

# CERAMENT<sup>®</sup> G with Gentamicin

## VALUE GUIDE

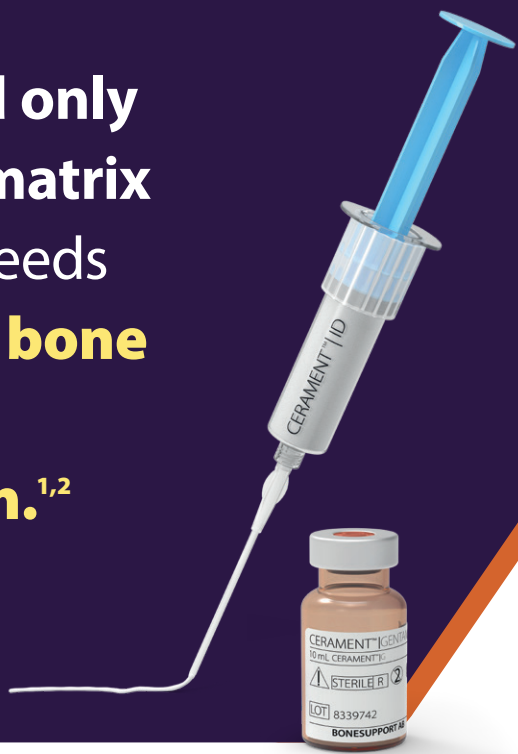
Breakthrough technology  
for better outcomes

*The **first and only** injectable antibiotic-eluting bone graft*



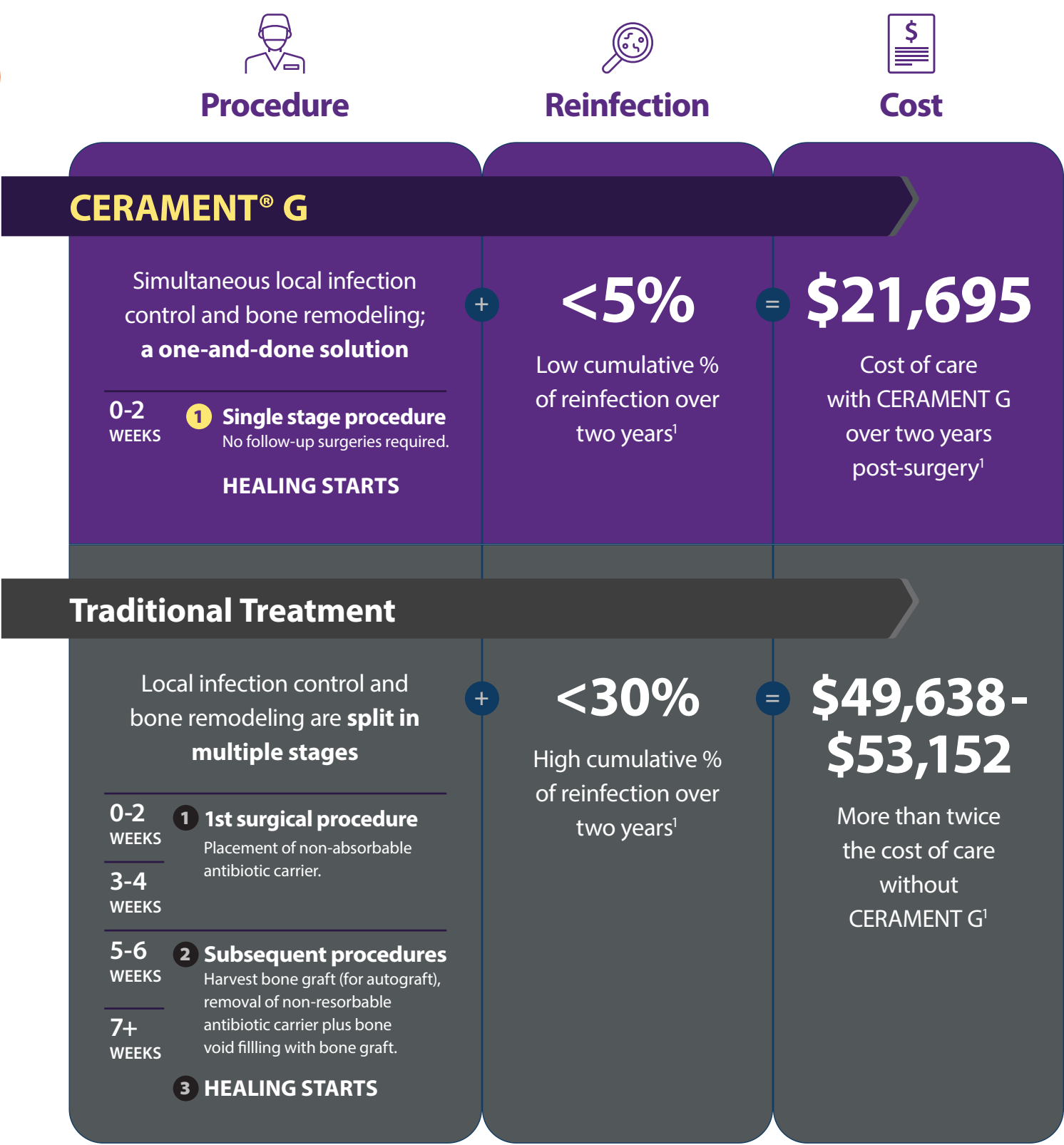
CERAMENT G is the **first and only** **FDA-cleared device-drug matrix** that addresses two clinical needs simultaneously: **promoting bone healing and protecting it against bacterial infection.**<sup>1,2</sup>

CERAMENT G is indicated for the management of bone infection and open fracture.



CERAMENT G Benefits	Importance
Proven bone remodeling <sup>1</sup>	Patients are at a lower risk of fractures and (re)infection when there is sufficient bone growth in a void
Unique formula	The unique ratio of hydroxyapatite and calcium sulfate is designed to enable CERAMENT to resorb at the same rate that bone forms
Proven consistent antibiotic elution above minimum inhibitory concentration (MIC) for a clinically relevant time period <sup>1</sup>	Prolonged low-level exposure to antibiotics may cause antibiotic-resistant organisms to evolve
All-in-one kit for closed mixing and injection (antibiotic included)	One kit used straight off the shelf Overall less exposure to antibiotics No off-label mixing
Reproducible mix and setting times	As a highly engineered product, a reproducible mix minimizes errors and ensures consistent delivery
Injectable to completely fill bone voids	Bone voids that are fully filled are not conducive environments for residual bacteria to grow in, thus decreasing the risk of infection recurrence
Evidence of sustained clinical effectiveness beyond six years	Bone infection can recur beyond two years of follow-up

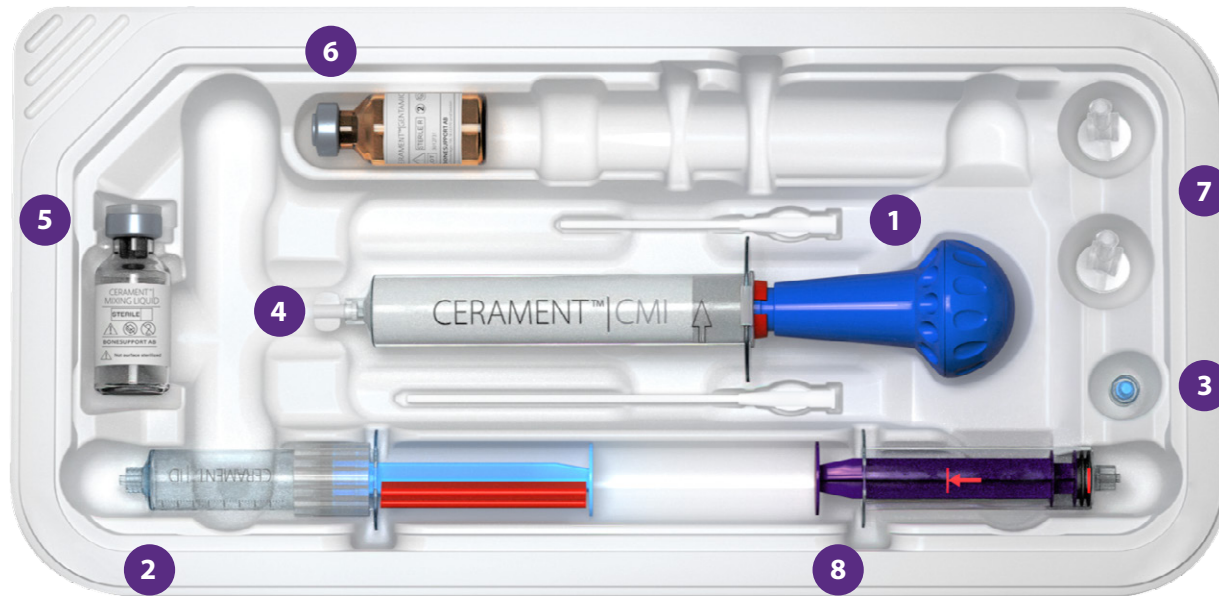
A **single-stage protocol** with CERAMENT G is a **cost-effective** strategy for bone infection compared to other protocols<sup>1</sup>



1 Ferguson, J., Athanasou, N., Diefenbeck, M., & McNally, M. (2019). Radiographic and Histological Analysis of a Synthetic Bone Graft Substitute Eluting Gentamicin in the Treatment of Chronic Osteomyelitis. Journal of bone and joint infection, 4(2), 76–84.  
2 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.  
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1 Carter, M., et al. "EE240 Does Single Stage Surgery of Long Bone Infection Using Gentamicin-Eluting Bone-Graft Substitutes Result in Decreased Cost and Improved Quality of Life Compared to Traditional Approaches?." Value in Health 25.12 (2022): S100.  
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## DESIGNED FOR SAFETY AND EFFICIENCY



### CERAMENT G Kit

- All-in-one kit for bone void filling
- All surface sterile
- Standardized mixing procedure
- Reproducible elution of local antibiotic
- Customizable filling using tip extenders
- Overall less exposure to antibiotics to staff

1. 2 x 11G tip extenders with tapered ends in 50mm and 100mm lengths
2. Injection Device (ID) syringe
3. Valve
4. Combined Mixing and Injection (CMI) syringe pre-filled with hydroxyapatite (HA)/pharmaceutical-grade calcium sulfate (CaS) powder
5. Mixing Liquid, sodium chloride 9 mg/mL liquid
6. Gentamicin sulfate, provides 17.5 mg gentamicin/mL paste
7. 2 x Dispensing pins
8. Syringe for preparing the gentamicin solution



**No additional mixing equipment needed**

**Size availability: 5mL, 10mL**

## ROBUST EVIDENCE ON CERAMENT TECHNOLOGY

**Largest amount of pre-clinical and clinical data of any bone substitute on the market (240+ publications and counting), including a level 1 RCT<sup>1</sup>**

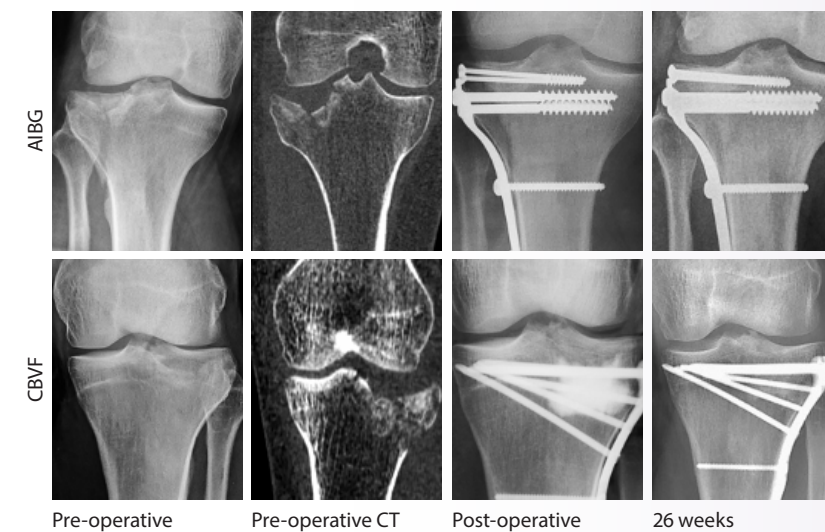


Figure 1: Bone remodelling before and after operation using autologous iliac bone graft or CERAMENT BVF

### Evidence-based bone healing

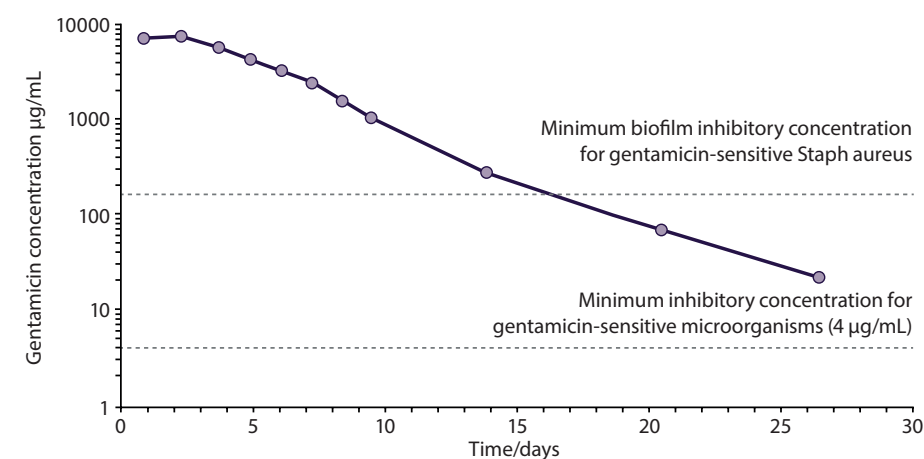
- Level 1 randomized controlled trial (RCT) – the CERTIFY study<sup>1</sup> involves 135 patients and shows that CERAMENT® BONE VOID FILLER (BVF) is as good as autograft (AIBG) in bone remodeling\*
- One and only orthobiologic product with robust long-term evidence: 94% infection-free after 6 year follow-up<sup>2</sup>



\*CERAMENT BVF is the base technology of CERAMENT without antibiotics

## Antibiotic stewardship in practice

### CERAMENT G ELUTION CURVE FROM IN VITRO DATA<sup>4</sup>



### Burst elution

- Safe and reliable elution of a local broad spectrum antibiotic, sustained release above MIC\* for at least 28 days<sup>3,4</sup>
- Serum levels well below systemic toxicity levels<sup>5</sup>
- No evidence of renal impairment caused by local gentamicin elution up to 525 mg<sup>6</sup>

\*The MIC, or minimum inhibitory concentration, is the lowest concentration (in µg/mL) of an antibiotic that inhibits the growth of a given strain of bacteria.

1 Hofmann, A et al., 'Autologous Iliac Bone Graft Compared with Biphasic Hydroxyapatite and Calcium Sulfate Cement for the Treatment of Bone Defects in Tibial Plateau Fractures: A Prospective, Randomized, Open-Label, Multicenter Study', The Journal of Bone and Joint Surgery, American Volume, 102.3 (2020), 179–93.  
2 McNally, M.A., et al., 'Mid- to Long-term Results of Single-Stage Surgery for Patients with Chronic Osteomyelitis Using a Bioabsorbable Loaded Ceramic Carrier', The Bone & Joint Journal, 104.B(9) (2022), 1095–1100.  
3 Stravinskias, M., Horstmann, P., Ferguson, J.Y., Hettwer, W., Nilsson, M., Tarasevicius, S., et al., 'Pharmacokinetics of Gentamicin Eluted from a Regenerating Bone Graft Substitute', Bone and Joint Research, 5.9 (2016), 427–35  
4 Data on file. BONESUPPORT AB, Sweden  
5 Stravinskias, M., Nilsson, M., Horstmann, P., Mørk Petersen, P., Tarasevicius, S., et al., 'Antibiotic Containing Bone Substitute in Major Hip Surgery: A Long Term Gentamicin Elution Study', Journal of Bone and Joint Infection, 3.2 (2018), 68–72  
6 Muir, R., Birnie, C., Hyder-Wilson, R., Ferguson, J., McNally, M.A., 'Does Local Implantation of Gentamicin Impair Renal Function in Patients Undergoing Surgery for Chronic Bone Infection?', International Journal of Research in Orthopaedics, 7.3 (2021), 438  
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IMPROVED OUTCOMES BRING VALUE

The Oxford Protocol<sup>1</sup>

Fracture-related  
infections/chronic osteomyelitis

Total patients: 100  
Mean follow-up: 6.05 years

94%

remained infection-free

97%

did not develop a fracture

17

less bed days<sup>6</sup>  
(\$15,572 direct cost savings  
per patient from reduced  
length of stay\*)

The Fix and Flap<sup>5</sup>

Open fractures

Total patients: 81  
Mean follow-up time: 55.8 months

96.3%

deep infection-free

96.3%

limb salvage rate

96%

bony union rate

The Silo Technique

Midfoot and hindfoot and intramedullary  
retrograde filling for the forefoot<sup>4</sup>

Diabetic foot osteomyelitis

Total patients: 47  
Mean follow-up time: 33 months

94%

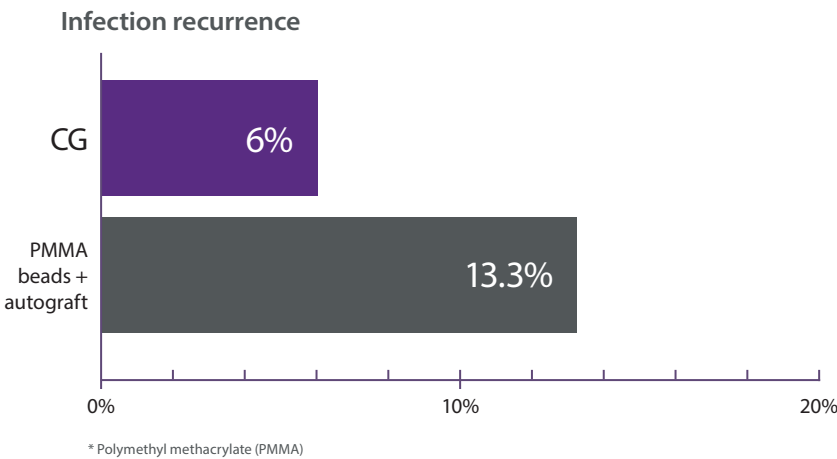
limb salvage rate

88%

infection-free

COMPARED TO PMMA BEADS + AUTOGRAFT

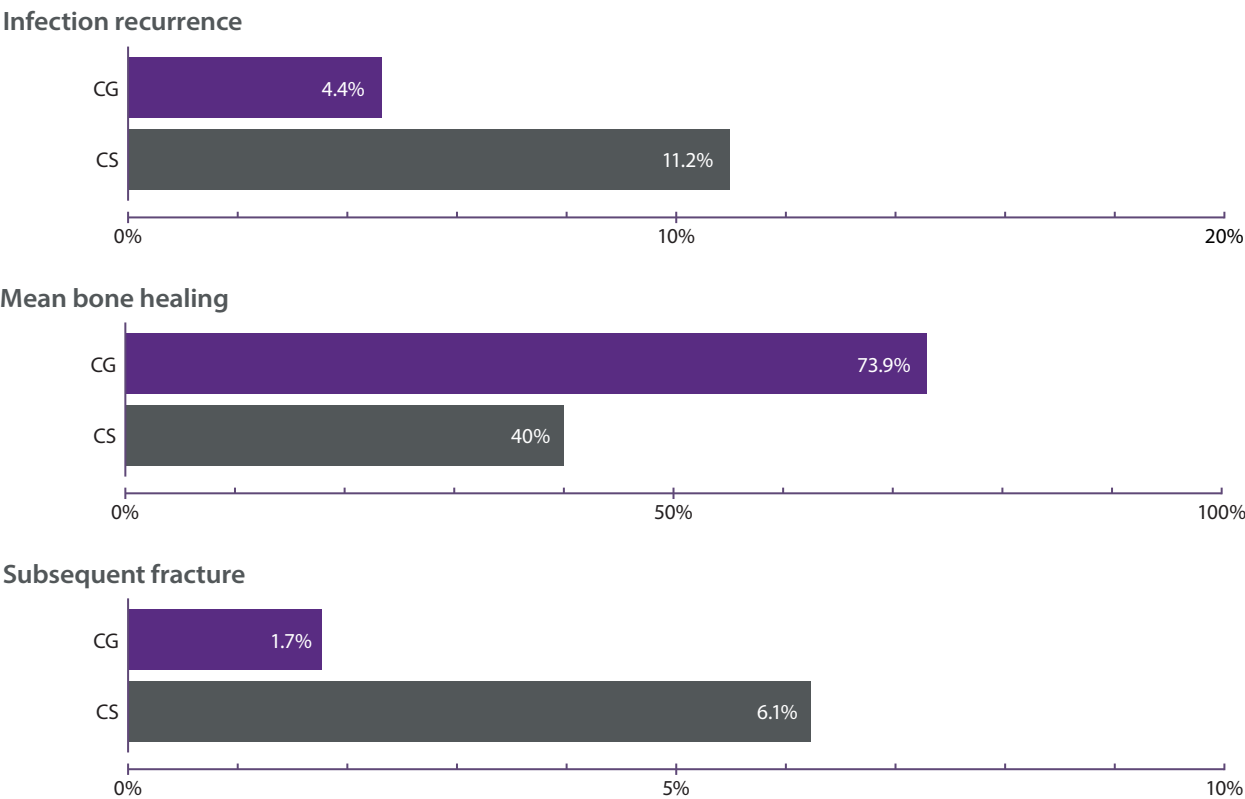
Injectable CERAMENT G (CG) paste vs. Gentamicin-impregnated PMMA\* beads + autograft with comparable patient cohorts<sup>1,2</sup>



**Infection  
recurs less**  
despite the CG group  
having longer  
follow-up time.

COMPARED TO CALCIUM SULFATE (CS) BEADS CONTAINING TOBRAMYCIN

Injectable CERAMENT G (CG) paste vs. calcium sulfate (CS) beads containing tobramycin<sup>3</sup>



\* Based on an average cost per bed day of £500; the average annual exchange rate between pound sterling and Australian dollar for 2021 was used (£1 = \$1.1832); data sourced from the Office for National Statistics (ons.gov.uk).

1 McNally, M.A., Ferguson, J.Y., Scarborough, M., Ramsden, A., Stubbs, D.A., Atkins, B.L., 'Mid- to Long-Term Results of Single-Stage Surgery for Patients with Chronic Osteomyelitis Using a Bioabsorbable Gentamicin-Loaded Ceramic Carrier', The Bone & Joint Journal, 104-B.9 (2022), 1095-1100

2 McNally, M.A., Small, J.O., Tofighi, H.G., Mollan R.A.B., 'Two-Stage Management of Chronic Osteomyelitis of the Long Bones', British Editorial Society of Bone and Joint Surgery, 75.3 (1993), 375-80

3 Ferguson, J et al., 'A Comparison of Clinical and Radiological Outcomes between Two Different Biodegradable Local Antibiotic Carriers Used in the Single- stage Surgical Management of Long Bone Osteomyelitis', Bone & Joint Research, 12.7 (2023), 412-22.

4 Vasukutty, N.L., Mordecai, S., Tarik, A., Subramaniam, M., Srinivasan B., 'Limb Salvage Surgery in Diabetic Foot Infection: Encouraging Early Results with a Local Antibiotic Carrier', 25.2 (2022)

5 Henry JA, Ali A, Elkhidir IH, Reid A, Wong J, Pillai A. Long-Term Follow-Up of Open Gustilo-Anderson IIIB Fractures Treated With an Adjuvant Local Antibiotic Hydroxyapatite Bio-Composite. Cureus. 2023 May 16;15(5):e39103. doi: 10.7759/cureus.39103. PMID: 37332443; PMCID: PMC10270668

6 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.

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## MANAGING BONE INFECTION WITH CERAMENT G

### The Burden of Bone Infection

Despite systemic antibiotics and medical advancements, bone infections are a common and significant burden for patients and healthcare systems:



**1 in 5**  
Bone infections recur<sup>1</sup>



**2+** surgical  
interventions  
typically required<sup>2</sup>



**20-30%** diabetic  
foot infections  
involve bone<sup>3</sup>



**6x** higher cost when  
fracture-related  
infection is present<sup>4</sup>

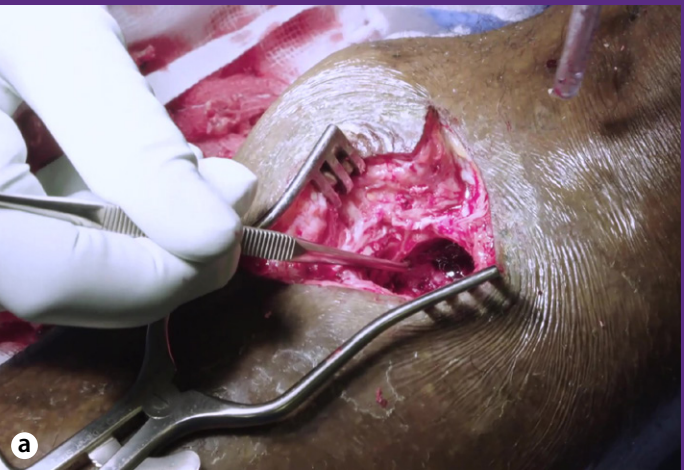
Bone infection is also associated with an **increased risk of amputation**.

**CERAMENT Calcium Sulfate + Hydroxyapatite 60%/40% is a safe and reproducible local antibiotic delivery system, with resorption that matches the body's bone ingrowth rate.**

1 Conterno, L.O., Turchi, M.D. Antibiotics for treating chronic osteomyelitis in adults. Cochrane Database Syst Rev. 2013;2013(9).  
2 Bezstarosti et al. Insights into treatment and outcome of fracture-related infection: a systematic literature review. Arch Orthop Trauma Surg 139, 61–72 (2019).  
3 Prompers, L., Huijberts, M., Apelqvist, J., Jude, E., Piaggini, A., Bakker, K., et al., 'High Prevalence of Ischaemia, Infection and Serious Comorbidity in Patients with Diabetic Foot Disease in Europe. Baseline Results from the Eurodiale Study', Diabetologia, 50.1 (2007), 18–25.  
4 O'Connor, O., Thahir, A., Krkovic, M., 'How Much Does an Infected Fracture Cost?', The Archives of Bone and Joint Surgery, 135.10(2) (2022), 135–40.  
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## ENABLING SINGLE-STAGE PROTOCOL

### Example of filling a bone void with CERAMENT G in a single-stage protocol



Dead bone is debrided, leaving dead space.



CERAMENT G is injected into the bone void.

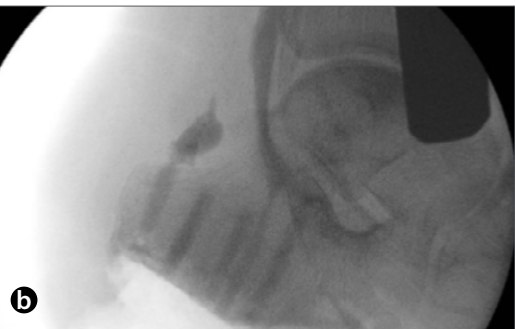
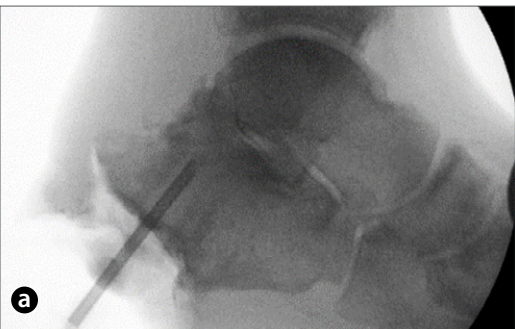


Bone void is completely filled.



CERAMENT G has set and wound is closed.

Note: Images are from a chronic osteomyelitis case and they are reproduced with kind permission from the Nuffield Orthopaedic Centre, Oxford UK.



**The Silo Technique**  
in cases of diabetic  
foot osteomyelitis.  
Silo type tunnels  
(four to five) are drilled  
into the os calcis and  
filled with 5mL of  
CERAMENT G.<sup>1</sup>

1 Drampalos, E., Hasan R.M., Kosmidis, C., Balal, M., Wong, J., Pillai, A., 'Single Stage Treatment of Diabetic Calcaneal Osteomyelitis with an Absorbable Gentamicin-Loaded Calcium Sulphate/Hydroxyapatite Biocomposite: The Silo Technique', Foot, 34 (2018), 40–44  
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## REIMBURSEMENT PROGRAMS

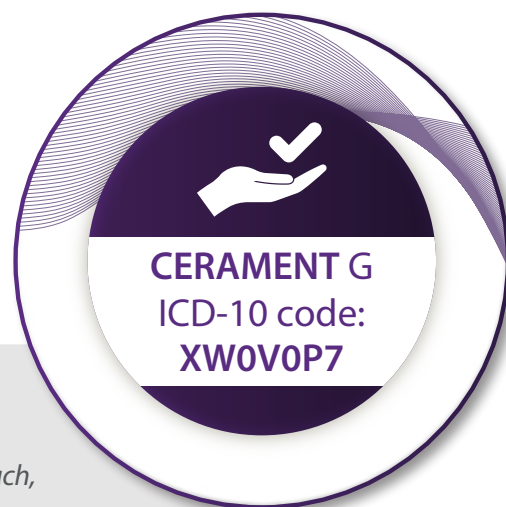
CERAMENT G qualifies for add-on payments when used for Medicare beneficiaries.

### Inpatient procedures: New Technology Add-On Payment (NTAP)

NTAP is intended to provide inpatient admissions with additional payment for use in bone infection when hospital costs exceed the payment threshold. 65% of the excess costs will be reimbursed (maximum payment is set at \$4,918).

**CERAMENT G can be identified in an inpatient procedure using the ICD-10-PCS code: XW0V0P7**

*Introduction of antibiotic eluting bone void filler into bones, Open Approach, New Technology Group 7*



### Outpatient procedures: Transitional Pass-Through Payment (TPT)

TPT is intended to cover the incremental cost of CERAMENT G treating bone infection in the hospital outpatient and ambulatory surgical center settings. It does not apply to procedures performed in the physician office or in an inpatient setting.

**CERAMENT G can be identified in an outpatient procedure using the HCPCS/CPT code: C1602**

*Orthopedic/device/drug matrix/absorbable bone void filler, antimicrobial-eluting (implantable)*



Please refer to the CERAMENT G Inpatient and Outpatient Coding & Billing Guides for more details on these programs and general coding information. **For reimbursement enquiries, call 1-866-903-2662 (leave a message with your name and phone number) or email [usreimbursement@bonesupport.com](mailto:usreimbursement@bonesupport.com).**

## CERAMENT G: A real breakthrough in the management of bone infections



### Reduced surgical interventions

Enabling single-stage protocols with CERAMENT G removes the burden of additional surgeries



### Increased safety and efficiency

Reproducible mixing minimizes errors and controlled antibiotic elution supports antibiotic stewardship



### Improved patient outcomes can generate cost savings

50-60% reduction in surgeries/reinfections<sup>1</sup>  
\$27,943 savings on average compared to multi-stage protocols<sup>1</sup>



To order, email [us.sales@bonesupport.com](mailto:us.sales@bonesupport.com) or call 1-877-719-6719

BONESUPPORT is a Scandinavian orthobiologics company founded in 1999 that develops, manufactures, and markets CERAMENT® – *an innovative portfolio of injectable and antibiotic-eluting bone void fillers.*

### CERAMENT® G with Gentamicin

A synthetic bone substitute with hydroxyapatite, calcium sulfate and the antibiotic gentamicin.

Remodels into bone within 6-12 months and elutes gentamicin.

Part Number	Product Description
A0535-06	CERAMENT® G with Gentamicin 5mL
A0535-05	CERAMENT® G with Gentamicin 10mL

### ORDERING DETAILS:

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