in accordance with the TÜV NORD Polska Sp. z o.o. auditing and certification procedures and is subject to regular surveillance audits.

TÜV NORD Polska Sp. z o.o. ul. Mickiewicza 26 40-085 Katowice www.tuv-nord.pl


PCA
POLSKA
CENNA
AGENCJA
Certyfikacji
CE

BurnTec®

FIRST AID FOR BURNS

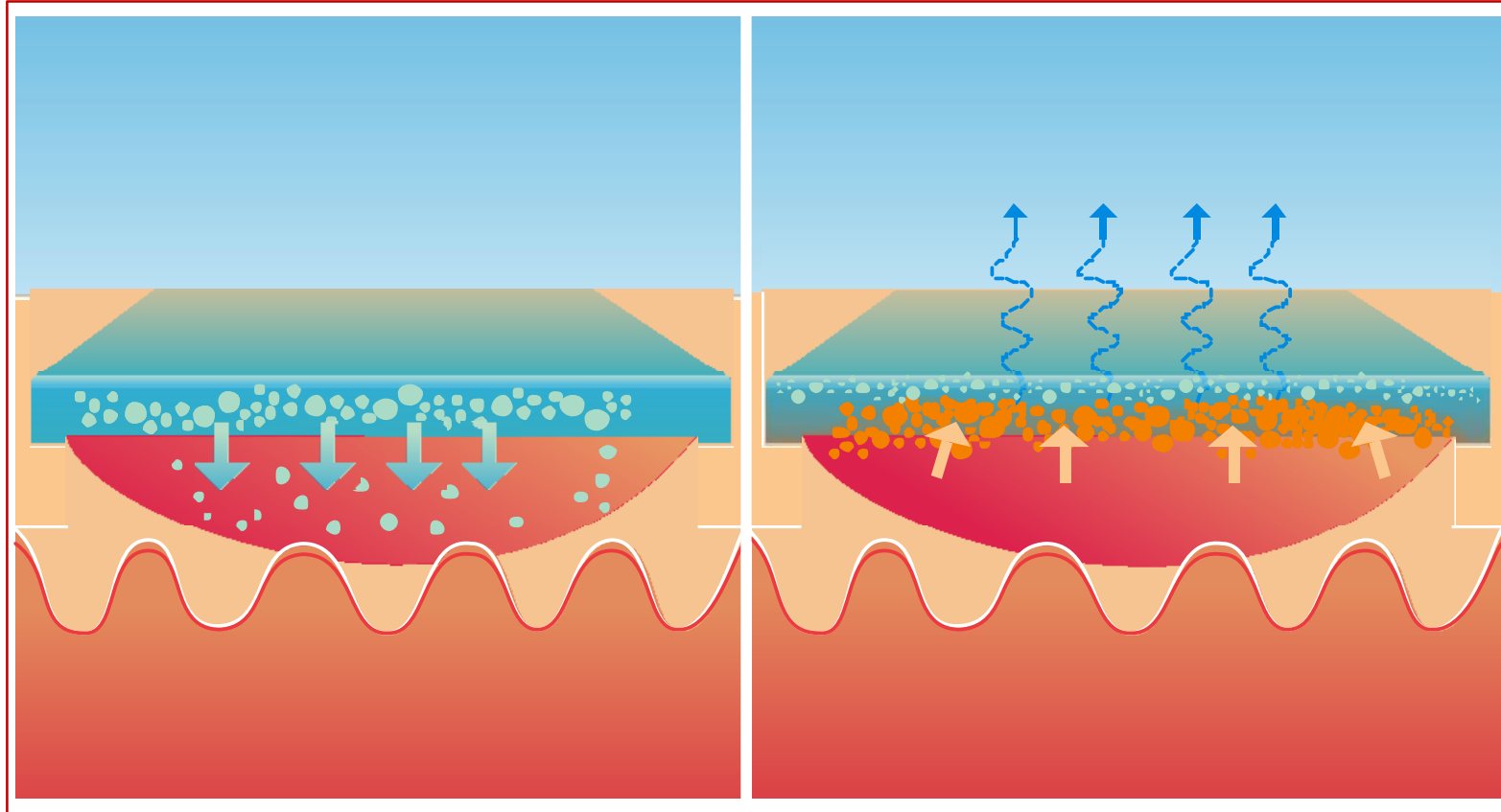


DRESSING PROPERTIES

- a hydrogel patch with 3.5 mm thickness and water content of approximately 90 %
- forms and maintains humid environment in the wound
- constitutes a barrier to external bacteria
- enables gas exchange (permeating oxygen)
- absorbs the wound exudate
- soothes pain, thus providing patient comfort
- does not adhere to the wound
- dressing change is painless
- biologically neutral, completely biocompatible
- Transparent - healing can be observed without removing the dressing
- plastic, thanks to which it can be used on body surfaces which are difficult to dress, e.g. palms, face



Hydrogel dressing regulates the moisture level in the wound



Hydrogel releases the absorbed moisture and hydrates dry wounds.

In the case of exudate wounds, the dressing absorbs the exudate into its structure.

BurnTec is a hydrogel dressing for universal use in first aid. It is used by emergency medical services, rescue and fire-fighting units, police and civil services. It is used not only in burn management, but in addition, it is effective in case of:

- ☞ deep abrasions
- ☞ open fractures
- ☞ all other skin injuries

As a stable hydrogel, the only one available on the market, it does not pose a risk of flooding the body cavities when used in combination with facial dressing and oxygen therapy.



Burn is defined as damage to the skin's surface and - depending on its degree - also to deeper tissues and organs caused by heat (thermal burn), corrosive substances (chemical burn), electric current (electric arc burn). Extensive burns, especially deep burns, additionally create the risk of shock, and resulting death of a victim.

Assessing the burns in terms of their depth and surface is an extremely important element Specially prepared classifications are used for this purpose.



ASSESSMENT OF THE BURN DEPTH

The burn depth is assessed by classifying the damage into four grades, as below:

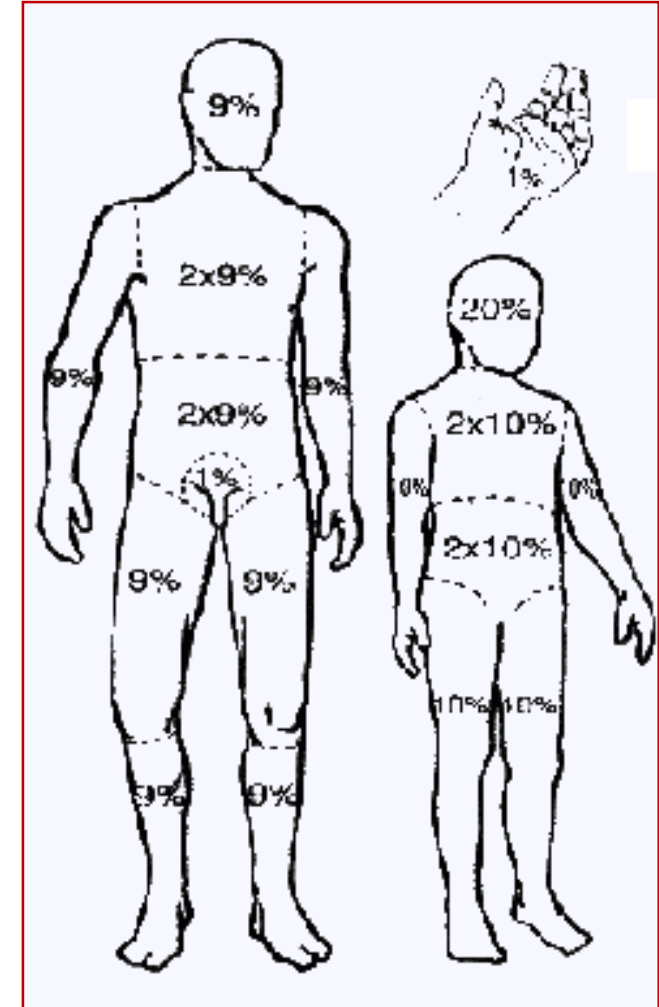
- 🌀 **first-degree burn:** covers only the epidermis; the treatment lasts about 2-3 days
- 🌀 **second-degree burn:** covers the epidermis and the deeper layers of the skin; there are two distinguished subgroups – **Ila** damage to the part of the dermis (blisters filled with serum fluid), **Ilb** complete skin burns
- 🌀 **third-degree burn:** necrosis includes the complete skin, including the dermal vessels and nerves, as well as adipose tissue.
- 🌀 **fourth-degree burn:** necrosis reaches deeper tissues including muscles, tendons and bones; in the most severe cases, the burnt part of the body is carbonized.



ASSESSING THE SIZE OF THE BURN

Assessing the size of a burn wound is as important as determining its depth. There are several schemes allowing such a calculation:

- 🌀 **Wallace rule of nines:** according to this rule, the body area is divided into areas of 9 percent
- 🌀 **rule of palm:** is used to assess the burn area in adults, according to which the burn victim's palmar area accounts for 1% of the total body area
- 🌀 **table and diagram methods:** based on specially developed tables and diagrams precisely determining the percentage distribution of each body surface; this method is most often used in burn treatment centers



ASSESSING THE SIZE OF THE BURN

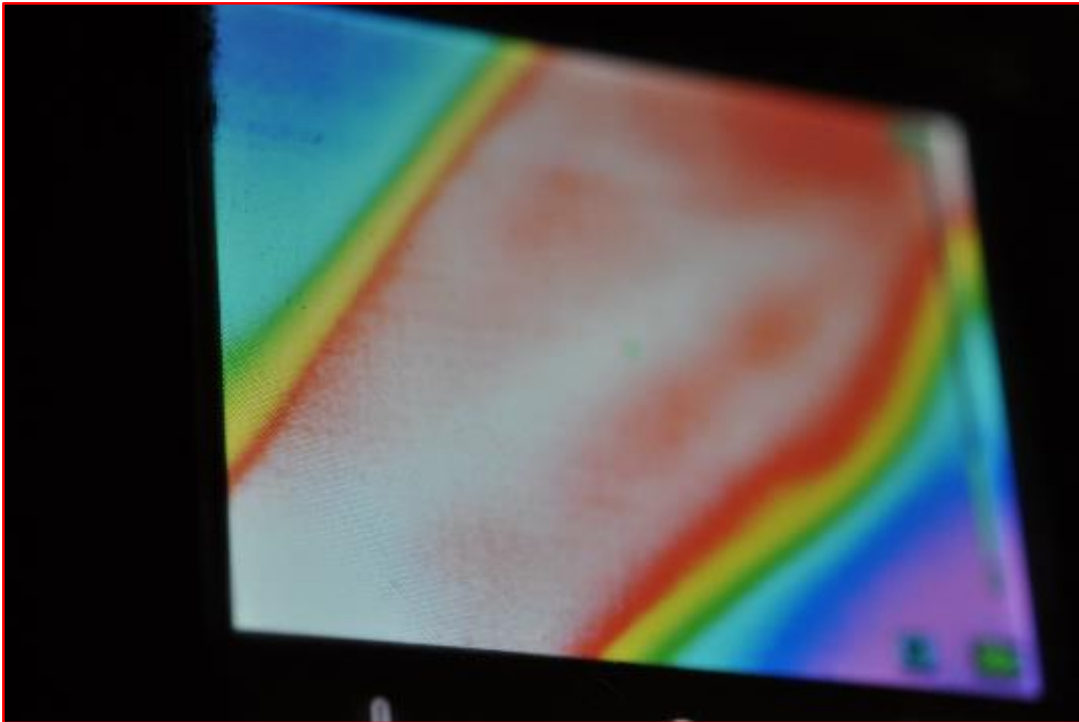
To make it easier to identify the extent of burns, each BurnTec dressing has an indication of the estimated percentage of total body surface to be covered.



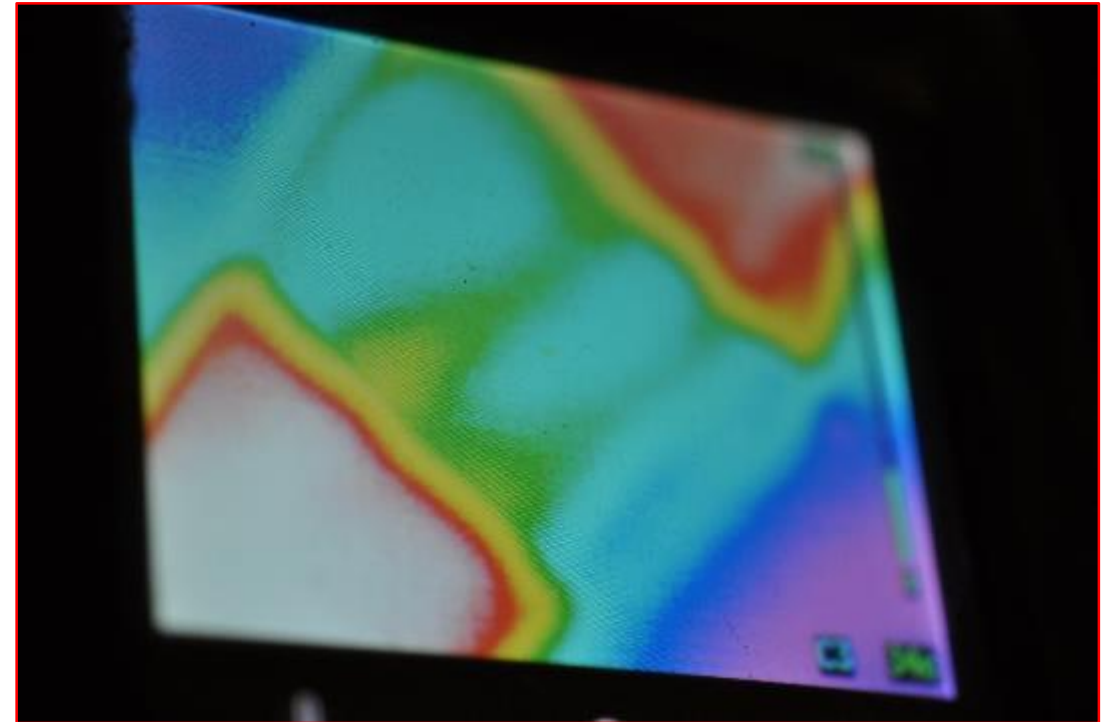
Hydrogel dressings are particularly suitable for first aid in case of burns. Hydrogels ensure effective cooling of the burns due to their high water content and thermal capacity.

- hydrogel dressings are characterized by high thermal capacity and high heat transfer coefficient
- there is no risk of developing hypothermia
- protection of the wound against infection (sterile dressing), the dressing is bacteriostatic
- possibility of continuing clinical treatment with hydrogel dressings





A forearm photo taken with a thermal imaging camera



The same forearm with hydrogel dressing, after 10 minutes.

At the moment, there are two types of hydrogel dressings on the market:

- ❧ Semi-fluid hydrogels – poured from a bag with a separate piece of non-woven fabric
- ❧ A hydrogel dressing in stable form where the non-woven fabric is combined with hydrogel.





BURNTEC DRESSING

- hydrogel in stable form, no risk of cooling substance spillage
- even distribution of hydrogel over the entire wound surface, even in case of extensive injuries
- the dressing is completely removed when changed - no additional intervention is needed in the morning
- it present is absorbent properties, the exudate is retained in the gel together with the toxins
- possibility to use in other injuries (open fractures, cuts, tears, abrasions)



HYDROGELS IN SEMI-FLUID FORM

- Risk of accidental spillage of cooling substance during dressing application
- the cooling substance pours down under the influence of gravity forces, causing uneven distribution of the hydrogel
- after removing the dressing, gel residue requires removing from the wound
- the dressing does not present absorbent properties
- applicable in case of burns only.

USE IN WOUND TREATMENT

Hydrogel dressings are used to treat burn wounds and, in addition, to treat all types of difficult-to-heal wounds, bedsores, ulcerations and other skin injuries, the therapy of which requires access to oxygen and a moist, sterile environment.



The hydrogel dressing absorbs the exudate and keeps the environment moist only within the wound.



Aqua-Gel in combination with a mesh dressing with silver. The dressings can be combined with enzymatic or pH-regulating agents.



Hydrogel dressing used on surgical wounds.

USE IN WOUND TREATMENT

BurnTec (in wound management known as Neoheal – both dressings are identical hydrogel composition) is often used in wound treatment. It is the best choice in covering of donor sites. During 10-14 days with 3-4 changes of dressings typical donor sites were healed properly. Changing of dressing is painless - hydrogel does not adhere to the wound.



USE IN WOUND TREATMENT – IIb deg. burn treatment because of hot exhaust of a motobike



10.07.2017



10.07.2017



19.07.2017



19.07.2017



19.07.2017



26.07.2017



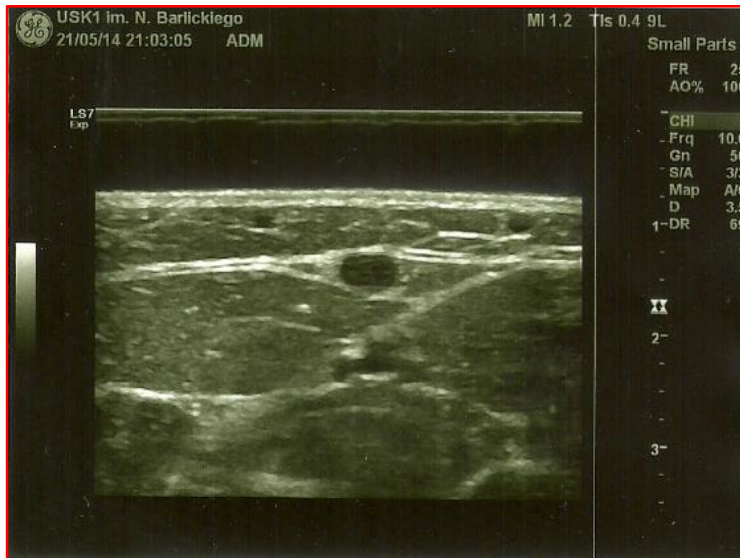
26.07.2017



08.08.2017

USE IN ULTRASONOGRAPHY

BurnTec can be used during ultrasound examinations as a special distance agent to improve the visibility of structures located near the surface or in case of wounds or injuries, including their examination.



STANDARD FOR US TROOPS - US MARINES, US NAVY

- NATO certificate with NCAGE Code for the manufacturer
- All BurnTec dressings are NSN (NATO Stock Number) listed
- BurnTec is a standard burn dressing of every IFAK (Individual First Aid Kit) of US Marine and US Navy Corps

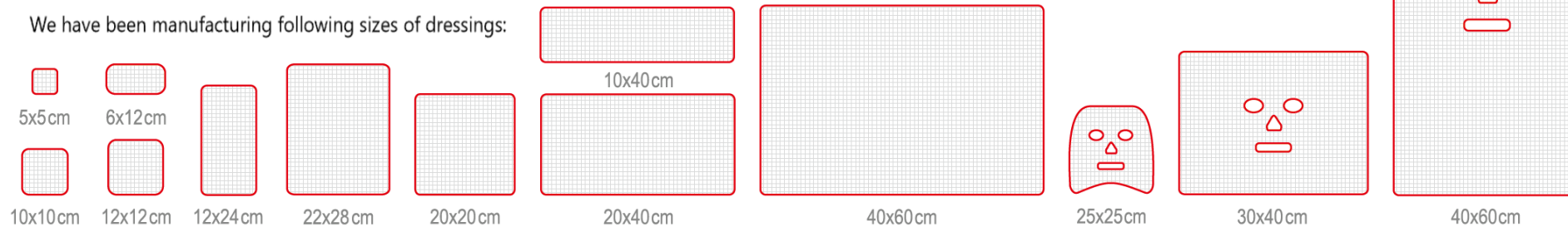


NATO Stock Numbers for BurnTec[®] sterile hydrogel dressings

Product Name	Size	NSN
BurnTec	5 cm x 5 cm	6510-43-0015993
BurnTec	6 cm x 12 cm	6510-43-0015996
BurnTec	10 cm x 10 cm	6510-43-0015995
BurnTec	12 cm x 12 cm	6510-43-0015994
BurnTec	12 cm x 24 cm	6510-43-0015998
BurnTec	20 cm x 20 cm	6510-43-0015999
BurnTec	10 cm x 40 cm	6510-43-0016000
BurnTec	22 cm x 28 cm	6510-43-0016001
BurnTec	40 cm x 60 cm	6510-43-0015997



We have been manufacturing following sizes of dressings:

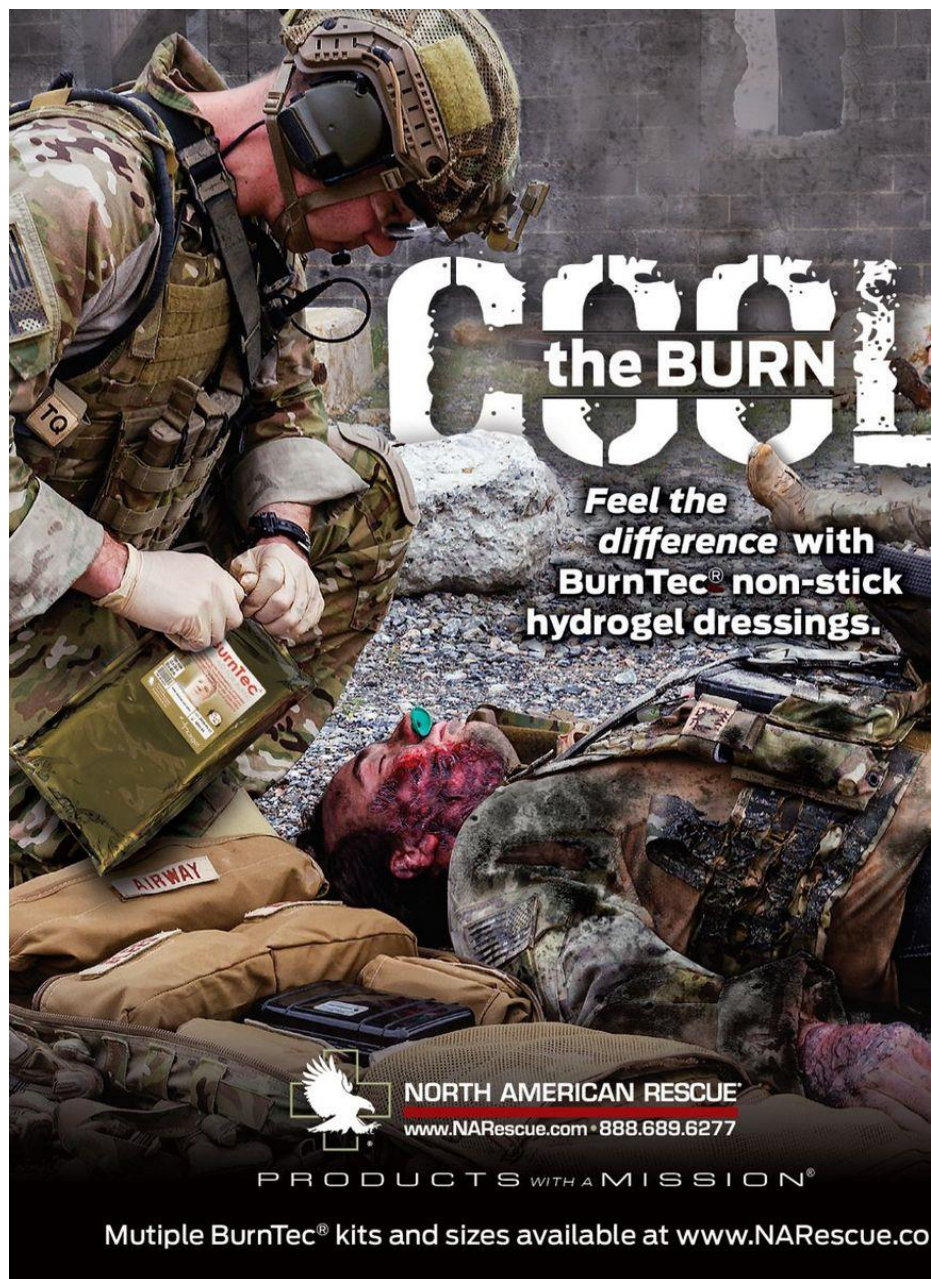


We also offer ready-made hydrogel dressing kits meeting the requirements of the National Headquarters of the State Fire Service (KG PSP) for R-1 emergency bag equipment.

The kit includes:

- 6x12 cm dressing – 4 pieces
- 10x10 cm dressing – 4 pieces
- 12x24 cm dressing – 2 pieces
- 10x40 cm dressing – 1 piece
- 20x20 cm dressing – 2 pieces
- 20x40 cm dressing – 2 pieces
- Face dressing – 2 pieces
- Semi-fluid hydrogel with antibacterial properties, 120 ml – 2 pieces
- Bag for dressing storage.





COOL
the BURN

Feel the difference with BurnTec® non-stick hydrogel dressings.

NORTH AMERICAN RESCUE
www.NARescue.com • 888.689.6277

PRODUCTS WITH A MISSION®

Multiple BurnTec® kits and sizes available at www.NARescue.com

 **BurnTec**®
FIRST AID FOR BURNS

 **Kikgel**

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Tel. 44 719 23 40
kik@kikgel.com.pl

ISO13485
certified

 **2274**

www.kikgel.com.pl