Septocoll® E
Dual-Action Collagen Fleece
What can patients and surgeons expect from us?
Reliable products, and expertise, which ensures secure application. Moreover, developments needed in the future.

Biomet is one of the leading orthopaedic companies worldwide. We develop and produce products for orthopaedic and trauma surgery. Our predominant competence enables us to accompany our clients continuously in clinical surgeries.

This vicinity has an impact: We take impulses in, and our own Research and Development Department is a direct contact partner for new ideas. Here we connect the clinically documented quality of our implants with the future orientated possibilities of bioactive materials. Through this we become an innovation force and are able to face the continuous developments in our markets more flexibly.

The results are products and performances, that aid the surgeons’ community, to support the healing process of their patients in a medically optimal, scientifically proven, and cost-effective manner.
Septocoll E is a resorbable, equine collagen fleece. It has a hemostatic effect and contains gentamicin providing prophylactic local antibiotic protection.

Septocoll E is suitable for use in septic and aseptic surgery. The fleece can be employed in all disciplines of bone and soft-tissue surgery.

**Resorbable Collagen for Hemostasis**

Due to their favorable physical surface properties, collagen fleeces shorten the bleeding time, reducing blood loss. They support the overall wound healing process by promoting rapid collagen and protein synthesis\(^1\),\(^2\).

The collagen used to manufacture Septocoll E is obtained only from equine tendons. TSE (Transmissible Spongiform Encephalopathy) does not occur in horses.

Biological resorption of Septocoll E is complete after approximately four weeks. Additional surgery to remove the hemostatic material is not necessary. Thus the patient’s mobility and sense of well-being can be restored quickly and cost-effectively.

**Additional Local Antibacterial Effect**

Septocoll E is impregnated with gentamicin to give antibiotic protection. It can therefore be applied, where reliable protection against secondary infection is required.

Septocoll E is the only fleece on the market that contains a combination of two gentamicin salts:

- **Gentamicin sulfate** is highly water-soluble, enabling a rapid release of the active substance.

- **Gentamicin crobefate** – recognizable by its distinct yellow color – is less water-soluble and thus induces a slow release of the antibiotic.

The combination of Gentamicin sulfate and crobefate therefore result in a lasting antibiotic protection. The blend of hemostatic properties and durable local antibiotic protection create optimal conditions for a rapid and smooth healing process.
The starting material for the manufacture of Septocoll E consists of natural, pure collagen fibrils extracted from horse tendons. These are both fully resorbable and water-insoluble.

**High-Tech Product**
A complex freeze-drying process connects the collagen fibrils to form a mesh (Fig. 01). The special manufacturing procedure produces a fleece with a large, active surface and good moisture stability. Unlike other collagen fleeces, which typically adhere to surgical instruments or wet gloves, Septocoll E does not stick.

**Hemostatic Effect**
In contact with blood, collagen causes platelet aggregation. Large numbers of platelets accumulate on the collagen fleece and release coagulation factors like thrombin. In conjunction with plasma factors these induce fibrinogenesis.

**Resorption**
Complete resorption of the collagen fleece takes place within approximately four weeks – depending on local blood circulation – by way of phagocytosis and enzymatic degradation [3].

Septocoll E contains exclusively type I collagen, which is best suited for biological degradation. Notable properties in this connection are high biocompatibility and low immunogenicity, as well as good controllability of resorption via cross-linking agents [4].

The collagen used in Septocoll E is well tolerated and supports the patient’s convalescence through significantly shorter wound healing times [5].
The antibiotic gentamicin has been used successfully in surgical wound care for many years (6, 7, 8, 9, 10, 11, 12, 13, 14). Gentamicin still has a good resistance profile.

**Local or Systemic**

Gentamicin can be administered systemically (Fig. 02) or locally (Fig. 03). If applied locally, however, substantially greater concentrations of antibiotics accumulate at the site of action than when it is administered systemically. At the same time, serum concentrations – and therefore potential adverse effects – are significantly lower (8, 15).

**Dual Principle of Action**

Due to its collagen matrix, Septocoll E induces hemostasis and promotes wound healing; in addition, because of the gentamicin contained in Septocoll E, a local antibiotic protection is also provided.

This dual principle of action — hemostasis and antibiotic protection — is provided by Septocoll E throughout treatment because the protracted release of the gentamicin ensures additional protection against secondary infections during the resorption phase of the fleece. The application of Septocoll E can therefore be recommended as a hemostat for:

- potentially contaminated wounds
- contaminated wounds
- revision operations in septic surgery

The application of Septocoll E has been documented in numerous studies (1, 4, 5, 16, 17).
Septocoll® E – Pharmacokinetics

Gentamicin sulfate:
Rapid release

Gentamicin crobafate:
Protracted release

Fig. 04
Fleeces only impregnated with gentamicin sulfate released 90% of their gentamicin sulfate content within 48 hours. Fleeces also impregnated with gentamicin crobafate, however, released gentamicin over a period of 10 days.\(^{18}\)

Septocoll E contains two gentamicin salts, which – based on their active substance content – are combined at a ratio of 1:1. They have different release kinetics.

High Initial Concentration
Gentamicin sulfate is highly water-soluble: The antibiotic is therefore released rapidly from the carrier material. This leads to a very high initial gentamicin concentration at the site of action. Within a short time, however, this level drops again to below the minimum inhibitory concentration (MIC) for causative microbes.

Lasting Effect
Gentamicin crobafate is a gentamicin salt that we developed in-house. It is less watersoluble than the sulfate and can therefore release the gentamicin on a protracted basis at the site of action. Aside from the high initial concentration, therefore, the antibiotic’s release from the fleece is controlled. The gentamicin crobafate gives the Septocoll E fleece its distinctive yellow color.

Fleeces only impregnated with gentamicin sulfate released 90% of their gentamicin sulfate content within 48 hours. Fleeces also impregnated with gentamicin crobafate, however, released gentamicin over a period of 10 days.\(^{18, 19}\) (Fig. 04).
We have optimized the use of Septocoll E in surgical applications: The fleece does not stick to surgical instruments and can be handled, shaped and cut easily with precision.

Scope of Application
Septocoll E is suitable for use in bone and soft-tissue surgery in all disciplines of septic and aseptic surgery. The fleece can be inserted as a hemostat into clean, clean-contaminated and contaminated wound cavities and can also be used for the following:

- diffuse capillary, arteriovenous, arterial or venous hemorrhages
- extensive capillary hemorrhages from parenchymatous organs
- as a support measure in conjunction with other methods of hemostasis

Due to its impregnation with gentamicin Septocoll E provides reliable protection against bacterial contamination.

Contraindications
Septocoll E must not be used in patients with known hypersensitivity to collagen and/or gentamicin.

Restrictions for Use
Septocoll E should only be used in conjunction with other methods of hemostasis at bleeding sites requiring ligation or at larger arterial and/or venous bleeding sites requiring suturing.

There is a lack of clinical experience regarding the safety of use in pregnant women, nursing mothers and children.

Presentation
Septocoll E is a medical device of class III. It is available in three sizes, 20 cm², 40 cm² and 80 cm², containing 35 mg, 70 mg and 140 mg of gentamicin, respectively. Each fleece is packed individually in sterile packaging.

Instructions for Use
Before implantation, all infected and necrotic tissue must be surgically removed.

The Septocoll E fleece should not be moistened before being inserted into the wound cavity, as this would reduce its hemostatic effect.

The use of an overflow drain is indicated in many cases to allow the wound secretion to drain off. Irrigation/suction drainage, however, causes too rapid elimination of the gentamicin and should therefore not be used in conjunction with Septocoll E.

Wounds treated with Septocoll E may produce a clear, yellowish secretion due to the gentamicin crobefate content

For further information, please review the instructions leaflet of the product.
Biological Resorption Studies

Comprehensive tests were carried out to examine the biocompatibility of Septocoll E. All the studies were performed at independent, accredited institutes in accordance with the specifications of the German Medical Devices Act (MPG) and in compliance with ISO 10993.

- Cytotoxicity test
- Mouse lymphoma assay
- Magnusson/Kligman sensitization test
- Systemic toxicity
- Short-term implant – 4 weeks
- Long-term implant – 12 weeks
- Carcinogenicity test on gentamicin crobefate

These tests confirmed unreservedly the biocompatibility of Septocoll E. In particular, no allergic reactions were observed. No implant remains were detected four weeks after insertion of the fleece.

Pharmacokinetic Studies

Study to evaluate the pharmacokinetic behavior after implantation of Septocoll or a collagen fleece loaded only with gentamicin sulfate in patients with bone infections.

Design
Prospective, randomized, single-blind study with parallel groups.

Patient Population
40 patients: 20 in the Septocoll group, 20 in the sulfate fleece group

Treatments and Dosages

Septocoll group: 2 fleeces Septocoll 40 (equivalent to 140 mg gentamicin base)
Sulfate fleece group: 1 sulfate fleece (equivalent to 120 mg gentamicin base)

The values measured were adjusted accordingly (factor 0.8 =120:140)

Results/Target Criteria/Endpoint
Comparison of the pharmacokinetics of the two gentamicin-loaded collagen fleeces, control period: 10 days
The pharmacokinetic behavior of Septocoll is superior to that of sulfate fleeces: In the Septocoll group, higher, longer-lasting and more evenly distributed gentamicin concentrations were found. In the Septocoll group, the urine and serum concentrations of gentamicin were lower.
Conclusion

Hemostatic, resorbable and well tolerated

Easy handling

Medical device – class III

Protracted gentamicin release

TSE-safety due to equine collagen

Septocoll in Abdominoperineal Rectal Resection (16)

Design
Multicenter, prospective, randomized, singleblind comparative study

Patient Population
97 patients with stage I-III rectal carcinoma,
49 in the Septocoll group,
48 in the control group

Treatments and Dosages
Septocoll group:  
1 x 2 g cefazolin i.v.
1 x 500 mg metronidazole i.v.
3 fleeces Septocoll 40

Control group:  
1 x 2 g cefazolin i.v.
1 x 500 mg metronidazole i.v.

Results/Target Criteria/Endpoint
control period: 8 weeks
Tolerability in the Septocoll group was very good with a primary wound healing rate of 88%, compared with 75% in the control group. As a result, there was neither hematoma nor seroma formation.

Septocoll After Surgical Treatment of a Pilonidal Sinus (5)

Design
Multicenter, controlled, single-blind study

Patient Population
103 patients,
51 in the Septocoll group,
52 in the control group

Treatments and Dosages
Septocoll group:  
1 fleece Septocoll 40,
primary wound closure

Control group:  
open treatment

Results/Target Criteria/Endpoint
Septocoll combined with primary wound closure resulted in a significantly shorter wound healing time, 17 days in the Septocoll group, compared with 68 days in the control group.
# Ordering Information

## Septocoll E – Collagen Fleece

<table>
<thead>
<tr>
<th>Product</th>
<th>Description and Size</th>
<th>Order No.</th>
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| Septocoll E 20, 5 x 4 cm, 1 fleece | 80 mg collagen (equine)  
29 mg gentamicin sulfate (equivalent to 17.5 mg gentamicin)  
87 mg gentamicin crobefate (equivalent to 17.5 mg gentamicin) | 30 2001 0001  
30 2001 0005 |
| Septocoll E 40, 5 x 8 cm, 1 fleece | 160 mg collagen (equine)  
58 mg gentamicin sulfate (equivalent to 35 mg gentamicin)  
175 mg gentamicin crobefate (equivalent to 35 mg gentamicin) | 30 2002 0001  
30 2002 0005 |
| Septocoll E 80, 10 x 8 cm, 1 fleece | 320 mg collagen (equine)  
116 mg gentamicin sulfate (equivalent to 70 mg gentamicin)  
350 mg gentamicin crobefate (equivalent to 70 mg gentamicin) | 30 2003 0001  
30 2003 0005 |
References


