Basic data

The product MB-Collagen is a product for professional users, such as nurses, caregivers and other work groups trained in medical wound treatment. The product has been CE certified since 1996. No previous generations or variants of the product exist. It is a Class III product, according to Rules 7, 18 and 21. The collagen contained in the product is of animal origin, source of collagen is pig skin.

MB-Collagen is offered in three sizes: 5*5, 5*10 and 10*10 cm.

The manufacturer of the product is the company:
MBP-Medical Biomaterial Products GmbH, Lederstraße 7, D-19306 Neustadt-Glewe.
Contact:
E-mail: info@mbp-gmbh.de

Tel: +49 38757-5090
The SRN (registration number of the company in the EUDAMED database) is: DE-MF-000004939.

Notified body, identification number: mdc medical device certification GmbH, CE 0483

The product is sold in retail units of three per box.

Size in mm	REF	UDI-DI
50*50	0505C	426023091001
50*100	0510C	426023091002
100*100	1010C	426023091003

GMDN: 45023; EMDN: M04041001; UMDNS: 15-2016.

Intended use of the product

Composition:

sterile porcine collagen matrix

Mode of action

The porous structure of the collagen sponge ensures a capillary suction effect and thus the absorption of the wound secretion. The wound secretion dissolves the porous structure and releases the native collagen. This has an accelerating effect on the formation of new granulation tissue in the granulation phase. The added collagen indirectly influences the epithelialisation or regeneration phase by stimulating the body's own collagen synthesis, whereby epithelialisation progresses rapidly. The newly formed tissue offers improved starting conditions for good cosmetic results, as is known from animal and human clinical studies.

Indications

Collagen pad for wound care, for single use, for

- Non-infected wounds with wound healing disorders
- Wounds with secondary wound healing in the granulation phase
- Wounds in the epithelialisation phase (e.g. leg ulcers, decubital ulcers, split-skin sites, burn wounds, secondary healing wounds, etc.).

Contraindications

Use on infected wounds.

Side effects

In individual cases, intolerance reactions to collagen occur. Occasionally, pain occurs after applying a dry preparation to the wound surfaces. Very rarely, existing infections are aggravated.

Use Pregnancy and lactation
No studies are available on the use of MB-Collagen during pregnancy and breastfeeding or on the influence on human reproductive ability. Before using MB-Collagen, the attending physician must therefore weigh up the benefits for the mother and the possible risks for the child on an individual basis.

Interactions

- Antiseptics that release chlorine (e.g. chloramine), as well as tannin and caustics that alter proteins, must not be used together with collagen.
- Ointments and powders as well as silicone preparations can alter the interstices of the collagen sheets, fleeces or sponges, so they should not be applied together with collagen.
- No fixation with polymethyl methacrylate adhesives
- Protein-damaging substances (tannic acid, silver nitrate) should also not be used.
- Wound disinfections should not be combined with MB collagen in the form of a moist wound dressing.

Dosage and method of application

Unless otherwise prescribed by the doctor, a collagen sponge corresponding to the size of the wound is placed on the moist wound under aseptic conditions. Fixation can be done with a non-woven compress or a gauze compress. The frequency of dressing changes depends on the amount of wound secretion:

- In case of heavy secretion: several times a day
- For moderate secretion: 1 x daily
- In case of weak exudation: after several days (provided that no signs of inflammation are present).
- If exudation is very weak or absent, it is necessary to moisten MB-Collagen with a physiological sodium chloride or Ringer's solution.

Storage instructions

The unopened, sterile pack must be stored below 24°C in a cool and dry place with good ventilation. MB-Collagen must be kept away from extremes of temperature and humidity. Do not use MB-Collagen after the expiry date.

Warnings, for attention

MB-Collagen is sterilized with y-radiation and must not be sterilized. Sterility is only guaranteed if the packaging is undamaged. MB-Collagen must not be reused once it has been removed from the packaging and/or has come into contact with a patient, as there is then an increased risk of contamination with subsequent risk of infection.

Product description, functional mechanism

MB collagen consists of naturally cross-linked animal collagen fibres and is available in the form of fleeces. To stimulate wound healing, collagen fleeces are used as wound dressings on non-infected burns and areas with wound healing disorders (chronic wounds). The collagen fleece accelerates and supports wound healing through its hemostatic effect and stimulates the release of various growth factors essential for wound healing such as PDGF and TGFβ by activating platelets.

MB collagen is a matrix into which the exuding blood or wound secretion (exudate) penetrates. Platelets are activated by contact with the collagen. The now altered surface shape leads to aggregation and clumping. At the same time, the release of coagulation factors is initiated, which initiates plasmatic blood coagulation, which leads to vessel occlusion with the formation of a fibrin scaffold. Hemostasis is accelerated by the platelet-activating effect of collagen.

At the same time, the wound dressing provides a capillary suction effect through the porous structure of the collagen sponge and thus ensures the absorption of the wound secretion. The wound secretion dissolves the porous structure of the wound dressing and releases the native collagen. This has an accelerating effect on the formation of new granulation tissue in the granulation phase. In chronic wounds, the exogenous collagen binds the activity of excess metalloproteases and thereby enables the body's own collagen synthesis, which leads to the build-up of the extracellular matrix of the granulation tissue.

The supplied collagen thus indirectly influences the regeneration and epithelization phase by stimulating and protecting the body's own collagen synthesis, whereby epithelization progresses rapidly. As a competing substrate, the exogenous collagen reduces the degradation of endogenous collagen by proteases that prevent the build-up of an extracellular matrix - a prerequisite for the free mobility of cells involved in this process (e.g. leukocytes, macrophages, fibroblasts, epithelial cells) - and the build-up of granulation tissue.

Properties:

- Effective local haemostyptic in the wound
- Wound protection
- Binding of the activity of excess metalloproteases, protection of the body's own collagen synthesis.
- Removal of proinflammatory factors from the wound by capillary exudate uptake
- Three-dimensional matrix for cellular and vascular infiltration, supports the build-up of endogenous tissue

Biological assessment

Results of biocompatibility tests confirm the high biocompatibility of the product according to DIN EN ISO 10993. Extensive biological studies with the help of animal experiments have been carried out and prove the clinical safety of the product. The many years of experience of MBP Medical Biomaterial Products GmbH with the sale of MB collagen as well as the continuous post-marketing monitoring show that the products are biocompatible within the scope of their intended use

Alternative treatment methods

The appropriate method for wound treatment is the basis of a successful therapy. MB-Collagen is mainly used in phase-appropriate wound therapy. The result of the examination of the wound status is decisive for the selection of the appropriate wound dressing: MB-Collagen is applied especially in the exudation phase and can, however, also be continued in the granulation phase. The preparations are completely absorbable. They should not be used in clinically infected defects. Difficult-to-heal, chronic defects are a domain for their use.

Alternative treatments at these stages of wound healing are dressings with e.g. honey, hyaluronic acid or hydrogels. Collagen products derived from another collagen source, e.g. beef, are also an alternative. Here, the individual patient benefit is decisive for the choice of the appropriate treatment method or material selection.

The use of collagen wound dressings is contraindicated in infected wounds. In this case, treatment is carried out according to the current state of the art, for example with antiseptics or silver-containing wound dressings.

User group

MB-Collagen may only be used by professional medical staff trained in the treatment of chronic wounds.

Summary of the clinical evaluation and post-marketing clinical follow-up (PMCF)

The clinical evaluation provided evidence that the product MB-Collagen, under normal intended use, meets the relevant essential safety and performance requirements and that its benefit/risk ratio is acceptable. Clinical data have demonstrated that MB-Collagen provides the intended performance (wound care of non-infected wounds with wound healing disorders, wounds with secondary wound healing in the granulation phase and wounds in the epithelialisation phase (e.g. leg ulcers, decubital ulcers, split skin removal sites, burn wounds, secondary healing wounds, etc.)). The performance (wound healing) is provided by the collagen (type I + III) the product is made of

- The wound healing mechanism triggered by the externally added collagen is state of the art and the treatment of wounds of this type (see above) is state of the art. Clinical results show that MB-Collagen is able to end the stagnation of chronic and difficult-to-heal wounds such as leg ulcers (of venous or arterial origin), diabetic foot syndrome or decubital ulcers and to initiate the processes of granulation, angiogenesis and re-epithelialization. Provided thorough debridement to remove stagnant necrotic tissue and bacterial evidence, collagen leads to a shift in the balance of wound healing factors resulting in accelerated wound healing. This is based, among other things, on its excellent haemostyptic properties, the binding of the proteolytic activity of proteolytic enzymes (neutrophil elastase, MMPs) occurring in abundance in chronic wounds, the protection of growth factors from proteolytic degradation by binding in a gel and the release of the same in the event of resorptive degradation of the gel, as well as the removal of proinflammatory RNS, ROS compounds and cytokines by exudate absorption, as has been demonstrated by preclinical studies. MB-Collagen thus contributes to improving the quality of life of patients, among other things by reducing the amputation rate and shortening inpatient stays, and represents a clinical benefit.

Based on the literature review and evaluation last conducted in 2022 as part of the clinical evaluation, the aim was to obtain information on the use of collagen-containing wound dressings in general and fleece wound dressings made of pure, non-cross-linked, native collagen in wound treatment in particular with regard to the following points:

- Composition, compatibility
- Indications and contraindications
- Therapy success and effectiveness
- Risks and side effects

The subject of the literature search was the product MB-Collagen of MBP GmbH as well as the similar product Suprasorb® C of Lohmann & Rauscher in the treatment of difficult-to-heal chronic wounds. The results of the literature search obtained and presented below served as the basis for assessing the clinical efficacy, safety and risk/benefit profile of the product MB-Collagen in the context of the broad range of approved collagen-containing wound dressings and for demonstrating its clinical, biological and technical performance.

For the product MB-Collagen, two preclinical in vivo studies (MB-Collagen) and for the similar product Suprasorb® C, seven preclinical in vitro studies (Suprasorb® C) could be used to determine the reactions of the tissue to the implanted material as a result of wound healing and immune response (MB-Collagen) or the influence of the material on wound healing-specific enzyme activities (Suprasorb® C).

As a result, twelve publications in category A were evaluated. In two of these papers, the material that makes up MB collagen was tested itself, in six papers Suprasorb® C, in one paper another porcine, in three papers another bovine collagen wound dressing. The two papers on MB collagen included a controlled randomised trial and a case series analysis. The studies with Suprasorb® C were designed as a comparative study in one case, but here only rated III due to the small number of participants, as comparative studies in two cases (one rated I) and three as case series evaluations (rated II). Wound treatments with Suprasorb® P (PU foam) + paraffin gauze, Suprasorb® F (self-adhesive, transparent polyurethane film) and ORC served as controls. Three studies represented case series analyses with Puracol, also a bovine fleece wound dressing.

P. Heinrich [45] presents results of the use of collagen fleece in the implantation of 80 bifurcation prostheses. While the right arm was treated with collagen fleece and a Redon drain, only a Redon drain was used for the left arm. Blood loss averaged 15ml ± 5ml on the right arm and 23ml ± 7ml on the left arm. Infections occurred in a total of 6% of patients, with 3 and 2 cases respectively. No differences were observed in clinical wound healing. The author points out the differences in the hemostatic effect of regenerated oxidized cellulose and collagen. While the hemostyptic effect of ROC is based on a mechanical effect of adhesion of capillaries, collagen triggers the coagulation cascade in contact with platelets. The author emphasizes that collagen hemostyptics have become an indispensable part of everyday clinical practice. Especially in parenchymal resections, brain operations, implantations of vascular and joint prostheses, they prove to be useful by accelerating local hemostasis of the smallest hemorrhages, which emerge profusely from the entire wound surface, or from stitch canal hemorrhages coming from vessels. Allergic effects of porcine collagen could be excluded in the observed applications. The

inflammation associated with resorption proceeded rapidly and without problems, and no increase in wound healing disorders was demonstrated with strict adherence to aseptic methods. **C. Thoma [93]** reports on the use of collagen fleece in hemostasis and wound healing of tooth extractions in patients under oral anticoagulants and with mild coagulopathies. Collagen fleece is recommended for surgical stomatology due to its remarkably good local tolerance and rapid healing of wounds. Tooth extraction cavities are subject to wound healing disturbing boundary conditions that compromise the stability of the coagulum formed, which inevitably leads to impaired wound healing. This is particularly true in cases of hemorrhagic diathesis. However, in patients with mild coagulation disorders, tooth extractions can be performed on an outpatient basis while maintaining therapies with anticoagulants, as the coagulum can be stabilized with the use of collagen fleece and suture closure of the wound. From the author's experience, collagen fleeces are shown to be superior to gelatin sponges. In the clinical trial, 134 teeth were extracted from 65 patients with mild coagulation disorders. The alveoli were loosely filled with collagen fleece and closed by suturing. In 102 extraction wounds, fibrin glue was also applied. Of the total of 7 observed post-extraction hemorrhages, 2 were caused by faulty suturing, and in 5 cases a Quick value of less than 10% was detected.

Table of coagulation disorder in 67 patients (from Thoma 1990) [93].

Clotting disorder	**n**
Oral anticoagulation with Falithrom® (phenprocoumon)	56
M.v. Willebrand-Jürgens	4
Thrombocytopenia	2
Panmyepathy	1
Platelet aggregation inhibition with Micristin® (acetylsalicylic acid)	1
Polycythaemia vera	1
F-VII deficiency	1
Referral due to unclear post-operative bleeding	1

With proper wound care and not too severe coagulopathy, no bleeding complications occurred, and healing was therefore completely undisturbed even in cases of coagulopathy. The resistance of the fleece-supported coagulum to saliva-induced fibrinolysis was increased and contributed to the good outcome of wound healing. Reference is made to the good handling properties of the fleece as well as its suitability as a carrier material for additional therapeutically active agents, as it remains dimensionally stable despite complete wetting with blood in the first phase of wound care.

Klammt et al [54] also investigated the hemostyptic and wound-healing effect of the collagen fleece in securing cavities that arise during the surgical removal of tumors, fistulas or teeth in malposition and whose maintenance of a stable coagulum is problematic. The clinical application was preceded by in vivo studies on domestic pigs. In addition to the collagen fleece (30 fillings), two other different materials (Collastypt, a bovine collagen fleece, and stabilized venous blood coagulum based on gelatin) were inserted into 60 prepared cavities of the jaw bone, 10 of which only bled spontaneously, and the healing process was documented histologically. The inserted collagen fleece was very quickly converted into a granulation tissue permeated by capillaries, more so than in the comparison samples, and was no longer detectable after 11 days. The cancellous bone near the defect showed increased activity with the collagen in place, osteoblastic bone formation was stronger than in the non-collagen comparison samples, and osteoclastic activity was also increased here in the border zone. Histologically recognizable defense reactions against the collagen fleece did not occur. With regard to wound healing, no differences were found between Collastypt, an established collagen fleece from Braun-Melsung, and the tested collagen fleece from MBP GmbH; wound healing was accelerated by the rapid formation of a granulation tissue rich in vessels and successfully led to new bone formation. Based on these results, a total of 37 cavities in the jaw were filled with collagen fleece from MBP GmbH in 1987/88 after surgical interventions (26 cavities with a diameter > 15 mm). Wound healing disorders in the form of postoperative fistulas were found in only 4 cases (10.8%), but these healed spontaneously. In all cases, bony regeneration was unremarkable.

The processes of hemostasis and wound healing are closely linked; as the first phase of wound healing**,** hemostasis provides initial impulses for the subsequent phases of wound healing through the release of mediators that cause chemotaxis, activation and mitogenesis of the cells of the immune system involved in the processes of wound healing, as well as tissue regeneration **[91].**

The available clinical reports confirm the positive effect that the collagen fleece, of which all MBP-GmbH collagen fleece products are made, has on hemostasis and wound healing. They also state that the use of the collagen fleece is not associated with any notable risks, that the products have a very favorable benefit/risk ratio and that they thus meet the basic safety and performance requirements.

The studies described with the collagen fleece of MBP GmbH by Heinrich [45], Thoma [93], Klammt et al [54], demonstrate the clinical efficacy and safety of the collagen fleece MB-Collagen in different procedures and a total of 221 applications and thus lay the foundation for the granting of a CE mark as a clinical trial. They provide evidence that the product MB-Collagen complies with the essential safety and performance requirements. There are no negative findings from active and passive market surveillance. MB-Collagen is a proven element in the range of modern wound dressings that contributes to the stimulation of proliferative, regenerative processes in stagnant chronic wounds and thus to wound healing through phase-appropriate application within specific treatment pathways.

No comprehensive case series analyses were published for MB collagen after 1990. Due to the unspectacular nature of the product, the known benefits of the material collagen and the fact that the collagen fleece always represents only one part of a more comprehensive treatment concept, this is also not to be expected. The clinical experience with the collagen fleece of the MB-Collagen wound dressing on its hemostyptic and wound healing promoting properties presented in the Keller (1990) literature collection sufficiently shows that it fulfils all expectations with regard to the clinical and safety aspect and meets the basic requirements.

Furthermore, the PMS data (market surveillance) of the product of the last five years were included in the assessment. MB-Collagen is a product that has been marketed as a CE-certified medical device since 1996 and has been used in everyday clinical practice without incident or clinical complaint. The use of collagen as a wound dressing corresponds to the current state of the art in medicine, it is an established technology, a legacy device, according to MDCG 2020-6. In the last 6 years alone, more than 30,000 patients have been treated with the product (66,060 products). There have been no clinical incidents, nor have any previously unknown side effects or contraindications been identified. Product-related risks associated with the intended use of the product MB-Collagen and comparable products are not described in the clinical outcome reports. Collagen fleeces lead to a reduction in the risk of serious consequences from the stagnation of chronic wounds and an unstoppable progressive course that could lead to organ loss through amputation or death. The phase-appropriate application in the overall concept of a modern, moist wound treatment including the elimination of the causal causes for the chronic stagnation of wound healing provides an essential impulse for the termination of the inflammatory phase and the transition to the regeneration/remodeling phase of wound healing. Thus, MB collagen accelerates wound healing and preserves tissue function, leading to improved patient quality of life, shortened inpatient stays and reduced costs for public and private healthcare systems. This far outweighs any risks that might be associated with the use of the product MB-Collagen. The product MB-Collagen itself does not pose any risks to safety in clinical use, and the risk of immune reactions to heterologous collagen is very low. Risks could arise from the application if wound dressings made of pure collagen are used on contaminated wounds without prior debridement and an incipient or progressive infection is not noticed in time. Furthermore, clinical results of comparable products were used to evaluate the performance of MB collagen. The studies of the comparator product also demonstrate the clinical performance of wound dressings consisting of collagen within the scope of the tendered indication and are therefore applicable as evidence of the clinical performance of the product MB-Collagen. No evidence questioning the clinical benefit and performance of the product was found in the literature review or in the evaluation of the company's own market surveillance. Evidence has been provided through the clinical evaluation that the MB-Collagen product performs as intended and is designed and manufactured to be suitable for its intended purpose under normal conditions of use - It is safe and effective. The use of MB-Collagen does not endanger the clinical condition and health or the safety of patients, users or other third parties. The residual risks present are presented, they are inherent in the nature of the product and are justified against the clinical benefit of the product to the patient. The residual risks are made known to the user via the instructions for use. The biological safety of the product has been demonstrated by in vitro and in vivo studies. The state of the art is that the use of pure collagen fleece wound dressings helps to reduce the complication rate for inflammation, infection and osteomyelitis compared to controls **(65, 44).** Based on the high level of complication-free experience with the MB-Collagen product (> 30,000 patients treated), no existing reports of serious adverse events in the FDA and BfArM databases for the MB-Collagen product or similar products, it is concluded that the MB-Collagen product meets the essential safety and performance requirements when used as intended. The clinical benefit of the product MB-Collagen was demonstrated in the clinical evaluation.

(44) Hanft JR et al; (2002): Healing of chronic foot ulcers in diabetic patients treated with a human fibroblast-derived dermis. J Foot Ankle Surg. 2002 Sep-Oct;41(5):291-9.

(45) Heinrich P; (1990): Stellenwert lokaler Hämostyptika. From Keller W (1990) in Medicamentum Berlin/DDR 1990 No. 90, b.

(54) Klammt J et al; (1990): Collagen haemostyptic fleece for filling bony cavities in the jaw. From Keller W (1990) in Medicamentum Berlin/DDR 1990 No. 90, c

(65) Marston WA et al; (2003): The Efficacy and Safety of Dermagraft in Improving the Healing of Chronic Diabetic Foot Ulcers. Diabetes Care 26:1701-1705, 2003

(91) Smith KJ et al; (1996): Histologic and immunohistochemical features in biopsy sites in which bovine collagen matrix was used for hemostasis. J Am Acad Dermatol. 1996 Mar;34(3):434-8.

(93) Thoma C; (1990): Application of "collagen haemostyptic fleece" for wound care after tooth extractions in coagulation disorders. From Keller W (1990) in Medicamentum Berlin/DDR 1990 No. 90, d.

Summary of post-market surveillance results according to PMCF plan.

From the information in the current literature, the data from public databases (MAUDE of the FDA and corrective measures of the BfArM) and the complaints received by MBP GmbH, no conclusions could be drawn regarding additional, previously unknown risks for the above-mentioned products.

It can therefore be assumed that, in accordance with the information provided in the instructions for use, there are no additional risks associated with the use of MBP GmbH's collagen fleece wound dressing MB-Collagen. Based on the available information on product safety and efficacy, no corrective measures, e.g. updating of risk management or amendment/supplementation of the IFU, are required.

M. Rangaswamy published 2021 results of 3 applications in which Biopad in combination with a platelet-enriched fibrin gel and autologous fat successfully led to the repair of difficult-to-heal tissue defects. No new publications were found on the clinical use of MB-Collagen and the other comparator products. Total sales volume in 2020: 1,629 boxes (4,887 products).

Thus, all risk mitigation measures and clinical requirements foreseen by the manufacturer seem to be fulfilled. Furthermore, neither possible systematic misuse nor use contrary to the intended purpose was detected. The overall results have no influence on the relevant parts of the technical documentation, preventive and/or corrective measures are not necessary. The performance of MB-Collagen has been shown to be reliable in clinical practice when used as intended.

Patient group, users, training courses

Persons or patient group: no restrictions, based on the clinical picture (wound treatment) older patients and diabetics tend to be treated. The products are applied by personnel who are medically trained in the treatment of chronic wounds. The treatment of chronic wounds with wound dressings made of collagen is state of the art and is taught as part of the training of specialist users. On request, training is provided by the medical product consultants of MBP GmbH.

Contact: info@mbp-gmbh.de, + 49 38757 5090.

Applied norms, laws and standards

The requirements of the following standards are applied within the scope of the manufacture, marketing and monitoring of the MB Collagen product (status: 27.07.2022). The standards are checked at regular intervals for the need of updating. The following standards are applied by MBP Medical Biomaterial Products GmbH as of today. An update will take place within the framework of the update of this SSCP.

- Medical Devices Act - MPG:2002-08, last amended on 26.05.2021
- Act on the Adaptation of Medical Device Law to Regulation (EU) 2017/745 and Regulation (EU) 2017/746 (Medical Devices EU Adaptation Act - MPEUAnpG), 19.05.2020, (MPDG), last amended on 26.05.2021.
- REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, 05.04.2017 (MDR)
- Medical Devices Operator Ordinance (Ordinance on the Installation, Operation and Use of Medical Devices) - MPBetreibV:1998-06, last amended on 26.05.2021

- Ordinance on the adaptation of medical device law to Regulation (EU) 2017/745 and Regulation (EU) 2017/746 (Medical Devices EU Adaptation Ordinance-MPEUAnpV), last amended on 21.04.2021.
- Ordinance on the reporting of suspected serious incidents involving medical devices and on the exchange of information between the competent authorities (Medical Devices User Reporting and Information Ordinance - MPAMIV), last amended 21.04.2021
- ASTM F 2212:2020 - Standard Guide for Characterization of Type I Collagen as Starting Material for Surgical Implants and Substrates for Tissue Engineered Medical Products (TEMPs)
- DIN EN ISO 13485:2021-12 (EN ISO 13485:2016 + AC:2018 + A11:2021) Medical devices - Quality management systems - Requirements for regulatory purposes
- DIN EN ISO 14971:2022-04 Medical devices - Application of risk management to medical devices
- DIN EN 62366-1:2021-08, Medical devices - Part 1: Application of fitness for use to medical devices
- DIN EN ISO 10993-1:2021-05, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system
- DIN EN ISO 10993-3:2015-02, Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.
- DIN EN ISO 10993-4:2017-12, Biological evaluation of medical devices - Part 4: Selection of blood interaction tests.
- DIN EN ISO 10993-5:2009-10, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- DIN EN ISO 10993-6:2017-09, Biological evaluation of medical devices - Part 6: Tests for local effects after implantation.
- DIN EN ISO 10993-9:2022-03, Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products
- DIN EN ISO 10993-10:2014-10, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type allergies.
- DIN EN ISO 10993-11:2018-09, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.
- DIN EN ISO 10993-12:2021-08, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
- DIN EN ISO 10993-18:2021-03, Biological evaluation of medical devices - Part 18: Chemical characterization of materials for medical devices in the context of a risk management system
- ISO/TS 10993-19:2020-03, Biological evaluation of medical devices - Part 19: Physical/chemical, morphological and topographical characterization
- DIN EN 556-1:2002-03, Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for medical devices sterilized in the final packaging, DIN EN 556-1 Corrigendum 1:2006-12
- DIN EN ISO 11137-1:2020-04 Sterilization of health care products - Radiation - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd.1:2013 + Amd.2:2018); German version EN ISO 11137-1:2015 + A2:2019
- DIN EN ISO 11137-2:2015-11, Sterilization of health care products - Radiation - Part 2: Determination of the sterilization dose
- DIN EN ISO 11137-3:2017-11, Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects.
- DIN EN ISO 11737-1:2021-10 (EN ISO 11737-1:2018 + A1:2021), Sterilization of health care products - Microbiological methods - Part 1: Determination of the population of microorganisms on products
- DIN EN ISO 11737-2:2020-07 Sterilization of health care products - Microbiological methods - Part 2: Tests for sterility in the definition, validation and maintenance of a sterilization process
- DIN EN ISO 22442-1:2021-08, Animal tissues and their derivatives used in the manufacture of medical devices - Part 1: Application of risk management.
- DIN EN ISO 22442-2:2021-04, Animal tissues and their derivatives used in the manufacture of medical devices - Part 2: Controls on procurement, material collection and handling.
- DIN EN ISO 22442-3:2008-03, Animal tissues and their derivatives used for the manufacture of medical devices - Part 3: Validation of elimination and/or inactivation of transmissible spongiform encephalopathy viruses and agents
- DIN EN 13726-1:2002-06 Test methods for primary dressings (wound dressings) - Part 1: Aspects of absorbent performance
- DIN EN 13726-3:2003-08 Non-active medical devices - Test methods for primary dressings (wound dressings) - Part 3: Waterproofness
- DIN EN 13726-4:2003-08 Non-active medical devices - Test methods for primary dressings (wound dressings) - Part 4: conformability
- DIN EN 13726-6:2003-8 Non-active medical devices - Test methods for primary dressings (wound dressings) - Part 6: Odour control
- DIN EN ISO 15223-1:2022-02 Medical devices - Symbols for use in the information to be provided by the manufacturer - Part 1: General requirements

Result of risk management, residual risks associated with the use of the product

The risk analysis has been completed. All listed risks including the use of material of animal origin (pig skin) are reduced as far as possible and according to the state of the art. All residual risks associated with clinical use or animal material are inherent in the nature of the product or determined by its indication. Treatment alternatives of synthetic origin were included in the evaluation and do not result in a better risk-benefit ratio in comparison, so that the benefit of using animal material outweighs the risk posed by animal material. The products are used by professionals, so the residual clinical risks are acceptable. Therefore, the overall risk of the products is acceptable according to the risk management plan, the products fulfil their intended purpose and can be used safely for the benefit of the patient when used as intended. No uncontrolled risks have been identified in the practical use of the products. The possible residual risks and undesirable effects, warnings and precautions are fully described in the instructions for use.

Languages, queries

The SSCP is provided by MBP Medical Biomaterial Products GmbH in German and English.
Translations into other languages can be requested from the manufacturer.

Should the user or patient have any questions about our product MB-Collagen or its application, please do not hesitate to contact us.

MBP-Medical Biomaterial Products GmbH, Lederstraße 7, D-19306 Neustadt-Glewe.

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Revision historie

Version	Change	Date
B	Separation of languages (only one document per language), alignment of the item "Intended use of the product" with the instructions for use, extension of the item: Summary of clinical evaluation and post-market clinical follow-up (PMCF); addition of EMDN and UMNDS code, Rule 21 added, shortening of the list of applied standards to those related to the product.	19.12.2022
A	Initial production	17.03.2022