English

Basic data

The Surgicoll, Hemocol and Diacoll products are products for medically trained professional users. 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.

Surgicoll and Hemocol are offered in the three sizes 5*5, 5*10 and 10*10 cm. Diacoll is offered in the size 2*2 cm.

The Hemocol product is identical to the Surgicoll product, they are two trade names of the same product.

Product	REF	Basic UDI-DI
Surgicoll 1*1 cm	S0101K	426023090901
Surgicoll 5*5 cm	S0505K	426023090902
Surgicoll 5*10 cm	S0510K	426023090903
Surgicoll 10*10 cm	S1010K	426023090904
Hemocol 1*1 cm	H0101K	426023090905
Hemocol 5*5 cm	H0505K	426023090906
Hemocol 5*10 cm	H0510K	426023090907
Hemocol 10*10 cm	H1010K	426023090908
Diacoll 2*2 cm	D0202K	426023090910

The first CE certification of the products according to MDD took place: 1996.

Manufacturer of the products 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

GMDN, EMDN, and UMDNS classification:

GMDN: 47201; EMDN: 47201, UMDNS: 16791.

Intended use of the products

Surgicoll/Hemocol

Indications

Absorbable, local hemostyptic, sterile, for single use. Use is indicated wherever capillary, venous, small arterial and diffuse oozing bleeding needs to be stopped and where conventional methods of hemostasis are either inadequate or technically difficult and time consuming. The product resorbs completely and does not require removal. Areas of application: General surgery, cardiothoracic and vascular surgery, neurosurgery, maxillofacial surgery and general stomatology, oto-rhino-laryngology, urology and gynecology.

Contraindications

Application to infected wound areas, if methyl methacrylate is used simultaneously, intravascular application. When using absorbable hemostatic agents on or near bone and nerve surfaces:

- Using the minimum amount necessary to achieve hemostasis; and,
- Remove as much of the agent as possible after hemostasis has been achieved.

This reduces the likelihood of nerve and soft tissue damage due to swelling of the absorbable hemostatic agent, and/or migration and swelling of fragments of the agent.

Warnings

The product is sterilized by means of gamma radiation and must not be resterilized. Sterility is only guaranteed if the packaging is undamaged. The product 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.

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 change the interstices of collagen fleeces, so that no joint use should take place here either.

Use during pregnancy and lactation

No studies are available on its use during pregnancy and lactation or on its influence on human reproductive capacity. Therefore, before using the product, an individual weighing of the benefits for the mother and the possible risks for the child must be carried out by the attending physician.

Application instructions

After opening the sterile packaging, the product is removed with sterile, dry instruments and applied to the wound with suitable aids and lightly pressed on. Using sterile scissors, the product can be cut to the desired size. It adheres immediately to the moist wound surface and forms a gel-like bond with the blood. Excess collagen material should be removed. In the case of external wounds, an additional overlay of e.g. non-woven fabric fixed with the aid of elastic bandages is recommended.

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 intensified.

Storage

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

Sterilization

Surgicoll is sterilized by the manufacturer using gamma irradiation. The product is supplied sterile and is intended for single use. The product must not be resterilized.

Diacoll

Indications

Diacoll is a sterile hemostyptic for external application for single use. Its use is indicated wherever capillary, venous, small arterial and diffuse oozing hemorrhage must be stopped and where conventional methods of hemostasis are either inadequate or technically difficult and time consuming. Areas of application: General surgery, cardiothoracic and vascular surgery, neurosurgery, maxillofacial surgery and general stomatology, oto-rhino-laryngology, urology and gynecology.

Contraindications

Application to infected wound areas, if methyl methacrylate is used simultaneously, intravascular application. When using absorbable hemostatic agents on or near bone and nerve surfaces:

- Using the minimum amount necessary to achieve hemostasis; and,
- Remove as much of the agent as possible after hemostasis has been achieved.

This reduces the likelihood of nerve and soft tissue damage due to swelling of the absorbable hemostatic agent, and/or migration and swelling of fragments of the agent.

Warnings

Diacoll is sterilized by gamma radiation and must not be resterilized. Sterility is only guaranteed if the packaging is undamaged. Diacoll 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.

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 change the interstices of collagen fleeces, so that no joint use should take place here either.

Use during pregnancy and lactation

No studies are available on the use of Diacoll during pregnancy and lactation or on its influence on human reproductive capacity. Therefore, before using Diacoll, the attending physician must individually weigh the benefits for the mother and the possible risks for the child.

Application instructions

After opening the sterile packaging, the product is removed with sterile, dry instruments and applied to the largely cleaned wound surface with suitable aids (e.g. swabs) and lightly pressed on. If necessary, Diacoll can be cut to the desired size with sterile scissors. It adheres immediately to the moist wound surface and forms a gel-like bond with the blood. Excess collagen material should be removed. In the case of external wounds, an additional layer of non-woven fabric fixed with the aid of elastic bandages is recommended.

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 intensified.

Storage

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

Sterilization

Diacoll is sterilized by the manufacturer using gamma irradiation. Diacoll is supplied sterile and is intended for single use. The product must not be resterilized.

Product description, working mechanism

The Surgicoll, Hemocol, and Diacoll products are porcine skin-derived, cell-free, non-pyrogenic, absorbable collagen fleeces intended for use as a local hemostyptic.

Surgicoll (= Hemocol) is an absorbable local hemostyptic for intraoperative use to stop capillary, venous, small arterial and diffuse oozing bleeding where conventional methods of hemostasis are either inadequate or technically difficult and time-consuming. Adapted to the surgical requirements and conditions of the wound, Surgicoll is offered as a rectangular fleece (Surgicoll) in four sizes. Diacoll is a topical hemostyptic for the treatment of skin defects, e.g. after vascular puncture (e.g. dialysis).

Hemostasis is a process of stopping bleeding that leads to sealing of injured vessels. The capillary suction effect of the fleeces leads to a concentration of platelets, their adhesion to the tripelhelical collagen fibers triggers their activation, aggregation and localization of the coagulation factors of the blood clotting cascade on the platelet membrane. The fibrin plug that forms closes injured vessels and leads to hemostasis.

Biological evaluation

Results of biocompatibility tests confirm the high biocompatibility of the products according to DIN EN ISO 10993. Extensive biological studies with the help of animal testing have been conducted and prove the clinical safety of the product. MBP Medical Biomaterial Products GmbH's many years of experience with the sale of Surgicoll, Hemocol and Diacoll, as well as continuous post-marketing monitoring, show that the products are biocompatible within the scope of their intended use.

Alternative treatment methods

In addition to absorbable hemostyptics consisting of porcine collagen, hemostyptics made from other sources of collagen or gelatin, such as bovine or equine, are also offered by other manufacturers. Furthermore, cellulose-based hemostyptics and various fibrin glues are available on the market, among others.

User group

The Surgicoll, Hemocol and Diacoll products may only be used by healthcare professionals.

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

The objective of this Clinical Evaluation was to provide evidence that the products Diacoll and Surgicoll, Hemocol, under normal intended use, meet the relevant essential safety and performance requirements and that their benefit/risk ratio is acceptable. This demonstration is based on clinical data of the products themselves, which were the basis of their initial approval in 1986, on clinical data of similar approved products, including one product with demonstrated clinical, technical, and biological equivalence, that are sufficiently available, and on information from relevant databases on adverse events associated with the use of comparable products that allow the assessment of adverse events for risk assessment.

In conclusion, the products Diacoll and Surgicoll, Hemocol meet the Essential Requirements in all criteria and their approval is justified. They are proven elements in the range of local hemostatic agents that lead to rapid hemostasis of small superficial wounds, especially in wound care after vascular puncture (Diacoll), and of capillary, venous, small arterial and diffuse oozing bleeding (Surgicoll) that can be stopped by conventional methods of hemostasis either inadequately or in a technically difficult and time-consuming manner.

Extensive clinical experience reports are available for MBP GmbH's hemostatic collagen fleece, demonstrating its effectiveness and safety in intraoperative use as a local hemostyptic in various applications, as well as its efficacy in patients with impaired coagulation. These results lead to the conclusion that the products Diacoll and Surgicoll, Hemocol meet the performance requirements for a local hemostyptic and thus the basic requirements.

The respective clinical outcome reports describe that no product-related risks are to be expected when the products Diacoll and Surgicoll, Hemocol are used as intended; immune defense reactions against porcine or bovine collagen are possible, but extremely rare. The products lead to a reduction in the risk of postoperative bleeding and required revision surgery. This is particularly true for patients who have impaired coagulation due to coagulopathies or anticoagulant therapy. Interruptions of a systemic anticoagulant therapy regime are thus not necessary, which reduces the risk of thrombosis in patients with e.g. vascular diseases. The induced accelerated hemostasis initiates subsequent wound healing, which is a performance characteristic of Diacoll in hemostatic wound care of vascular punctures. With a reduction in treatment time and low material usage, the

aforementioned products lead to a reduction in costs for public and private healthcare systems and an improvement in patients' quality of life. This far outweighs any risks that may be associated with the use of the Diacoll and Surgicoll products. The benefit/risk ratio of the products under evaluation thus meets the basic requirements.

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 regarding 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 MBP GmbH's Diacoll and Surgicoll/Hemocol collagen fleeces. 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.

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

MBP GmbH has not received any complaints from clinical use regarding the products sold in 2021 (5,253 packages, 63,036 products). MBP GmbH has not received any complaints from clinical use regarding the products sold in 2021 (744 packages, 8,928 products). The post-marketing surveillance plan includes post-marketing clinical follow-up of the products. Sources for generating clinical data after CE approval include active user and customer surveys, feedback from users or customers (complaints), and literature reviews and clinical follow-up studies according to MEDDEV 2.12/2 as part of the PMS and clinical evaluation. The return of application-relevant information from clinical practice on the products Diacoll and Surgicoll/Hemocol is recorded directly by the user or, on the basis of contractual agreements, by the distributors and forwarded to MBP GmbH. For this purpose, in addition to the vigilance system, annual surveys on the performance of the products are sent out, analyzed and, if necessary, used as an opportunity to re-evaluate the benefit/risk ratio and incorporate appropriate changes in the IFU. To date, no corresponding feedback has been received for the products Diacoll and Surgicoll/Hemocol (last survey conducted in 02/2021).

New literature on the clinical use of Diacoll and Surgicoll/Hemocol has not appeared. Several papers mention the use of comparator products made from pure collagen, such as Lyostypt, which is described as an effective local hemostyptic e.g. in uterine fibrinoid embolization (combined with Trisacryl gelatin microspheres (TAGM)), endonasal surgery for tumor removal or tooth extraction under ongoing anticoagulation therapy.

In the brochure "The Von Willenbrand Syndrome" published by the German Hemophilia Society to combat bleeding disorders in 2020, Hemocol is listed as a local hemostatic agent to be used in Von Willebrand syndrome.

No new evidence was obtained on the safety and risk/benefit ratio for hemostyptics made from pure collagen, and thus for Diacoll and Surgicoll/Hemocol.

Patient group, user, training offer

Individuals or patient population: no restrictions, based on the clinical picture. There are no studies available on the use during pregnancy and lactation and on its influence on human reproductive capacity. Therefore, before using the product, an individual weighing of the benefits for the mother and the possible risks for the child must be carried out by the attending physician.

On request, training is provided by the medical device consultants of MBP GmbH.

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

Applied norms, laws and standards

- 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), May 19, 2020, (MPDG), last amended May 26, 2021.
- REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, 05.04.2017 (MDR).
- Medical Device Operator Ordinance (Ordinance on the Installation, Operation and Use of Medical Devices) - MPBetreibV:1998-06, last amended on 26.05.2021
- Regulation on the adaptation of medical device law to Regulation (EU) 2017/745 and Regulation (EU) 2017/746 (Medizinprodukte-EU-Anpassungsverordnung-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 on 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 serviceability 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 toxicity for reproduction
- 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 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 allergy.
- 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 identified as "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 control of the use 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: Adaptability
- DIN EN 13726-6:2003-8 Non-active medical devices - Test methods for primary dressings (wound dressings) - Part 6: Odor 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 in connection 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 come to 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 skilled personnel, so the residual clinical risks are acceptable. Accordingly, the overall risk of the products is acceptable according to the risk management plan, the products fulfill their intended purpose and can be used safely for the benefit of the patient when used as intended. No unmanaged risks have been identified in the practical use of the products. The possible residual risks and undesirable effects, warnings and precautions are fully included 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.

Should the user or patient have any questions about our products or their application, please do not hesitate to contact us.

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

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Change history

Version C: Last modified on 22.12.2022, Actuality check.

Version B: Last modified on 22.12.2022, the following changes were made compared to the previous version:

- Separation of languages into two documents.
- Addition of the nomenclatures EMDN and UMDNS.
- Addition of the year of the first CE registration of the product.
- Correction "UDI-DI" to "Basic UDI-DI
- Shortening the list of applied standards and common specification to those with direct relevance to the products.
- Addition of a change history.

Version A: The SSCP was created with version A on 04/25/2022 for the first time for the products Surgicoll and Diacoll.