

CERAMENT® G with Gentamicin

PRODUCT BROCHURE

The First and Only Injectable Antibiotic-Eluting Bone Graft

Indicated for use in the management of bone infection

96%

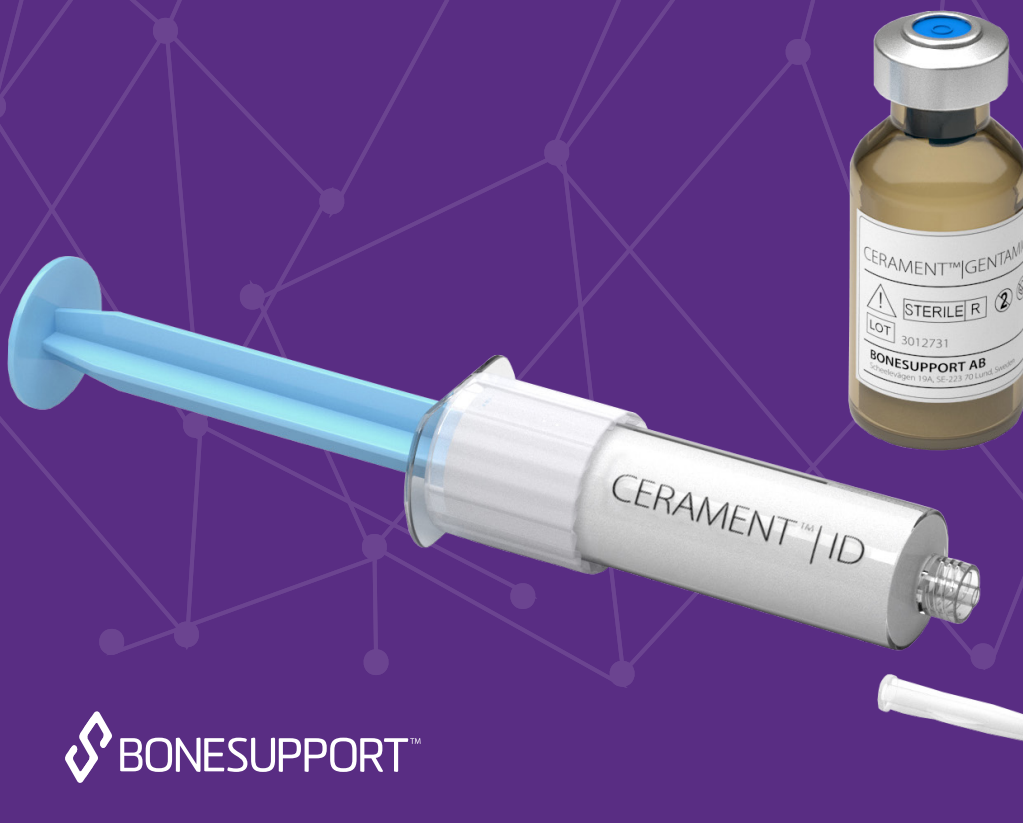
SUCCESS IN ERADICATION
OF INFECTION³

58%

REDUCTION IN
READMISSIONS⁴

39%

REDUCTION IN
LENGTH OF STAY⁴



 BONESUPPORT™

CERAMENT® G with Gentamicin

FIRST AND ONLY

Injectable antibiotic-eluting bone void filler

CERAMENT® G with gentamicin is the first and only injectable combination antibiotic-eluting bone graft substitute indicated for the management of bone infection. CERAMENT offers proven bone remodeling with reliable elution of a local broad spectrum antibiotic and is backed by years of clinical safety and efficacy data.

- Proven bone remodeling⁴
- Local, broad spectrum antibiotic-elution
- 96% success in eradication of infection³
- Injectable, drillable and moldable into beads
- Pre-measured, self-contained sterile mixing
- Consistent, safe and reliable antibiotic elution
- Robust data supporting safety and efficacy

An FDA-Designated Breakthrough Device:

Reserved for therapies that treat serious and life-threatening conditions and which have demonstrated substantial improvement over other therapies and/or is the first of its kind.

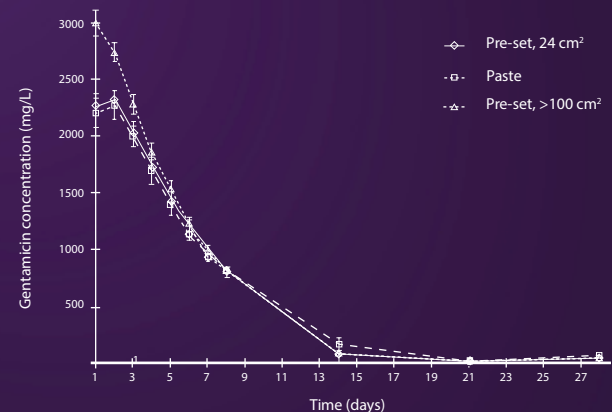


SAFE AND EFFECTIVE

Broad Spectrum Antibiotic Elution

CERAMENT® G provides a high initial burst of gentamicin, with sustained elution above MIC (minimum inhibitory concentration) for 28 days. Blood serum elution stays well below the systemic toxicity threshold and the gentamicin is completely eluted at 30 days, helping to reduce the risk of inducing antibiotic resistant bacteria.^{1,2}

In vitro Elution



High burst above >2000mg/L
Stays well above MIC for 28 days¹

ALL IN ONE

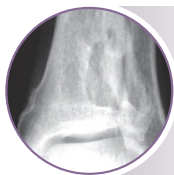
Combined Antibiotic-Bone Graft

CERAMENT® G is the first and only combination antibiotic-bone graft substitute with the proven ability to simultaneously remodel bone and provide reliable, consistent and safe local antibiotics to promote and protect bone healing.

CERAMENT G DUAL MODE OF ACTION

PROMOTE BONE REMODELING

- Proven bone remodeling



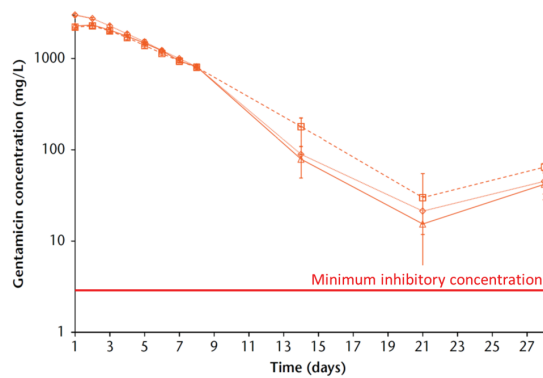
Debridement and Injection of CERAMENT G: CERAMENT is highly flowable to completely fill voids and cracks



The bone is healed at 6-12 months: The CaS in CERAMENT is fully resorbed, HA is embedded in bone and natural bone building continues increasing mechanical strength

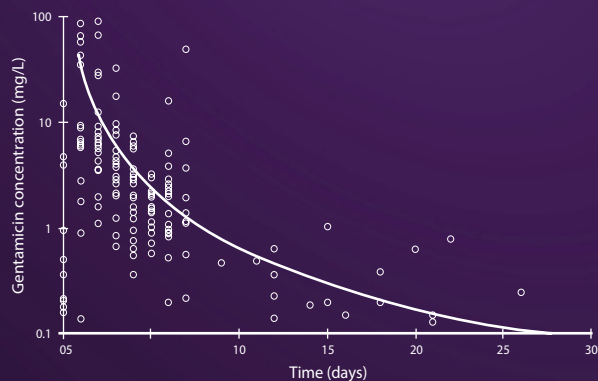
PROTECT BONE HEALING

- High burst of a local broad spectrum antibiotic.
- Sustained release above MIC* for 28 days.
- Serum levels well below systemic toxicity levels.¹
- Consistent elution independent of surface area.¹



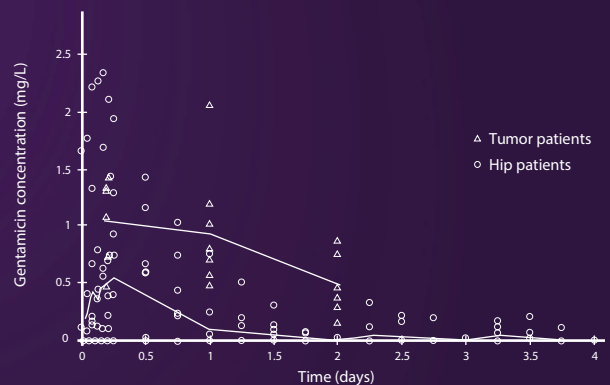
* The minimum inhibitory concentration (MIC) is the lowest concentration of a chemical, usually a drug, which prevents visible growth of bacterium.

Detectable Gentamicin Levels in Urine



Complete elution at 30 days, helping reduce the risk of inducing antibiotic resistant bacteria ²

Gentamicin Levels in Blood Serum



<3mg/L, well below systemic toxicity threshold of 10mg/L¹

ONE AND DONE

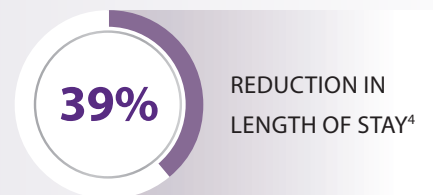
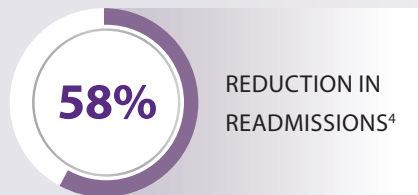
Promotes bone healing and elutes antibiotic locally

CERAMENT® G is one product that addresses two important clinical needs; bone infection and bone remodeling, providing significant improvement in clinical outcomes while saving on cost and time.

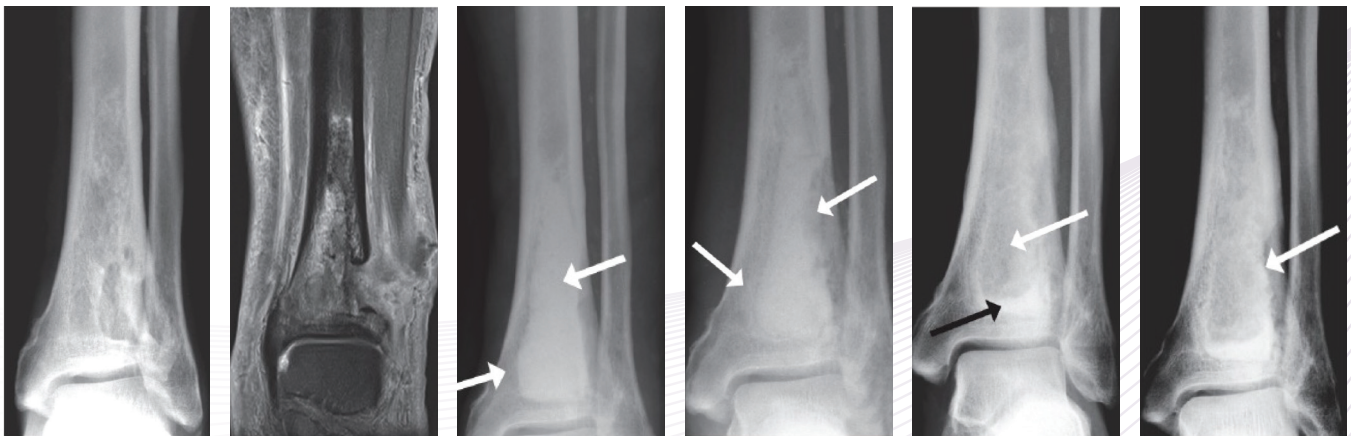
Unlike other bone grafting options, CERAMENT® G can be delivered in a single-stage procedure because of its unique ability to simultaneously remodel bone and deliver local antibiotics to protect bone healing.

- Supports a single-stage, on-label dead space management option for osteomyelitis
- Provides greater OR efficiency with consistent, pre-measured, self-contained mixing
- Offers product standardization, minimizes waste and reduces inventory needs

Oxford Protocol Results: A multi-disciplinary team approach to treating osteomyelitis in a single-stage surgery.

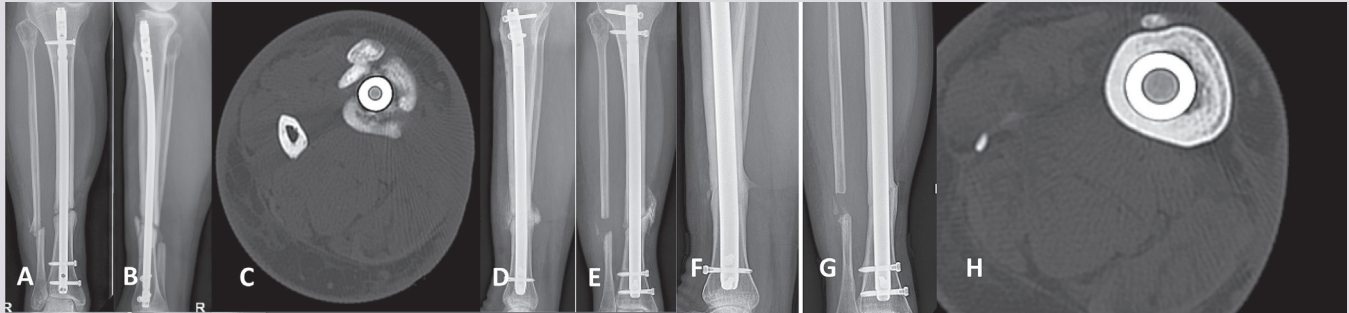


CHRONIC OSTEOMYELITIS



Distal Tibia with Chronic Osteomyelitis: After proper surgical debridement, CERAMENT® G was implanted to manage the dead space in this patient suffering from 10+ years of haematogenous osteomyelitis. The CERAMENT® G remodeled to bone in over 18 months and helped successfully prevent reinfection.³

FRACTURE RELATED INFECTION



Fracture related infection 12 months after surgery and non-union of the tibial shaft after intramedullary nailing of a II° open tibial fracture (AO-42. A2) (fig. a-c). After local debridement and intramedullary reaming, Cerament® G was inserted, followed by internal stabilization with intramedullary nailing (fig. d, e). After 18 months full bone consolidation was seen (fig. f-h).⁵

DIABETIC FOOT INFECTION



A 62 year old, poorly controlled Type 1 diabetic with a midfoot osteomyelitis after Tendo-Achilles Lengthening, midfoot derotational osteotomy internal fixation using beams and plates. Revision undertaken with debridement, removal of metalwork, and injection of CERAMENT® G to fill the remaining bony dead space (Fig. 1). 6 months post-op the foot remained stable, infection-free, and the patient was walking comfortably in a customized orthosis. CERAMENT® G helped to eradicate infection, fill the dead space, and provide stability to the midfoot.⁶

IMPROVE BONE INFECTION OUTCOMES

Better Outcomes Result in Lower Cost of Care

By incorporating CERAMENT® G into your osteomyelitis treatment plan, you can improve quality and clinical outcomes with reduced re-infection rates, re-fractures, and amputations, thereby decreasing costs and burden of care while offering an alternative to amputation.

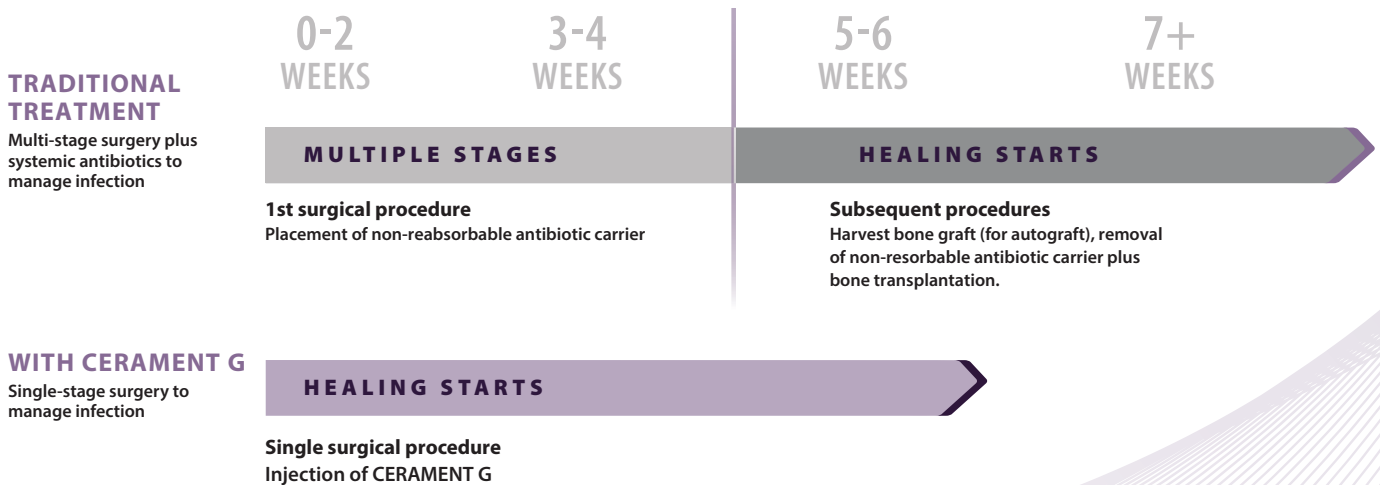
Clinical Value Metrics

- Fewer surgical interventions (single-stage approach)
- Convenient, all-in-one, pre-measured kit
- Predictable performance in the O.R.
- Safety and efficacy that is clinically supported

Hospital Value Metrics

- Reduction in readmissions and length of stay⁴
- Improved clinical outcomes³
- O.R. resource/time efficiencies⁴
- Product standardization with complete kit
- Supports antibiotic stewardship

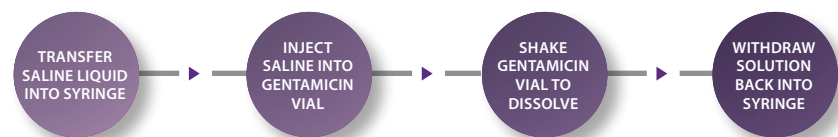
Managing bone infections is simplified with CERAMENT® G



EASY MIXING

Pre-measured, Self-contained, Predictable

Step 1: Prepare the Gentamicin Solution

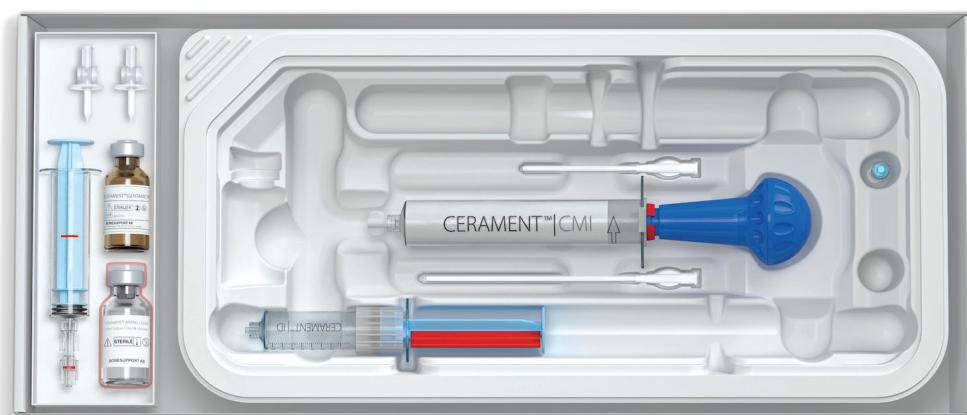


Step 2: CERAMENT G Mixing and Setting Time



Convenience Counts

- Pre-measured and self-contained
- Easy 30-second mix
- Injectable and drillable
- Moldable into beads
- No temperature sensitivities



*Kit contents vary slightly by location, please refer to the IFU for more information

REFERENCES

1. Stravinskas et al. 'Pharmacokinetics of gentamicin eluted from a regenerating bone graft substitute - In vitro and clinical release studies'. *Bone Joint Res.* 2016; 5:427-435.
2. Stravinskas et al. 'Antibiotic Containing Bone Substitute in Major Hip Surgery: A Long Term Gentamicin Elution Study'. *J Bone Joint Infect.* 2018; 3(2):68-72.
3. McNally et al. 'Single-stage treatment of chronic osteomyelitis with a new absorbable, gentamicin-loaded, calcium sulphate/ hydroxyapatite biocomposite'. *J Bone Joint Infect.* 2016 Sep; 98-B(9):1289-96.
4. Ferguson et al. "A retrospective cohort study comparing clinical outcomes and healthcare resource utilisation in patients undergoing surgery for osteomyelitis in England: a case for reorganising orthopaedic infection services." *J Bone Joint Infect.* 2021 Apr: vol. 6,5 151-163. 28.
5. Pesch et al. Treatment of fracture-related infection of the lower extremity with antibiotic-eluting ceramic bone substitutes: case series of 35 patients and literature review. *Infection.* 2020 Jun;48(3):333-344.
6. Reproduced with permission of M. Tiruveedhula, MD, FRCS (T&O), Basildon, Essex, UK
7. Inspired Health Market Research Survey Data

Get CERAMENT® G with Gentamicin and get more from your bone graft.

TO ORDER

us.sales@bonesupport.com



PRODUCTS

| | |
|----------------------------------|----------|
| CERAMENT® G with Gentamicin 5ml | A0450-11 |
| CERAMENT® G with Gentamicin 10ml | A0450-10 |



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