Cortoss™
Bone Augmentation Material

Aliquot
Delivery System

Product Portfolio

Cortoss

2110-0008, Delivery Gun

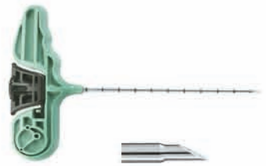
2101-0005, Cartridge, 5cc
2101-0010, Cartridge, 10cc
2101-0210, Cartridge, 20cc

2110-0031, Mix-tips, Luer, 3-pk

Aliquot

2090-0501, Syringe Delivery System, 4-inch
2090-0504, Syringe Delivery System, 6-inch
2090-0502, Plunger Delivery System, 4-inch
2090-0505, Plunger Delivery System, 6-inch

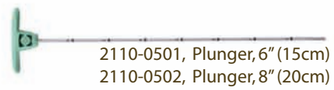
Not pictured:
2090-0503, Biopsy Kit
(Includes Catheter and Plunger)



2110-0505, 11-Gauge Beveled-tip Needle, 4" (10cm)
2110-0524, 11-Gauge Beveled-tip Needle, 6" (15cm)

2110-0506, 11-Gauge Diamond-tip Needle, 4" (10cm)
2110-0529, 11-Gauge Diamond-tip Needle, 6" (15cm)

2110-0513, Side-port Syringe, 1cc



2110-0501, Plunger, 6" (15cm)
2110-0502, Plunger, 8" (20cm)

2110-0503, Catheter, 6" (15cm)
2110-0526, Catheter, 8" (20cm)

2110-0504, Reamer, 6"
2110-0525, Reamer, 8"

2110-0507, Flexible Extension, 2", 3-pk

ORTHOVITA®
Architects of the New Biomaterials Age™

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Cortoss™
Bone Augmentation Material

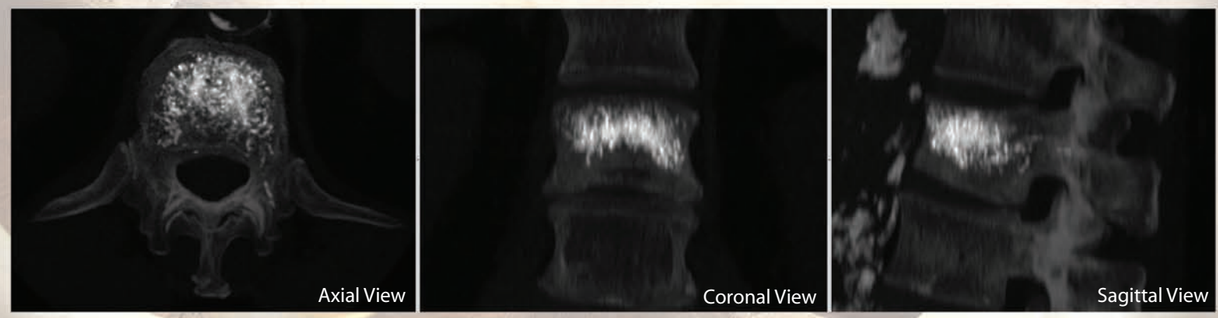
An Upgrade to the Everyday Experience

Clinically relevant evolution in vertebral compression fracture treatment.

	Cortoss	PMMA
Synthetic	√	√
Injectable	√	√
Non-resorbable	√	√
Methacrylate foundation	√	√
Optimzed for VCF	√	
Mimics cortical bone	√	
Bioactive*	√	
Mix-on-demand	√	
Start/stop delivery	√	

Cortoss has been clinically proven to meet or exceed the safety and effectiveness of Polymethylmethacrylate (PMMA) for vertebral augmentation:

- **Flow and Fill:** Advanced properties improve short-term pain and long-term function
- **Safety:** Fewer adjacent fractures**; no consequences from exotherm or volatile monomer
- **Control:** Unmatched flexibility with mix-on-demand and start/stop delivery
- **Data:** Unprecedented compilation of clinical support



CT images of Cortoss in a vertebral compression fracture.

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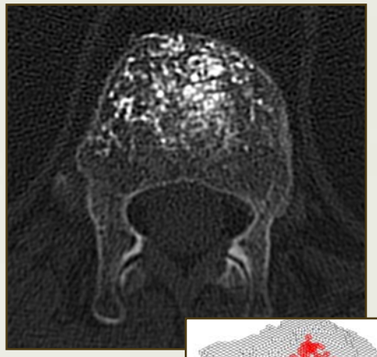
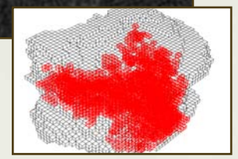
* The bioactive response of Cortoss has not been assessed in any clinical investigation and the results from laboratory or animal testing may not be predictive of human clinical experience.
** In patients with one level treated and no previous fracture.

Cortoss material properties create **flow** characteristics and **fill** patterns that improve procedural **safety** and **control**.



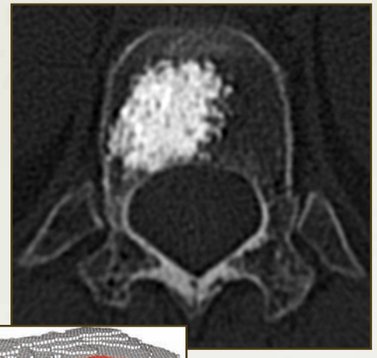


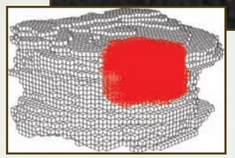
Cortoss augmentation with dispersed distribution. Fill simulation courtesy of Sun, K., et.al.[1]

Material Distribution

Compared to Polymethylmethacrylate (PMMA), Cortoss:

- Augments by conforming to and coating the framework of trabecular bone
- Flow promotes a dispersed and symmetric fill pattern
- Shows greater interdigitation and bone bonding properties
- More closely resembles cortical bone





PMMA augmentation with compact distribution. Fill simulation courtesy of Sun, K., et.al.[1]

Cortoss has been clinically proven to exceed the safety and effectiveness of PMMA with respect to[2]:

Injection Volume:
30% less material is required to achieve equivalent or better pain relief and functional outcome.

Adjacent Fracture:
The fill pattern provides a more physiologic transfer of loads resulting in a 43% reduction in subsequent adjacent fractures*.

Pain Reduction:
Greater improvement in pain scores at the pivotal 3-month time point.

Functional Outcome:
Better long-term (24-month) functional outcome.

Cortoss Pivotal IDE Study

Metric	Cortoss (n=162)	PMMA (n=94)
Injection Volume	2.3	3.5
Subsequent Fractures	10.3%	18.2%
Symptomatic Leaks	0.9%	0.8%
VAS Improvement† (3-month)	**86.6%**	**75.0%**
ODI Maintenance†	**96.7%**	**88.4%**

†Indicates statistically significant difference between Cortoss and PMMA. Data is reported at 24 months except as noted.

References:
1. Sun, K (et. al.), "Cement Filling Pattern Has A Significant Effect On Biomechanics of Vertebroplasty". 52nd Annual Meeting of the Orthopaedic Research Society, 2006.
2. Data from pivotal IDE study on file at Orthovita, Inc.

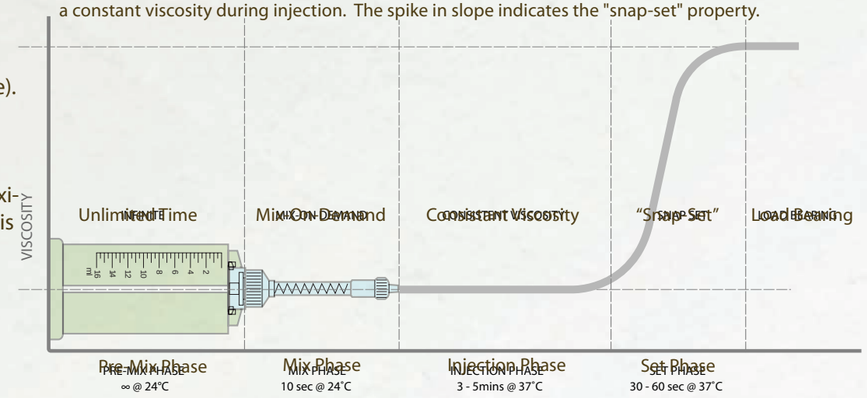
Indications: Cortoss is indicated for the fixation of pathological fractures of the vertebral body using vertebral augmentation procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

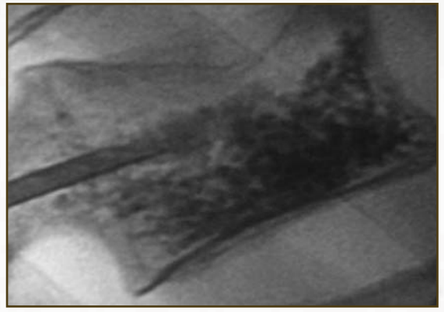
Intra-operative **control** takes on new meaning as the concepts of ***mix-on-demand*** and ***start/stop*** are introduced.

- Predictable viscosity for approximately 3 minutes at body temperature (up to 8 minutes at room temperature).
- "Snap-set" means immediate weight bearing. Physiologic compressive strength (approximately 75% of cortical bone) is achieved in as little as 15 minutes.
- No time constraints in the pre-injection phase.

Cortoss Viscosity Profile

As depicted in this graph, Cortoss is insensitive to time prior to injection and maintains a constant viscosity during injection. The spike in slope indicates the "snap-set" property.





Under fluroscopic guidance, the controlled interdigitated fill of Cortoss is evident.

Start/stop delivery provides greater procedural flexibility in the event that:

- ***A leak occurs or is about to occur*** - Because of the flow characteristics, Cortoss generates less inertia, which means that flow will stop quickly once the pressure of injection is released. The small amount of material at the site of the fissure will polymerize, effectively "sealing" the leak. The infinite pre-injection phase allows the operator to stay in control of the procedure rather than being controlled by the material. Further injection can commence at any time until an adequate fill is achieved.
- ***There is a need to reposition the needle to augment the fill*** - Fracture clefts quite often consume the majority of the injected material, with only sparse augmentation of the surrounding structure. With **start/stop** delivery, the injection can be terminated so the needle can be repositioned to the areas adjacent to the cleft, and then re-started.

In either case, Cortoss will build upon and bond to itself thereby eliminating any concerns about the stability of the final result.