Collatamp®G Instructions for Use (IFU)

1. Introduction
Collatamp G is a sterile fully absorbable haemostatic device for implantation. It is composed of bovine collagen incorporating gentamicin sulfate at a locally effective dose. The product is available in three different sizes. Dimensions and composition are presented below:

Size (cm)	Bovine collagen		Gentamicin sulfate (base)	
	mg/implant	mg/cm²	mg/implant	mg/cm²
5 × 5 × 0.5	70	2.8	50 (32.5)	2.0 (1.3)
10 × 10 × 0.5 5 × 20 × 0.5	280		200 (130)	

2. Intended use
Collatamp G is intended to be used during surgery to achieve local haemostasis when blood comes into contact with the released tissue factors and exposed collagen fibrils. The adhesion and aggregation of platelets is induced on the collagen fibrils at the surface of Collatamp G.

3. Indications
Collatamp G is used for local haemostasis of capillary, parenchymatous and seeping haemorrhages in areas with a high risk of infection (determined by the surgeon on a case-by-case basis, including patient-related, surgery-related, and physiological factors).

4. Dosage and method of administration
The Collatamp G implant procedure should be performed by an appropriately trained surgeon under aseptic conditions. The blister should be aseptically removed from the outer sealed pouch and then, the implant sponge can be taken aseptically from the blister and should be used immediately. Avoid any unsterile handling of the product before or during application to avoid contamination.
Collatamp G is administrated as follows:
- Collatamp G can be cut to size to fit the area to be treated.
- Place a dry Collatamp G on the area to be treated, which should be as dry as possible, and light pressure applied for about a few minutes to achieve better adhesion.
- Up to 3 large Collatamp G sponges (10 × 10 × 0.5 or 5 × 20 × 0.5 cm) can be used, depending on the size of the area requiring haemostasis. However, the patient's body weight should be taken into account. The number and size of the implants should be selected so that a total dose of 9 mg gentamicin sulfate per kg body weight is not exceeded.

5. Contraindications
Do not use Collatamp G:
- If a protein allergy is known.
- If any signs of hypersensitivity (severe allergy) to gentamicin has been observed or the patient is allergic to other aminoglycosides.
- If the patient is suffering from myasthenia gravis.
- In paediatric populations (0-18 years) due to a lack of data on safety.

6. Pregnancy and lactation
There is no adequate data from the use of gentamicin in pregnant women. Studies in animals have shown reproductive toxicity. Because of the potential risk of inner ear and renal damage to the foetus, gentamicin should not be used in pregnancy unless in case of a life-threatening indication and if no other therapeutic options are available.
Gentamicin is excreted in breastmilk and was detected in low concentrations in serum of breastfed children. A decision must be made whether to discontinue breastfeeding or to discontinue/abstain from gentamicin therapy.

7. Precautions for use
Use Collatamp G with caution in case of:
- Impaired renal function
- Vestibular or hearing disorders
- Neuromuscular disease
- Immune disease
- Connective tissue disease
- Advanced age
- Dehydration
- Electrolyte imbalance

After implantation of Collatamp G, systemic gentamicin plasma amounts may temporarily reach therapeutic levels. Collatamp G should be used with extreme caution if used in combination with other gentamicin-containing products. In case of combined therapy, gentamicin serum levels should be measured, and should not exceed 12 mg/L.
If required, serum aminoglycoside levels may be determined during implant treatment and renal function monitored by measuring serum creatinine concentrations (particularly in patients who are elderly, diabetic, have renal/hepatic impairment, or have a history of ear infections or hearing impaired).
Special caution is advised in patients with reduced renal function and patients taking other medication such as:
- Antibiotics that also affect kidneys or hearing (such as aminoglycosides, cephalosporins, methicillin)
- Anticoagulants (e.g. warfarin and phenindione)
- Antifungal medication (e.g. amphotericin B)
- Medicines used to treat muscle weakness conditions (e.g. neostigmine, pyridostigmine, botulinum toxin)
- Immunosuppressants (e.g. cyclosporin)
- Anti-cancer medicines (e.g. cisplatin)
- Some diuretics, such as ethacrynic acid and furosemide
- Non-steroidal anti-inflammatory agents to treat pain and inflammation (e.g. indomethacin)
- Medicines used to treat osteoporosis (e.g. bisphosphonates)

If several implants are used, use of an overflow drain is recommended.
Long-term continuous therapy with gentamicin should be avoided. Prolonged use may lead to the emergence of resistant organisms. There is no evidence that single use Collatamp G administration in patients promotes or induces the formation of resistance against gentamicin.
Do not use the implant alone to treat a suspected or confirmed infection, appropriate systemic antibiotics must be administered.

8. 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.

G. 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 and takes up a certain amount of blood. Collagen also promotes granulation and epithelialisation. Collatamp G is completely absorbed (it is estimated that Collatamp G will be predominantly degraded within 4-8 weeks regardless of the site of implantation).
The gentamicin included in Collatamp G is an antibiotic of the aminoglycosides family that helps to prevent infections caused by gentamicin-sensitive bacteria that might occur at the site of implantation. The administration of Collatamp G might not prevent an infection with gentamicin-resistant bacteria. The risk of infection is based on individual/combination of factors.

10. Undesirable effects
Serious adverse reactions including neurotoxicity (vertigo, tinnitus), ototoxicity (potential hearing loss, deafness, balance loss) and nephrotoxicity have occurred primarily in patients receiving systemic gentamicin therapy. However, systemic absorption following implantation of Collatamp G is unlikely to constitute a comparable risk.
Rare / very rare incidents (maximum 1 incident by sales volume of 10,000 units) potentially associated with Collatamp G use include delayed/impaired wound healing, local infection / secretion, haematoma, seroma, elevated creatinine levels, sensitisation/hypersensitivity reactions, and thrombosis. Categories and ranges have been calculated based on `probability of occurrence' estimates using the manufacturer's risk management rating system. As a reference parameter, the probability of occurrence of an ´event per patient´ is used, which is based on product sales numbers.

11. Information/warnings
Implants are for single use only and are delivered sterile. Implants are supplied in unit packages allowing sterile presentation. If any aspect of the packaging is damaged, sterility cannot be guaranteed. Use of the implant is then under the total responsibility of the user.
Wetting Collatamp G prior to implantation may result in loss of efficacy through premature elution of the water-soluble gentamicin sulfate.
Do not re-sterilise, there is a risk of deterioration of the material during a second sterilisation and this risk is not controlled.
Once the sterile barrier system (outer pouch) is opened, the implant must be used or discarded. Once opened, single packs of Collatamp G may not be kept for later use.
Any implant which has been implanted cannot be reused. In case of an error in use, the implant is not designed for cleaning without risk of deterioration. If Collatamp G requires surgical removal or replacement, the procedure should be performed under aseptic conditions.

12. Storage conditions
Store in original package.
Store between +4°C and +25°C. Store in a clean, dry place.
Verify the integrity of all aspects of the sterile packaging. DO NOT use if open or damaged. Do not use after the expiry date.

13. Disposal
Any unused or discarded product must be disposed of in accordance with local regulations in force.

Legal category: Class III Medical Device (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.

Distributor and legal manufacturer: SERB SA, Avenue Louise 480, 1050 Brussels, Belgium

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Adverse reactions should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard, or Search for MHRA Yellow Card in the Google Play or Apple App Store Adverse reactions should also be reported to SERB SA via email at safety@serb.com