Summary of Safety and Clinical Performance (SSCP)

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the medical device Suprathel®.

The SSCP is not intended to replace the Instructions For Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for healthcare professionals.

1. Device Identification and general information

1.1 Device trade names	**Suprathel®, Suprathel® 250**
1.2 Manufacturer's name and address	PolyMedics Innovations GmbH (PMI) Heerweg 15 D 73770 Denkendorf, Germany
1.3 Manufacturer's single Registration number (SRN)	DE-MF-000006353
1.4 Basic UDI	426018402AAA0000001PQ
1.5 Medical device nomenclature description/text	GMDN 64853: Synthetic wound matrix dressing
1.6 Class of device	III *(according to Medical Device Regulation (MDR) (EU) 2017/745 Annex VIII, rule 8)*
1.7 Year when the first certificate (CE) was issued covering the device	2004
1.8 Authorised representative if applicable	n/a
1.9 NB's name and NB's single identification number	DEKRA, 0124

SUPRATHEL® variant 1

Basic UDI-DI:
426018402AAA0000001PQ

				UDI –DI (Device Identifier)		UDI –PI (Product Identifier)			
Product name	**Size (cm)**	**Sales Unit**	**Packaging Level**	**GS1**	**GTIN**	**AI Shelf Life**	**Shelf Life**	**AI LOT**	**LOT**
SUPRATHEL®	5 x 5	1	Inner	**(01)**	04260184020003	(17)	YYMMDD	(10)	P-YYYY-NN-ZZ
			outer		04260184020010				
		5	Inner		04260184020003				
			outer		04260184020027				
	9 x 10	1	inner		04260184020034				
			outer		04260184020041				
		5	inner		04260184020034				
			outer		04260184020058				
	18 x 10	1	inner		04260184020065				
			outer		04260184020072				
		5	inner		04260184020065				
			outer		04260184020089				
	18 x 23	1	inner		04260184020096				
			outer		04260184020102				
		5	inner		04260184020096				
			outer		04260184020119				
	hand shape	2	inner		04260184020126				
			outer		04260184020133				
	face mask	1	inner		04260184020140				
			outer		04260184020157				

SUPRATHEL® variant 2

Basic UDI-DI:
426018402AAA0000001PQ

				UDI –DI (Device Identifier)		UDI –PI (Product Identifier)			
Product name	**Size (cm)**	**Sales Unit**	**Packaging Level**	**GS1**	**GTIN**	**AI Shelf Life**	**Shelf Life**	**AI LOT**	**LOT**
SUPRATHEL® 250	5 x 5	1	inner	**(01)**	04260184020164	(17)	YYMMDD	(10)	P-YYYY-NN-ZZ
			outer		04260184020171				
		5	inner		04260184020164				
			outer		04260184020188				
	9 x 10	1	inner		04260184020195				
			outer		04260184020201				
		5	inner		04260184020195				
			outer		04260184020218				
	18 x 10	1	Inner		04260184020225				
			outer		04260184020232				
		5	inner		04260184020225				
			outer		04260184020249				
	18 x 23	1	inner		04260184020256				
			outer		04260184020263				
		5	inner		04260184020256				
			outer		04260184020270				

2. Intended use of the device

2.1. Intended purpose

- Suprathel® is an absorbable, microporous membrane and an alloplastic skin substitute for the treatment of epidermal and dermal wounds .

2.2. Indications and target population(s)

- Suprathel® is indicated for patients with epidermal and dermal wounds, including abrasions, split skin graft donor sites, 2nd degree burns as well as 2nd degree burns mixed with 3rd degree burned areas.
- Suprathel® is used for patients with chronic wounds, such as venous and arterial ulcers, as well as diabetic wounds.

2.3. Contraindications and/or limitations

- Suprathel® should not be used on infected wound sites or on severely bleeding wounds without additional hemostatic treatment.
- Suprathel® should not be applied on chronic dry wounds.

3. Device Description

3.1. Description of the device

Suprathel® characteristics:

- single use, one-time application skin substitute
- highly permeable to oxygen and water vapour
- composed of three synthetic and bioresorbable components: lactide, trimethylene carbonate and caprolactone
- no medicinal substances, tissue or blood derivates incorporated
- wound application possible with both sides of the device
- enables visual assessment of the healing process due to its transparency after contact to the wound

Suprathel® sizes and shape:

- Available in two variants with different thicknesses: 50 - 150 µm and 180 - 320 µm
- Solid, rectangular sheets in sizes: 5 x 5 cm, 9 x 10 cm, 18 x 10 cm up to 18 x 23 cm, hand shape and face mask
- Suprathel may be manually trimmed by the user to other shapes and sizes as needed for optimal coverage of the affected areas

3.2. A reference to previous generation(s) or variants if such exist, and a description of the difference

Not applicable

3.3. Description of any accessories which are intended to be used in combination with the device

Not applicable

3.4. Description of any other devices and products which are intended to be used in combination with the device

Suprathel® can be used either alone or in combination with various conventional gauze dressings with and without fatty additives. Combination with such dressings may serve to further secure the membrane and prevent dislocation.

4. Risks and warnings

4.1. Residual risks and undesirable effects

All performed risk analyses conclude with an acceptable overall benefit/risk ratio.

The three risks in the „non-acceptable" field were analyzed and accepted since the benefits far outweigh the risks. All three of them are linked to potentially serious infections as indicated in this SSCP at section contraindications and warnings and precautions. However, the probability of occurrence is linked either to sterility issues which by definition can occur with a certain probability, or to a hazardous situation that has never occurred in the entire product history of more than 15 years.

Acceptable residual risks are provided to the users within the Instructions for Use. Corresponding warnings and precautions resulting from the accepted residual risks are listed below.

4.2. Warnings and precautions

- Do not apply a product, where the sterility may not be ensured as this may lead to severe infections
- The content is sterile unless sterile packaging is damaged
- In case of packaging damages, the sterility of the product is not ensured. The unused contents of opened or damaged sterile packages are to be discarded
- Do not reuse and do not resterilise. If the product is nevertheless reused, this may lead to impairment of product performance characteristics (reduced permeability, elasticity, adherence capability as well as sterility). Such changes of material properties may in turn lead to treatment impairments, such as inadequate wound healing as well as infections

- In the case of known allergies against components of Suprathel®, the membrane should not be applied.
- Suprathel® should be removed immediately if there are any signs of allergic reactions to the material. Suprathel® should be removed in cases of severe pain or accumulations of wound secretions
- Coverage of intact skin may lead to skin macerations and should be avoided

4.3. Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable

Not applicable

5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

5.1. Summary of clinical data related to equivalent device

Not applicable

5.2. Summary of clinical data from conducted investigations of the device before the CE-marking,

Acc. to MDCG 2019-9	2nd degree burns and split skin donor sites (SSDS)	Chronic wounds
Identity of the investigation/study: If performed under the Medical Device Directives or the MDR, then give the **CIV ID** or **single identification number**. Add reference details if the clinical investigation report is available in Eudamed72.	DE/CA37/1540/KP-1 Not available in EUDAMED	DE/CA37/PolyMedics/KP-1 Not available in EUDAMED
Identity of the device including any model number/version	Suprathel®	Suprathel®
Intended use of the device in the investigation	Treatment of split skin grafts and second degree burns	Local Treatment of Ulcus Cruris
Objectives of the study	The aim of the study was to examine whether Suprathel® is superior to the established procedures for split skin donor sites and burns in terms of pain behavior.	Target of the study was the measurement of the influence of Suprathel® on the wound area (main target), the wound pain, the inflammatory activity of the skin, the wound surface and the wound secretion

Study design: randomised controlled trial, other pivotal trial, short-term feasibility study, other; and the duration of the follow-up	Prospective, randomized, two center clinical study Marienhospital (Stuttgart) and the Surgical Hospital Berlin with Prof. K.-K. Dittel as the Principal Investigator	Prospective, multicenter study Six hospital departments from four hospitals enrolled 22 patients duration of the treatment was limited to 24 weeks
Primary and secondary endpoint(s)	study endpoints: 1. Pain, 2. Healing time, frequency of local events, quality of scarring	study endpoints: 1. Wound area 2. Pain, inflammatory activity (skin, wound surface), wound secretion, detect side effects
Inclusion/exclusion criteria for subject selection	Inclusion criteria: - Patients 18 years of age or older who are capable of giving consent and for whom - One split thickness skin removal or multiple split thickness skin removals for the purpose of a Skin grafting is necessary. The minimum size of the entire split skin removal site must not be less than 8 x 10 cm. - At least one contiguous area or two corresponding areas a 2nd degree burn over a total of at least 1.5 % of the body surface area show. Exclusion criteria: General exclusion criteria - Pregnancy - Age under 18 years and over 80 years - Burns that are so severe that artificial respiration must be performed and thus consent to the study is not possible - Burns with an ABSI greater than 10, because in these patients the vital threat is so high that the conduct of a study does not seem justifiable Medical history exclusion criteria - Dialysis requirement	Inclusion criteria: - Written documentation of consent - Location of the wound distal to the knee joint - Age of the wound at least 3 months - Area of the wound maximum 25cm² - (Presumed) availability during the six-month period of the Study participation Exclusion criteria: - Younger than 18 years - Pregnancy and non-exclusion of pregnancy - Risk of pregnancy occurring during study integration - Study integration (for women, failure to meet at least one of the of the following criteria: - Onset of menopause more than 2 years ago, - Postmenopausal sterilization, surgical sterilization, commitment to contraception during the - Contraception during study integration with hormones, IUD or - Diaphragm/condom+spermicide)4. - Breastfeeding period

	- Heart failure NYHA 3 or greater - Ongoing chemotherapy - Blood coagulation disorders (Quick value permanently below 50) Local exclusion criteria Burns in the regions will not be included in the study: - Face, - Neck, - Palm of the hand, - Genitals, - Buttocks, and - Soles of the feet. Secondary exclusion criteria - Acute danger to life occurring during treatment, - Severe general infections, - Drug problem not primarily recognized (delirious state).	- Incapacity or inability to consent (e.g. dementia) - Custody (by court or official order) or (already effected or initiated) - Appointment of a guardian (which has already taken place or has been initiated) - Severe general illness requiring intensive care - Complete immobility - Malignancy in need of treatment or not treated curatively - Current immunosuppressive or chemotherapeutic treatment - Heart failure NYHA 3 or higher and cardiac-related leg edema - Severe liver disease with effects on the organism - Derail diabetes mellitus (HbA1c >10%) - Apoplexy within the last 6 months - Dependency disease affecting internal organs (exception: - Nicotine abuse) - Presence of at least 1 ulcer larger than 25cm². - Venous or arterial vascular status in need of surgery (3 months after inclusion in the study possible) - Concomitant deep infection, especially with bone involvement (phlegmon, lymphangiitis, osteomyelitis) - Circular ulcers (so-called gaiter ulcers) - Systemic antibiotic therapy started or started in the last 4 weeks with a probable antibiotic therapy with a presumed duration of >7 days. - Contraindication for Suprathel® (especially infected or heavily bleeding wounds). - Expected non-compliance (incl. known drug use) - Simultaneous participation in another clinical trial with existing insurance coverage.
Number of enrolled subjects, including if applicable in different treatment arms	Two groups. 22 patients were enrolled in Group A (Skin covering at burns S1: Split skin grafts) and 24 patients were enrolled in Group B (Skin covering at burns S2: Covering of second degree burns).	22 patients in cohort design with absence of a control group

Study population: main baseline characteristics of each study group, including **gender** and **age** of enrolled subjects	Group A: 22 patients [18 males, 4 females; mean age 39.6 years (range 18-64 years)] Group B: 24 patients [20 male, 4 females; mean age 40.5 years, (range 19-64 years)]	The patients were 73 (±10) years old, 73% female and all suffered from ulcus cruris, which persisted at enrollment for 12 (±6) months in average
Summary of **study methods**	Wound pain: Visual Analog Scale (VAS) Healing time: Timing of complete epithelialization. Infections: Swabs (three-day intervals)	Survey of the wound area: Area calculation (length times width in cm^2) Definition of healing: complete epithelialization Wound pain: Visual Analog Scale (VAS):
Summary of results: any **clinical benefits74**; any **undesirable side-effects** or **adverse events**, and their frequency in relation to time; any results on **long-term benefits or risks**, for example implant survival rates at 5 or 10 years and/or cumulative experience in patient-years. A **statement of percentage completeness of follow-up** should be provided. Add a note if the **study is still ongoing for long-term follow up**.	With reference to the primary endpoint "pain", statistically significant evidence was generated that, in the case of split-skin graft donor sites Suprathel® reduces pain compared to the use of paraffin gauze [Group A; Suprathel® – group: mean 10-day pain score was 0.92; (median: 1.0; range 0.2-1.8); Jelonet®-group: mean 10-day pain score was 2.1 (median 2.8; range 0.4-3.0; p=0.0002], Also in the case of 2nd degree burns, a reduction of pain compared to use of Omiderm® was observed. [Group B; Suprathel®-group: mean 10-day pain score was 1.0 (median:0.9, range:0.2-1.8); Omiderm®-group: mean 10-day pain score was 1.59 (median 1.0, range 0.6-2.5); p=0.0072]No statistically significant results with respect to healing time was documented [p= 0.5 (A+B); Group A: complete re-epithelization after a mean 10.5-day period (median: 10.5, range: 6-14) in the Suprathel®-group and after a 10.85-day period (median: 11, range 6-14); Group B: complete re-epithelization after a mean 10.2-day period (median:10.0, range 10-16) in the Suprathel®-group and after 10.3-day period (median:10.0, range 6-16) in the Omiderm®-group].	At the end of the study, max. after 24 weeks, in 73% of the cases the ulcus was completely healed, in all cases who remained in the protocol the wound size was smaller. The average wound size shrunk from 7.5 cm2 (±7.3 median 4.0) to 1.0 cm2 (±2.2 median 0.0) ($p<0.001$) in the per protocol analysis. The wound pain measured by using a visual analog scale (VAS) improved from 2.5 (±2.4, max. 8) to 0.1 (±0.3, max. 1) (p=0.002) with Suprathel®. Any inflammatory activity was observed in 66.7% of wounds at the start of the trial, only 6.7% remained at the endpoint (p=0.004). In 100% of cases the observer judged the wound surface satisfactory after 66.7% at the start of the trial (p=0.1). No secretion was found in 73.3% of cases in comparison to 20.0% in the beginning (p=0.02).
Any **limitations of the study**, such as high	Not reported	Not reported

loss to follow-up, or potential confounding factors that may question the results.		
Any **device deficiency** and any **device replacements** related to safety and/or performance during the study.	Not reported	Not reported

Indication: small 3rd degree areas

The Approval was based on a collection of six case studies from the Marienhospital (Stuttgart) carried out by Dr. Uhlig. The report attests a positive risk/benefit balance for patients, since: Spontaneous healing is possible without transplantation. Also, re-transplantations can be carried out in a targeted fashion using less split skin. And better cosmetic results are obvious because "overgrafting" can be avoided.

5.3. Summary of clinical data from other sources (published Literature)

The most important findings identified as clinical benefits are:

- Easy use,
- Significant pain relief,
- less pain medication,
- less cost and effort for dressing changes,
- reduced length of hospital stay,
- fast(er) healing process,
- improved epithelization (histological research),
- good scar assessment (VSS/POSAS results),
- less oxidative stress,
- reduced pro-inflammatory cytokines
- increased telomerase expression

5.4. Overall summary of the clinical performance and safety

Clinical performance

The main clinical benefits of applying the Suprathel® medical device based on the current scientific knowledge are summarized in the following table:

Product claims made by PMI	Study Findings* related to device performance
Easy one-time application and assessment	Easy application of device

Significant Pain Relief	Significant Pain Relief Less pain medication required
Lower treatment costs	Less cost and effort for dressing changes Less costs due to less pain medication required Reduced length of patient hospital stays
Quick healing process	Fast(er) healing process Improved epithelization
Excellent cosmetic results	Improved epithelization Good scar assessment
Reduced inflammatory reaction	Less oxidative stress Reduced pro-inflammatory cytokines Increased telomerase expression
Reduced transplantation rate	Reduced need for grafting

* *literature/references are listed at the end of the SSCP*

Clinical safety

With respect to device safety, none of the published studies reported any additional risks, for example due to increased infection rates or allergic reactions.

No adverse events or undesirable effects have ever been reported. Additionally, there have never been any customer complaints regarding the clinical safety of patients or where the product's defined specifications and quality were impacted.

5.5. Ongoing or planned post-market clinical follow-up

To continuously monitor the product's safety and performance, the Clinical Evaluation of the Suprathel® medical device is regularly updated with newly acquired clinical data throughout the device's life cycle. Due to its long-term product experience, PMCF studies are not required to establish further safety and performance evidence.

6. Possible diagnostic or therapeutic alternatives

Possible alternative treatment options for the above-mentioned indications:

- silver sulfadiazines creams
- traditional wound dressings (such as gauze dressings)
- hydrocolloid-, alginate-, hydrogel- polyurethane film and foam dressings,
- silicon-coated nylon dressings,
- wound dressings with antimicrobial properties

7. Suggested profile and training for users

The use of the medical device is restricted to healthcare professionals only. The application and aftercare procedures are described in the Instructions for Use accompanying the medical device and no additional user trainings are required in order to be able to apply Suprathel® correctly.

The suggested patient profile comprises patients within the above-mentioned indications. Apart from patients showing symptoms listed in the contraindications or known allergies against device components, there are no restrictions on the use of Suprathel® or any other patient selection criteria.

8. Reference to any (harmonized) standards and CS applied

Harmonised Standards	Brief Description
Common specifications	Not available for the product
DIN EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
DIN EN 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices
DIN EN ISO 14971	Medical devices – Application of risk management to medical devices
DIN EN ISO 14155	Clinical Investigation of Medical Devices for Human Subjects - Good Clinical Practice
DIN EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system
DIN EN ISO 10993-3	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
DIN EN ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
DIN EN ISO 10993-6	Biological evaluation of medical devices – Part 6: Tests for local effects after implantation
DIN EN ISO 10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
DIN EN ISO 10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
DIN EN ISO 10993-12	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
DIN EN ISO 11737-1	Sterilization of medical devices - Requirements for the estimation of population of microorganisms on a product
DIN EN ISO 11737-2	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
DIN EN ISO 11137-1	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
DIN EN ISO 11137-2	Sterilization of Health Care Products - Radiation - Part 2: Establishing The Sterilization Dose
DIN EN 556-1	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
DIN EN IS0 11607-1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
DIN EN IS0 11607-2	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes

DIN EN ISO 20417	Medical devices – Information to be supplied by the manufacturer
DIN EN ISO 15223-1	Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling And Information To Be Supplied - Part 1: General Requirements
DIN EN 868-2	Packaging for terminally sterilized medical devices - Part 2: Sterilization wrap - Requirements and test methods
DIN EN 868-5	Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods
DIN EN IS0 14698-1	Cleanrooms and associated controlled environments -- Biocontamination control -- Part 1: General principles and methods
DIN EN IS0 14698-2	Cleanrooms and associated controlled environments -- Biocontamination control -- Part 2: Evaluation and interpretation of biocontamination data
ISTA 2a	Partial Simulation Performance Tests - Packaged Products 150 lb (68 kg) or Less
USP <151>	Pyrogen Study
ASTM F1886/F1886M	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
ASTM F88/F88M	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F3039	Standard Test Method for Detecting Leaks in Nonporous Packaging or Flexible Barrier Materials by Dye Penetration

9. Literature references

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10. Revision history

SSCP version number	Date issued	Change description	Revision validated by the Notified Body
1	2021.05.26	Initiation of the document	☐ Yes Validation language: ☐ No
2	2022.03.17	Update with inclusion of the indication chronic wounds	☐ Yes Validation language: ☐ No
3	2022.05.30	Update concerning amendment of a full list (harmonized) standards (MDD)	☐ Yes Validation language: ☐ No
4	2022.06.30	Correction of formatting errors in chapter 1	☐ Yes Validation language: ☐ No
5	2022.11.28	Reference update to latest CER in header	☐ Yes Validation language: ☐ No
6	2023.02.14	Shortening of text paragraphs	☐ Yes Validation language: ☐ No