



ICD-10-PCS Procedure Code Request:  
***Insertion of Implantable Bone Void Filler  
With Antibiotic Elution***

BONESUPPORT, Inc.

# CERAMENT G - Device/Drug Product Overview

## What is it?

- An implantable, **device/drug combination**, bone void filler consisting of hydroxyapatite, calcium sulfate, and gentamicin sulfate (an antibacterial agent).
- CERAMENT G paste, the mixture in its final finished form, delivers 17.5 mg gentamicin/mL
- It has been granted Breakthrough Designation by the FDA.

## Where is it Used?

- CERAMENT G is indicated for use as an adjunct to systemic antibiotic therapy and surgical debridement (standard treatment approach to a bone infection) where there is a need for supplemental bone void filler material.
- CERAMENT G is intended to fill bone gaps and voids created when infected bone is debrided, resorbing at the rate of bone remodeling, while preventing colonization from gentamicin-sensitive microorganisms in order to protect bone healing.



# CERAMENT G - Device/Drug Product Overview

## What Does it Do?

CERAMENT G has two modes of action:

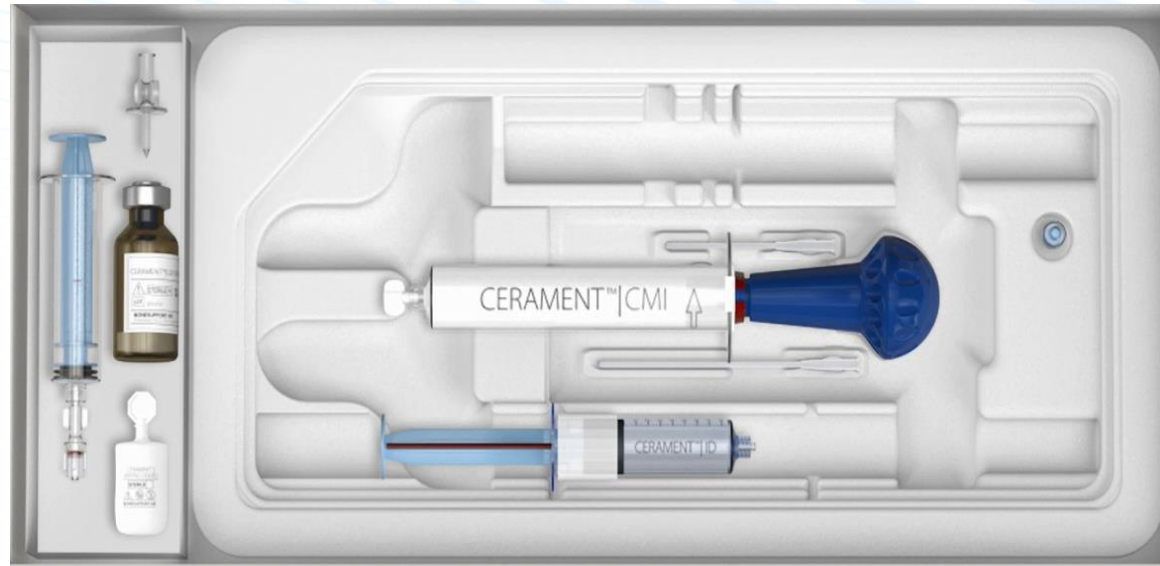
- Primary mode of action: serves as a resorbable, osteoconductive, ceramic bone void filler intended to fill gaps and voids in the skeleton system created when infected bone is debrided.
- Secondary mode of action: prevents colonization of gentamicin-sensitive microorganisms in order to protect bone healing.
- It is the first combination bone void filler that also elutes an antibiotic.
- It provides the first on-label solution for a one-stage surgical approach to treating bone infections, eliminating the need for secondary bone grafting surgery, thereby, improving outcomes.

## How does it work?

- CERAMENT G exhibits a reliable local antibiotic elution rate, inhibiting colonization from gentamicin-sensitive microorganisms to protect bone healing.
- It has an optimal ratio of calcium sulfate and hydroxyapatite, for a controlled implant resorption matching the body's natural bone remodeling rate over 6-12 months.

## CERAMENT G - Device/Drug Kit Components

- CERAMENT G is provided in a cardboard container that has two sections: one small and one large.



- The small section contains the gentamicin (drug) components, gentamicin powder and saline, to prepare the gentamicin liquid component
- The large section contains the powder components, the CERAMENT Combined Mixing Injection (CMI) syringe, and syringe for delivering the CERAMENT paste (device).



# CERAMENT G Procedural Steps

- CERAMENT G is used as a bone void filler, as part of the surgical treatment of bone infection.
- After the surgical site has been prepared and any dead bone is debrided (removed), the CERAMENT G paste is prepared by the surgeon or surgical tech and prepped for injection.

## Mixing steps

1. The gentamicin powder is mixed with the saline provided, to make a gentamicin liquid.
2. The gentamicin liquid is added to the powder in the CERAMENT CMI syringe, and the two are mixed.
3. The resulting CERAMENT G paste is transferred to a smaller delivery syringe.



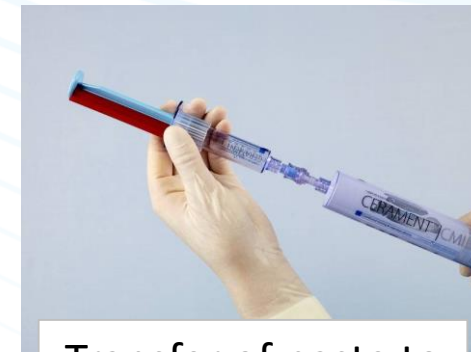
Gentamicin  
powder vial



Saline vial



Combined mixing  
injection syringe

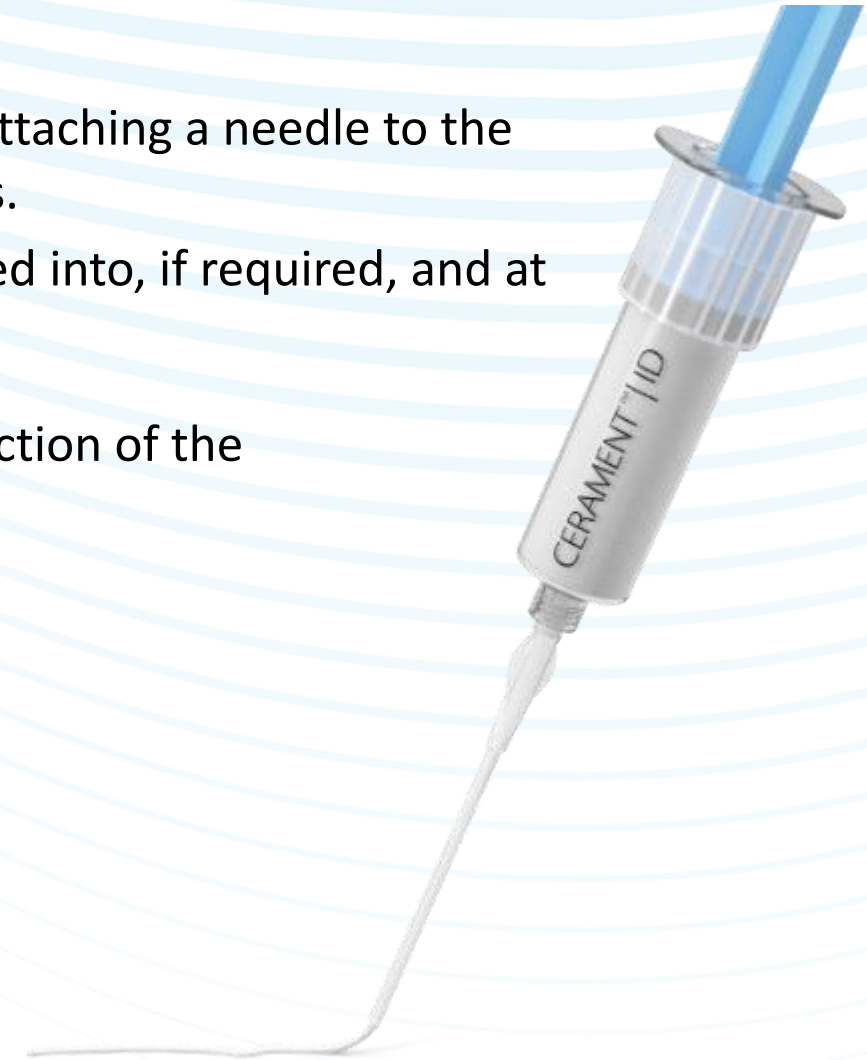


Transfer of paste to  
delivery syringe

# CERAMENT G Procedural Steps

## Implantation of CERAMENT G

- 4 minutes after the start of mixing, the paste is ready to be used.
- It can be injected using the tip extenders provided in the kit or by attaching a needle to the delivery syringe, or it can be placed into a bead mold to form beads.
- 15 minutes after the start of mixing, CERAMENT G can also be drilled into, if required, and at 20 minutes, it is fully set, at which time the wound can be closed.
- ✓ The use of CERAMENT G is normally dictated into the procedure section of the provider/operative note into the medical record.
- ✓ Complete bone remodeling is seen within 6-12 months.



## CERAMENT G - Device/Drug Usage

- CERAMENT G is available in two sizes: **5mL** and **10mL**.
  - The number of product units used for a case depends on the size of the bone void, so multiple units may be used.
  - It can be and will be used in both inpatient and outpatient settings.
  - It is a permanent implant (not to be surgically removed).
- It is not necessary to identify a range of specific sites that CERAMENT G can be used in. It is a gentamicin-eluting bone void filler that can be used to fill gaps and voids of any bone.

# CERAMENT G Complaint Rates & Adverse Events

The below information contains *adverse events and complaints* since the first launch in Europe in 2013

- Total units shipped (2014-2019) = **13,804**
- Total complaints (2014-2019) = **57**
- Lifetime complaint rate = **0.41%**

## Detailed complaint breakdown:

- **41** technical complaints
- **16** medical complaints:
  - **6** cases related to drainage (including white drainage)
  - **6** cases related to leakage into soft tissue
  - **3** cases related to infection
  - **1** case related to erythema



# CERAMENT G & Procedural Naming Conventions

- CERAMENT G is not known by any other names.
- Bone infection is also referred to as:
  - Osteitis
  - Osteomyelitis
  - Fracture-related infection
  - Diabetic foot infection
  - Post-traumatic osteomyelitis
  - Implant-related infection
- Existing ICD-10-PCS codes relate only to devices or the manual (off-label/non-FDA-approved) mixing of products, not specific to combination device/drug products, which means there are currently no codes to capture the use of a combination device/drug bone void filler such as CERAMENT G.

## Summary

- No other combination bone void filler and antibiotic product is cleared or approved for use in the United States.
- CERAMENT G is being evaluated by the FDA as a device/drug combination product and has been granted Breakthrough Designation.
- CERAMENT G offers the possibility of a single-stage surgery because the bone void filler is resorbed at the rate of bone remodeling, while eluting antibiotic in order to protect from bacterial colonization of the bone void filler.
- A single-stage procedure eliminates the need for a second operation, avoids donor site morbidity, lowers total treatment costs and time, and improves patient quality of life.
- CERAMENT G will be used in conjunction with bone procedure codes, but those procedure codes cannot presently appropriately identify a combination device/drug product.



Thank you