FDA Executive Summary

Prepared for the October 26 & 27, 2022 Meeting of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee

Classification of Absorbable Synthetic Wound Dressings

Device Type: Absorbable Synthetic Wound Dressing

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1. Introduction

Per Section 513(b) of the Food, Drug, and Cosmetic Act (the Act), the Food and Drug Administration (FDA) is convening the General and Plastic Surgery Devices Panel of the Medical Device Advisory Panel (the Panel) for the purpose of obtaining recommendations regarding the classification of absorbable synthetic wound dressings, a pre-amendments device type which remains unclassified. Specifically, the FDA will ask the Panel to provide recommendations regarding the regulatory classification of absorbable synthetic wound dressings. These are a subset of devices currently cleared under the product code "FRO". The device names and associated product codes are developed by the Center for Devices and Radiological Health (CDRH) in order to identify the generic category of a device for FDA. While most of these product codes are associated with a device classification regulation, some product codes, including "FRO", remain unclassified.

FDA is holding this panel meeting to obtain input on the risks to health and benefits of the absorbable synthetic wound dressings. The Panel will discuss whether the absorbable synthetic wound dressings should be classified into Class II (subject to General and Special Controls). If the Panel believes that classification into Class II is appropriate for absorbable synthetic wound dressings, the Panel will also be asked to discuss appropriate controls that would be necessary to mitigate the risks to health.

1.1 Current Regulatory Pathways

Absorbable synthetic wound dressings are a pre-amendments, unclassified device type. This means that this device type was marketed prior to the Medical Device Amendments of 1976, but was not classified by the original classification panels. Currently these devices are being regulated through the 510(k) pathway and are cleared for marketing if their intended use and technological characteristics are "substantially equivalent" to a legally marketed predicate device. Since these devices are unclassified, there is no regulation associated with the product code.

1.2 Device Description

An absorbable synthetic wound dressing is a device intended to cover a wound, to absorb exudate, and to maintain appropriate moisture balance within the wound. Such wound dressings are composed of absorbable synthetic materials (e.g., lactide-caprolactone copolymer, polydioxanone, glycolic acid and trimethylene carbonate copolymer, biodegradable polyurethane), often presented as a fibrous matrix.

These devices are provided in the form of a sheet to cover a wound and reduce the dressing change frequency or to provide a temporary scaffold for cellular infiltration before being completely or partially (e.g., only the wound contacting layer) resorbed into the wound via hydrolytic mechanisms. All cleared absorbable synthetic wound dressings are intended to either completely or partially degrade in the wound, although the degradation time varies from weeks to months depending on the dressing material.

Absorbable synthetic wound dressings are provided sterile and may be used alone or in conjunction with a secondary, non-resorbable wound dressing for securement. While an absorbable synthetic wound dressing is intended to be left in place on wounds after topical application, an absorbable synthetic wound dressing is not intended as a long-term skin substitute, a temporary synthetic skin, or to accelerate the wound healing process. An absorbable synthetic wound dressing does not contain animal-derived materials, antimicrobials, drugs, or biologics.

2. Regulatory History

Wound dressings, including absorbable synthetic wound dressings, are pre-amendments devices that have been in commercial distribution since prior to May 28, 1976.

FDA has cleared 11 absorbable synthetic wound dressings. Please refer to Table 1for a listing of the manufacturers, device names, and associated 510(k) submission numbers for cleared absorbable synthetic wound dressings:

Table 1: 510(k) Clearances for Absorbable Synthetic Wound Dressings

510(k) Number	Trade Name	Sponsor
K031684	TOPKIN WOUND DRESSING	BIOMET MERCK GMBH
K090160	SUPRATHEL WOUND AND BURN DRESSING	POLYMEDICS INNOVATIONS GMBH
K132397	Gore Bio-A Wound Matrix	Gore
K142879	BTM Wound Dressing	Polynovo Biomaterials Pty Ltd
K161067	Mirragen Advanced Wound Matrix, 4x4", Mirragen Advanced Wound Matrix, 2x2", Mirragen Advanced Wound Matrix, 1x6"	ENGINEERED TISSUE SOLUTIONS, LLC
K170300	Restrata Wound Matrix	Acera Surgical, Inc.
K170213	SupraSDRM Biodegradable Matrix Wound Dressing	Polymedics Innovations Gmbh
K172140	NovoSorb BTM Wound Dressing (2cm x 2cm), NovoSorb BTM Wound Dressing (10cm x 10cm), NovoSorb BTM Wound Dressing (10cm x 20cm), NovoSorb BT Wound Dressing (20cm x 40cm)	Polynovo Biomaterials Pty Ltd
K173544	Phoenix Wound Matrix	Nanofiber Solutions, Inc.
K193583	Restrata	Acera Surgical Inc.

K221686	NovoSorb Matrix	PolyNovo Biomaterials Pty Ltd

3. Indications for Use

The Indications for Use (IFU) statement identifies the disease or condition the device will diagnose, treat, prevent, cure or mitigate, including a description of the patient population for which the device is intended.

Absorbable synthetic wound dressings have been cleared for the following indications for use:

- Temporary coverage of non-infected skin defects, such as superficial wounds under sterile conditions
- Maintain a moist wound healing environment
- Management of wounds, including:
    - Partial and full thickness wounds
    - Pressure (stage I - IV) ulcers
    - Venous ulcers
    - Ulcers caused by mixed vascular etiologies
    - Venous stasis ulcers
    - Chronic vascular ulcers
    - Diabetic ulcers
    - Tunneled/undermined wounds
    - Partial thickness burns
    - Trauma wounds (abrasions, lacerations, first and second degree burns, skin tears)
    - Cuts
    - Acute wounds
    - Surgical wounds (donor sites/grafts, post-Moh's surgery, post laser surgery, podiatric, wound dehiscence)
    - Superficial wounds
    - Draining wounds

4. Clinical Background

4.1 Disease Characteristics

There is a wide variety of acute and chronic wounds. Acute wounds can affect anyone and usually occur suddenly and heal at a predictable rate; these include cuts, post-surgical wounds, burns, and traumatic wounds. Chronic wounds develop over time and do not heal at an expected rate. The most common chronic wounds are venous ulcers, diabetic ulcers, and pressure ulcers. An acute wound can sometimes develop into a chronic wound.

The pathophysiology of wounds varies greatly and depends on many factors, including blood supply, blood pressure, infection, and other comorbidities (e.g., diabetes).

4.2 Patient Outcomes

Patient history, physical examination, and laboratory studies including bloodwork, cultures, and radiologic imaging may be used to ascertain the wound diagnosis. Depending on the wound type, the patient may be asked about pain, functional status, and quality of life.

4.3 Currently Available Treatment

As there is a wide variety of wound types, there is a range of standard of care methods, depending on the wound type and wound healing progression. Wounds are typically managed by applying a dressing to cover and protect the wound and maintain a moist wound environment. In addition, there is a variety of other wound care modalities available including compressive dressings, bioengineered dressings, grafts, negative pressure wound therapy, pressure relief devices, hyperbaric oxygen, and topical drugs.

Various national and international organizations (e.g., The Wound Healing Society, American Academy of Dermatologists, American Burn Association, Infectious Diseases Society of America, American Society of Plastic Surgeons) have published clinical guidelines providing wound care recommendations.[1,2,3,4,5] Some of these organizations may be corporate-sponsored. Although these clinical guidelines target different types of wounds, they generally recommend debridement, rinsing, and providing a moist wound environment as part of wound care. Most guidelines do not specify the use of a particular type of wound dressing as recommendations for dressing selection are based on patient-specific wound care needs such as the need for exudate management or prevention of fluid loss.

4.4 Risks

FDA has identified the following risks to health associated with absorbable synthetic wound dressings:

[1] American Academy of Dermatologists: Wound healing and treating wounds: Chronic wound care and management (2016), *available at* https://www.jaad.org/action/showPdf?pii=S0190-9622%2815%2902183-0

[2] The Wound Healing Society: Chronic Wound Care Guidelines: Diabetic Foot Ulcers, Pressure Ulcers, Venous Ulcers, Arterial Ulcers (2015), *available at* https://woundheal.org/Publications/WHS-Wound-Care-Guidelines.cgi

[3] ABA Guidelines for Burn Care Under Austere Conditions: Surgical and Nonsurgical Wound Management (2016), *available at* http://ameriburn.org/wp-content/uploads/2017/05/guidelines_for_burn_care_under_austere_conditions_.98589-2.pdf

[4] Infectious Diseases Society of America: Clinical Practice Guideline for Diagnosis and Treatment of Diabetic Foot Infections (2012), *available at* https://academic.oup.com/cid/article/54/12/e132/455959

[5] American Society of Plastic Surgeons: Clinical Practice Guideline – Chronic Wounds of Lower Extremity (2007), *available at* https://www.plasticsurgery.org/documents/medical-professionals/quality-resources/ASPS-Evidence%E2%80%90Based-Clinical-Practice-Guideline-Methodology.pdf

Table 2: Risks to Health and Descriptions/Examples for Absorbable Synthetic Wound Dressings

Identified Risk	Description/Examples
Toxicity	This can result from device materials or degradants of the absorbable materials, which can be toxic.
Adverse Tissue Reaction	This can result from the use of device materials, including any associated impurities, residues and degradants, which are not biocompatible.
Infection	This can result from inadequate device sterilization or inadequate packaging integrity.
Delay in wound healing	This can result from device materials or degradants of the absorbable materials, which may interfere with the wound healing process. This can also result from incomplete bio-resorption of the dressing into the wound.
Failure of device integration	This occurs when the dressing, which is intended to provide a temporary scaffold for cellular infiltration, does not effectively degrade in the wound, and thus resulting in dressing retention in the wound and interference with the wound healing process.

The Panel will be asked whether this list is a complete and accurate list of the risks to health presented by absorbable synthetic wound dressings and whether any other risks should be included in the overall risk assessment of the device type.

5. Literature Review

5.1 Methods

A systematic literature review was conducted in an effort to gather any published information regarding the safety and effectiveness of absorbable synthetic wound dressings.

On May 16, 2022 and July 18-20, 2022, literature searches were performed to identify all published studies for absorbable synthetic wound dressings in two databases (PubMed and EMBASE) with two search periods (April 1, 2012 – April 1, 2022 for the first search and April 1, 2012 – July 18, 2022 for the second search).

The searches were performed together with other wound dressings being presented at this classification panel, including wound dressings with animal-

derived materials and hemostatic wound dressings with and without thrombin. The literature searches were performed using multiple search terms related to wound dressing, with hedges for study design and publication years, and the searches were limited to publications in English. Detailed methods, search terms and filters are provided in Appendix A.

Because the two systemic literature searches did not return any articles relevant to absorbable synthetic wound dressings, a supplemental literature search was conducted to identify literature reporting clinical outcomes related to the use of absorbable synthetic wound dressings. The search was conducted in the PubMed database for randomized controlled trials (RCTs) or cohort studies (prospective/retrospective), using the brand names of the eleven cleared synthetic absorbable wound dressings listed in Table 1 as the search items.

5.2 Results

The two systemic literatures searches (SLR) performed on May 16, 2022 and July 18-20, 2022 returned a total of fourteen articles which met the search inclusion criteria. Of the fourteen included articles, five articles were relevant to the safety and effectiveness of wound dressings with animal-derived materials, nine articles were relevant to the hemostatic wound dressings with and without thrombin, none of the articles were found relevant to absorbable synthetic wound dressings.

Because the two SLR searches did not identify any absorbable synthetic dressing related articles, a supplemental search was conducted with a modified search criteria (i.e., removing the patient number search limitation previously used, which excluded the studies with N < 100 patients per arm for the first search and N < 75 patients per arm for the second search). The supplemental literature search performed in PubMed yielded seven relevant articles, including three randomized control trials[6,7,8], two prospective comparative studies[9,10], one prospective case series[11] and one retrospective study[12]. Of the seven selected studies, two studies

[6] Armstrong DG, Orgill DP, Galiano RD, Glat PM, DiDomenico LA, Carter MJ, Zelen CM. *A multi-center, single-blinded randomized controlled clinical trial evaluating the effect of resorbable glass fiber matrix in the treatment of diabetic foot ulcers*. Int Wound J. 2022 May;19(4):791-801.
[7] Schwarze H, Kuntscher M, Uhlig C, Hierlemann H, Prantl L, Ottomann C, Hartmann B. *Suprathel, a New Skin Substitute, in the Management of Partial-Thickness Burn Wounds.* Ann Plast Surg 2008;60: 181–185.
[8] Schwarze H, Kuntscher M, Uhlig C, Hierlemann H, Prantl L, Noack N, Hartmann B. *Suprathel, a new skin substitute, in the management of donor sites of split-thickness skin grafts: Results of a clinical study*. Burns 2007; 33:850-854.
[9] Keck M, Selig HF, Lumenta DB, Kamolz LP, Mittlbock M, Frey M. *The use of Suprathel in deep dermal burns: First results of a prospective study*. Burns 2012; 38:388-395.
[10] Kaartinen IS, Kuokkanen H. *Suprathel ® causes less bleeding and scarring than Mepilex ® Transfer in the treatment of donor sites of split-thickness skin grafts*. J Plast Surg Hand Surg 2011; 45(4-5):200-3.
[11] Li H, Lim P, Stanley E, Lee G, Lin S, Neoh D, Liew J, Ng SK. *Experience with NovoSorb® Biodegradable Temporising Matrix in reconstruction of complex wounds*. ANZ Journal of Surgery 2021; 91(9):1744–50.
[12] Wu SS, Wells M, Ascha M, Gatherwright J & Chepla K. *Performance of biodegradable temporizing matrix vs*

were conducted in the United States, five studies were from outside of the United States. The included studies reported on 15[10] – 97[12] patients whose mean ages ranged from 39.6[8] - 64.3[6] years. The length of follow-up ranged from 3[6,7,8,9,10] – 18[11] months. Appendix B provides full details on the individual selected studies.

5.3 Adverse Events Associated with Absorbable Synthetic Wound Dressings

Of the seven selected studies, four studies assessed the safety of absorbable synthetic wound dressings. One study[12] found no significant difference in complications of infection, dehiscence, and hematoma or seroma between standard of care (SOC) treatment (collagen wound dressing) and absorbable synthetic wound dressing. One study[6] assessing the use of an absorbable glass wound dressing in the diabetic foot ulcer care reported less incidence of adverse events and infection of index ulcer than the SOC group (collagen alginate wound dressing). Other two studies[7,9] reported that no allergic reactions or infections were identified from the use of absorbable synthetic wound dressings compared with the SOC group (a polyurethane membrane and split-thickness skin graft).

5.4 Effectiveness Associated with Absorbable Synthetic Wound Dressings

All selected studies assessed the effectiveness of absorbable synthetic wound dressings and two[11,12] of them assessed the use of absorbable synthetic wound dressings in the staged reconstruction of complex wounds as a temporary covering and scaffold to prepare the wound bed for skin grafting in the second stage. One study[12] reported significantly lower rate of skin graft failure using an absorbable synthetic wound dressing as compared with the SOC group using collagen-based wound dressing and similar wound closure rate. One study[11] reported high integration rate of absorbable synthetic wound dressings into wounds in a prospective case series for complex wounds with exposure of a critical structure, but not requiring a traditional split-skin graft. In a RCT study for diabetic foot ulcer[6], the absorbable synthetic wound dressing showed significantly improved wound healing as compared with the SOC group (collagen alginate dressing) (percentage wound area reduction at 12-weeks: 79% for the test group vs 37% for the SOC group; neuropathic score at 12-weeks: 2.0 for the test group vs –0.6 for the SOC group). Two studies[7,8] reported similar healing time and re-epithelization between the absorbable synthetic wound dressing and the SOC group (a hydrophilic polyurethane membrane and a paraffin gauze) in the care of second-degree burns and skin graft donor sites. One study[9] reported similar scar formation and scar quality between the absorbable synthetic wound dressing and the SOC group (split-thickness skin graft), but a prolonged time to healing with the absorbable synthetic wound dressing in the care of deep partial-thickness

collagen-chondroitin silicone bilayer dermal regeneration substitutes in soft tissue wound healing: a retrospective analysis. Wounds 2022; 34(4):106-115.

dermal wounds. Another study[10] reported less pain and bleeding, but similar epithelialization between the absorbable synthetic dressing and the SOC group (polyurethane foam coated with silicone elastomer) in the care of donor sites of split-thickness skin grafts.

5.5 Overall Literature Review Conclusions

The original systemic review of the published literature did not identify literature describing absorbable synthetic wound dressings for use to cover the wound, to absorb exudate, and to maintain appropriate moisture balance within the wound. A supplemental search was performed using the device brand name to identify literature reporting clinical outcomes related to the use of cleared absorbable synthetic wound dressings, and seven articles returned. The selected studies included randomized controlled trials (RCTs) or cohort studies (prospective/retrospective) containing 15-97 patients, which described absorbable synthetic wound dressings used to cover the wound or as a temporary scaffold. These studies did not report additional risks or adverse events as compared with the SOC groups. The absorbable synthetic wound dressings had similar complication rate, healing time and re-epithelization in the treatment of different wound types when compared to the SOC groups.

6. Risks to Health Identified through Medical Device Reports (MDRs)

6.1 Overview of the MDR System

The MDR system provides FDA with information on medical device performance from patients, health care professionals, consumers and mandatory reporters (manufacturers, importers and device user facilities). The FDA receives MDRs of suspected device-associated deaths, serious injuries, and certain malfunctions. The FDA uses MDRs to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products. MDRs can be used effectively to:

- Establish a qualitative snapshot of adverse events for a specific device or device type
- Detect actual or potential device problems used in a “real world” setting/environment

Although MDRs are a valuable source of information, this passive surveillance system has limitations, including the submission of incomplete, inaccurate, untimely, unverified, duplicated, or biased data. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to potential under-reporting of events and lack of information about the frequency of device use. Finally, the existence of an adverse event report does not definitely establish a causal link between the device and the reported event. Because of these limitations, MDRs comprise only one of the FDA’s tools for assessing

device performance. As such, MDR numbers and data should be taken in the context of the other available scientific information.

6.2 MDR Data: Absorbable Synthetic Wound Dressings

Individual MDRs for absorbable synthetic wound dressings are reported through FDA's Manufacturer and User Facility Device Experience (MAUDE) Database, which houses mandatory reports from medical device manufacturers, importers, and user facilities, as well as voluntary reports from entities such as health care professionals, patients and consumers.

A search of MDRs was performed to identify adverse events using the brand names of the products listed in Table 1, through April 1, 2022 with no date restriction. The search returned a total of 10 reports; MDRs that met the criteria for serious injury totaled eight reports, and two reports were labeled as death. The two deaths, upon review of the MDRs, were found to be unrelated to the wound dressing. The reporting country for five reports was the United States, and five reports were initiated outside of the United States. All MDRs were submitted by the manufacturers. For the 10 reports, 12 unique adverse events were described in the reports. Table 3 lists these 12 adverse events described by the 10 MDRs in order of descending prevalence.

Table 3: Adverse Events Described in MDRs for Absorbable Synthetic Wound Dressings

Adverse Events	Count
Alteration in Body Temperature	3
Insufficient Information	2
Pleural Effusion	1
Hemorrhage/Bleeding	1
Hematoma	1
Congestive Heart Failure	1
Cancer	1
Hyperthermia	1
Death	1
Appropriate Clinical Signs, Symptoms, Conditions Term / Code Not Available	1
Respiratory Failure	1
Failure of Implant	1

The MDRs were reviewed in their entirety. One patient developed a squamous cell carcinoma in the area where the absorbable synthetic wound dressing was utilized. However, the patient had received radiation treatments in the same area, so the direct cause of this outcome cannot be determined from the review of this MDR. One manufacturer reported 3 separate incidences of persistent febrile episodes despite aggressive antibiotic therapy at a single hospital. Of these three reports, two of the patients had acute burn injuries and one was a patient with

necrotizing fasciitis. As such, the contribution of the wound dressing to the febrile episodes cannot be determined from these MDRs. There were multiple reports detailing failure of device integration, or unintentional premature removal of device.

7. Recall History

7.1 Overview of Recall Database

The Medical Device Recall database contains Medical Device Recalls classified since November 2002. Since January 2017, it may also include correction or removal actions initiated by a firm prior to review by the FDA. The status is updated if the FDA identifies a violation and classifies the action as a recall and again when the recall is terminated. FDA recall classification may occur after the firm recalling the medical device product conducts and communicates with its customers about the recall. Therefore, the recall information posting date ("create date") identified on the database indicates the date FDA classified the recall, it does not necessarily mean that the recall is new.

7.2 Recall Results: Absorbable Synthetic Wound Dressings

The FDA conducted queries of the Medical Device Recall database on August 18, 2022, to identify recalls related to absorbable synthetic wound dressings. One recall (Z-1030-2022) was identified, which was a Class II[13] recall that was initiated due to misprinted expiration date on the device packaging. The identified recall appears to be due to manufacturing error and does not suggest additional risks associated with absorbable synthetic wound dressings as a product class.

8. Summary

In light of the information available, the Panel will be asked to comment on whether absorbable synthetic wound dressings:

meet the statutory definition of a Class III device in accordance with section 513 of the Food, Drug, and Cosmetic Act (FD&C Act):

- insufficient information exists to determine that general and special controls are sufficient to provide reasonable assurance of its safety and effectiveness, and

- the device is purported or represented to be for use in supporting or sustaining human life, or for a use which is of substantial importance in preventing impairment of human health, or

[13] Recalls are classified into a numerical designation (I, II, or III) by the FDA to indicate the relative degree of health hazard presented by the product being recalled. A Class I recall is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death. A Class II recall is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. A Class III recall is a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

- if the device presents a potential unreasonable risk of illness or injury

or would be more appropriately regulated as Class II, in which:

- general and special controls, which may include performance standards, postmarket surveillance, patient registries and/or development of guidelines, are sufficient to provide reasonable assurance of safety and effectiveness;

or as Class I, in which:

- the device is subject only to general controls, which include registration and listing, good manufacturing practices (GMPs), prohibition against adulteration and misbranding, and labeling devices according to FDA regulations.

For the purposes of classification, FDA also considers the following items, among other relevant factors, as outlined in 21 CFR 860.7(b):

1. The persons for whose use the device is represented or intended;

2. The conditions of use for the device, including conditions of use prescribed, recommended, or suggested in the labeling or advertising of the device, and other intended conditions of use;

3. The probable benefit to health from the use of the device weighed against any probable injury or illness from such use; and

4. The reliability of the device.

The Panel will be asked whether they believe absorbable synthetic wound dressings would be appropriately regulated as Class II. If the Panel does not agree with FDA's proposed classification, the Panel will be asked to provide their rationale for recommending a different classification.

8.1 Special Controls

FDA believes that special controls, in addition to general controls, can be established to mitigate the risks to health identified, and provide a reasonable assurance of the safety and effectiveness of absorbable synthetic wound dressings. Following is a risk/mitigation table, which outlines the identified risks to health for this device type and the recommended controls to mitigate the identified risks:

Table 4: Summary of Risks to Health and Proposed Mitigations for Absorbable Synthetic Wound Dressings

Identified Risk	Recommended Mitigation Measure
Toxicity	Biocompatibility evaluation Performance testing Labeling

Adverse tissue reaction	Biocompatibility evaluation Performance testing and descriptive information Pyrogenicity testing Labeling
Infection	Sterilization testing/validation/information Shelf-life validation Labeling
Delays in wound healing	Biocompatibility evaluation Animal performance testing Performance testing and descriptive information Labeling
Failure of device integration	Animal performance testing Performance testing Labeling

Based on the identified risks and recommended mitigation measures, FDA believes that the following special controls would provide reasonable assurance of safety and effectiveness for absorbable synthetic wound dressings:

1. Performance testing and descriptive information must demonstrate the functionality of the device to achieve the specified use, including establishing the physical and chemical characteristics of the device. The following must be provided:
   i) Identity, quantification, and purpose of each component in the finished product;
   ii) Specification and characterization of each component in the finished product; and
   iii) Final release specifications for the finished product.

2. Performance data must demonstrate the sterility of the device.

3. The device, including any degradants, must be demonstrated to be biocompatible, non-pyrogenic and contain endotoxin level within acceptable limits.

4. Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

5. Animal performance testing must demonstrate that the device materials and degradants do not delay the wound healing process and can be appropriately integrated into the surrounding tissues.

6. Performance data must demonstrate that the device performs as intended under anticipated conditions of use, including complete degradation of any absorbable material(s) in the wound and evaluation of expected worst-case conditions.

7. The labeling must include:
    i) A description of the intended user population.
    ii) Specific instructions regarding the proper placement, sizing, duration of use, frequency of dressing change, maximum use life per application of the dressing, maximum total use life of the dressing, and removal of the dressing, if applicable.
    iii) A list of each ingredient or component within the finished device, including the functional role of that ingredient or component within the device.
    iv) If the device has non-resorbable components, a warning statement for the potential retention of those components in the wound or the surrounding area.
    v) A contraindication for any known sensitivity to components within the device.
    vi) A contraindication if there are incompatibilities with other therapies.
    vii) A shelf life.
    viii) A statement regarding when to discontinue use of the device after multiple reapplications based on biocompatibility and performance testing, if applicable.
    ix) Any statements in the labeling must be clear such that they may be understood by the end user, supported by appropriate evidence, and consistent with the intended use of covering a wound, absorbing exudate, and maintaining appropriate moisture balance within the wound.
    x) Disposal instructions.

If the Panel believes that Class II is appropriate for the absorbable synthetic wound dressings, the Panel will be asked whether the identified special controls appropriately mitigate the identified risks to health and whether additional or different special controls are recommended.

8.2 Overview of Proposed Classification/FDA Recommendation

Based on the safety and effectiveness information gathered by the FDA, the identified risks to health and recommended mitigation measures, we recommend that absorbable synthetic wound dressings indicated for use to cover a wound, to absorb exudate, and to maintain appropriate moisture balance within the wound be regulated as Class II devices.

878.4023 Absorbable Synthetic Wound Dressings.

(a) *Identification.* An absorbable synthetic wound dressing is a device intended to cover a wound, to absorb exudate, and to maintain appropriate moisture balance within the wound. These devices may additionally be intended as a scaffold for cellular infiltration. It is composed of absorbable synthetic materials, such as biodegradable polymers. Absorbable synthetic wound dressings may be used

alone or in conjunction with a secondary, non-resorbable wound dressing for securement. An absorbable synthetic wound dressing is not intended as a long-term skin substitute, a temporary synthetic skin, or to accelerate the wound healing process. An absorbable synthetic wound dressing does not contain animal-derived materials, antimicrobials, drugs, or biologics.

(b) *Classification.*
Class II (special controls). The special controls for this device are:

1. Performance testing and descriptive information must demonstrate the functionality of the device to achieve the specified use, including establishing the physical and chemical characteristics of the device. The following must be provided:
   i) Identity, quantification, and purpose of each component in the finished product;
   ii) Specification and characterization of each component in the finished product; and
   iii) Final release specifications for the finished product.

2. Performance data must demonstrate the sterility of the device.

3. The device, including any degradants, must be demonstrated to be biocompatible, non-pyrogenic and contain endotoxin level within acceptable limits.

4. Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

5. Animal performance testing must demonstrate that the device materials and degradants do not delay the wound healing process and can be appropriately integrated into the surrounding tissues.

6. Performance data must demonstrate that the device performs as intended under anticipated conditions of use, including complete degradation of any absorbable material(s) in the wound and evaluation of expected worst-case conditions.

7. The labeling must include:
   i) A description of the intended user population.
   ii) Specific instructions regarding the proper placement, sizing, duration of use, frequency of dressing change, maximum use life per application of the dressing, maximum total use life of the dressing, and removal of the dressing, if applicable.
   iii) A list of each ingredient or component within the finished device, including the functional role of that ingredient or component within the device.

iv) If the device has non-resorbable components, a warning statement for the potential retention of those components in the wound or the surrounding area.
v) A contraindication for any known sensitivity to components within the device.
vi) A contraindication if there are incompatibilities with other therapies.
vii) A shelf life.
viii) A statement regarding when to discontinue use of the device after multiple reapplications based on biocompatibility and performance testing, if applicable.
ix) Any statements in the labeling must be clear such that they may be understood by the end user, supported by appropriate evidence, and consistent with the intended use of covering a wound, absorbing exudate, and maintaining appropriate moisture balance within the wound.
x) Disposal instructions.

Based on the available scientific evidence, the FDA will ask the Panel for their recommendation on the appropriate classification of the absorbable synthetic wound dressings.

Appendix A: Literature Search Terms and Filters for Absorbable Synthetic Wound Dressings

On July 18-20, 2022, literature searches were performed to identify all published studies for absorbable synthetic wound dressings with the search periods of April 1, 2012 to April 1, 2022 and April 1, 2012 to July 18, 2022 in two databases: PubMed and EMBASE. The searches were performed together with other wound dressings being presented at this classification panel, including wound dressings with animal-derived materials and hemostatic wound dressings with and without thrombin.

The search terms used for the PubMed search are presented in the tables below.

Table 5: Wound Dressing PubMed Literature Search Strategy (July 18, 2022)

Wound Dressings		
Set	**Query**	**Results**
Filters: English, Human, 2012-2022		
6	#3 OR #4	1,557
5	#4 NOT #2	47
4	((Wound[tiab] or "Wounds and Injuries"[Mesh]) AND (dressing*[tiab] OR bandage*[tiab] or "Bandages"[Mesh])) AND (hemostat[tiab] OR hemostatic[tiab] OR "Collagen"[Mesh] AND "Hemostatics"[Mesh])	74
3	#1 NOT #2	1,510
2	(("negative pressure"[tiab]) OR (comment[pt] OR editorial[pt] OR letter[pt] OR news[pt] OR "Book Illustrations"[pt] OR congress[pt] OR annual[tiab] OR book[tiab] OR comment[tiab] OR chapter[tiab] OR note[tiab] OR review[tiab] OR symposium[tiab] OR poster[tiab] OR abstract[tiab] OR "conference paper"[tiab] OR "conference proceeding"[tiab] OR "conference review"[tiab] OR congress[tiab] OR editorial[tiab] OR erratum[tiab] OR letter[tiab] OR note[tiab] OR meeting[tiab] OR sessions[tiab] OR "short survey"[tiab] OR symposium[tiab] OR animal[tiab] OR rat[tiab] OR rats[tiab] OR mouse[tiab] OR mice[tiab] OR goat[tiab] OR goats[tiab] OR pig[tiab] OR pigs[tiab] OR cadaver[tiab] OR dog[tiab] OR dogs[tiab] OR monkey[tiab] OR monkeys[tiab] OR ape[tiab] OR apes[tiab]))	1,967,773
1	(Wound[tiab] or "Wounds and Injuries"[Mesh]) AND ((dressing*[tiab] OR bandage*[tiab] or "Bandages"[Mesh]) AND ("animal derived"[tiab] or "absorbable synthetic*"[tiab] or "wound dressing*"[tiab] or Biologic[tiab] or "Biologic* dressing*"[tiab] or "Biological Dressings"[Mesh] or collagen[tiab] or "Collagen"[Mesh] or "contact layer"[tiab] or "Acellular dermal matrix"[tiab] or "porcine dermal matrix"[tiab] or "decellularized extracellular matrix"[tiab] or "decellularized dermal graft"[tiab] or "decellularized xenograft"[tiab] or "porcine dermis"[tiab] or "bovine dermis"[tiab] or "skin substitute*"[tiab] or (dermal[tiab] and scaffold*[tiab]) or (synthetic[tiab] and "hybrid-scale"[tiab] and matrix[tiab]) or (resorbable[tiab] and "glass fiber"[tiab] and matrix[tiab]) or (biodegradable[tiab] and "temporizing matrix"[tiab]) or (synthetic[tiab] and "skin substitute*"[tiab])))	1,510

Table 6: Wound Dressings PubMed Search Strategy, Trade Names (July 20, 2022)

Wound Dressings		
Set	**Query**	**Results**
Filters: English, Human, 2012-2022		
3	#1 OR #2	277
2	hemostat* and ("quickclot"[tiab] or hemosorb[tiab] or "chito-seal"[tiab] or "hemcon bandage"[tiab] or "neptune pad"[tiab] or "comfort-band"[tiab] or biopad[tiab] or "quikclot acs+"[tiab] or (bleedarrest[tiab] and (particles[tiab] or foam[tiab])) or woundstat[tiab] or bloodstop[tiab] or "softseal-stf" or "chitogauze"[tiab] or celstat[tiab] or posisep[tiab])	3
1	("animals"[MeSH] OR "animal"[Title/Abstract]) AND ("biobrane"[Title/Abstract] AND "temporary wound dressing"[Title/Abstract])) OR "medifil"[Title/Abstract] OR "skintemp"[Title/Abstract] OR "viaderm"[Title/Abstract] OR "collagen wound dressing"[Title/Abstract] OR "bilayer matrix wound dressing"[Title/Abstract] OR ("animals"[MeSH Terms:noexp] OR "animal"[All Fields])) AND ("wound dressing"[Title/Abstract] OR "oasis wound matrix"[Title/Abstract] OR ("hydrolyzed collagen"[Title/Abstract] AND "chondroitin sulfate"[Title/Abstract]) OR "polysulfated glycosaminoglycan"[Title/Abstract] OR "awbat"[Title/Abstract] OR "collagen sponge"[Title/Abstract] OR "matristem wound matrix"[Title/Abstract] OR "collagen powder"[Title/Abstract] OR "porcine dermal matrix"[Title/Abstract] OR "collagen wound dressing"[Title/Abstract] OR "procoll"[Title/Abstract] OR "covagen"[Title/Abstract] OR "flowable wound matrix"[Title/Abstract] OR "ologen collagen matrix"[Title/Abstract] OR "symphony"[Title/Abstract] OR "matriderm"[Title/Abstract] OR "macro-channels"[Title/Abstract])	274

The search terms used for the EMBASE search are presented in the tables below.

Table 7: Wound Dressings EMBASE Literature Search Strategy (July 19, 2022)

Wound Dressings		
Set	**Query**	**Results**
Filters: English, Human, 2012-2022		
6	#3 OR #5	3,910
5	#4 NOT #2	1,572
4	(('bandages and dressings'/mj OR 'bandages and dressings' OR bandage*:ab,ti OR dressing*:ab,ti) AND (absorbable:ab,ti OR synthetic:ab,ti OR 'hemostatic agent'/mj OR hemostatic:ab,ti OR collagen:ab,ti OR 'animal derived':ab,ti OR 'extracellular matrix':ab,ti OR 'extracellular matrix'/mj) OR 'biological dressing'/mj OR 'collagen dressing'/mj OR 'hemostatic dressing'/mj)	
3	#1 NOT #2	3,202
2	'negative pressure':ab,ti OR 'editorial'/exp OR 'letter'/exp OR 'medical illustration'/exp OR 'book'/exp OR 'poster'/exp OR 'conference abstract'/exp OR 'conference paper'/exp OR 'conferences and congresses'/exp OR 'conference review'/exp OR 'erratum'/exp OR 'symposium'/exp OR 'short survey'/exp OR 'note'/exp OR 'chapter'/it OR 'conference abstract'/it OR 'conference paper'/it OR 'editorial'/it OR 'letter'/it OR 'note'/it OR 'review'/it OR 'short survey'/it OR abstract:nc OR annual nc OR conference nc OR 'conference proceeding':pt OR 'conference review':it OR congress nc OR meeting nc OR sessions:nc OR symposium:nc OR [conference abstract]/lim	6,425

	OR [conference paper]/lim OR [conference review]/lim OR [editorial]/lim OR [letter]/lim OR [note]/lim OR [short survey]/lim OR comment:ti OR book:pt OR comment:ab,ti OR annual:ab,ti OR 'conference proceeding':ab,ti OR note:ab,ti OR meeting:ab,ti OR sessions:ab,ti OR 'short survey':ab,ti OR animal:ab,ti OR rat:ab,ti OR rats:ab,ti OR mouse:ab,ti OR mice:ab,ti OR goat:ab,ti OR goats:ab,ti OR pig:ab,ti OR pigs:ab,ti OR cadaver:ab,ti OR dog:ab,ti OR dogs:ab,ti OR monkey:ab,ti OR monkeys:ab,ti OR ape:ab,ti OR apes:ab,ti	
1	('wound'/mj OR wound:ab,ti) AND ('bandages and dressings'/mj OR dressing*:ab,ti OR bandage*:ab,ti) AND ('animal derived':ab,ti OR 'absorbable synthetic*':ab,ti OR 'wound dressing*':ab,ti OR biologic:ab,ti OR 'biologic* dressing*':ab,ti OR 'biological dressing'/mj OR collagen:ab,ti OR 'collagen'/mj OR 'contact layer':ab,ti OR 'acellular dermal matrix':ab,ti OR 'porcine dermal matrix':ab,ti OR 'decellularized extracellular matrix':ab,ti OR 'decellularized dermal graft':ab,ti OR 'decellularized xenograft':ab,ti OR 'porcine dermis':ab,ti OR 'bovine dermis':ab,ti OR 'skin substitute*':ab,ti OR (dermal:ab,ti AND scaffold*:ab,ti) OR (synthetic:ab,ti AND 'hybrid-scale':ab,ti AND matrix:ab,ti) OR (resorbable:ab,ti AND 'glass fiber':ab,ti AND matrix:ab,ti) OR (biodegradable:ab,ti AND 'temporizing matrix':ab,ti) OR (synthetic:ab,ti AND 'skin substitute*':ab,ti))	9,274

Table 8: Wound Dressings EMBASE Search Strategy, Trade Names (July 20, 2022)

Wound Dressings		
Set	**Query**	**Results**
Filters: English, Human, 2012-2022		
3	#1 OR #2	314
2	hemostat* AND (quickclot OR hemosorb OR 'chito-seal' OR 'hemcon bandage' OR 'neptune pad' OR 'comfort-band' OR biopad OR 'quikclot acs' OR (bleedarrest AND (particles OR foam)) OR woundstat OR bloodstop OR 'softseal-stf' OR chitogauze OR celstat OR posisep	25
1	animal AND (biobrane AND 'temporary wound dressing' OR medifil OR skintemp OR viaderm OR 'bilayer matrix wound dressing' OR 'oasis wound matrix' OR ('hydrolyzed collagen' AND 'chondroitin sulfate') OR 'polysulfated glycosaminoglycan' OR awbat OR 'collagen sponge' OR 'matristem wound matrix' OR 'collagen powder' OR 'porcine dermal matrix' OR 'collagen wound dressing' OR procoll OR covagen OR 'flowable wound matrix' OR 'ologen collagen matrix' OR symphony OR matriderm OR 'macro-channels')	289

The table below summarizes the patients, interventions, comparisons, outcomes, timing, and settings (PICOTS) elements that were used to inform the inclusion/exclusion criteria used in the two literature searches. Only comparative studies on human subjects, with a minimum of 100 patients per study arm, were included in the review for the first search. The second search included comparative studies on human subjects with a minimum of 75 patients per study arm.

Table 9: Patients, Interventions, Comparisons, Outcomes, Timing, and Settings (PICOTS) Eligibility of Literature Review Studies

PICOTS	Inclusion Criteria	Exclusion Criteria

Population	Patients requiring coverage/protection in the management of wound healing using wound dressings.	Patients that do not require wound management using wound dressings.
Intervention	Absorbable synthetic wound dressings (FRO) Hemostatic wound dressings with and without thrombin (FRO) Collagen and/or animal-derived wound dressings (KGN)	No wound dressing Other types of wound dressings
Comparison	• One wound dressing vs. another wound dressing • No use of a wound dressing	No exclusion
Outcomes	All wound dressing devices: 1. Mortality (all-cause) 2. Adverse tissue reactions (local) 3. Adverse tissue reactions (systemic) 4. Duration of use Hemostatic dressings: 1. Time to clot 2. Survival Subgroups: 1. Sterile vs. non-sterile products 2. With vs. without thrombin 3. Diabetics vs. non-diabetics 4. For hemostatic dressings: Minor, moderate, and severe bleeding	Studies will be excluded if they do not report any of the specified outcomes.
Timing	All	None
Setting	US and OUS	No exclusion
Study Design	• Randomized controlled trials (RCTs) • Cohort studies (prospective/retrospective)	Laboratory studies Nonclinical studies (e.g., narrative reviews, commentaries) Economic and cost effectiveness analyses Cross-sectional studies Case-control studies Systematic literature reviews (SLRs), meta-analyses Case series (≥10 patients) and case reports (≤9 patients) Animal studies Original search: N <100 per arm Second search: N <75 per arm
Language	Articles published in English	Non-English language
Publication dates		Published outside of date ranges

In total, the first SLR search identified 1,677 unique records for screening at the title/abstract level. After excluding 1,552 records that were not relevant to the review at this level, there were 125 full-text articles assessed for eligibility. The most common reasons references were excluded at the abstract level were completely off topic (n=354), animal study (n=296), and fewer than 100 patients per study arm (n=202). Full text for all

125 records were retrieved and screened, and 13/125 of the references were determined to meet the inclusion criteria. Of the 13 included articles, five articles were relevant to the safety and effectiveness of wound dressings with animal-derived materials, eight articles were relevant to the hemostatic wound dressings with and without thrombin. None of the articles were relevant to absorbable synthetic wound dressings.

The second SLR search identified an additional 3,341 unique records for screening at the title/abstract level. After excluding 3,305 records that were not relevant to the review at this level, there were 36 full-text articles assessed for eligibility. The full-text 36 articles were retrieved and screened, and 2/36 articles were determined to meet the inclusion criteria. Of the 2 additionally included articles, one article was relevant to the safety and effectiveness of wound dressings with animal-derived materials, another article was relevant to the hemostatic wound dressings with and without thrombin. None of the articles were relevant to absorbable synthetic wound dressings.

Because the two SLR searches did not identify any articles related to absorbable synthetic wound dressings, a supplemental search was conducted with the brand names and a modified search criteria (i.e., removing the patient number search limitation previously used, which excluded the studies with N < 100 patients per arm for the first search and N < 75 patients per arm for the second search). The supplemental literature search performed in PubMed yielded seven relevant articles. The details of each study are provided in Appendix B.

Appendix B: Literature Evidence Table

Table 10: Studies Included in the Supplemental Literature Search for Absorbable Synthetic Wound Dressings

Study Characteristics	Patient Characteristics	Device Brand/ Manufacturer	Effectiveness and Safety Outcomes
Reference: Wu et al. 2022[12] **Country:** USA Case Western Reserve University School of Medicine; MetroHealth Medical Center (Cleveland, OH) **Study Design:** Retrospective study **Purpose:** To compare wound healing rates and complication rates between NovoSorb BTM and CCS skin substitute **Length of follow-up:** The median follow-up time 6.9 months with a range of 3.2–12.3 months. **Funding Source:** Not reported	**Patients (N):** 97 patients (51 - BTM group, 46 - CCS group) **Age Mean (SD):** 48.2 (18.0) years BTM: 51.6 (18.7) years CCS: 44.5 (14.3) years **Sex (% male):** 64 (66%) **Diagnosis:** burn, trauma, iatrogenic, compartment syndrome, skin cancer, and osteomyelitis. **Inclusion criteria:** Patients aged 18 years or older who underwent wound reconstruction with either BTM or CCS bilayer skin substitute between January 1, 2015, and July 31, 2020. **Exclusion criteria:** Patients were excluded if they died during the study period or were younger than 18 years at the time of dermal template placement, or if multiple or other skin substitutes were applied.	**Intervention:** NovoSorb Biodegradable Temporizing Matrix (BTM) (PolyNovo Ltd) **Comparator:** Collagen-chondroitin Silicone (CCS) Bilayer Dermal Regeneration Substitutes (Integra LifeSciences) **All:** Patients were identified using relevant Current Procedural Terminology codes. The decision to use a particular dermal template was at the discretion of the attending surgeon based on the wound and patient-specific qualities. The median template size was 147 cm^2 and 100 cm^2 for BTM and CCS, respectively. Skin grafts were applied to 39 patients (84.8%) treated with CCS compared with 28 (54.9%) treated with BTM; the remaining wounds healing secondarily.	The template-related and skin graft-related complications of infection, dehiscence, and hematoma or seroma were comparable between groups. The rate of skin graft failure was significantly higher in the CCS cohort (n = 9 [23.1%]) compared with the BTM group (n = 1 [3.6%]) (P =.006). More secondary procedures were required after CCS placement (mean ± standard deviation, 1.9 ± 1.8; range, 0–9) than after BTM (mean, 1.0 ± 0.9; range 0–4) (P =.002). There was no statistical significance in the frequency of definitive closure between BTM and CCS (n = 31 [60.8%] vs n = 28 [60.9%], respectively; P =.655).

Reference: Li et al. 2021[11] **Country:** Australia **Study Design:** a multi-centered, prospective case series from January 2019 to December 2020. **Purpose:** To explore the safety and effectiveness of NovoSorb BTM **Length of follow-up:** 3-18 months **Funding Source:** Not reported.	**Patients (N):** A total of 27 patients with 35 wounds **Age:** 47-95 years **Sex:** 19 males and 8 females **Diagnosis:** Complex wounds**,** including deep dermal and full-thickness burns, necrotising fasciitis and free flap donor site. **Inclusion criteria:** Complex wounds with (1) exposure of a critical structure such as tendon and bone, (2) failure of previous skin graft and (3) wound bed where the surgeon did not expect a traditional split-skin graft (SSG) to take. **Exclusion criteria:** Active infection or residual malignancy.	**Intervention:** NovoSorb Biodegradable Temporizing Matrix (BTM) (PolyNovo Ltd) **Comparator:** Not applicable	Thirty-three wounds had 100% integration of BTM at the time of second-stage reconstruction. In one of the cases, the BTM failed to integrate over exposed calvarium despite an absence of haematoma or infection. This patient subsequently had a transposition flap. The other case had an incomplete integration of the BTM with 10% loss. The SSG was taken over the 90% BTM, with the rest of the wound healed by secondary intention. Seven patients had partial graft loss after the second-stage reconstruction, which all healed by secondary intention.
Reference: Armstrong et al. 2022[6] **Country:** USA **Study Design:** A multi-center, single-blinded randomized controlled clinical trial. NCT02399826 in *ClinicalTrials.gov* **Purpose:** To compare a unique resorbable glass microfiber matrix with a standard of care group (SOC, collagen alginate dressing)	**Patients (N):** 40 patients (20 - BBGFM group, 20 - SOC group) **Age mean (SD):** BBGFM - 61.0 (13.81) SOC - 64.3 (9.32) **Sex (% male):** BBGFM - 10 (50%) SOC - 10 (50%) **Diagnosis:** Diabetic foot ulcers (DFUs) **Inclusion criteria:** Type 1 or type 2 diabetes mellitus (ADA diagnostic criteria); wound diabetic in origin and	**Intervention:** Mirragen Advanced Wound Matrix (BBGFM), a borate-based absorbable glasses, along with a padded three-layer dressing **Comparator:** SOC, collagen alginate dressing (Fibracol), along with a padded three-layer dressing. **All:** Both groups received standard diabetic foot care including glucose monitoring, weekly debridement when needed and an offloading device.	The result illustrated in the intent-to-treat analysis at 12 weeks showed that 70% (14/20) of the BBGFM-treated DFUs healed compared with 25% (5/20) treated with SOC alone (adjusted P = .006). Mean percentage area reduction (PAR) of wounds at 12 weeks was 79% in the BBGFM group compared with 37% in the SOC group (adjusted P = .027). Mean change in neuropathic score between baseline and up to 12 weeks of treatment was 2.0 in the BBGFM group compared with -0.6 in the SOC group where positive improvement in scores is better (adjusted P

Length of follow-up: 12-weeks **Funding Source:** ETS WoundCare; Rolla Missouri, Grant/ Award Number: 001	larger than 1.0 cm^2; wound present for a minimum of 4 weeks duration; no signs of infection. **Exclusion criteria:** Wound probing to ligament/tendon/joint capsule/fascia/bone; Index ulcer caused by a medical condition other than diabetes; Index ulcer associated with carcinoma; Subjects with a history of more than 2 weeks treatment with immune-suppressants, cytotoxic chemotherapy, or application of topical steroids to the ulcer surface within 1-month prior to screening.		= .008). The mean number of BBGFM applications was 6.0. In conclusion, adding BBGFM to SOC significantly improved wound healing with no adverse events related to treatment compared with SOC alone.
Reference: Schwarze, et al., 2008[7] **Country:** Germany **Study Design:** A prospective, randomized, bicentric, nonblinded, clinical study **Purpose:** To evaluate the impact on wound healing of Suprathel in partial thickness burn injuries. **Length of follow-up:** 3-month follow-up after complete reepithelization.	**Patients (N):** 30 patients with second-degree burn injuries; Mean total body wound surface area (TBWSA) was 478 cm^2; The ABSI score ranged between 3 and 8 (mean ABSI, 4.6). **Age mean:** 40.4 years **Sex:** 24 males and 6 females **Diagnosis:** In this study, only second-degree burn lesions and patients with an Abbreviated Burn Severity Index (ABSI) score ≤ 10 were included. **Inclusion criteria:** Patient age 18 - 80	**Intervention:** Suprathel, a synthetic, absorbable dressing (POLYMEDICS INNOVATIONS GMBH) **Comparator:** Omiderm, a transparent, hydrophilic polyurethane membrane **All:** Burn injuries were randomly selected, partly treated with Omiderm and partly treated with Suprathel. The first gauze change was applied the fifth day postoperatively, followed by regular wound inspection	There was no significant difference between the 2 dressings tested regarding healing time and reepithelization (mean 10.2-days for Suprathel vs. mean10.3-days for Omiderm). There was a significant lower pain score for patients treated with Suprathel (P = 0.0072) (mean 10-day VAS pain score 1.0 for Suprathel vs. 1.59 for Omiderm). Throughout the treatment period, no infection was detected in any burn wounds of both study groups. Moreover, none of the patients experienced hypertrophic scars or any allergic reactions to any of the dressings during a 3-month follow-up period after complete reepithelization.

	years; superficial or mid-dermal partial thickness burn injury of at least 1.5% of total body surface area. **Exclusion criteria:** pregnancy, patients with cardiac problems, coagulation problems, burn injuries of the face, palmar and plantar area, genitals, and buttock.	until complete reepithelization.	
Reference: Schwarze, et al., 2007[8] **Country:** Germany Berlin Trauma Center and Marien Hospital Stuttgart **Study Design:** A prospective, randomized, two center clinical study **Purpose:** To evaluate the impact on wound healing of Suprathel in donor sites of split-thickness skin grafts. **Length of follow-up:** 3-month follow-up after complete reepithelization.	**Patients (N):** 22 burn patients treated with split-thickness skin grafts **Age mean:** 39.6 years with a range of 18-64 years. **Sex:** 18 males and 4 females **Diagnosis:** Contact burns requiring treatment with skin grafting; In all patients, skin harvesting was performed with an air-driven dermatome using a fresh cutting blade each time; Prior to dressing application, a gauze soaked in epinephrine-saline solution was temporarily applied to the freshly harvested donor sites. **Inclusion criteria:** Patient age 18 - 80 years; skin donor sites measured at least 8 cm x 4 cm or larger, and located on the anterolateral or anteromedial thigh,	**Intervention:** Suprathel, a synthetic, absorbable dressing (POLYMEDICS INNOVATIONS GMBH) **Comparator:** Jelonet, a paraffin gauze dressing **All:** Donor sites of skin grafts were randomly selected; partly treated with Jelonet and partly treated with Suprathel. First gauze change was carried out the fifth day postoperatively followed by regular wound inspection until complete re-epithelization.	There was no significant difference between the two materials tested regarding healing time and re-epithelization (mean 10.5-day for Suprathel vs. mean 10.85-day for Jelonet). There was a significantly lower pain score for patients treated with Suprathel ($p = 0.0002$) (mean 10-day VAS pain score 0.92 for Suprathel vs. 2.1 for Jelonet). Wound areas treated with Suprathel required less frequent dressing changes.

	or the lower extremity. **Exclusion criteria:** pregnancy, patients with cardiac problems, coagulation problems.		
Reference: Keck, et al., 2012[9] **Country:** Austria Vienna Burn Center Medical University Vienna **Study Design:** A prospective, non-blinded controlled non-inferiority study **Purpose:** To analyze time to healing and scar quality in matched areas of deep partial-thickness burn for Suprathel and skin grafts. **Length of follow-up:** 30 and 90 days, postoperatively.	**Patients (N):** 18 patients with deep partial-thickness dermal wounds **Age mean:** 45 years with a range of 25–83 years **Sex:** 11 males and 7 females **Diagnosis:** Patients with deep-partial-thickness dermal burn wounds. **Inclusion criteria:** patients older than 18 years of age suffering from deep partial-thickness dermal burn wounds. **Exclusion criteria:** Patients in the case of concomitant immune mediated disease, active tumor disease or pregnancy and in case of an Abbreviated Burn Severity Index (ABSI) higher than 13.	**Intervention:** Suprathel, a synthetic, absorbable dressing (POLYMEDICS INNOVATIONS GMBH) **Comparator:** Split-thickness skin graft (STSG). Autologous skin grafts were preferably taken from the thigh, meshed in a 1:1.5 manner and stapled to the wound. **All:** Surgery took place between days 3 and 5 post trauma. General anesthesia was performed during surgery. After early tangential excision, matched deep-partial-thickness areas were covered with 0.1 mm STSGs and Suprathel (two areas of at least 100 cm^2) for direct intra-individual comparison. Both study locations were covered with fatty gauze. An experienced burn surgeon regularly inspected the wounds until complete re-epithelialisation was achieved.	Fifteen days after surgery, complete wound closure was present in 44.4% (8/18) of all areas covered with Suprathel and 88.9% (16/18) in the split-thickness skin graft (STSG) area ($p = 0.008$). Evaluation of the total Vancouver Scar Scale (VSS), Patient and Observer Scar Assessment Scale (POSAS) and cutometry satisfied the criterion of noninferiority for Suprathel on day 30. Ninety days after surgery, only the Observer Scar Scale showed that Suprathel is non-inferior to STSG, albeit the mean total VSS and Patient Scar Scale were better in Suprathel areas. No occurrence of allergic reactions or infections were identified from the use of Suprathel. In comparison to STSGs, Suprathel showed a prolonged time to healing, whereas the follow-up on postoperative days 30 and 90 showed at least comparable results in terms of scar formation and scar quality.

Reference: Kaartinen, et al., 2011[10] **Country:** Finland Tampere University Hospital **Study Design:** A prospective study **Purpose:** To compare the effects of Suprathel and Mepilex Transfer on donor sites of split thickness skin grafts. **Length of follow-up:** 14 days, 1-month, 3-month follow-up.	**Patients (N):** 15 patients **Age mean (SD):** 60 (16) years, range 16-78 years **Sex:** 9 males 5 females **Diagnosis:** 14 patients who had split thickness skin grafting in Tampere University Hospital; a total of 22 donor sites. **Inclusion criteria:** All donor sites were located on the thigh. **Exclusion criteria:** pregnancy, cortisone treatment, immune-suppression, skin disease, anti-coagulation, bleeding disorder, or unstable heart disease.	**Intervention:** Suprathel, a synthetic, absorbable dressing (POLYMEDICS INNOVATIONS GMBH) **Comparator:** Mepilex Transfer (Molnlycke Health Care), consisting of flexible and hydrophilic polyurethane foam coated with a soft layer of silicone. **All:** Each wound was divided into proximal and distal halves of equal size, one of which was covered with Suprathel and the other was covered with Mepilex Transfer. The position of the dressings was randomized. Suprathel was covered with one layer of paraffin gauze (Jelonet). Both sides of the wound were covered with two layers of dry gauze and bandage. The patient remained in the ward for at least 5 days and were followed in the outpatient clinic at 14 days, 1 month and 3 months.	Significantly less pain and bleeding were observed on the VAS in the Suprathel covered wounds than in the Mepilex Transfer covered wounds at 1 day and 5 days postoperatively. There was no significant difference in epithelialization between the two groups. 21 out of 22 donor sites were at least 96% epithelialized at 14 days postoperatively. Suprathel produced a better scar at the three months' follow up as measured using Vancouver Scar Scale (VSS).
Abbreviations: N: patient number; p: p-value; SD: standard deviation; SOC: standard of care			