Basic data

The product MB-Collagen is a product for professional users such as nurses, carers and other working groups trained in medical wound treatment. The product has been CE-certified since 1996. There are no previous generations or variants of the product. It is a class III product, according to rules 7, 18 and 21. The collagen contained in the product is of animal origin, the source of the collagen is pig skin.

MB-Collagen is available 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 sales units of three pieces 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

Product description
sterile, for single use
MB-Collagen is a sponge-like wound dressing made from porcine collagen.

Users
This wound dressing is intended exclusively for use by healthcare professionals. Please note that the use of this dressing requires appropriate professional training and knowledge of wound care.

Patient target group, pregnancy and breastfeeding
This wound dressing is intended exclusively for use on adults. No studies are available on the safety and efficacy in children, pregnant or breastfeeding women, or on the influence on human fertility. Use in these groups of people is therefore not recommended. Before using MB-Collagen, the treating physician must therefore individually weigh up the benefits for children, the mother and the possible risks for the child.

Mode of action

The porous structure of the collagen sponge ensures a capillary suction effect and thus 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 during the granulation phase. The collagen supplied has an indirect effect in the epithelialisation and regeneration phase by stimulating the body's own collagen synthesis, which causes epithelialisation to progress rapidly.

Intended use (indication)
Collagen dressing 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

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 during pregnancy and breastfeeding
No studies are available on the use of MB collagen during pregnancy and breastfeeding or on its influence on human fertility. Before using MB collagen, the treating 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 tannins and caustics that alter proteins, must not be used together with collagen.
- Ointments and powders as well as silicone preparations can alter the spaces between the collagen films, fleeces or sponges so that 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 disinfection 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 appropriate to the size of the wound is placed on the moist wound under aseptic conditions. It can be fixed in place with a non-woven dressing or a gauze dressing. The frequency of dressing changes depends on the level of wound secretion:

- In case of heavy secretion: several times a day
- For moderate secretion: 1 x daily
- In case of slight exudation: after several days (provided that there are no signs of inflammation)
- If the 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 not be exposed to extreme temperatures and extreme humidity. MB-Collagen must not be used after the expiry date.

Warnings, to be observed

MB-Collagen is sterilised with y-radiation and must not be resterilised. 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 a 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 nonwovens. To stimulate wound healing, collagen fleeces are used as wound dressings on non-infected burn wounds and areas with wound healing disorders (chronic wounds). The collagen fleece accelerates and supports wound healing through its haemostatic effect and stimulates the release of various growth factors that are essential for wound healing, such as PDGF and TGFβ, by activating thrombocytes.

MB collagen forms 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 triggers plasmatic blood coagulation, which leads to vascular occlusion with the formation of a fibrin scaffold. Haemostasis is accelerated by the platelet-activating effect of the collagen.

The wound dressing also ensures a capillary suction effect due to the porous structure of the collagen sponge and thus 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 during the granulation phase. In chronic wounds, the exogenous collagen binds the activity of excess metalloproteases and thus enables the body's own collagen synthesis, which leads to the formation of the extracellular matrix of the granulation tissue.

The collagen supplied thus indirectly influences the regeneration and epithelialisation phase by stimulating and protecting the body's own collagen synthesis, as a result of which epithelialisation progresses rapidly. As a competing substrate, the exogenous collagen reduces the degradation of endogenous collagen by proteases, which prevent the formation 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 formation of granulation tissue.

Properties:

- Effective, local haemostatic agent in the wound
- Wound protection
- Binding of the activity of excess metalloproteases, protection of the body's own collagen synthesis
- Removal of pro-inflammatory factors from the wound by capillary exudate absorption
- Three-dimensional matrix for cellular and vascular infiltration, supports the development of the body's own tissue

Biological evaluation

The results of the biocompatibility tests confirm the high biocompatibility of the product in accordance with DIN EN ISO 10993. Extensive biological studies using animal testing have been carried out and confirm the clinical safety of the product. MBP Medical Biomaterial Products GmbH's many years of experience with the sale of MB collagen and continuous post-marketing monitoring show that the products are biocompatible when used as intended

Alternative treatment methods

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

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

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

User group

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

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

The clinical evaluation demonstrated that the product MB-Collagen fulfils the relevant essential safety and performance requirements under normal intended use and that its benefit/risk ratio is acceptable. The clinical data 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 epithelisation phase (e.g. leg ulcers, decubital ulcers, split-thickness skin removal sites, burn wounds, secondary healing wounds, etc.)). The performance (wound healing) is provided by the collagen (type I + III) of which the product consists - 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 in medicine. The clinical results show that MB-Collagen is able to end the stagnation of chronic and difficult-to-heal wounds such as leg ulcers (venous or arterial origin), diabetic foot syndrome or decubital ulcers and to initiate the processes of granulation, angiogenesis and re-epithelialisation. Provided that thorough debridement is carried out to remove stagnant necrotic tissue and bacterial deposits, the collagen leads to a shift in the balance of wound healing factors, resulting in accelerated wound healing. This is based on, among other things its excellent haemostyptic properties, the binding of the proteolytic activity of proteolytic enzymes (neutrophil elastase, MMPs) that occur in excess in chronic wounds, the protection of growth factors from proteolytic degradation by binding them in a gel and releasing them in the event of resorptive degradation of the gel and the removal of pro-inflammatory RNA, ROS compounds and cytokines through exudate absorption, as has been demonstrated in preclinical studies. MB-Collagen thus contributes to improving the quality of life of patients, e.g. by reducing the amputation rate and shortening hospital stays, and represents a clinical benefit.

Based on the literature research 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-crosslinked, 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 from MBP GmbH and the similar product Suprasorb® C from Lohmann & Rauscher for the treatment of chronic wounds that are difficult to heal. The results of the literature search obtained and presented below served as a basis for assessing the clinical efficacy, safety and risk/benefit profile of the product MB-Collagen in the context of the wide 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) were used to determine the reactions of the tissue to the implanted material as a result of wound healing and immune response (MB-Collagen) and the influence of the material on wound healing-specific enzyme activities (Suprasorb® C).

As a result, twelve publications in category A were analysed. In two of these papers, the material of which MB collagen is made was itself tested, in six papers Suprasorb® C, in one paper another porcine collagen wound dressing and in three papers another bovine collagen wound dressing. The two studies on MB collagen comprised a controlled randomised study and a case series analysis. The studies with Suprasorb® C were designed as comparative studies in one case, but only rated III due to the small number of participants, in two cases as comparative studies (one rated I) and three as case series analyses (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 were case series analyses with Puracol, also a bovine non-woven wound dressing.

P. Heinrich [45] presents the 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 in the left arm. Blood loss averaged 15 ml ± 5 ml on the right arm and 23 ml ± 7 ml 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 haemostatic effect of regenerated oxidised cellulose and collagen. While the haemostatic effect of ROC is based on a mechanical effect of the adhesion of capillaries, collagen triggers the coagulation cascade in contact with the thrombocytes. The author emphasises that collagen haemostatic agents have become an integral part of everyday clinical practice. They are particularly useful in parenchymal resections, brain operations and implantations of vascular and joint prostheses due to the accelerated local haemostasis of the smallest haemorrhages, which leak profusely from the entire wound surface, or from puncture channel haemorrhages originating from vessels. Allergising effects of porcine collagen could be excluded in the applications observed. The inflammation associated with resorption proceeded quickly and smoothly, and no increase in wound healing disorders could be demonstrated with strict adherence to aseptic methods. **C. Thoma [93]** reports on the use of collagen fleece in haemostasis and wound healing of tooth extractions in patients taking oral anticoagulants and with mild coagulopathies. Due to its remarkably good local tolerability and rapid healing of wounds, collagen fleece is recommended for surgical stomatology. Tooth extraction cavities are subject to wound healing-disrupting boundary conditions that jeopardise the stability of the coagulum formed, which inevitably leads to impaired wound healing. This is particularly true in cases of haemorrhagic diathesis. In patients with mild coagulation disorders, however, tooth extractions can also be performed on an outpatient basis while maintaining anticoagulant therapy, as the coagulum can be stabilised by using collagen fleece and suture closure of the wound. In the author's experience, collagen fleeces are superior to gelatine sponges. In the clinical test, 134 teeth were extracted from 65 patients with mild coagulation disorders. The alveoli were loosely filled with collagen fleece and closed with sutures. Fibrin glue was also used in 102 extraction wounds. Of the total of 7 cases of secondary haemorrhage observed, 2 were caused by incorrect suturing and in 5 cases the Quick value was found to have fallen below 10%.

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

Coagulation 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 postoperative haemorrhage	1

With proper wound care and not too severe coagulopathy, no bleeding complications occurred, so healing was 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 and its suitability as a carrier material for additional therapeutically effective 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 haemostyptic and wound-healing effect of the collagen fleece in securing cavities that occur during oral surgery to remove tumours, fistulas or malpositioned teeth and where maintaining 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 stabilised venous blood coagulum based on gelatine) were inserted into 60 prepared cavities of the jawbone, 10 of which only bled spontaneously, and the healing process was documented histologically. The collagen fleece introduced was very quickly transformed into granulation tissue interspersed with capillaries, more so than in the comparative samples, and was no longer detectable after 11 days. The cancellous bone close to the defect showed increased activity when collagen was used, the osteoblastic bone formation was stronger than in the non-collagen comparison samples, the osteoclastic activity was also increased here in the border area. There were no histologically recognisable defence reactions against the collagen fleece. With regard to wound healing, no differences were found between Collastypt, a collagen fleece from Braun-Melsung established on the market, and

the tested collagen fleece from MBP GmbH; wound healing was accelerated by the rapid formation of a vascularised granulation tissue and successfully led to the formation of new bone. Based on these results, a total of 37 cavities in the jaw were filled with collagen fleece from MBP GmbH after surgical procedures in 1987/88 (26 cavities with a diameter > 15 mm). Only in 4 cases (10.8%) were wound healing disorders in the form of postoperative fistulae observed, which healed spontaneously. In all cases, bony regeneration was unremarkable.

The processes of haemostasis and wound healing are closely linked. As the first phase of wound healing, haemostasis provides the initial impetus 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 and new tissue formation **[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 haemostasis and wound healing. They also show that the use of the collagen fleece is not associated with any notable risks, that the products have a very favourable benefit/risk ratio and that they therefore meet the basic safety and performance requirements.

The described studies 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 provide the basis for the granting of a CE mark as a clinical trial. They provide proof that the MB-Collagen product fulfils the basic 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, which contributes to the stimulation of proliferating, regenerating processes in stagnating 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 collagen as a material and the fact that the collagen fleece is only ever part of a more comprehensive treatment concept, this is not to be expected. The clinical experience with the collagen fleece of the MB-Collagen wound dressing presented in the Keller (1990) collection of literature on its haemostyptic and wound healing properties sufficiently shows that it fulfils all expectations with regard to the clinical and safety aspects and meets the basic requirements.

Furthermore, the PMS data (market surveillance) of the product over the last five years was included in the evaluation. 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 any incidents or clinical complaints. The use of collagen as a wound dressing corresponds to the current state of 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 nonwovens 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 modern, moist wound treatment, including the elimination of the causal causes of chronic stagnation of wound healing, provides a significant impetus for the termination of the inflammatory phase and the transition to the regeneration/remodelling phase of wound healing. MB collagen thus accelerates wound healing and preserves tissue function, which leads to an improvement in the patient's quality of life, shorter hospital stays and a reduction in costs for public and private healthcare systems. This far outweighs any potential risks associated with the use of the MB-Collagen product. The product MB-Collagen itself does not pose any risks to safety in clinical use; the risk of defence reactions against heterologous collagen is very low. Risks may arise from use if wound dressings made of pure collagen are applied to contaminated wounds without prior debridement and an incipient or progressive infection is not recognised in good 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 collagen wound dressings in the context of the advertised indication and are therefore applicable as proof of the clinical performance of the product MB-Collagen. Within the scope of the literature research and the evaluation of our own market observation, no evidence was found that would call into question the clinical benefit and performance of the product. The clinical evaluation provided evidence that the product MB-Collagen fulfils the intended performance and is designed and manufactured to be fit for its intended

purpose under normal conditions of use - it is safe and effective. The use of MB Collagen does not jeopardise the clinical condition and health or safety of patients, users or other third parties. The existing residual risks are presented, they are inherent in the nature of the product and are justified in relation to the clinical benefit of the product for the patient. The residual risks are made known to the user via the instructions for use. The biological safety of the product has been proven 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 product MB-Collagen (> 30,000 patients treated), no existing reports of serious adverse events in the FDA and BfArM databases for the product MB-Collagen or similar products, it is concluded that the product MB-Collagen meets the basic safety and performance requirements when used as intended. The clinical benefit of the product MB-Collagen has been 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): Importance of local haemostatic agents. 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 actions of the BfArM) and the complaints received by MBP GmbH, no conclusions could be drawn about additional, previously unknown risks for the above-mentioned products.

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

M. Rangaswamy published results of 3 applications in 2021, 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 application of MB collagen and the other comparator products. Total sales volume in 2020: 1,629 boxes (4,887 products)

Thus, all risk minimisation measures and clinical requirements specified by the manufacturer appear to be fulfilled. Furthermore, neither possible systematic misuse nor improper use were identified. 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 proven to be reliable in clinical practice when used as intended.

Patient group, users, training programme

Persons or patient group: no restrictions, based on the clinical picture (wound treatment), the tendency is towards older patients and diabetics. The products are applied by personnel medically trained in the treatment of chronic wounds. The treatment of chronic wounds with collagen wound dressings is state of the art and is taught as part of the training of specialised users. On request, training courses can be organised by MBP GmbH's medical product consultants.

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

Applied norms, laws and standards

The requirements of the following standards are applied during the manufacture, placing on the market and monitoring of the MB-Collagen product (22/02/2023). The standards are reviewed at regular intervals to determine whether they require updating. The following standards are currently applied by MBP Medical Biomaterial Products GmbH. They will be updated as part of the update of this SSCP.

- Medical Devices Act - MPG:2002-08, last amended on 26/05/2021
- Act on the Adaptation of Medical Devices Law to Regulation (EU) 2017/745 and Regulation (EU) 2017/746 (Medical Devices EU Adaptation Act - MPEUAnpG), 19 May 2020, (MPDG), last amended on 26 May 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 Devices Law to Regulation (EU) 2017/745 and Regulation (EU) 2017/746 (Medical Devices EU Adaptation Ordinance - MPEUAnpV), last amended on 21 April 2021
- Ordinance on the Reporting of Suspected Serious Incidents involving Medical Devices and on the Exchange of Information between the Competent Authorities (Medical Device User Notification and Information Ordinance - MPAMIV), last amended on 21 April 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 purpose to medical devices
- DIN EN ISO 10993-1:2021-05, Biological evaluation of medical devices - Part 1: Evaluation and testing as part of 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 tests for interaction with blood
- 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 the 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: Systemic toxicity testing
- 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 characterisation of materials for medical devices as part of a risk management system
- ISO/TS 10993-19:2020-03, Biological evaluation of medical devices - Part 19: Physical/chemical, morphological and topographical characterisation
- DIN EN 556-1:2002-03, Sterilisation of medical devices - Requirements for medical devices to be marked as "STERILE" - Part 1: Requirements for medical devices sterilised in the final packaging, DIN EN 556-1 Corrigendum 1:2006-12
- DIN EN ISO 11137-1:2020-04 Sterilisation of health care products - Radiation - Part 1: Requirements for the development, validation and control of the use of a sterilisation 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, Sterilisation of health care products - Radiation - Part 2: Determination of sterilisation dose
- DIN EN ISO 11137-3:2017-11, Sterilisation 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), Sterilisation of health care products - Microbiological methods - Part 1: Determination of the population of microorganisms on products
- DIN EN ISO 11737-2:2020-07 Sterilisation of health care products - Microbiological methods - Part 2: Sterility testing in the definition, validation and maintenance of a sterilisation 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, sourcing and handling
- DIN EN ISO 22442-3:2008-03, Animal tissues and their derivatives used in the manufacture of medical devices - Part 3: Validation of elimination and/or inactivation of viruses and transmissible spongiform encephalopathy agents

- DIN EN 13726-1:2002-06 Test methods for primary dressing materials (wound dressings) - Part 1: Aspects of absorption behaviour
- DIN EN 13726-3:2003-08 Non-active medical devices - Test methods for primary dressing materials (wound dressings) - Part 3: Water-tightness
- DIN EN 13726-4:2003-08 Non-active medical devices - Test methods for primary dressing materials (wound dressings) - Part 4: Adapt-ability
- DIN EN 13726-6:2003-8 Non-active medical devices - Test methods for primary dressing materials (wound dressings) - Part 6: Odour control
- DIN EN ISO 15223-1:2022-02 Medical devices - Symbols for use in information to be provided by the manufacturer - Part 1: General requirements

Result of risk management, residual risks in connection with the use of the product

The risk analysis has been finalised. All listed risks, including the use of material of animal origin (pig skin), have been reduced as far as possible and in accordance with the state of the art. All residual risks associated with the clinical application or the animal material are inherent in the nature of the product or are determined by its indication. Treatment alternatives of synthetic origin were included in the assessment 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 specialised personnel so that the residual clinical risks are acceptable. Accordingly, 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 were identified in the practical use of the products. The possible residual risks and undesirable effects, warnings and precautions are contained in full in the instructions for use.

Languages, queries

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

If the user or patient has 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.

Contact:

E-mail: info@mbp-gmbh.de

Tel: +49 38757-5090

Revision history

Version	Amendment	date
C	Review 2024, update of the intended purpose.	22.07.2024
B	Separation of languages (only one document per language), Rule 21 added, harmonisation of the item "Intended use of the device" 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, shortening	19.12.2022

	of the list of applied standards to those relating to the product.	
A	Initial creation	17.03.2022