



One Way or Another!

GENTA-COLL[®] resorb

Haemostasis and Antibiotic Infection
Prevention in **Spinal Surgery**

Haemostasis and Antibiotic Infection Prevention in Spinal Surgery

Case Report

**Senior Physician Dr. Wahle,
Helios Clinic Erfurt, Orthopaedic Clinic**

Case history:

- Female patient, 76-year-old
- Extremely overweight
- 4/06 posterior lumbar interbody fusion (PLIF) L3/4 due to major spinal stenosis with alternating signs of radicular pain on the left side and marked spinal claudication
- Generally free from symptoms and normalisation of walking distance post-operatively

Since November 2006, worsening lumbar pain radiating to both legs (left>right), here in particular into the left hip and thigh region. Pain in the lumbar region at rest and under exertion with a "breakthrough feeling". Patient feels general malaise and has reduced physical capacity.

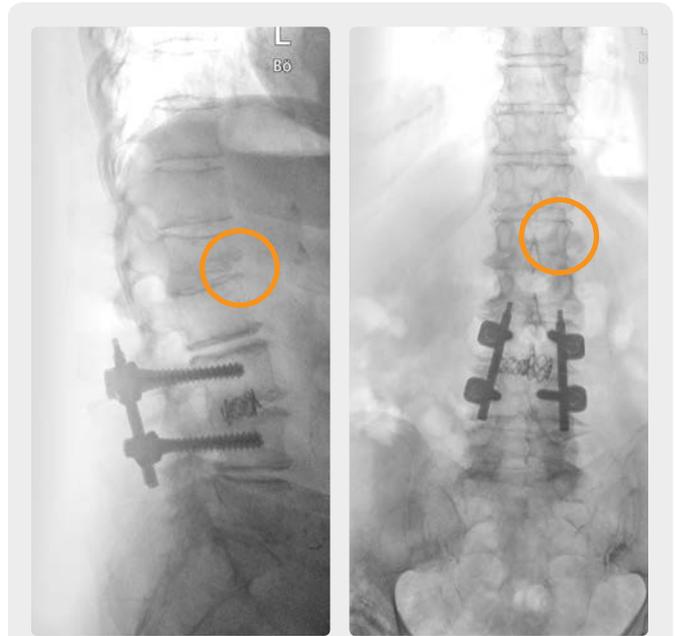
X-ray:

Osseous restoration L3/4, destruction of ventral end plate L1

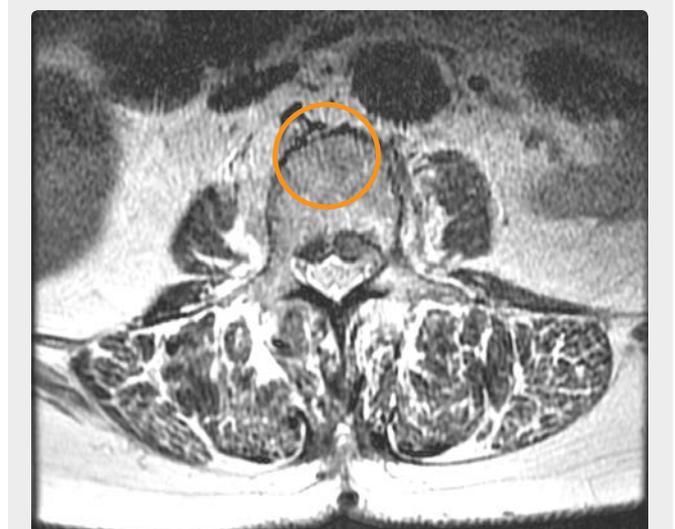
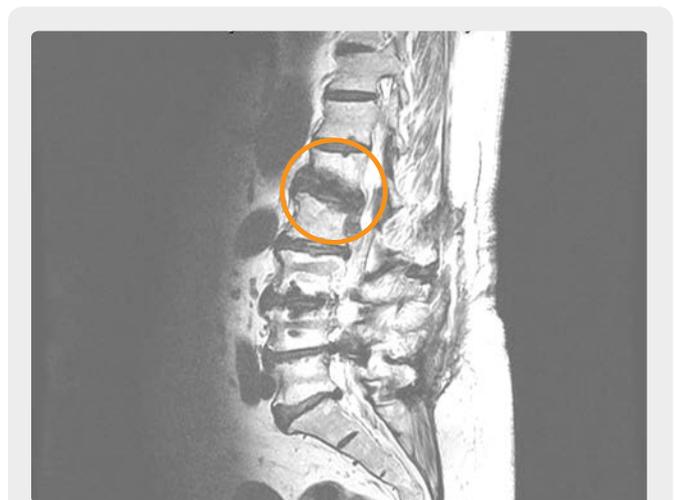
MRI:

Spondylodiscitis L1/2 with destruction of end plate L1, epidural abscess

Due to increasing weakness in both legs and significant lumbar pain, the indication was given for single-step dorsal-ventral-dorsal stabilisation with partial corpectomy and abscess debridement.



X-ray: Osseous restoration L3/4, destruction of ventral end plate L1



MRI: Spondylodiscitis L1/2 with destruction of end plate L1, epidural abscess

Surgical procedure:

1. Iliac crest: Removal of left dorsal spongiosa, filling and haemostasis of the removal area using collagen sponge.

2. Dorsal: Removal of instrumentation L3/4, insertion of new pedicle screws T12 to L4, taking into account the overall "soft" bony structure and the anticipated partial ventral resection of L1 and L2, prior to insertion of the screws, cladding of the pedicles with small rolled-up GENTA-COLL® *resorb* sponges

3. Ventral: Partial corpectomy of L1 with marked destruction of the end plate to around the middle of the vertebral body, insertion of a ventral placeholder ("basket") filled with a mixture of spongiosa and GENTA-COLL® *resorb* sponge, application of a small sponge onto the dorsal dura, ventral below the vessels and on the left lateral below the iliopsoas muscle

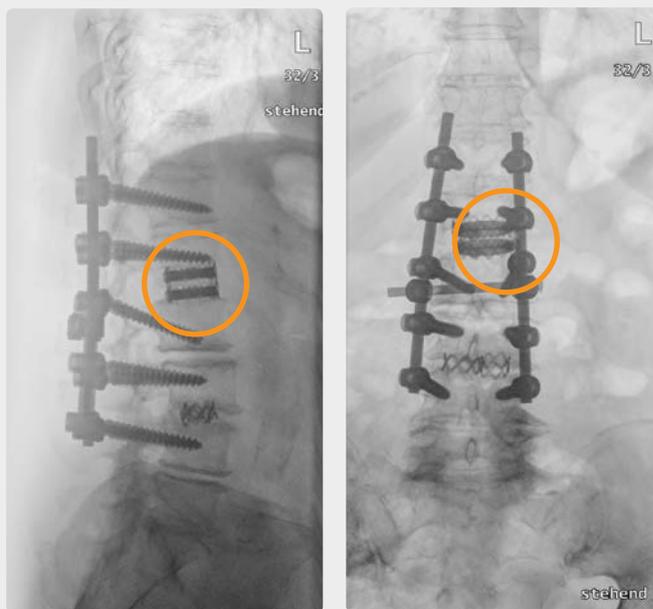
4. Dorsal: Insertion of the rods into the pedicle screws and fixing in the anatomically correct position, partial laminectomy of L 1, abscess removal, lavage of the spinal canal, coverage of the exposed dura and rod system using GENTA-COLL® *resorb* sponges.

- Primary wound healing of all surgical access points
- Post-operative wearing of a corset for three months, including early functional aftercare
- No microbiological evidence of bacteria
- Histology: Inflammation due to bacterial infection
- Systemic antibiotic treatment with oral Ciprofloxacin 2 x 500 mg for 8 weeks until extensive normalisation of the inflammatory parameters has taken place
- Complete remission of neurological symptoms in both legs
- Rapid abatement of the symptoms of back pain
- After completion of rehabilitation programme, extensive independence at home

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"However, experience has shown that it is precise wherever controlled and perfect haemostasis takes place and that the processes of wound healing are also extremely favourable."

Prof. Dr. med. Rudolf Ascherl



Post-operative X-ray



The proven properties of KOLLAGEN *resorb*™ collagen sponge...

- ▶ hemostyptic
- ▶ resorbable
- ▶ malleable
- ▶ highly absorbable
- ▶ structurally stable + elastic in the moist wound environment

...in combination with the antibiotic protection of gentamicin:

GENTA-COLL® *resorb* is recommended for haemostasis

- ▶ for clean and contaminated wounds
- ▶ in septic surgery, e.g. during surgical revision procedures
- ▶ where a high risk of infection is present

Haemostasis with zero compromise thanks to the careful processing of native equine collagen

The use of native equine collagen guarantees exceptional product safety¹. As an organic material, collagen is a firmly established medical product and is completely resorbed, thereby eliminating the secondary surgical interventions to remove the material². KOLLAGEN *resorb*™ can also have a positive action on blood clotting, as it induces platelet aggregation. Collagen serves not only as a guide rail for cell adhesion (to support blood clotting), it also provides chemotactic stimulus.

Thanks to its structure, KOLLAGEN *resorb*™ is able to absorb large quantities of fluid. This purely mechanical process ensures the absorption of deposited material, bacteria and fibrin coatings, etc. via secretory absorption.

KOLLAGEN *resorb*™ is dimensionally stable and can be applied dry or wet (e.g. using physiological saline solution) in or onto open wound areas.

Rapid and safe haemostasis is vital in spinal surgery in particular to prevent any subsequent adhesions. In this field, KOLLAGEN *resorb*™ can be used in areas such as:

Disc surgery

- ▶ For haemostasis and filling of the intervertebral disc space

Spongiosa removal, e.g. on the iliac crest

- ▶ For haemostasis and filling/coverage of the removal area

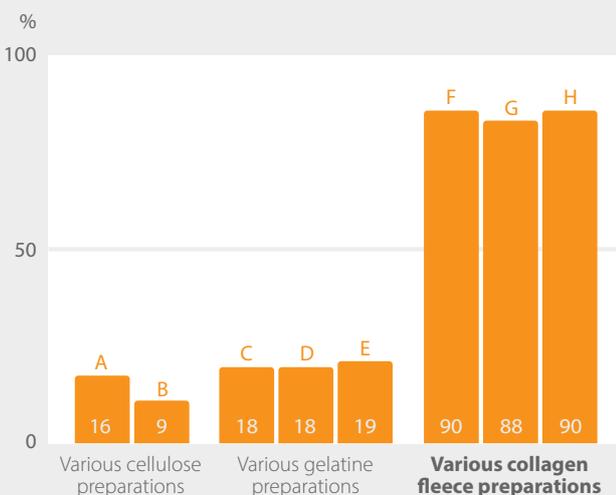
For haemostasis in infected tissue GENTA-COLL® *resorb* should be used in place of KOLLAGEN *resorb*™.

The advantages of collagen for wound healing:

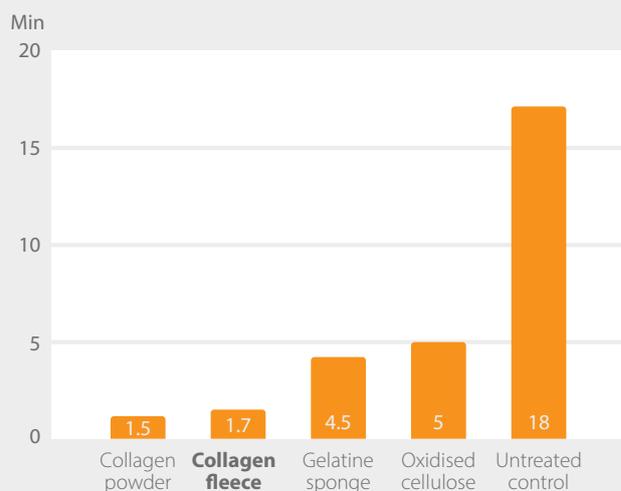
- **Biocompatibility**
- **Degradable and absorbable**
- **Biological matrix structure**
- **Cell adhesion and proliferation**
- **A base for soft tissue**
- **Biodegradability**
- **Can be incorporated**
- **Permeability**
- **Osteoconductivity**
- **pH stability**
- **Proven low antigenicity**

Extent of platelet aggregation

Five minutes after contact with various wound surfaces (determined by light transmission)



Bleeding time from a standardised spleen wound



Collagen fleece preparations promote a much more extensive platelet aggregation than any other preparations. Collagen fleeces or powders are proving to be significantly more effective than gelatine sponges or cellulose. They are rapidly and completely absorbed by the body, with native collagen also promoting granulation and epithelisation⁴.

Getting a Grip on Safe Haemostasis: KOLLAGEN *resorb*[™]

Dosage*

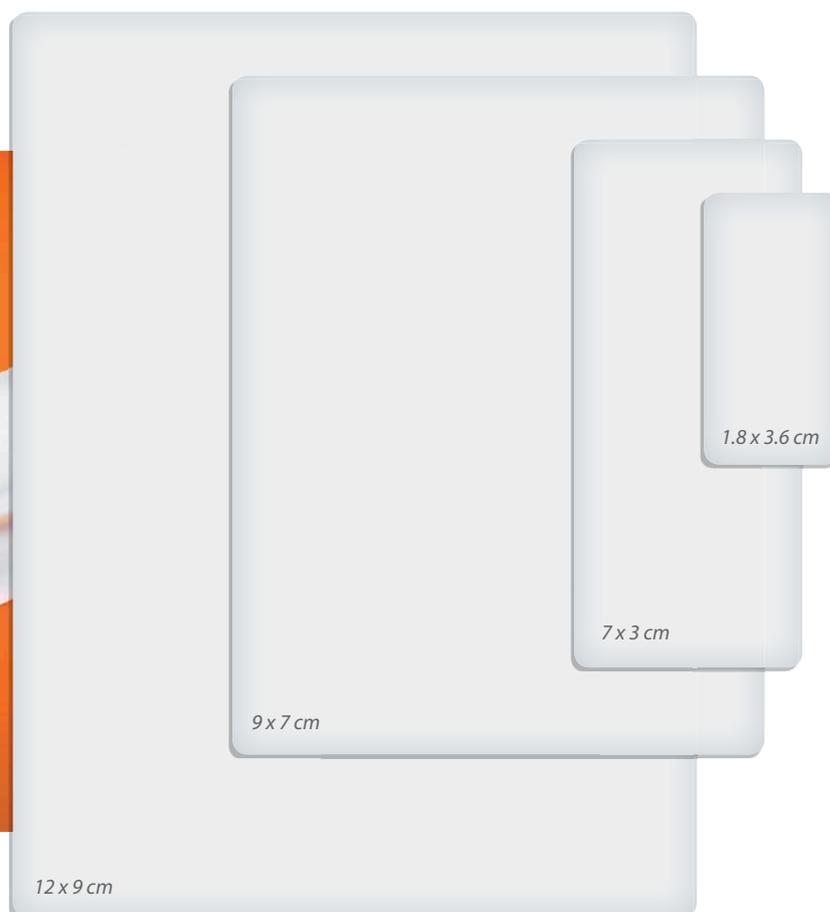
Unless prescribed otherwise, cut KOLLAGEN *resorb*[™] to the required size and apply to the defect without further pre-treatment. Fix the KOLLAGEN *resorb*[™] in place either using a dressing for external applications, or for internal applications, to reinforce the homeostatic action, use a surgical glue, such as GRF glue, fibrinogen-thrombin-F-XIII glue, or if need be, use conventional suturing.

*Please refer to the instruction for use



REM image of a collagen sponge

Shown in original size exactly ▶



1 cm² KOLLAGEN *resorb*[™] contains: 2.8 mg equine native collagen fibrils

GENTA-COLL[®] *resorb*

The tried and tested properties of collagen in combination with antibiotic protection



Gentamicin sulphate

Gentamicin sulphate belongs to the aminoglycosides group and has a broad antibacterial spectrum of action.⁵ For certain antibiotics, e.g. aminoglycosides, the highest possible serum level of the active substance is decisive in terms of the range of bactericidal action and the duration of the post-antibiotic effect. It is scientifically undisputed that long-term lower serum aminoglycoside levels are not advisable and in fact favour the proliferation of resistant bacteria. Due to the local application, high initial levels are produced at the implantation site, however, no toxic serum levels are reached in the entire organism. Research shows that this typical effect is relatively independent of the implantation environment and of the applied dose.⁶

GENTA-COLL[®] *resorb* is a haemostatic collagen sponge that contains the aminoglycoside antibiotic gentamicin sulphate to prevent infections or contamination by wound bacteria. The loose filling of the defect with GENTA-COLL[®] *resorb* prevents the formation of a wound haematoma, thereby reducing the risk of bacterial infection of the wound area.

GENTA-COLL[®] *resorb* – A medical device based on high-quality collagen

In spinal surgery, GENTA-COLL[®] *resorb* supports the surgical procedure as an adjuvant measure.

Spondylitis or spondylodiscitis spinal fusion using extraneous materials or autologous spongiosa

- Crushed and mixed with the spongiosa to fill the vertebral body defect
- Coverage of the implanted foreign materials (e.g. cages or metal screws)
- Prophylactic coverage of the intact dura in the infected wound area
- Coverage of the surgical site and filling of soft tissue defects after debridement

In revision surgery to remove implants

- To fill screw channels after removing extraneous material

For new instrumentation

- To cover the (metal) surface of implanted extraneous materials

Disc surgery

- For haemostasis and filling of the intervertebral disc space

Spongiosa removal, e.g. on the iliac crest

- For haemostasis and as filling/protective coverage of the removal area

Safe is Safe: GENTA-COLL[®]resorb

GENTA-COLL[®]resorb

Composition and presentation:

1 sponge in size **10 x 10 x 0.5 cm** or **5 x 20 x 0.5 cm** contains:

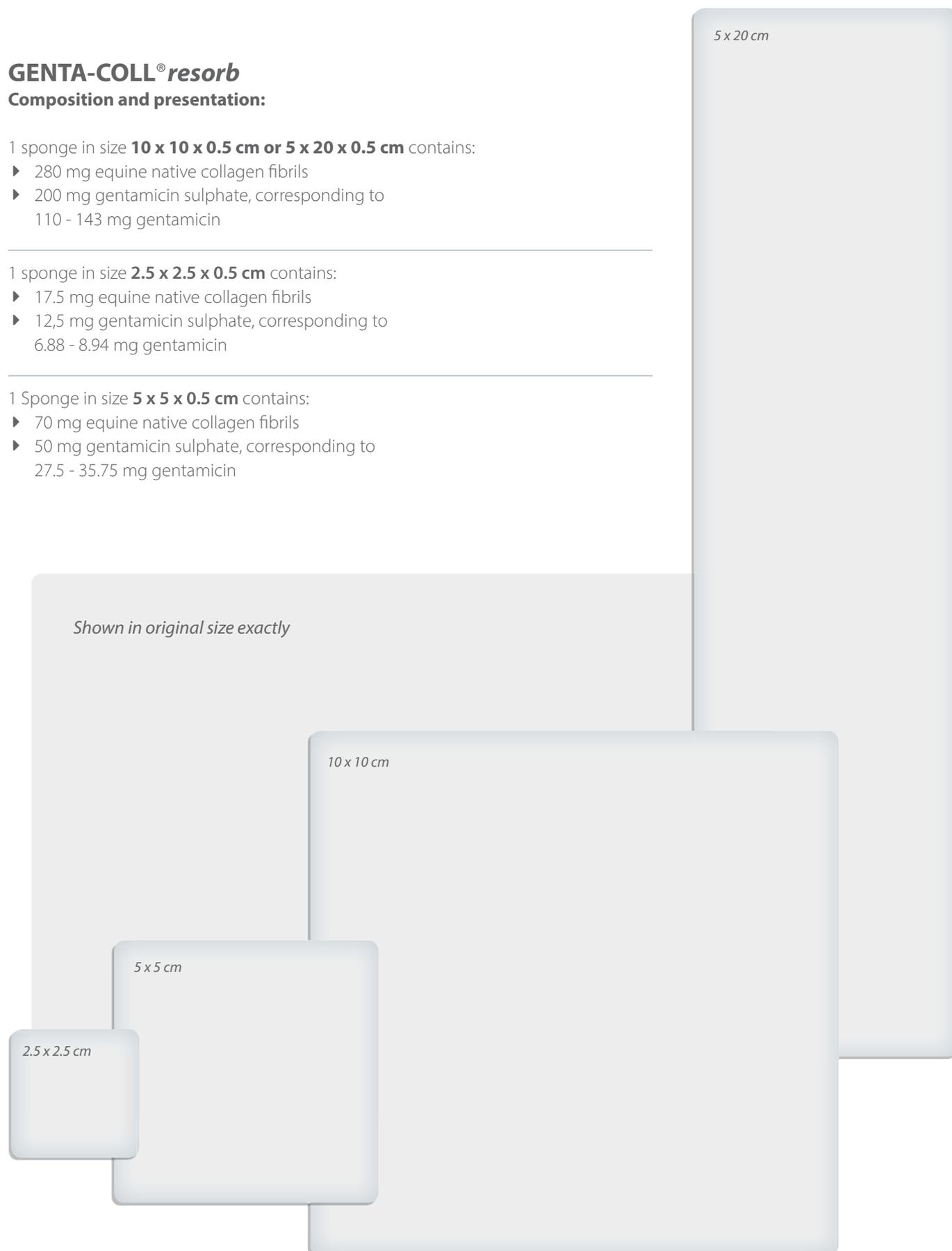
- ▶ 280 mg equine native collagen fibrils
- ▶ 200 mg gentamicin sulphate, corresponding to 110 - 143 mg gentamicin

1 sponge in size **2.5 x 2.5 x 0.5 cm** contains:

- ▶ 17.5 mg equine native collagen fibrils
- ▶ 12,5 mg gentamicin sulphate, corresponding to 6.88 - 8.94 mg gentamicin

1 Sponge in size **5 x 5 x 0.5 cm** contains:

- ▶ 70 mg equine native collagen fibrils
- ▶ 50 mg gentamicin sulphate, corresponding to 27.5 - 35.75 mg gentamicin



Product sizes and codes

GENTA-COLL®resorb

SPONGE SIZE	PACK CONTENTS	REF
2.5 x 2.5 cm	1 sponge	GC125
2.5 x 2.5 cm	5 sponges	GC525
5 x 5 cm	1 sponge	GC15
5 x 5 cm	5 sponges	GC55
10 x 10 cm	1 sponge	GC110
10 x 10 cm	5 sponges	GC510
5 x 20 cm	1 sponge	GC1520

KOLLAGEN-resorb®

SPONGE SIZE	PACK CONTENTS	REF
1.8 x 3.6 cm	12 sponges	RK1836
7 x 3 cm	5 sponges	RK9001
9 x 7 cm	5 sponges	RK9011
12 x 9 cm	5 sponges	RK1209



We will be happy to send you the corresponding instruction for use on request.

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RESORBA Medical GmbH, Am Flachmoor 16, 90475 Nürnberg, Germany
T +49 9128 / 91 15 0 F +49 9128 / 91 15 91 E infomail@resorba.com W resorba.com