



Safety is paramount

GENTA-COLL[®] resorb

Concepts for the closure of **sternal incisions**

GENTA-COLL[®] *resorb* for haemostasis and antibiotic infection prevention
STEEL WIRE for post-sternotomy adaptation

GENTA-COLL® *resorb* in thoracic and cardiac surgery

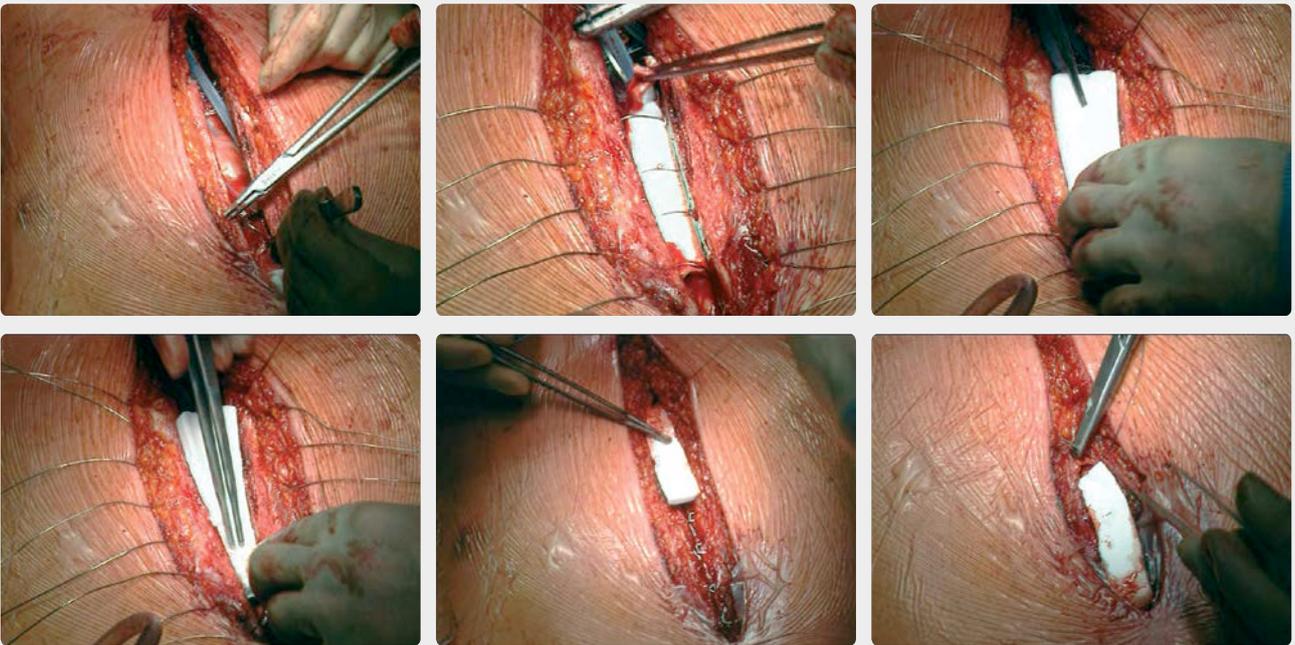
A median sternotomy is performed in the majority of surgical procedures performed on the heart. Postoperative wound infections after a sternotomy are a rare complication. Their frequency fluctuates between 1 and 4 %.

Given the significant subsequent costs and the physical and psychological stresses for the patient, the use of GENTA-COLL® *resorb* can be a useful addition to conventional surgical and prophylactic approaches.

In at-risk patients in particular:

- **in diabetic patients**
- **in overweight patients**
- **in patients with immunosuppression**

The use of GENTA-COLL® *resorb* is recommended due to its hemostyptic action and the resultant improved wound and bone healing.



With the kind permission of Dr. U. P. Rosendahl, Lahr Heart Centre

Application

The GENTA-COLL® *resorb* sponge can be cut into strips or inserted as a whole sponge via the following methods:

- ▶ Retrosternal, under the steel wires
- ▶ Intrasternal, between the bone areas
- ▶ Presternal, before the final wound closure

Sternal closure

STEEL WIRE for the safe and secure closure of sternal incisions

The extreme tensile forces when closing a medial incision to the sternum place special demands on the suture material:

- **Extremely tear-resistant**
- **Safe handling**
- **Firm knot hold**

The monofilament STEEL WIRE used in RESORBA offers exceptional handling properties and excellent tissue tolerability.

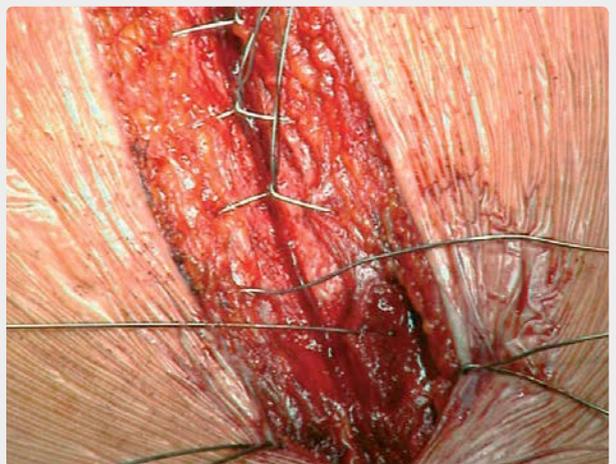
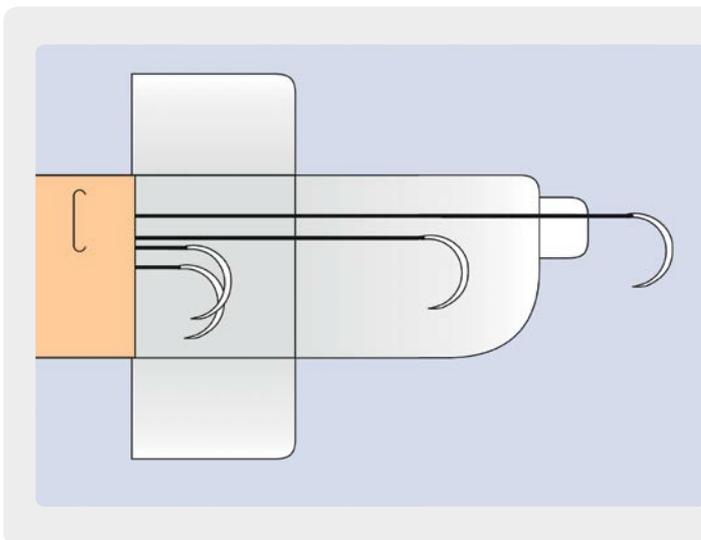
This ensures the safe and secure stabilisation of the sternum and the long-term fixing of the sternum halves.

The new generation of HRTX needle offers a high performing taper point in combination with safe support in the needle holder.

In patients with a known nickel and/or chromium allergy, don't use STEEL WIRE.

▼ Multi-L-Pack

Wire for closure of sternal wounds is offered in the Multi-L-Pack to avoid the memory effect. This ensures rapid, problem-free removal of the individual combinations.





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

GENTA-COLL® *resorb*

A medical device based on high-quality collagen

GENTA-COLL® *resorb* is a haemostatic collagen sponge that contains the aminoglycoside antibiotic gentamicin sulphate to prevent infections or contamination by wound bacteria.

The use of native equine collagen guarantees exceptional product safety.³

The collagen is completely resorbed⁴, thereby eliminating the secondary surgical interventions which are necessary when non-resorbable materials are used. The native structured collagen fibrils activate coagulation like endogenous collagen.⁴

- After the blood comes into contact with GENTA-COLL® *resorb*, the thrombocytes aggregate around the collagen fibres, triggering haemostasis.
- After application, GENTA-COLL® *resorb* fills in the missing volume, forming a guide rail for the tissue reaction, which actively promotes the migration and adhesion of actively dividing cells.
- 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.

- **Hemostyptic**
- **Resorbable**
- **Malleable**
- **An ideal carrier material for fibrin sealants**
- **Highly absorbent**
- **Structurally stable + elastic in the moist wound environment**

Gentamicin sulphate

Gentamicin sulphate belongs to the aminoglycosides group and has a broad antibacterial spectrum of action¹. 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.²

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

Sponge sizes

Shown in original size exactly

5 x 20 cm

10 x 10 cm

5 x 5 cm

2.5 x 2.5 cm

Product sizes and codes

GENTA-COLL® resorb

SPONGE SIZE		PACK CONTENTS	REF
2.5 x 2.5 cm	6.25 cm ²	1 sponge	GC125
2.5 x 2.5 cm	6.25 cm ²	5 sponges	GC525
5 x 5 cm	25 cm ²	1 sponge	GC15
5 x 5 cm	25 cm ²	5 sponges	GC55
10 x 10 cm	100 cm ²	1 sponge	GC110
10 x 10 cm	100 cm ²	5 sponges	GC510
5 x 20 cm	100 cm ²	1 sponge	GC1520



STEEL WIRE, monofilament, packaged in a multi-L pack

NEEDLE	EP	USP	CONTENTS / LENGTH (M)	REF	PACK CONTENTS
HRTX50	7	5	1 x 0.45	L99061	1 dozen
HRTX50	8	6	1 x 0.45	L99071	1 dozen
HRTX50	9	7	1 x 0.45	L99069	1 dozen
HRTX50	7	5	4 x 0.45	L99063	1 dozen
HRTX50	8	6	4 x 0.45	L99064	1 dozen
HRTX50	9	7	4 x 0.45	L99065	1 dozen
HRTX50	7	5	6 x 0.45	L99066	1 dozen
HRTX50	8	6	6 x 0.45	L99067	1 dozen
HRTX50	9	7	6 x 0.45	L99070	1 dozen
HRTX50	8	6	8 x 0.45	L99068	1 dozen

1/2 circle, strong round body,
taper point



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

References

- Craig W.A., Leggett J., Totsuka K., Vogelman B. (1988): Key pharmacokinetic parameters of antibiotic efficacy in experimental animal infections. *J. Drug Dev.*, 1 (S3): 7 - 15
- Grimm H. (1989): Bakteriologische und pharmakokinetische Aspekte der topischen Antibiotikaanwendung. Kollagen als Wirkstoffträger [Bacteriological and pharmacokinetic aspects of topical antibiotic application. Collagen as a drug carrier.] Einsatzmöglichkeiten in der Chirurgie [Possible applications in surgery]. Ed. Stemberger A., Ascherl R., Lechner F., Blümel G., Schattauer Verlag, Stuttgart New York, 33 - 37
- Mendel V. (Hrsg.), Beyer M. (co-author) (1989): Knochen- und Weichteilinfektionen. [Bone and soft tissue infections]. Perimed textbook publishing company ISBN 3-88429-341-9
- Moore R.D., Lietman P.S., Smith C.R. (1987): Clinical response to aminoglycoside therapy: Importance of the ratio of peak concentration to minimal inhibitory concentration. *The Journal of Infectious Diseases* 155 (1): 93 - 99
- Ph. Eur. Supplement to the European Pharmacopoeia Supplement 2000 (2000): 5.2.8 Minimization of the risk of the transmission of transmissible spongiform encephalopathies in traditional medicines and health supplements. Ph.Eur.- Supplement 2000
- Scherer M.A. (1996) Munich: Resorbierbare Arzneistoffträger aus Kollagen mit Gentamicin - Vergleich der Bioverfügbarkeit und der histologischen Reaktion im Tierversuch. Unveröffentlicht
- Stemberger A., Fritsche H., et al (1978): Fibrinogenkonzentrate und Kollagenschwämme zur Gewebeklebung [Fibrinogen and Collagen Sponges for Tissue Sealing]. *Med. Welt* 29 (17): 720 - 724
- Stemberger A., Lehner S., Odar J. (1999): Biodegradable surgical wound dressings - Stability, elasticity and tear resistance as markers of quality. Authorized translation from *Ellipse* 15 (4): 101 - 105
- Grimm H. (1989): Local antibacterial therapy in traumatology? *Forum Traumatologie Osteitis-Therapie*, Essex Pharma GmbH
- Ruszczak, Friess / *Advanced Drug Delivery Reviews* (2003) Collagen as a carrier for on-site delivery of antibacterial drugs (S3 -16)/ Innocoll GmbH Saal Germany
- Schimmer, Özkur, Sinha, Hain, Gorski, Hager, Ley Gentamicin - Collagen sponge reduces sternal wound complications after heart surgery: A controlled prospectively, randomized, double blind study, *American Ass. for Thoracic Surgery* (2012) 194 - 200
- Chang, Svinivasa, MacCormick, Hill, FRACS Metanalyse von 15 klinischen Studien, *Anal. of Surgery* 2013 - Gentamicin - Collagen Implants to reduce Surgical Site Infection 732-734
- Kowalewski, Pawliszak, Zaborowska, Navarese, Szwed, Kowalkowska, J.Kowalewski, Borkowska, Anisimowicz, Gentamicin-collagen sponge reduces the risk of sternal wound infections after heart surgery: Meta-analysis

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