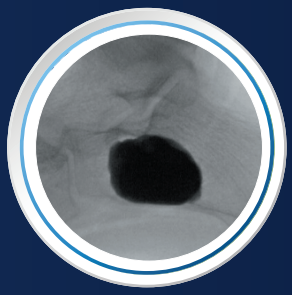
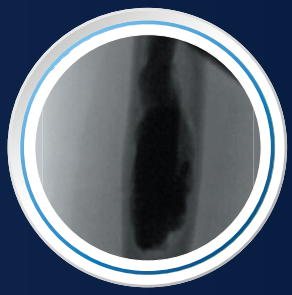
CERAMENT®
BONE VOID FILLER

PEDIATRIC BROCHURE

Indicated for Use in
Pediatric Patients Age 9+



Benign Bone Tumors



Cysts

Giant Cell Tumors

BONESUPPORT™

CERAMENT® BONE VOID FILLER

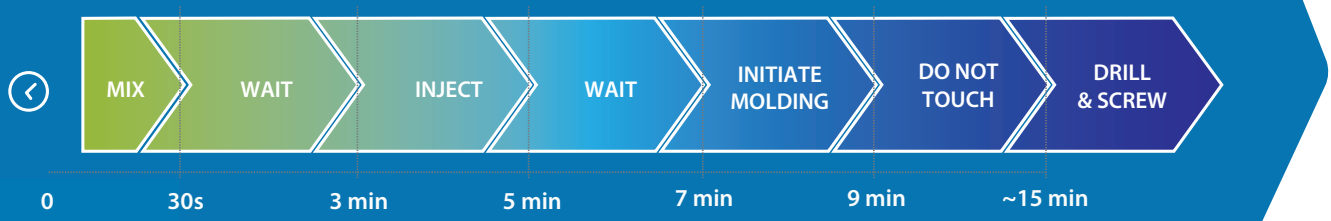
CERAMENT® is an injectable, moldable, drillable and radiopaque bone substitute which provides rapid and complete bone remodeling within 6-12 months[1]. Compare this to phosphate products which may inhibit bone growth and take years to remodel bone.

CERAMENT is supported by over 240 clinical publications, including a Level I randomized controlled trial against the gold standard autograft.

Unique features:

- ***Injectable, Moldable, Drillable***
- ***Rapid and complete bone remodeling[1]***
- ***Highly visible under fluoroscopy***
- ***30 second, enclosed sterile mix***
- ***Not temperature sensitive***
- ***Non-exothermic***
- ***Robust clinical data***
- ***Cleared for pediatrics***

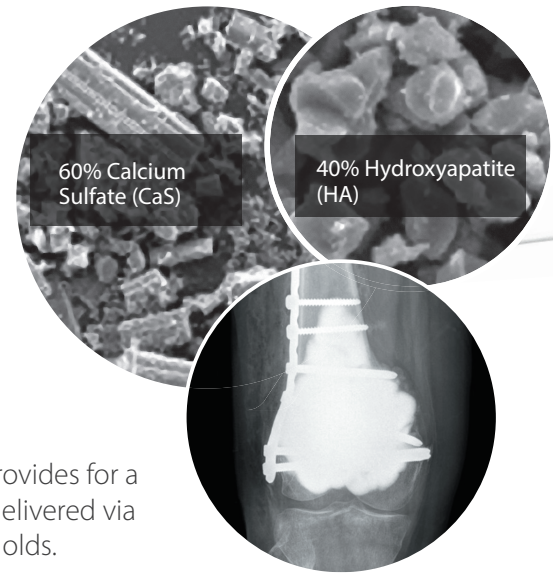
Consistent Mixing and Handling



Highly Flowable

CERAMENT® consists of 40% hydroxyapatite (HA) and 60% calcium sulfate (CaS).

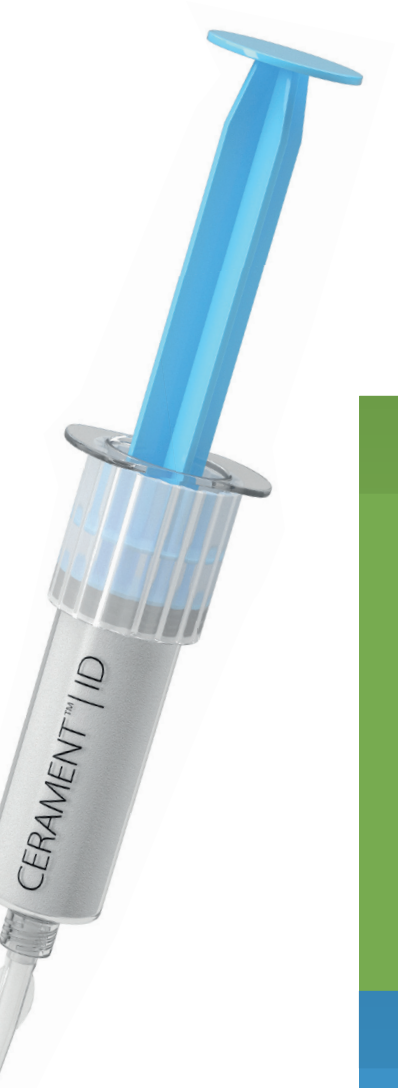
The CaS works as a delivery tool for the osteoconductive HA

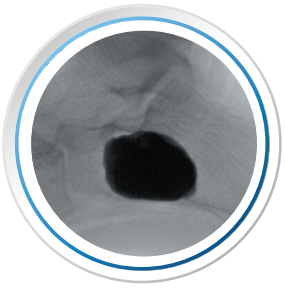


Visible Under Fluoroscopy

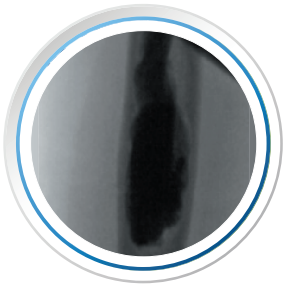
The addition of a liquid radiopacity enhancing agent provides for a radiographically visible injectable paste which can be delivered via traditional needles, rigid or flexible cannulas, or bead molds.

Pediatric Applications





Benign Bone Tumors



Cysts

Giant Cell Tumors

LEVEL I RCT AGAINST AUTOGRAFT

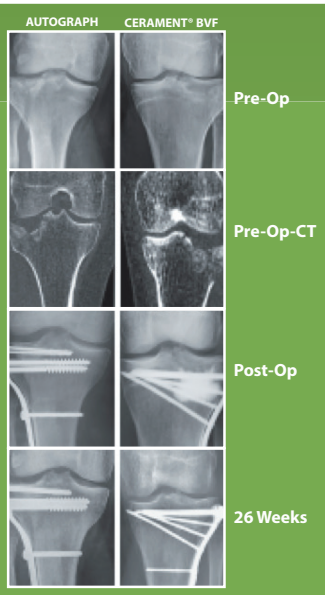
Journal of Bone and Joint Surgery American (2020)[1]

Author: Hofmann et al.

Level I non-inferiority study comparing CERAMENT to autograft in acute traumatic fractures of the proximal tibia.

RESULTS SHOWED CERAMENT:

- As good as autograft
- Proven bone remodeling
- Less post-op pain
- Less blood loss
- Trend towards shorter duration of surgery



PEDIATRIC EVIDENCE

Journal of Children's Orthopaedics (2020)[2]

Author: Dong et al.

Level III study of 38 patients (mean age 12.4) comparing CERAMENT and ChronOS in percutaneous treatment of active simple bone cysts.

RESULTS SHOWED CERAMENT:

- Better resorption rate (resorbed in 100% of cases vs. 76% with ChronOS)
- Lower recurrence, refracture and infection rates
- Faster healing
- Trend towards shorter duration of surgery

REFERENCES

1. Hofmann et al. Autologous Iliac Bone Graft Compared with Biphasic Hydroxyapatite and Calcium Sulfate Cement for the Treatment of Bone Defects in Tibial Plateau Fractures. J Bone Joint Surg Am. 2020 Feb 5;102(3):179-193.

2. Dong et al. Percutaneous cyst aspiration with injection of two different bioresorbable bone cements in treatment of simple bone cyst. Journal of children's orthopaedics vol. 14,1 (2020): 76-84. doi:10.1302/1863-2548.14.190155

Pediatric Case 1

Unicameral Bone Cysts (UBC)

15 year old male with a history of pathologic right calcaneus fractures

Technique:

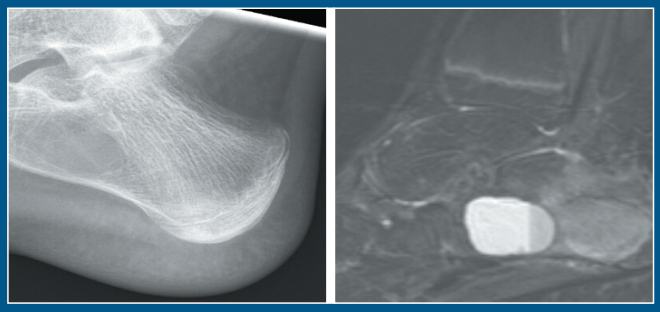
1. 5mm incision
2. 2.7mm drill bit to enter the cortex
3. Enter with 11ga Jamshidi
4. Aspirate and send to cytology
5. Curettage
6. Irrigate with normal saline followed by a 3-minute hydrogen peroxide soak. Irrigate again with saline.
7. Check cyst fill with 50% diluted Omnipaque
8. Fill with CERAMENT*

*BONESUPPORT recommends using a second ventilation cannula

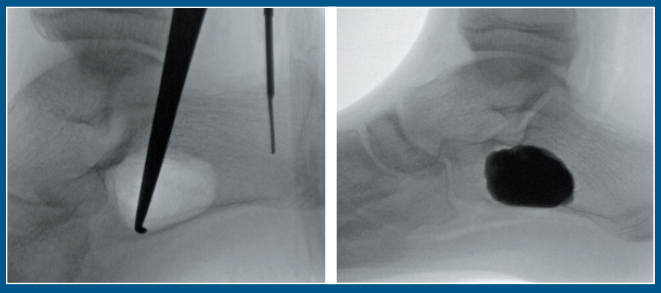
Outcome:

At 2 months post-op the patient was pain free and back to playing sports.

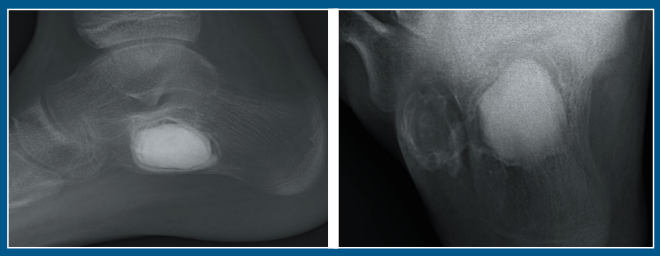
By 6 months post-op the CERAMENT has resorbed and bone remodeling is visible.



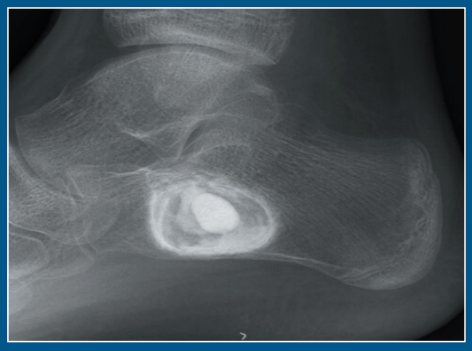
Pre-op



Intra-Op



2 Weeks Po-Op



2 Months Post-Op

6 Months Post-Op

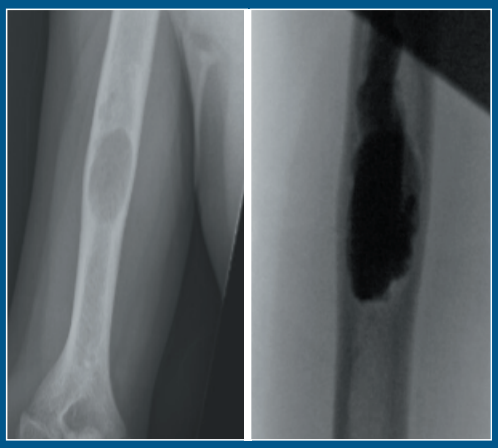
Credit: Alexandra Callan, MD

Pediatric Case 2

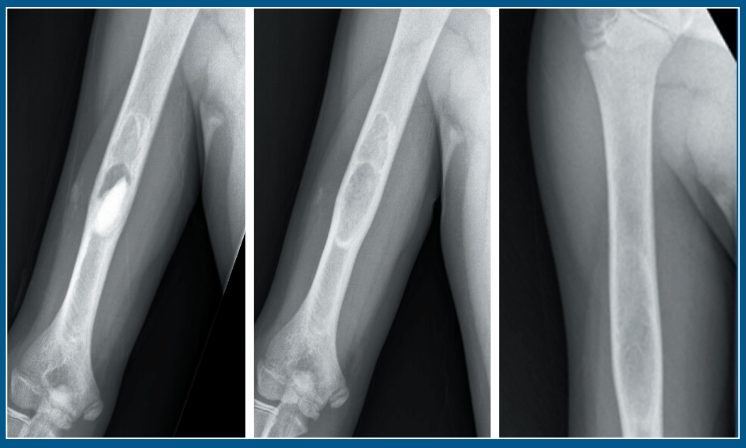
Unicameral Bone Cyst (UBC) + Pathologic Fractures with Pain

13 year old baseball pitcher with recurrent UBC and history of pathologic fractures

- At 4 weeks post-op, significant resorption of CERAMENT can be seen at the proximal aspect of the cyst.
- By 10 weeks post-op the CERAMENT has almost fully resorbed and the cyst is beginning to fill with trabecular bone.
- The patient is fully back to fast-pitch baseball by 6 months post-op.
- After 1 year the CERAMENT has fully remodeled to bone and there is no evidence of recurrence.



Pre-Op **Intra-Op**



4 Weeks Post-Op **10 Weeks Post-Op** **6 Months Post-Op**

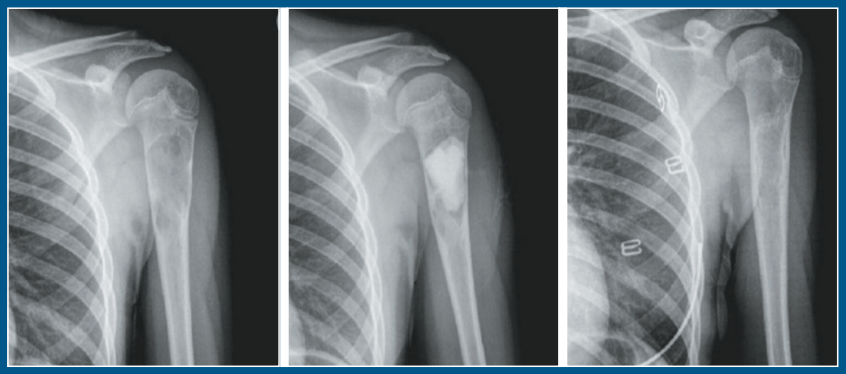
12 Months Post-Op

Credit: Alexandra Callan, MD

Pediatric Case 3

Unicameral Bone Cyst (UBC) of Humerus

- To minimize soft tissue leakage, a mini-invasive technique was used.
- 15mL of CERAMENT was injected using a two-cannula method; one for injection and a second for venting / negative pressure.
- To enable bone remodeling, proper contact with cancellous bone was ensured by spot-wise scratching of the epithelial lining with the tip of the needle until bleeding was seen in the saline.
- Full bone remodeling was achieved after 12 months.



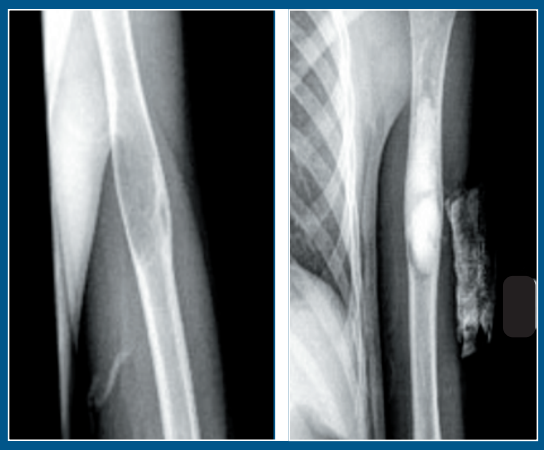
Pre-Op | **Post-Op (15 mL CERAMENT injected)** | **Full Bone Remodeling at 12 Months**

Pediatric Case 4

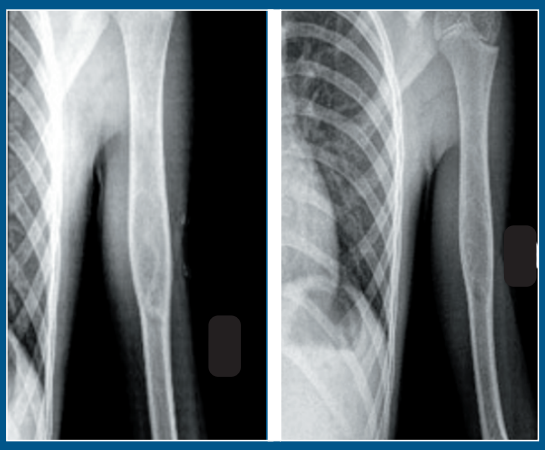
Unicameral Bone Cyst (UBC)

9 year old girl with UBC of Humerus

- Injected void with 18mL of CERAMENT BONE VOID FILLER.
- CERAMENT is clearly visible after surgery and at 4 months bone remodeling is seen throughout CERAMENT, which becomes more uniform until full remodeling is seen at 12 months.



Pre-Op | **Immediate Post-Op**



4 Months Post-Op | **12 Months Post-Op**

Credit: Kaczmarczyk J. et al. BMC Musculoskeletal Disorders 2015 and White Paper

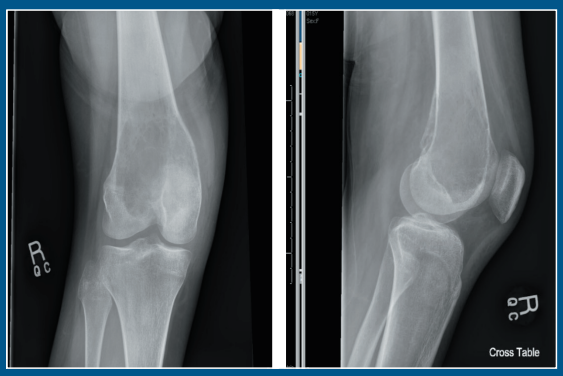
Pediatric Case 5

Giant Cell Tumor

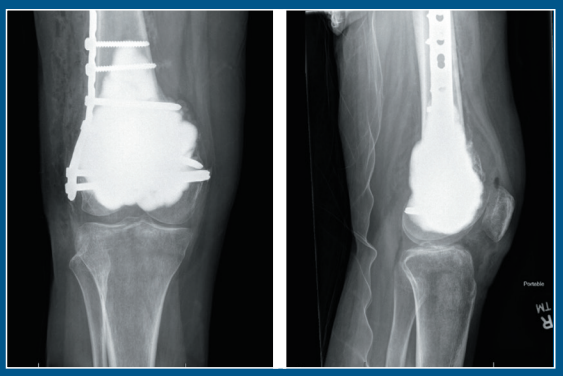
16 year old girl with Giant Cell Tumor of Right Distal Femur

- Pre-op images show extensive lesion extending into the epiphysis.
- Tumor was treated through curettage and margin expansion using an argon beam laser and hydrogen peroxide.
- Void was filled with 140cc of CERAMENT BONE VOID FILLER.
- Augmented with a lateral locking plate to provide structural support.
- Restricted weight-bearing and focused initially on range of motion.
- At 3 months, CERAMENT is beginning to resorb.
- At 7 months, CERAMENT is continuing to resorb and remodel to bone. Patient was pain free and able to weight-bear at this point.
- At 18 months, no further imaging due to patient long distant proximity. No evidence of recurrence.

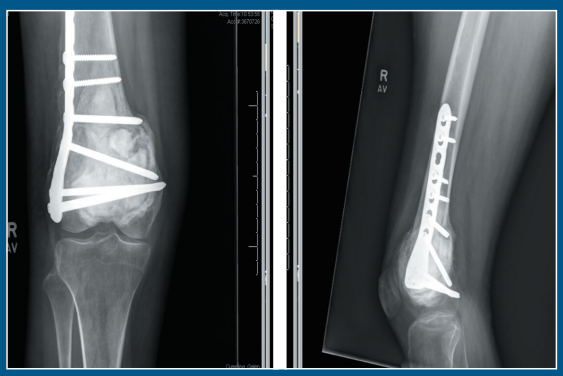
Pre-Op



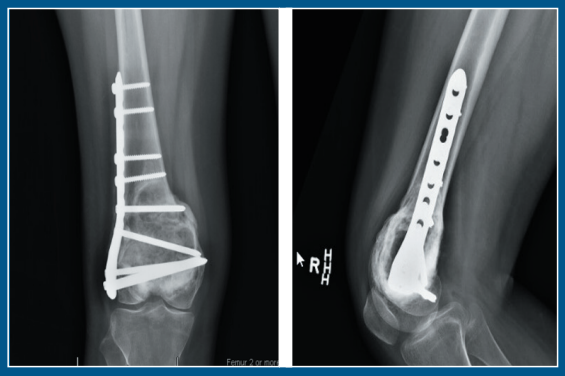
Post-Op



3 Months Post-Op

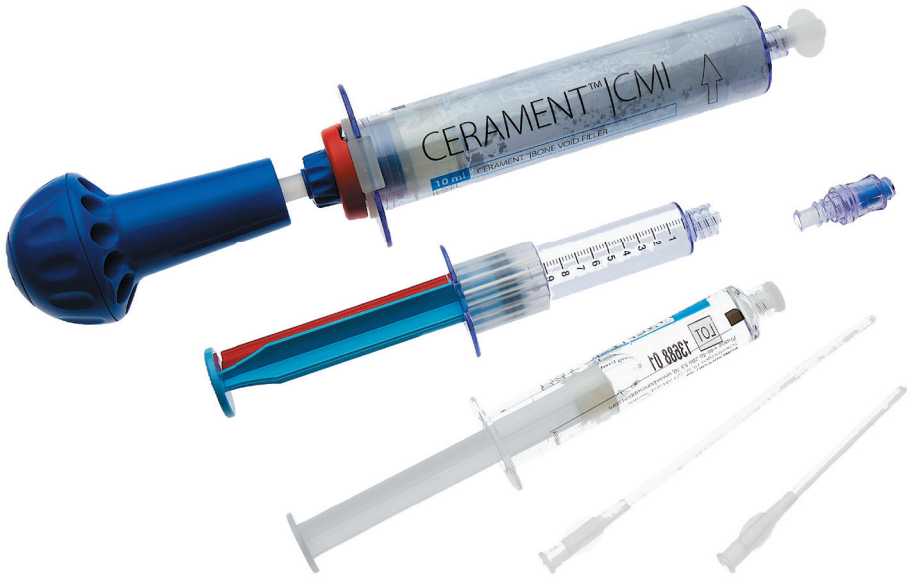


7 Months Post-Op

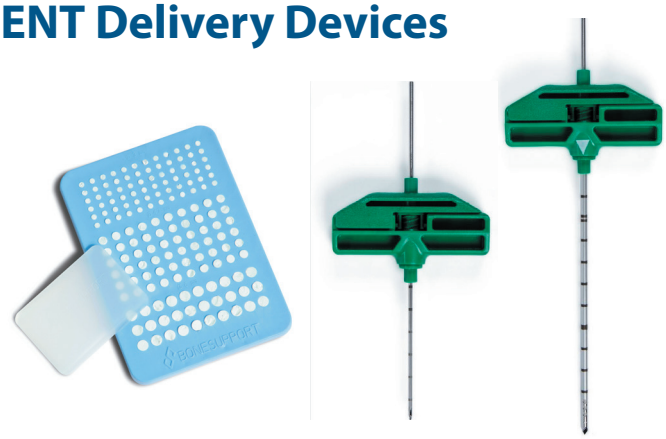


Credit: Judd E. Cummings, MD

CERAMENT® BONE VOID FILLER



CERAMENT Delivery Devices



ORDER NOW!

Product Description	Code
CERAMENT® BONE VOID FILLER 5 mL	A0210-09
CERAMENT® BONE VOID FILLER 10 mL	A0210-08
CERAMENT® BONE VOID FILLER 18 mL	A02-11
CERAMENT® BEAD TRAY	AO513
BONESUPPORT Delivery Cannula 11Ga x 120mm, closed tip, side port delivery	74389-01M
BONESUPPORT Delivery Cannula 15Ga x 60mm, open tip, end port delivery	74388-01M

TO ORDER

1.877.719.6718

US.SALES@BONESUPPORT.COM

BONESUPPORT™

BONESUPPORT, INC.,
60 William St, Suite 330
Wellesley, MA 02481

T: 1.877.719.6718
E: us.sales@bonesupport.com
W: bonesupport.com

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