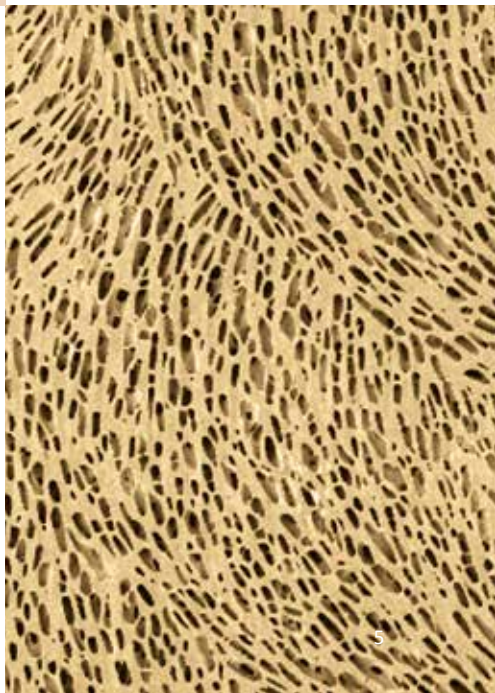
SUPRATHEL®

THE **TEMPORARY** SECOND SKIN

PMI
The Wound Healing Company



Intelligent wound care with a temporary skin substitute

SUPRATHEL® **is an innovative skin substitute indicated for the treatment of epidermal and dermal wounds. Successful use of the product has been demonstrated in the management of burns and STSG donor sites.**

Just like a second skin, SUPRATHEL® covers the wound and leads the wound through a quick, complication free healing process. **SUPRA**THEL® was developed analogous to the human skin and thus shares the same properties such as elasticity, permeability to water vapor and impermeability to bacteria.

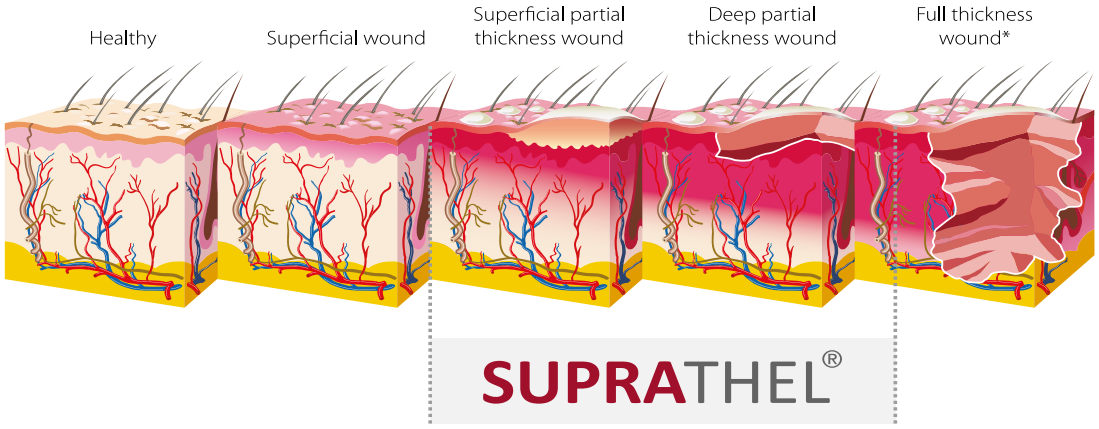
SUPRATHEL® is a single application product that is applied directly to a disinfected and debrided wound bed, where it stays intact until the wound is completely healed. After it is applied, the membrane becomes translucent and makes inspection of the healing process possible.

Indications for use

SUPRATHEL® **was developed for the treatment of epidermal and dermal wounds.**
SUPRATHEL® covers a wide range of wound care:

- Split-thickness skin graft (STSG) donor sites
- Burns
  - Superficial
  - Partial thickness
  - Partial thickness with 3° areas

Positioning in the treatment of wounds



*Full thickness burns not indicated in the US and Canada

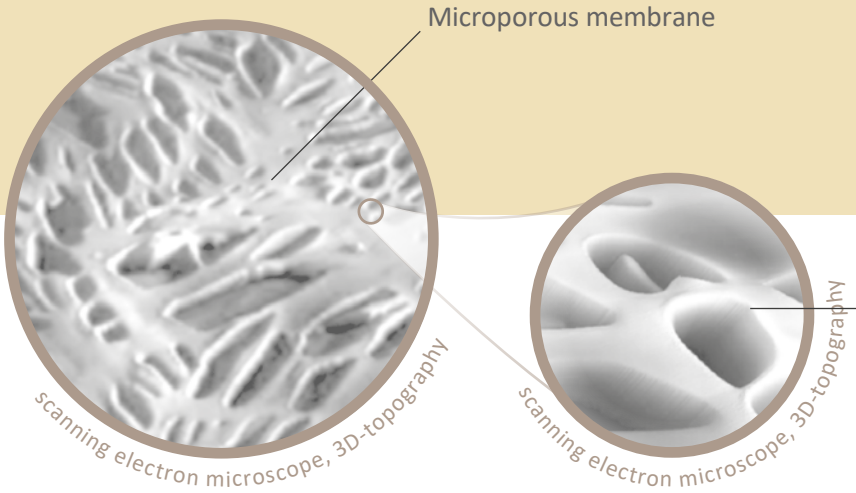
- Alginate
- Hydrofibres
- Hydrogels
- Foam dressing
- Hydrocolloids
- Film dressing
- Collagen dressing

- Cadaver-based scaffolds
- STSG
- Mesh-graft transplantations
- Cultured epithelial autografts (CEA)
- Acellular grafts
- Dermal substitutes
- Xenograft

Properties

Composition	Lacto-capromer
Degradation	Hydrolytically
Plasticity	> 50 % elongation at break
Permeability to water vapor	40 - 70 ml/m² (hour) approx. 1.000 - 1.700 per day
Porosity	70 - 80 %

The unique combination of strong features

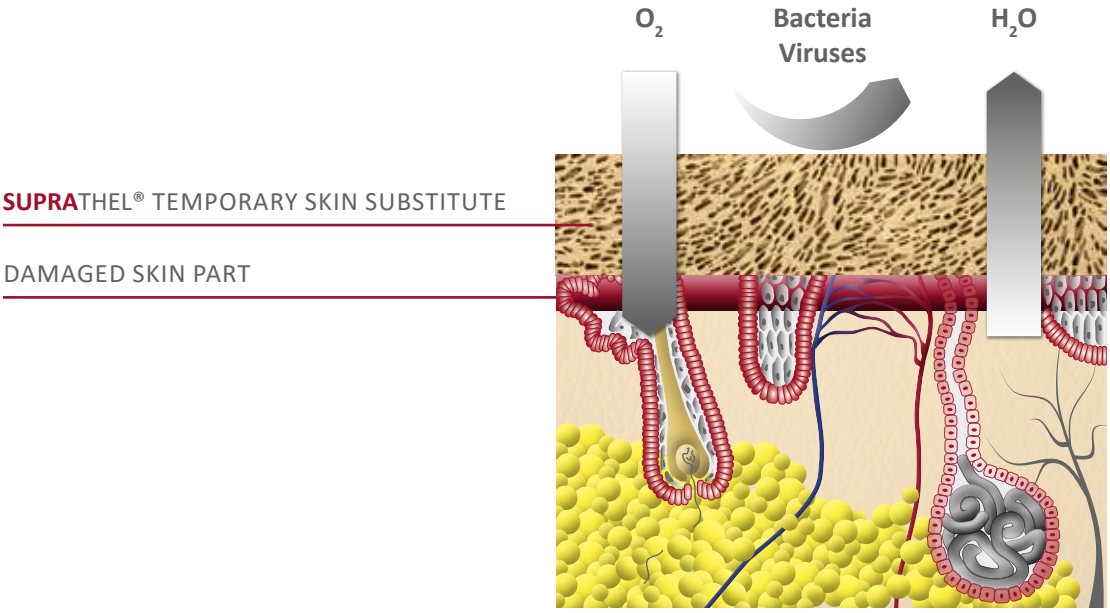


Copolymer* from
- Lactide
- Trimethylene carbonate
- ε-Caprolactone

* The individual components have been successfully used in surgery for decades.

SUPRATHEL® **is purely synthetic and therefore does not bear any residual risks as is the case with biological products of human or animal origin.**

Literature suggests that lactate may stimulate the healing process by supporting angiogenesis[1-6] and the re-building of the dermis[7-10]. The potential of lactate to act as a free radical scavenger and therefore to be able to reduce oxidative stress has been demonstrated within the literature[11].



Literature

[1] Lu et al. 2002: J. Biol. Chem. 277:23111-5.
[2] Lu et al. 2005: J. Biol. Chem. 280:41928-39.
[3] Constant et al. 2000: Wound. Repair Regen. 8:353-360.
[4] Rendl et al. 2001: Br. J. Dermatol. 145:3-9.
[5] Beckert et al. 2006: Wound. Repair Regen. 14: 321-324.
[6] Nareike et al. 2005: Am. J. Physiol. Endocrinol. Metab. 289:E534-42.
[7] Green and Goldberg 1964: Nature 204: 347-9.
[8] Hunt et al. 1978: Am J Surg. 135(3):328-32.
[9] Klein et al. 2001: J Hand Surg Am 26(5):847-54.
[10] Wagner et al. 2004: Wound. Repair Regen. 12:368-73.
[11] Groussard et al. 2000: J ApplPhysiol. 89: 169–175.

The advantages of working with **SUPRA**THEL®

- **One-time wound dressing, no change of SUPRATHEL® needed**
- **Significant pain relief** [1-4] **– by up to 60%**
  - » Less anesthesia and pain medication required [1,5,6]
- **Low rate of infections** [1,2, 5,7-9]**, no biological risk**
  - » Synthetic, biocompatible, absorbable
  - » No reported allergic reactions
- **Fast wound healing** [1,2,5]
  - » Improved epithelization [3,11]
- **Lower treatment costs** [2,4,5]
  - » Less cost and effort for dressing changes [2,9]
  - » Shorter hospital stay [5]
- **Excellent cosmetic outcomes and scar quality** [4,7,8]
- **Low inflammatory reaction** [12]
- **Reduced transplantation rate** [6]

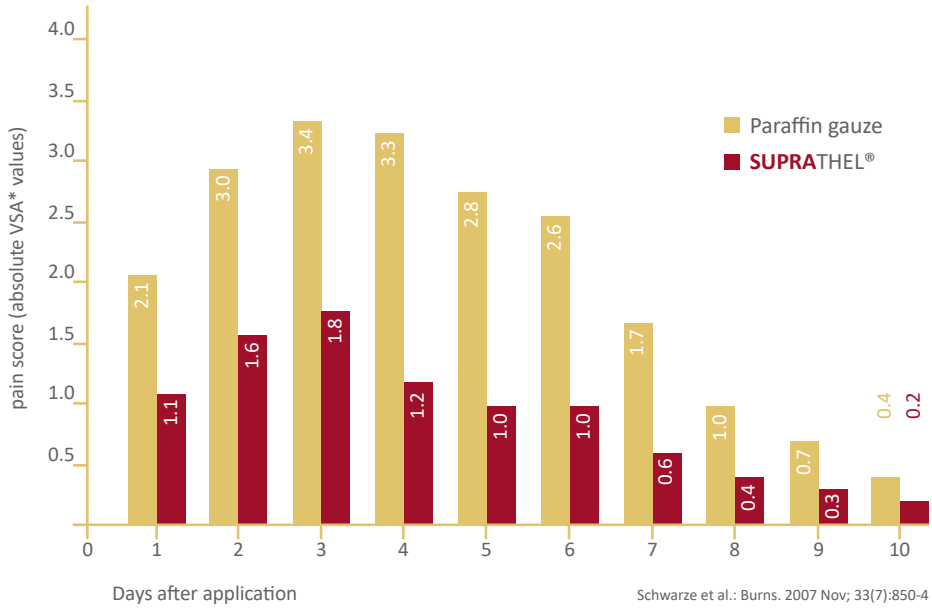
Literature

[1] Schwarze et al. 2007: Burns. 2007 Nov;33(7):850-4
[2] Schwarze et al. 2008: Ann Plast Surg. 2008 Feb;60(2):181-5
[3] Uhlig et al. 2007: Burns. 2007 Mar;33(2):221-9
[4] Kaartinen and Kuokkanen 2011: Burns. 2012 May;38(3):388-95.
[5] Everett et al. 2015: J Wound Care. 2015 Jul;24(7):S4-8.
[6] Schriek et al. 2022: Eur. Burn J. 2022, 3, 1–9
[7] Keck et al. 2012: Burns. 2012 May;38(3):388-95.
[8] Hundeshagen et al. 2018: J Burn Care Res. 2018 Feb 20;39(2):261-267.
[9] Markl et al. 2010: Ann Plast Surg. 2010 Nov;65(5):490-6
[10] Gürünluoglu et al. 2019: J Burn Care Res. 2019 Jun 21;40(4):444-450
[11] Gürünluoglu et al. 2019: J Burn Care Res. 2019 Apr 26;40(3):302-311
[12] Demircan et al. 2021: Ulus Travma Acil Cerrahi Derg. 2021 Jan;27(1):122-131

SUPRATHEL®

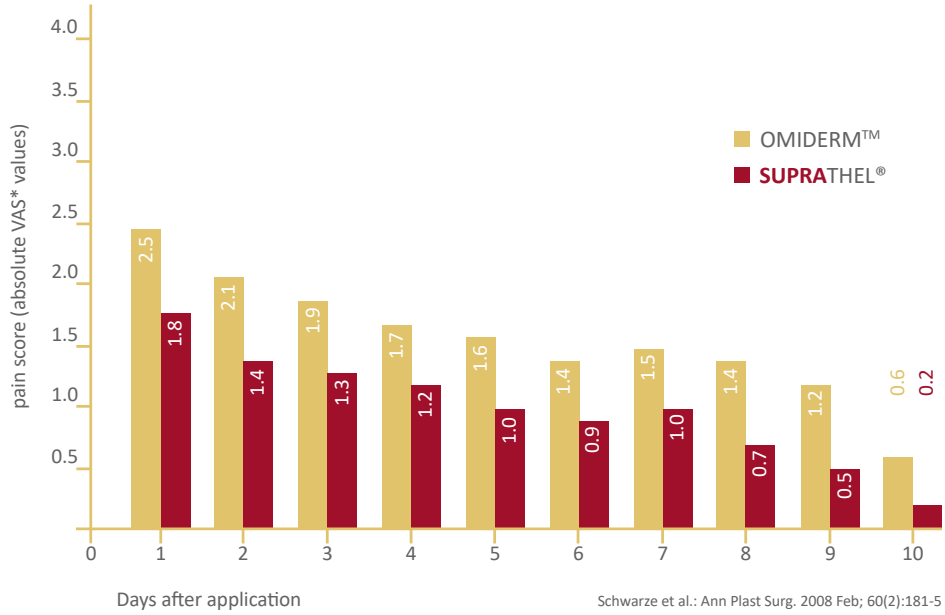
Facts and Figures

Pain benefits at STSG donor sites



Schwarze et al.: Burns. 2007 Nov; 33(7):850-4

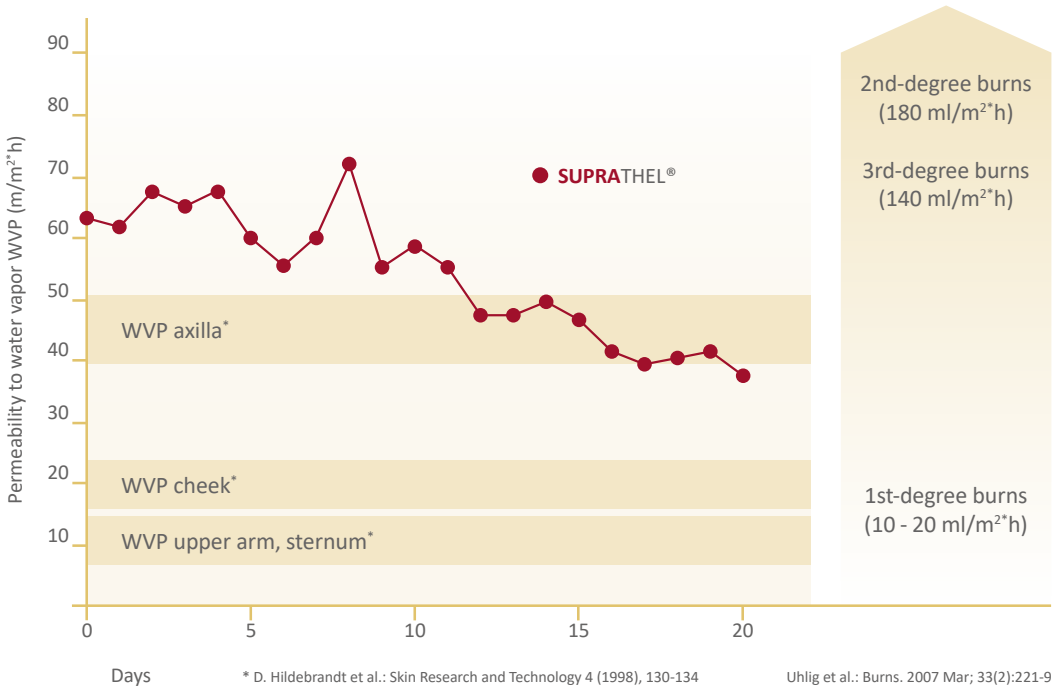
Pain benefits in cases of burns



Schwarze et al.: Ann Plast Surg. 2008 Feb; 60(2):181-5

Effective. Efficient. Reliable.

Permeability to water vapor

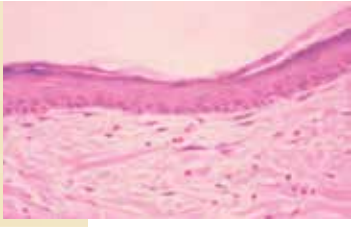


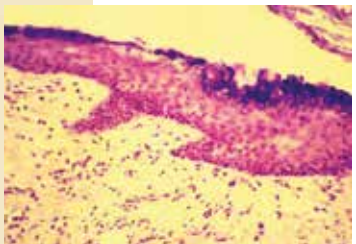
* D. Hildebrandt et al.: Skin Research and Technology 4 (1998), 130-134

Uhlig et al.: Burns. 2007 Mar; 33(2):221-9

Histology

- No inflammatory reaction
- Good vascularized dermal tissue
- Completely formed stratum basale
- Increased epithelization

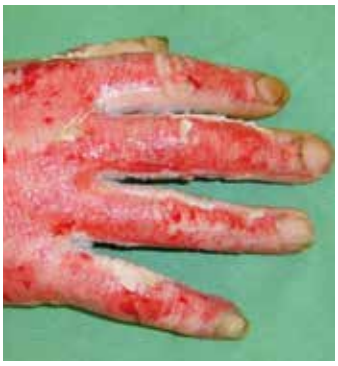




» 2a° burn: biopsy 14 days after the application of **SUPRA**THEL®

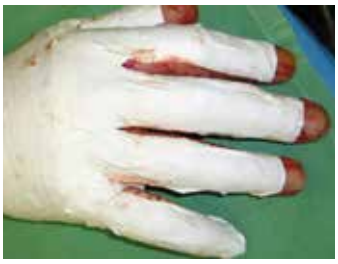
Uhlig et al.: Burns, 2007 Mar; 33(2):221-9

The Temporary Second Skin
Application



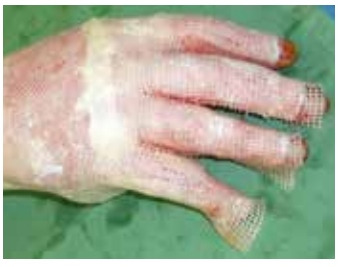
Wound preparation

Complete removal of all necrotic and nonviable tissue must be performed prior to placement of SUPRATHEL®. The wound bed should be thorougy cleaned and inspected. All contamination sources should be removed. Second degree burns require thorough debridement to ensure the absence of all contaminated and devitalized tissue.



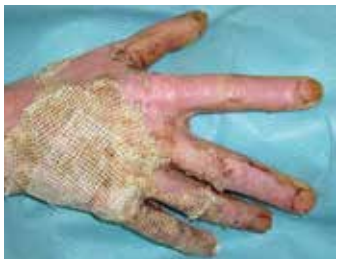
Application of SUPRATHEL®

SUPRATHEL® contours well to all parts of the body. After application to the injured site the membrane becomes translucent, allowing for visualization and inspection of the healing process.



Dressing SUPRATHEL®

SUPRATHEL® should be covered with 1-2 layers of petroleum based gauze which are left intact until the wound is fully healed. Only outer dressings should be changed after inspection of SUPRATHEL® or if they become soiled.

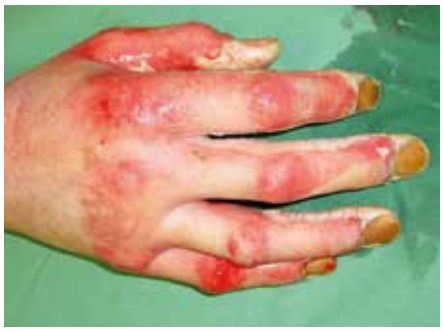


Removal of SUPRATHEL®

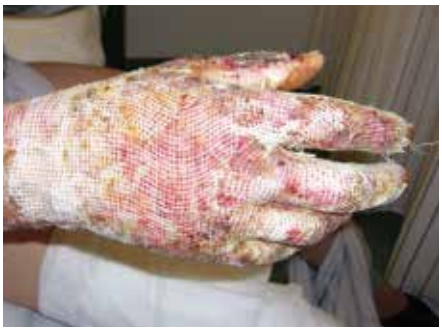
SUPRATHEL® starts to detach from the skin following epithelization and may be removed without causing pain. SUPRATHEL® that is still adhered should be left intact.

Application with burns on the hands

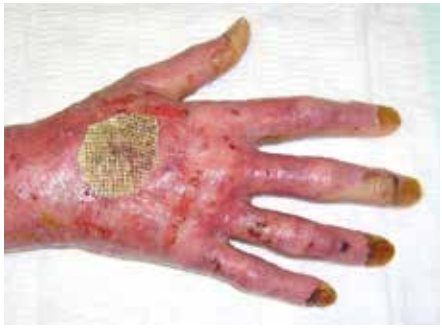
59 years old, electric burns, mainly superficial partial thickness/deep partial thickness



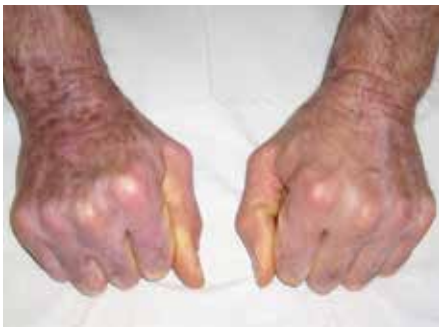
» Day 1, debridement



» Day 6



» Day 21



» After 8 months

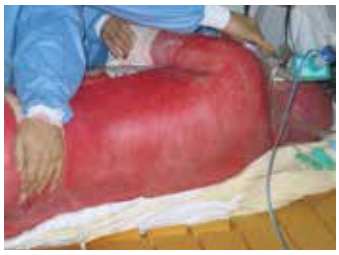
Uhlig et al.: Handchir Mikrochir Plast Chir. 2007 Oct; 39(5):314-9

Advantages

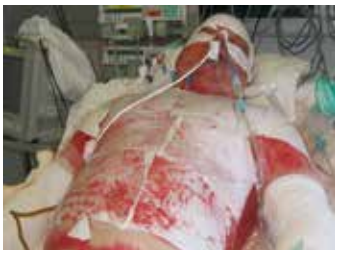
Due to its excellent adhesion and flexibility it can easily be applied to difficult body parts, such as hands, fingers and toes allowing for early range of motion without disrupting the intimate contact between **SUPRA**THEL® and the wound bed.

Application with large scale burns

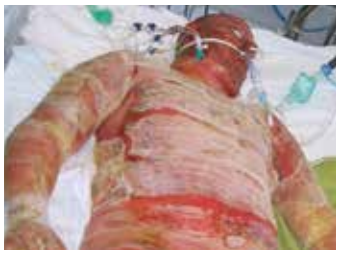
38 years old, 95 % BSA, ABSI 13, mainly superficial partial thickness/deep partial thickness



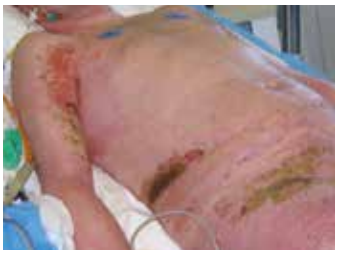
» Day 2, debridement



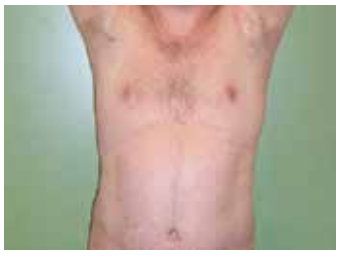
» Day 2, application of SUPRATHEL®



» Day 7, SUPRATHEL® *in situ*



» 4 weeks after trauma



» 2.5 years after trauma

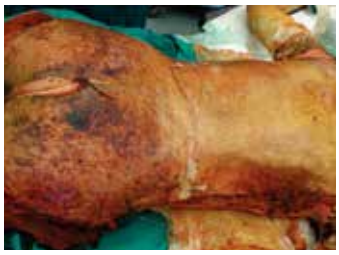
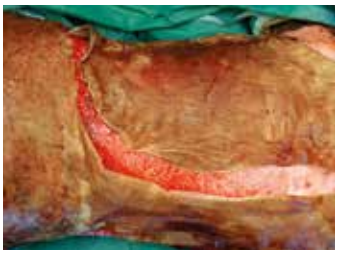
Uhlig et al.: Osteo trauma care 2007; 15: 2-7

Treatment concept

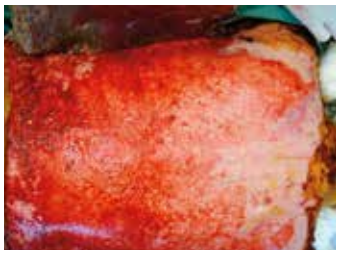
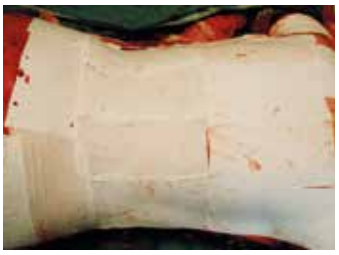
- Application of **SUPRA**THEL® on large areas of burned skin with various depths of burns as primary measure after surgical debridement
- Quick epithelization after a scarless healing of the burns after 8 to 14 days
- Possible transplantation of deeper areas which are not yet healed
- Scarless healing is also possible with large scale burns

Application on partial thickness burns

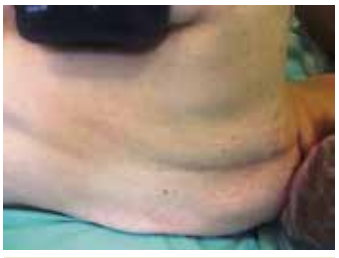
36 years old, 90 % BSA, mainly deep partial thickness

» Day 0

» Day 0, debridement and application of SUPRATHEL®

» Day 18

» After 24 months

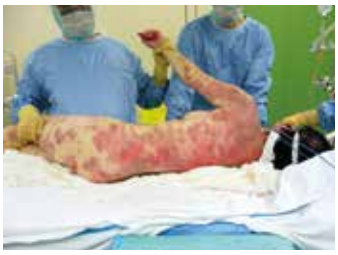
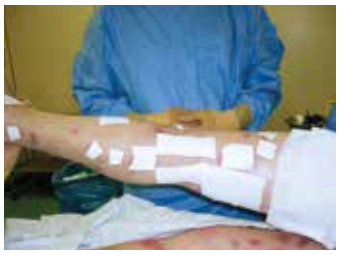
Kamolz et al.: Eur Surg (2008) 40/1:19–26

Advantages

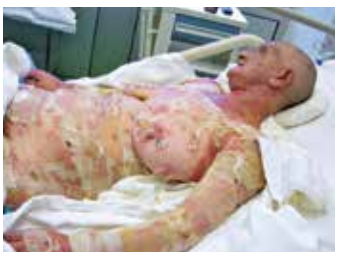
- Quick epithelization of deep partial thickness burns
- **SUPRA**THEL® serves as primary measure for the application on large scale deep dermal burns
- Available STSG donor sites can be used for obvious full thickness degree burns
- Second transplantation after the specific identification of full thickness burns
- Almost scarless healing even with deep dermal burns

Application on wounds caused by TEN (Toxic Epidermal Necrolysis)/Lyell‘s Syndrome

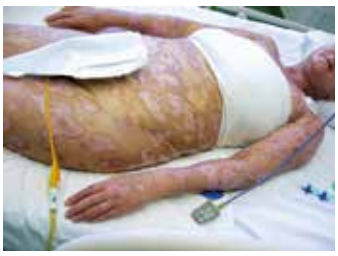
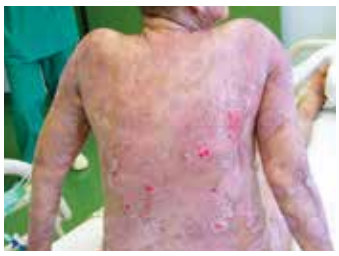
48 years old, TEN (Toxic Epidermal Necrolysis), superficial partial thickness, 80 % BSA

» Day 0




» Day 6

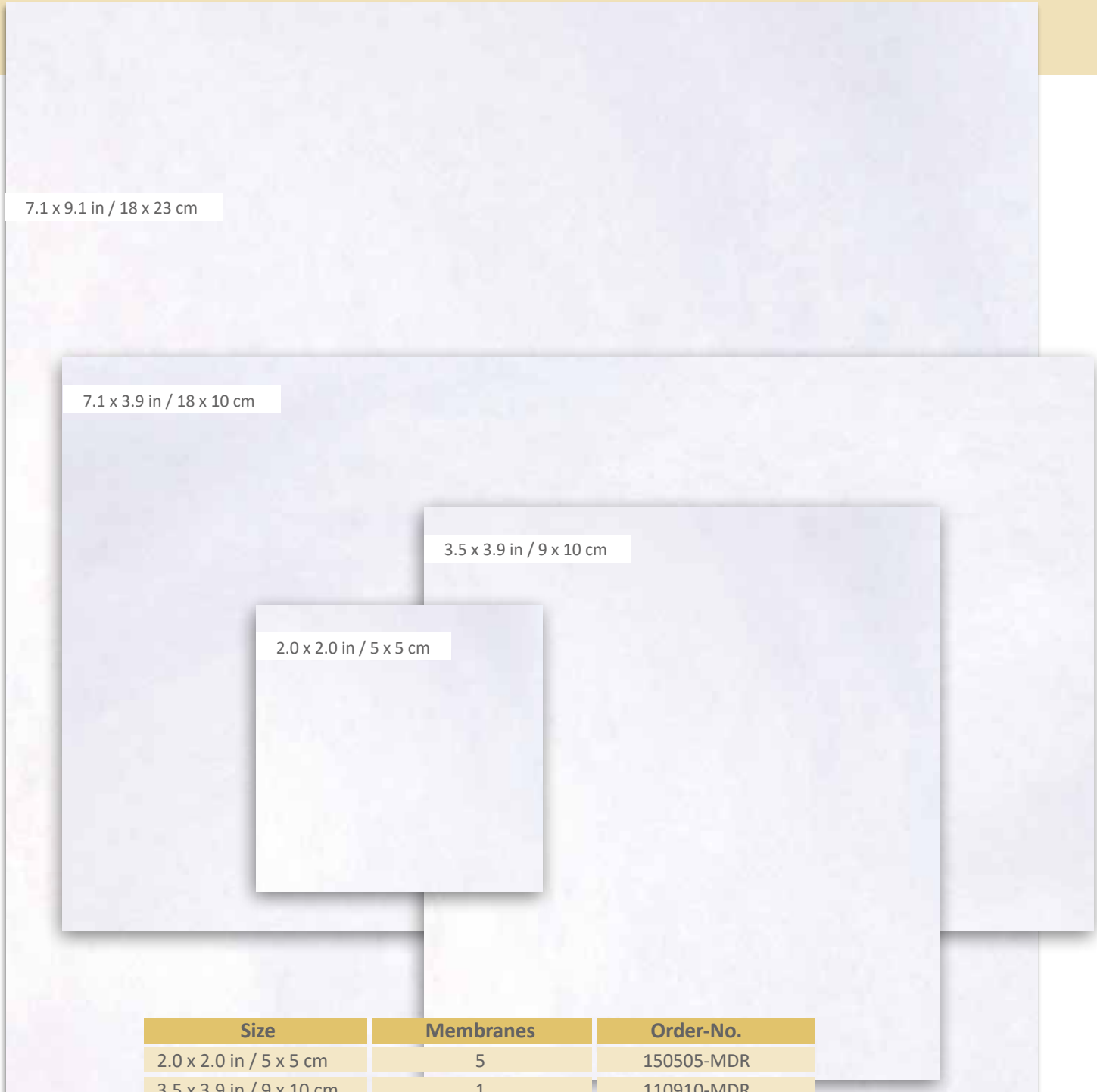
» After 4 weeks

Uhlig, internal study, Marienhospital Stuttgart

Advantages

- **SUPRA**THEL® can be applied easily and safely, even to large areas
- Immediate pain relief after application
- Excellent coverage of wounds, no change of **SUPRA**THEL® needed
- Significantly less effort for nursing staff
- Cost reduction due to high efficiency

SUPRATHEL® packing unit



Size	Membranes	Order-No.
2.0 x 2.0 in / 5 x 5 cm	5	150505-MDR
3.5 x 3.9 in / 9 x 10 cm	1	110910-MDR
3.5 x 3.9 in / 9 x 10 cm	5	150910-MDR
7.1 x 3.9 in / 18 x 10 cm	1	111810-MDR
7.1 x 3.9 in / 18 x 10 cm	5	151810-MDR
7.1 x 9.1 in / 18 x 23 cm	1	111823-MDR
7.1 x 9.1 in / 18 x 23 cm	5	151823-MDR

Pictures show membranes in their original sizes.

Scientific publications on **SUPRA**THEL®

Baartmans MG, Dokter J, den Hollander JC, Kroon AA, Oranje AP. Use of Skin Substitute Dressings in the Treatment of Staphylococcal Scalded Skin Syndrome in Neonates and Young Infants. Neonatology. 2011;100(1):9-13.

Blome-Eberwein SA, Amani H, Lozano DD, Gogal C, Boorse D, Pagella P. Burns. A bio-degradable synthetic membrane to treat superficial and deep second degree burn wounds in adults and children – 4 year experience. Burns. 2020 Aug 29;S0305-4179(20)30507-6.

Demircan M, Gürünlüoğlu K, Gözükara Bağ HG , Koçbıyık A, Gül M, Üremiş N, Gül S, Gürünlüoğlu S, Türköz Y, Taşçı A. Impaction of the polylactic membrane or hydrofiber with silver dressings on the interleukin-6, tumor necrosis factor-α, transforming growth factor-b3 levels in the blood and tissues of pediatric patients with burns. Ulus Travma Acil Cerrahi Derg. 2021 Jan;27(1):122-131.

Everett M, Massand S, Davis W, Burkey B, Glat PM. Use of a copolymer dressing on superficial and partial-thickness burns in a paediatric population. J Wound Care. 2015 Jul;24(7):S4-8.

Fischer S, Kremer T, Horter J, Schaefer A, Ziegler B, Kneser U, Hirche C. Suprathel(®) for severe burns in the elderly: Case report and review of the literature. Burns. 2016 Aug;42(5):e86-92.

Galati V, Vonthein R, Stang F, Mailaender P, Kisch T. Split thickness skin graft versus application of the temporary skin substitute suprathel in the treatment of deep dermal hand burns: a retrospective cohort study of scar elasticity and perfusion. Int J Burns Trauma. 2021 Aug 15;11(4):312-320.

Gürünlüoğlu K, Demircan M, Koç A, Koçbıyık A, Taşçı A, Durmuş K, Gürünlüoğlu S, Gözükara Bağ H. The Effects of Different Burn Dressings on Length of Telomere and Expression of Telomerase in Children With Thermal Burns. J Burn Care Res. 2019 Apr 26;40(3):302-311.

Gürünlüoğlu K, Demircan M, Taşçi A, Üremiş MM, Türköz Y, Bağ HG, Akinci A, Bayrakçi E. The effects of two different burn dressings on serum oxidative stress indicators in children with partial burn. J Burn Care Res, Jun 21;40(4):444-450.

Harenberg PS, Hrabowski M, Ryssel H, Gazyakan E, Germann G, Engel H, Reichenberger MA. Febrile Ulceronecrotic Mucha-Habermann Disease. Eplasty. 2010 Jul 16;10: e53.

Highton L, Wallace C, Shah M. Use of Suprathel® for partial thickness burns in children. Burns. 2013 Feb;39(1):136-41.

Hundeshagen G, Collins VN, Wurzer P, Sherman W, Voigt CD, Cambiaso-Daniel J, Nunez Lopez O, Sheaffer J, Herndon DN, Finnerty CC, Branski LK. A Prospective, Randomized, Controlled Trial Comparing the Outpatient Treatment of Pediatric and Adult Partial-Thickness Burns with Suprathel or Mepilex Ag. J Burn Care Res. 2018 Feb 20;39(2):261-267.

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