



COLLATAMP® G

Gentamicin collagen resorbable implant

- ◆ Collatamp® G is used for local haemostasis of capillary, parenchymatous and seeping haemorrhages in areas with a high risk of infection.
- ◆ This product contains gentamicin sulphate at a locally effective dose. Systemically effective therapeutic blood or plasma levels are not generally achieved.
- ◆ Collatamp® G is a gentamicin-collagen implant used during cardiac¹, vascular², orthopaedic³, gastro-intestinal⁴ surgery as well in electrocardiology.⁵

◆ Presentations

5 cm x 5 cm x 0,5 cm
50 mg gentamicin sulphate

10 cm x 10 cm x 0,5 cm
200 mg gentamicin sulphate

5 cm x 20 cm x 0,5 cm
200 mg gentamicin sulphate



◆ Possibilities of usage whole or cutted



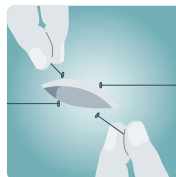
May be cut to the appropriate size



May be cut into pieces



May be rolled to fit the body lumen



Suturing

◆ Dosage and method of administration

- Up to 3 Collatamp® G implants (10 x 10 cm and 5 x 20 cm) can be used, depending on the size of the area requiring haemostasis.
- Do not exceed a total dose of 9 mg gentamicin sulphate per kg body weight.
- Use a dry Collatamp® G on the area to be treated, as dry as possible.
- Apply a light pressure for about 3 minutes.
- Collatamp® G is absorbed quickly and completely.

1. Kowalewski M. et al., *Journal of Thoracic and Cardiovascular Surgery* 2015; Vol 149, N°6: 1631-1640

2. Almeida C; et al., *International Journal of Surgery* 2014; 12: 1100 - 1104

3. Wilson C.J. Et al., *International Journal of Advanced Joint Reconstruction* 2018; 5 (1):19-29

4. de Bruin A.F.J. et al., *International Journal of Surgery* 2012; 12: 21-27

5. Futyma P. et al., *Cardiostim* 2017; Poster N°P1497

Collatamp® G Composition: Renatured bovine collagen, Gentamicin sulphate. Collatamp G contains, per cm² : 2.8 mg collagen 2.0 mg gentamicin sulphate (equivalent to 1.3 mg gentamicin base) **Indications:** Collatamp G is used for local haemostasis of capillary, parenchymatous and seeping haemorrhages in areas with a high risk of infection. This product contains gentamicin sulphate at a locally effective dose. Systemically effective therapeutic blood or plasma levels are not generally achieved. **Contraindications:** Collatamp G should not be used if a protein allergy is known or intolerance towards gentamicin has been observed. No experience has been gained in use during pregnancy and breastfeeding. For this reason, the indication should be strictly established during pregnancy and breast-feeding. The indication for Collatamp G should also be strictly established in patients with impaired renal function. **Side effects:** No side effects have been reported to date. If the recommended maximum dose is exceeded, gentamicin-specific side effects cannot be ruled out completely, especially in the case of renal failure. **Interaction with other substances:** No interactions have been reported to date. If adjuvant systemic treatment with gentamicin, other aminoglycoside antibiotics or other ototoxic or nephrotoxic drugs is necessary, the cumulative effects should be taken into account. **Dosage and method of administration:** If not otherwise prescribed, Collatamp G is administered as follows: Collatamp G can be cut to size to fit the area to be treated. Up to 3 Collatamp G implants (10 x 10 cm) can be used, depending on the size of the area requiring haemostasis. However, the patient's body weight and the total amount of gentamicin should be taken into account. In general, the number and size of the implants should be selected so that a total dose of 9 mg gentamicin sulphate per kg body weight is not exceeded. A dry Collatamp G is placed on the area to be treated, which should be as dry as possible, and light, pressure applied for about 3 minutes to achieve better adhesion. Gloves and instruments should be wetted to prevent Collatamp G from adhering to them. **Storage and shelf-life:** Once opened, single packs of Collatamp G may not be kept for later use or re-sterilised. Collatamp G should be stored between 4° C and 25° C. Collatamp G must not be used after the expiry date. **Do not use if the sterile packaging is open or damaged. Keep this product out of the reach of children. Packaging size:** Collatamp G 5 cm x 5 cm x 0.5 cm (Pack containing 1 piece) Collatamp G 10 cm x 10 cm x 0.5 cm (Pack containing 1 piece) Collatamp G 5 cm x 20 cm x 0.5 cm (Pack containing 1 piece) **Properties:** Haemostasis is triggered when blood comes into contact with released tissue factors and exposed endogenous collagen fibrils or renatured collagen fibrils like those in Collatamp G. The adhesion and aggregation of platelets is induced on the renatured collagen fibrils of Collatamp G and the plasmatic coagulation process is accelerated. The sponge-like structure of Collatamp G stabilises the wound clot, Collatamp G taking up a certain amount of blood. Collagen also promotes granulation and epithelialisation. Collatamp G is absorbed quickly and completely. Gentamicin is added to help prevent any infections that might occur at the site of implantation. **Detailed prescribing information:** Information about this product including : adverse reactions, precautions, contraindications, and method of use can be obtained by contacting SERB SA at medinfo.uk1@serb.eu. **Legal category:** Class III Medical Device. **Distributor:** SERB SA, Avenue Louise 480, 1050 Brussels, Belgium. **Legal manufacturer:** Syntacoll GmbH, Donaustrasse 24, 93342 Saal/Donau, Germany.

Adverse reactions should be reported.
Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.
Adverse reactions should also be reported to SERB SA via email at medinfo.uk1@serb.eu.

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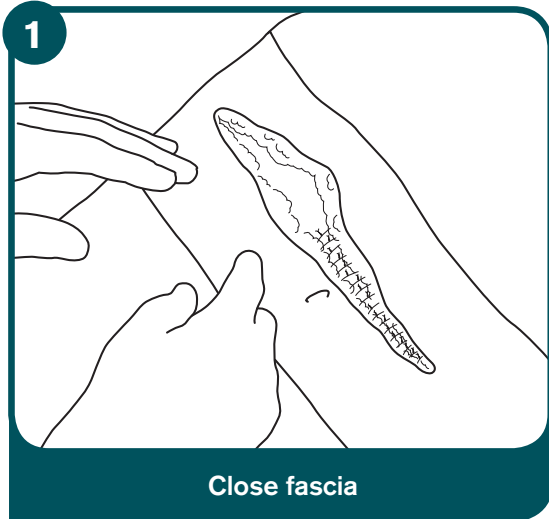
CE0123

CE marking and identification number of the notified body.
Product conforms to the essential requirements of the Council Directive 93/42/EEC concerning medical devices.

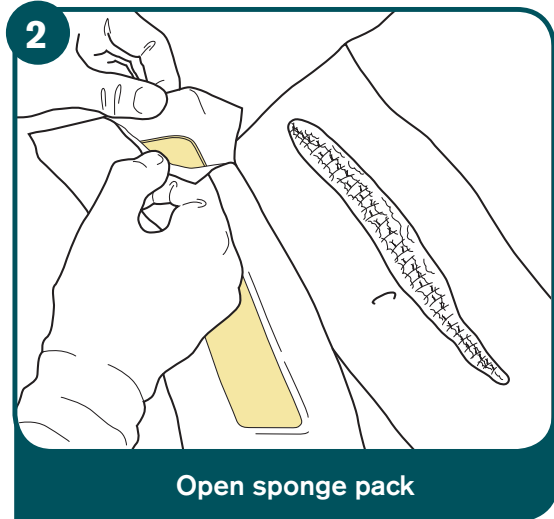


COLLATAMP[®] G

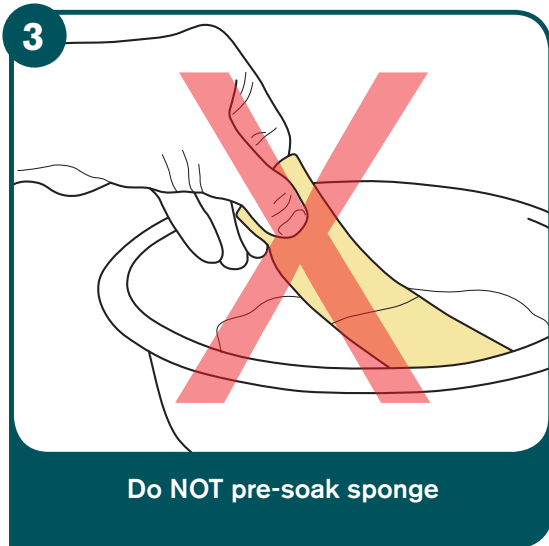
Gentamicin collagen resorbable implant



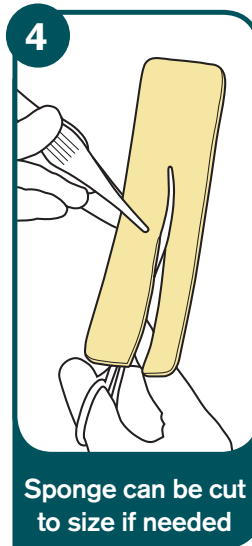
Close fascia



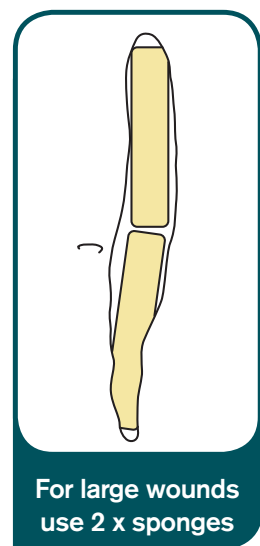
Open sponge pack



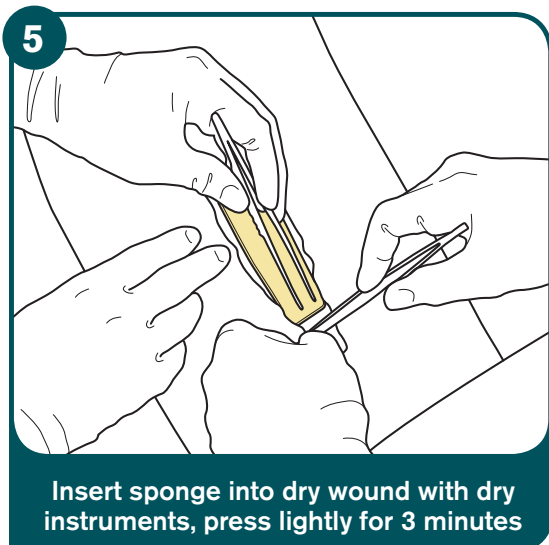
Do NOT pre-soak sponge



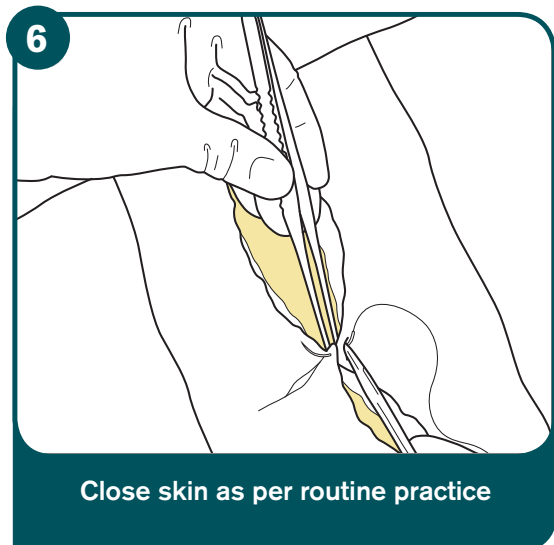
Sponge can be cut to size if needed



For large wounds use 2 x sponges



Insert sponge into dry wound with dry instruments, press lightly for 3 minutes



Close skin as per routine practice