CaLmit®

Resorbable Calcium Salt bone void filler device (Calcium Sulphate Powder for Beads and Paste)
Instructions For Use (IFU)
For Use By Registered Medical Practitioner ONLY

DESCRIPTION OF PRODUCT

CaLmit®, a product of Avalent Life Private Limited under the generic name "Resorbable Calcium Salt bone void filler device (Calcium Sulphate Powder for Beads and Paste)" is a bioresorbable Calcium Sulphate based carrier for delivering antibiotics, anti-microbial chemicals, drugs or growth factors required for infection control, tissue & bone repair and regeneration. CaLmit® is ideal for sustained infection control at the site of application through its long-term drug/ antibiotic delivery resulting in the intended clinical benefit.

INTENDED USE

CaLmit® is an absorbable, biocompatible bone void filler developed for the management of bone defects arising from trauma, infection, or surgical procedures. It is intended for use in non- load- bearing applications where the mechanical stability of the bone is not dependent on the filler. CaLmit® is suitable for placement in bone voids in areas such as the extremities, pelvis, or spine, as determined by clinical judgement. When mixed with compatible antibiotics, it facilitates the localized delivery of antimicrobial agents to infected sites, providing therapeutic support in the management of orthopedic infections.

INDICATION FOR USE

CaLmit® acts as a Resorbable Calcium Salt bone void filler device (Calcium Sulphate Powder for Beads and Paste) to address all types of bone or joint tissue infection resulting from traumatic events, chronic underlying pathologies or elective surgical procedures. Because of the excellent bio compatible nature of CaLmit®, it offers transient delivery of anti-infectives (antibiotics/ antimicrobials) without any cytotoxic effect at the site of implantation to deliver varieties of anti-infective factors in a sustainable and prolonged manner. CaLmit® generally resorbs and is eliminated within 60 to 90 days after implantation in an uneventful way.

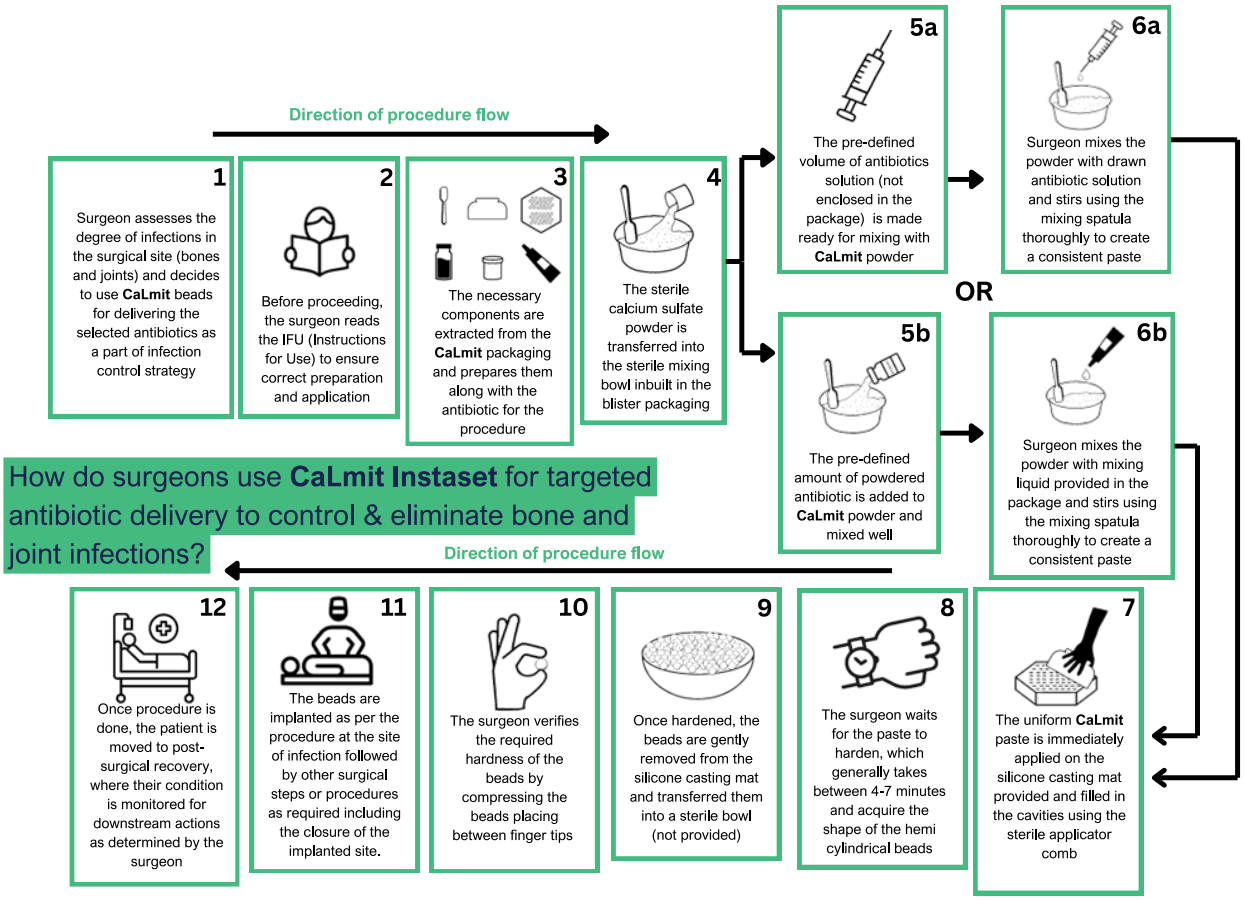
CONTRAINDICATIONS

The use of CaLmit® is contraindicated in the following situations:
Cases where the bone voids require mechanical support or stabilization with implants to maintain structural integrity.
In patients with known hypersensitivity to calcium sulphate or any components used in the formulation or preparation.
In individuals with severe renal impairment or disorders affecting calcium metabolism.
In cases of active bleeding at the implantation site where product containment cannot be ensured.
In pregnant or lactating women, due to the absence of clinical safety data.
In patients unable or unlikely to adhere to postoperative care and monitoring requirements.

METHODS OF APPLICATION

The surgeon makes the decision on the quantity and size of CaLmit® beads based on the clinical evaluation.
The product is supplied as an aseptic product along with materials for mixing of components and casting for the preparation of beads.
The surgeon makes the decision whether to use antibiotics during the preparation of the beads, and if so, the type of antibiotics.
Please refer to the **schematic diagram for the stepwise method for preparation and application of the beads** and **corresponding quantity of materials** provided.

No	Product code	Output as paste	Mixing fluid to be added	Output as beads	Included accessories in each Calmit® package					
					Mixing fluid vial	Mixing blister bowl	Mixing standalone bowl	Mixing spatula	Silicone mat	Applicator
1	3107-101-05	5 cc	3 ml	12cc	01	01	NA	01	01	01
2	3107-101-10	10 cc	6 ml	25cc	01	01	NA	01	01	01
3	3107-101-20	20 cc	12 ml	50cc	01	NA	01	01	01	01



The entire procedure of preparation and application must be performed under aseptic conditions.
Materials provided in the package are gamma sterilized and must be handled only according to the aseptic practices.
CaLmit® is formulated for impregnating antibiotics in both liquid and solid forms.
Appropriate volume of Sterile **Mixing fluid** is provided for preparing the paste when solid (powder) forms of antibiotics are used.
When liquid antibiotics are used, the sterile **Mixing fluid** provided in the package may **NOT** be necessary**.**

PRECAUTIONS

This is a one-time application device. Hence prepared beads if extra after application, needs to be discarded as per hospital waste policy.
For use by only qualified Healthcare Professionals.
Pre-operative diagnosis and evaluation of patients is mandatory to assess the suitability of use of the device.
The implantation site must be moist and free of blood or body fluid leakage or tissue debris or coagulated blood before application.
Use of saline or water is recommended to cleanse the area only if required.
Intra operative bleeding and post operative capillary oozing of blood, lymphatic or other body fluids must be arrested at the site prior to the application of the device.
Intact beads are prepared with defined amount of antibiotics loaded on to it. Hence beads may be applied without fragmenting it.
Over filling and pressure induced filling of beads are strictly discouraged.
The proper aseptic technique must be maintained throughout preparation and implantation.
The safety and effectiveness of CaLmit® have not been established in pediatric patients.
Monitor serum calcium levels in high- risk patients, especially when large volumes are implanted.
Perform appropriate debridement of infected or necrotic tissue before placement of CaLmit beads for optimal treatment outcome.

ADVERSE EFFECTS
The potential for complications associated with all surgical practices are not addressed using the device and may need an independent approach to address such events.
Proximal area micro fracturing around the infected site may be required to limit the boundary of infection.
Fracture or extrusion of the bone void filler, with or without particulate debris generation
Deformity of the bone at the site
As with any bone void filler, there may be partial or no osseous ingrowth into the bone void.
Transient hypercalcemia may be an unintended event of implanting the device in rare cases.
Store and handle the product according to manufacturer's guidelines to maintain product integrity.

STORAGE
Store in cool, dry place away from direct sunlight and heat.

STERILISATION
The product is double packaged, and gamma sterilized. Sterility is guaranteed on packages that are not damaged or compromised till the expiry date.
Do NOT use the product if package integrity is damaged or compromised.

WARNING
CaLmit® is indicated only for infection control and may not offer therapeutic benefits other than described.
The device must be prepared and used exactly as indicated for optimal results.
The product is intended as an adjunct device for antibiotic delivery when mixed with antibiotics prior to application.
Selection of antibiotics is purely a decision of the surgeon or the care provider and is based on the pre-operative diagnostic tests and evaluation.
Mixing CaLmit® with antibiotics not validated for compatibility may affect the product's handling characteristics, resorption rate or antimicrobial effectiveness.
Not intended for intravascular, intrathecal, or intradural use.
Exercise caution when implanting near vital neurovascular structures as extrusion or migration implanted beads may pause a risk.

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