

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP)

Part I: for healthcare professionals

(Part II: for patients or lay persons – located below)

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 SupraSDRM[®].


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	SupraSDRM[®], SupraSDRM[®] 1100
1.2 Manufacturer's name and address	PolyMedics Innovations GmbH (PMI) Am Hegelesberg 1 73230 Kirchheim unter Teck, 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 <i>(according to Medical Device Regulation (MDR) (EU) 2017/745 Annex VIII, rule 8)</i>
1.7 Year when the first certificate (CE) was issued covering the device	2019
1.8 Authorised representative if applicable	n/a
1.9 NB's name and NB's single identification number	DEKRA, 0124
1.10 SSCP Identifier	SSCP-SupraSDRM

Summary of Safety and Clinical Performance (SSCP)

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
	∅ 12 mm	1	Inner outer	(01)	04260184020287 04260184020294	(17)	YYMMDD	(10)	KDM-YYYY-NN-ZZ PDM-YYYY-NN-ZZ
	∅ 18 mm	1	Inner outer		04260184020300 04260184020317				
	∅ 24 mm	1	inner outer		04260184020324 04260184020331				
	1x1	1	inner outer		04260184020348 04260184020355				
	2x2	1	inner outer		04260184020362 04260184020379				
	4x4	1	inner outer		04260184020386 04260184020393				
	5x5	1	inner outer		04260184020409 04260184020416				
	9x9	1	inner outer		04260184020423 04260184020430				
	9x12	1	inner outer		04260184020447 04260184020454				
	18x9	1	inner outer		04260184020461 04260184020478				
	18x18	1	inner outer		04260184020485 04260184020492				

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
	∅ 12 mm	1	Inner outer	(01)	04260184020508 04260184020515	(17)	YYMMDD	(10)	KDM-1100- YYYY-NN-ZZ PDM-1100- YYYY-NN-ZZ
	∅ 18 mm	1	Inner outer		04260184020522 04260184020539				
	∅ 24 mm	1	inner outer		04260184020546 04260184020553				
	1x1	1	inner outer		04260184020560 04260184020577				
	2x2	1	inner outer		04260184020584 04260184020591				
	4x4	1	inner outer		04260184020607 04260184020614				
	5x5	1	inner outer		04260184020621 04260184020638				
	9x9	1	inner outer		04260184020645 04260184020652				
	9x12	1	inner outer		04260184020669 04260184020676				
	18x9	1	inner outer		04260184020683 04260184020690				
	18x18	1	inner outer		04260184020706 04260184020713				

Summary of Safety and Clinical Performance (SSCP)

2. Intended use of the device

2.1. Intended purpose

- ❖ SupraSDRM® is an absorbable foam membrane and alloplastic skin substitute for the treatment of epidermal and dermal wounds.

2.2. Indications and target population(s)

- ❖ SupraSDRM® 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.
- ❖ SupraSDRM® is used for patients with chronic wounds, such as venous and arterial ulcers, as well as diabetic wounds.

2.3. Contraindications and/or limitations

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

3. Device Description

3.1. Description of the device

SupraSDRM® 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 derivatives 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

SupraSDRM® sizes and shape:

- Available in two variants with different thicknesses: 1,5 - 2,1 mm and 0,8 mm - 1,4 mm
- rectangular and circle sheets
- SupraSDRM® 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

There are no accessories associated with the SupraSDRM® medical device.

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

The SupraSDRM® device 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 SupraSDRM® membrane and prevent dislocation.

Summary of Safety and Clinical Performance (SSCP)

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 family history of more than 20 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 SupraSDRM® the membrane should not be applied. SupraSDRM® should be removed immediately if there are any signs of allergic reactions to the material.
- ❖ SupraSDRM® should be removed immediately if there are any signs of allergic reactions to the material SupraSDRM® 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

PolyMedics Innovations GmbH has also implemented a Post-Market-Surveillance system with the aim of instituting a systematic procedure to proactively collect the most up to date performance and risk information.

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

See below points 5.2 – 5.5

Summary of Safety and Clinical Performance (SSCP)

5.2. Summary of clinical data from conducted investigations of the equivalent device Suprathel®

Acc. to MDCG 2019-9	2 nd degree burns & split skin donor sites (SSDS)	Chronic wounds
<p>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 Eudamed.</p>	<p>DE/CA37/1540/KP-1</p> <p>Not available in EUDAMED</p>	<p>DE/CA37/PolyMedics/KP-1</p> <p>Not available in EUDAMED</p>
<p>Identity of the device including any model number/version</p>	Suprathel®	Suprathel®
<p>Intended use of the device in the investigation</p>	Treatment of split skin grafts and second degree burns	Local Treatment of Ulcus Cruris
<p>Objectives of the study</p>	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
<p>Study design: randomised controlled trial, other pivotal trial, short-term feasibility study, other; and the duration of the follow-up</p>	<p>prospective, randomized, two center clinical study</p> <p>Marienhospital (Stuttgart) and the Surgical Hospital Berlin with Prof. K.-K. Dittel as the Principal Investigator</p>	<p>prospective, multicenter study</p> <p>Six hospital departments from four hospitals enrolled 22 patients</p> <p>duration of the treatment was limited to 24 weeks</p>
<p>Primary and secondary endpoint(s)</p>	<p>study endpoints:</p> <ol style="list-style-type: none"> 1. Pain, 2. Healing time, frequency of local events, quality of scarring 	<p>study endpoints:</p> <ol style="list-style-type: none"> 1. Wound area 2. Pain, inflammatory activity (skin, wound surface), wound secretion, detect side effects
<p>Inclusion/exclusion criteria for subject selection</p>	<p>Inclusion criteria:</p> <ul style="list-style-type: none"> - 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. <p>Exclusion criteria:</p> <p>General exclusion criteria</p> <ul style="list-style-type: none"> - 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. <p>Medical history exclusion criteria</p> <ul style="list-style-type: none"> - Dialysis requirement. - Heart failure NYHA 3 or greater. - Ongoing chemotherapy. - Blood coagulation disorders (Quick value permanently below 50). <p>Local exclusion criteria</p>	<p>Inclusion criteria:</p> <ul style="list-style-type: none"> - 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 <p>Exclusion criteria:</p> <ul style="list-style-type: none"> - 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. - Breastfeeding period - Incapacity or inability to consent (e.g. dementia) - Custody (by court or official order) or (already effected or initiated)

Summary of Safety and Clinical Performance (SSCP)

	<p>Burns in the regions will not be included in the study:</p> <ul style="list-style-type: none"> - Face, - Neck, - Palm of the hand, - Genitals, - Buttocks, and - Soles of the feet. <p>Secondary exclusion criteria</p> <ul style="list-style-type: none"> - acute danger to life occurring during treatment, - severe general infections, - drug problem not primarily recognized (delirious state). 	<ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - 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, lymphangitis, 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. wound) - Expected non-compliance (incl. known drug use) - Simultaneous participation in another clinical trial with existing insurance coverage.
<p>Number of enrolled subjects, including if applicable in different treatment arms</p>	<p>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).</p>	<p>22 patients in cohort design with absence of a control group</p>
<p>Study population: main baseline characteristics of each study group, including gender and age of enrolled subjects</p>	<p>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)]</p>	<p>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</p>
<p>Summary of study methods</p>	<p>Wound pain: Visual Analog Scale (VAS) Healing time: Timing of complete epithelialization. Infections: Swabs (three-day intervals)</p>	<p>Survey of the wound area: Area calculation (length times width in cm²) Definition of healing: complete epithelialization Wound pain: Visual Analog Scale (VAS):</p>
<p>Summary of results: any clinical benefits; 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.</p>	<p>With reference to the primary target criterion, statistically significant evidence was accumulated that, in the case of split-skin graft donor sites [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], Suprathel® reduces pain compared to use of paraffin gauze, and also that in the case of 2nd degree burns [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], there is a reduction of pain compared to use of Omiderm®. No statistically significant improvement 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</p>	<p>At the end of the study, max. after 24 weeks, in 73% of the cases the ulcer 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).</p>

Summary of Safety and Clinical Performance (SSCP)

	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].	
Any limitations of the study , such as high loss to follow-up, or potential confounding factors that may question the results.	Not reported	Not reported
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 for the equivalent device Suprathel® 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
- lower long-term reintervention rates, such as scar contracture releases
- reduced need for sedated postoperative dressing changes

The most important finding identified as clinical benefit for SupraSDRM® is:

- faster healing process in chronic wounds

5.4. An overall summary of the clinical performance and safety

Clinical performance

The main clinical benefits of applying the SupraSDRM® medical device and its equivalent device Suprathel® based on the current scientific knowledge are summarized in the following tables:

SUPRASDRM®

Product claims made by PMI	Study Findings* related to device performance
Faster healing time in chronic wounds	Faster healing time in chronic wounds compared with a collagen wound covering and fish skin graft

Summary of Safety and Clinical Performance (SSCP)

SUPRATHEL® (equivalent device)

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
Reduced need for reconstructive surgeries	Lower long-term reintervention rates, such as scar contracture releases Less reconstructive procedures
Reduced length of stay in hospital	Reduced length of stay in hospital
Reduced need for sedated postoperative dressing changes	Less sedated postoperative dressing changes

* underlying literature/references are available upon request

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 SupraSDRM® medical device is regularly updated with newly acquired clinical data throughout the device's life cycle.

Due to the long-term experience of the equivalent device Suprathel® within the same product family, 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

Summary of Safety and Clinical Performance (SSCP)

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 SupraSDRM® 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 SupraSDRM® or any other patient selection criteria.

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

(Harmonized) Standards	Brief Description
Common specifications	Non 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 ISO 11607-1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
DIN EN ISO 11607-2	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes

Summary of Safety and Clinical Performance (SSCP)

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 ISO 14698-1	Cleanrooms and associated controlled environments -- Biocontamination control -- Part 1: General principles and methods
DIN EN ISO 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

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Summary of Safety and Clinical Performance (SSCP)

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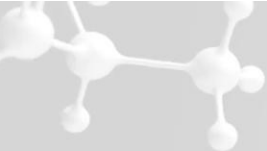
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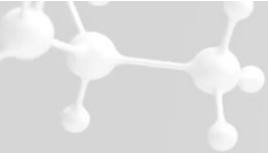
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10. Revision history

SSCP version no.	Date issued	Change description	Revision validated by the Notified Body
01	2022.06.20	The SSCP document was firstly initiated and written based on the new requirement of the MDR (EU) 2017/745.	<input type="checkbox"/> Yes Validation language: EN <input type="checkbox"/> No
02	2022.12.06	Correction of chapter 1.7 (the year when the first certificate (CE) was issued covering the device was corrected to “2019”) and chapter 3 (information concerning shapes and size was amended).	<input type="checkbox"/> Yes Validation language: EN <input type="checkbox"/> No
03	2023.02.14	Only editorial change: Due to the extremely high translation costs into the 24 EU national languages, the SSCP was formulated more concisely. For example, extensive text passages were converted into bullet points, etc.	<input checked="" type="checkbox"/> Yes Validation language: EN <input type="checkbox"/> No
04	2024.04.01	Substantive change: Due to the official change of the manufacturer's address (relocation of the company headquarters to Kirchheim unter Teck), the manufacturer's address was also updated in the SSCP.	<input checked="" type="checkbox"/> Yes Validation language: EN <input type="checkbox"/> No
05	2024.07.22	Substantive change: As part of the annual updates to the PMCF report and the CER, the SSCP was also updated accordingly. The CER reference in the header was updated and part II for patients or lay persons was added.	<input checked="" type="checkbox"/> Yes Validation language: EN <input type="checkbox"/> No
06	2024.10.22	Expansion of the "faster wound healing" claim to include CW, with reference to Liden et al. (2024), based on DEKRA feedback/review	<input checked="" type="checkbox"/> Yes Validation language: EN <input type="checkbox"/> No
07	2025.02.28	Substantive change: Update after annual PMCF activities: Additional product claims for equivalent device Suprathel® (“Reduced need for reconstructive surgeries” and “Reduced length of patient hospital stays”)	<input checked="" type="checkbox"/> Yes Validation language: EN <input type="checkbox"/> No
08	2026.03.18	Substantive change: Update after annual PMCF activities: Additional product claims for equivalent device Suprathel® (“Reduced need for postoperative dressing changes”)	<input checked="" type="checkbox"/> Yes Validation language: EN <input type="checkbox"/> No



SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP)

Part II: for patients or lay persons

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 SupraSDRM®. The information presented below is intended for patients or lay persons.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace an Implant card or the Instructions For Use to provide information on the safe use of the device.

1. Device Identification and general information

1.1 Device trade names	SupraSDRM®, SupraSDRM® 1100
1.2 Manufacturer's name and address	PolyMedics Innovations GmbH (PMI) Am Hegelesberg 1 73230 Kirchheim unter Teck, Germany
1.3 Basic UDI	426018402AAA0000001PQ
1.4 Year when the first certificate (CE) was issued covering the device	2019

2. Intended use of the device

2.1. Intended purpose

- ❖ SupraSDRM® is an absorbable foam membrane and alloplastic skin substitute for the treatment of epidermal and dermal wounds.

2.2. Indications and intended patient groups

- ❖ SupraSDRM® 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.
- ❖ SupraSDRM® is used for patients with chronic wounds, such as venous and arterial ulcers, as well as diabetic wounds.
- ❖ Apart from patients with allergies against device components, there are no patient selection criteria, such as age or gender.

2.3. Contraindications

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

3. Device Description

3.1. Description of the device

SupraSDRM® 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 derivatives 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

SupraSDRM® sizes and shape:

- Available in two variants with different thicknesses: 1,5 - 2,1 mm and 0,8 mm - 1,4 mm
- rectangular and circle sheets
- SupraSDRM® may be manually trimmed by the user to other shapes and sizes as needed for optimal coverage of the affected areas.

3.2. Description of how the device is achieving its intended mode of action

Supra SDRM® is an equivalent product to Suprathel®, but it is thicker and has larger pores. It is a synthetic skin substitute designed to mimic human skin, sharing properties like elasticity, water vapor permeability, and bacterial impermeability. Being fully synthetic, it avoids risks associated with human or animal products. The degradation products of Supra SDRM® may aid healing by supporting angiogenesis and dermis rebuilding, similar to Suprathel®.

Supra SDRM® is a thin, elastic membrane that adheres to the wound surface on its own, usually without needing stitches. For traumatic wounds, it is applied once to the cleaned and disinfected wound and

Summary of Safety and Clinical Performance (SSCP)

remains until healing is complete. For chronic wounds, it is also applied to cleaned and disinfected wounds, with periodic changes based on wound conditions. The membrane becomes transparent, allowing easy monitoring of the healing process, including wound margins. Its permeability allows evaluation of exudate and wound odor. Supra SDRM® can be easily removed from healed skin without causing pain, indicating successful epithelization.

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

There are no accessories associated with the SupraSDRM® medical device.

4. Risks and warnings

Contact your healthcare professional if you believe that you are experiencing side effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

4.1. How potential risks have been managed

All known risks were evaluated and mitigated as part of risk analyses. All performed risk analyses conclude with an acceptable overall benefit/risk ratio.

4.2. Remaining risks and undesirable effects

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 family history of more than 20 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.

4.3. 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 SupraSDRM® the membrane should not be applied. SupraSDRM® should be removed immediately if there are any signs of allergic reactions to the material.
- ❖ SupraSDRM® should be removed immediately if there are any signs of allergic reactions to the material. SupraSDRM® 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

Summary of Safety and Clinical Performance (SSCP)

4.4. 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. Clinical background of the device

Supra SDRM® is an equivalent product to Suprathel®, designed to mimic natural skin by providing a protective barrier and creating an optimal environment for healing. It helps reduce pain and the risk of infection.

The effectiveness and safety of Supra SDRM® were determined based on the extensive data available for Suprathel®. Suprathel® has been demonstrated to be effective in various studies, supporting its use in clinical settings.

An approval study for burns and donor sites showed that the device creates an optimal healing environment, and significantly reduce pain. Two further studies expanded the indications to include chronic wounds and small third-degree areas, confirming their benefits in these conditions. Since approval, 64 publications have been published, highlighting the following advantages: easy one-time application and assessment, significant pain relief, lower treatment costs, quick healing process, excellent cosmetic results, reduced inflammatory reaction, reduced transplantation rate, reduced need for reconstructive surgeries, reduced length of stay in hospital and reduced need for sedated postoperative dressing changes.

To date two published studies on Supra SDRM® itself have demonstrated that wounds heal faster in chronic wounds (CW). Additional publications, including a health-economic analysis based on existing data and a non-comparative case series, are consistent with these findings.

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

Burns and donor sites: Approval Study Summary

The approval study for Suprathel involved 46 patients with second-degree burns and split skin donor sites at two hospitals in Germany. The study aimed to compare pain levels between Suprathel and traditional dressings. Results showed that Suprathel significantly reduced pain compared to paraffin gauze and Omiderm. The study also monitored wound healing time and the occurrence of local complications like infections and allergies, with no significant differences observed. Additionally, the study highlighted the easy handling of Suprathel, making it a convenient option for both patients and healthcare providers.

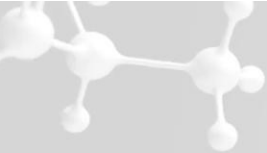
Chronic Wounds

Earliest Case Studies:

In 2008, Dr. Uhlig treated eight patients with chronic ulcers using Suprathel. The patients, averaging 76 years old, had ulcers for about 14 months. Treatment lasted around 222 days, with all ulcers healing completely. Immediate pain reduction was noted.

Clinical Trial:

In 2010, a clinical trial was conducted across six departments in four hospitals, involving 22 patients with leg ulcers. The study aimed to measure Suprathel's impact on wound size, pain, inflammation, and secretion over 24 weeks. Patients, mostly women with an average age of 73, had ulcers for about 12 months. By the end of the study, 73% of ulcers healed completely, wound size significantly reduced, pain



Summary of Safety and Clinical Performance (SSCP)

decreased, and inflammation was minimized. The trial demonstrated Suprathel's effectiveness in promoting healing and reducing discomfort in chronic wound patients.

Small 3rd degree areas

The approval was based on six case studies from Marienhospital Stuttgart by Dr. Uhlig. It highlights that spontaneous healing is possible without the need for transplantation. Additionally, if re-transplantations are needed, they can be done more precisely using less skin. This approach also leads to better cosmetic results because excessive grafting can be avoided.

5.3. Clinical safety

Regarding the safety of the device, no studies have reported any additional risks, such as increased infections or allergic reactions. There have been no adverse events or unwanted effects. Furthermore, there have never been any customer complaints about the safety of patients or the quality of the product.

6. Possible diagnostic or therapeutic alternatives

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation

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 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 SupraSDRM® 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 SupraSDRM® or any other patient selection criteria.