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System Overview

Cortoss Bone Augmentation Material is an injectable, bioactive* composite material that mimics the mechanical properties of human cortical bone. The composite has a constant paste-like viscosity during injection and sets quickly to create a load-bearing implant. Post implantation, the bioactive glass components begin to create an environment that, in animal studies, has been proven to facilitate bone growth directly on the implant, as seen in Figure 1.¹

Cortoss is inherently hydrophilic, which enables it to coat and support the existing trabecular structure. Cortoss has been clinically proven to meet the standard set by the safety and effectiveness of PMMA for vertebral augmentation:

- **Flow and Fill:** Properties improve short-term pain and long-term function²
- **Safety:** Low incidence of adjacent fractures²; minimal exotherm³ and monomer release⁴
- **Control:** Procedural flexibility with mix-on-demand and start/stop delivery⁵
- **Data:** Robust compilation of clinical data⁵

The following technique guide illustrates how vertebral bodies can be augmented using Cortoss with the Aliquot Delivery System (supplied separately). Real-time biplanar fluoroscopy performed under strict sterile conditions is recommended for this procedure.

* 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.

Bone formation on surface in a rabbit at 8 weeks.¹
Cortoss Technique Guide  Cortoss Components

**Delivery Gun**
(holds cartridge and advances pistons to deliver Cortoss)

**Cortoss Cartridge**

**Mix-tip**
(delivery nozzle that blends the Cortoss pastes initiating the polymerization process)
Cortoss Technique Guide  Aliquot Components

**Cortoss Needle with Stylet**
(used to enter the vertebra)

**Micro-reamer**
(placed through Needle to create an access path for the Catheter)

**Catheter**
(placed through the Needle to deliver Cortoss)

**Plunger**
(placed through the Catheter to advance Cortoss into the vertebral body)

**Flexible Extension**
(connected between the Syringe and Catheter)

**1cc Side-port Syringe**
(connected to the Catheter to advance Cortoss into the vertebral body)

Open the Cartridge Door on the Delivery Gun.

Hold the Cartridge so that the numbered side faces up.

Note: The Cartridge Notch (arrow) opposite the numbered surface will engage the Delivery Gun.

Place the Cartridge, numbered side up, into the Delivery Gun and fully seat.
Close the Cartridge Door to lock the Cartridge in place.

Push the Piston Rack fully forward until the pistons stop within the Cartridge.

Remove the Cartridge Cap by rotating it one quarter turn in a counter-clockwise direction.

A gentle toggle of the cap may facilitate its removal.

Balance the plungers by slowly squeezing the trigger of the Delivery Gun to express a small amount of material from the Cartridge. Wipe any excess material from the end of the Cartridge.

Attach a Mix-tip to the Cartridge by aligning the v-spike on the Mix-tip with the corresponding v-notch on the Cartridge. Press the Mix-tip firmly against the Cartridge housing and rotate the lock ring one quarter turn clockwise until it meets its mechanical stop.

DO NOT SQUEEZE THE TRIGGER AT THIS STAGE.
Introduce the Needle with the correctly seated stylet into the vertebral body under fluoroscopic control. The exact path to be followed depends on whether a transpedicular or extrapedicular approach is employed. The penetration of the cortex may require a slight twisting motion or gentle use of a small mallet. Using the lateral fluoroscopic view, the Needle should be stopped just inside the vertebral body. Remove the Stylet once satisfied with the placement of the needle.

Insert the Micro-reamer into the Needle. Create a channel in the bone to facilitate Catheter placement by advancing and rotating the Micro-reamer within the Needle. Rotation of the Micro-reamer through at least 180° will ensure a complete channel. The shaft of the Micro-reamer is graduated and extends a maximum of 3cm beyond the tip of the Needle. Use caution not to perforate the anterior cortex of the vertebral body. Remove the Micro-reamer once channel has been created.

**Precaution:** When using Cortoss Bone Augmentation Material, take care to avoid breaching the endplates, anterior wall of the vertebral body and pedicle wall when placing the delivery needle and catheter. See Cortoss package insert.
Attach a 1cc Syringe to a Catheter to form a Syringe/Catheter assembly. Ensure that Syringe plunger is pulled back completely and in the locked position. If not locked, rotate 90°.

Use of a syringe greater than 1cc may make injection more difficult which may diminish control of the injection.

Alternatively, a Flexible Extension can be used (as shown) to reduce exposure to the radiographic beam.

Prime the Delivery System by attaching the Mix-tip to the Syringe side port and slowly squeezing the trigger until a small amount of material is expressed from the distal end of the Catheter. The Syringe and Catheter accommodate approximately 1cc and 0.7cc of Cortoss respectively.
Injecting Cortoss

After disengaging the Mix-tip, the Syringe/Catheter assembly is passed through the Needle and advanced to the most anterior point of the reamed path. A small amount of Cortoss is injected under fluoroscopic control while checking for leaks. Cortoss has a dispersed fill pattern and injections of 1cc or less are recommended.

**Warning:** Leaks can occur if the needle is located in a vein, if unseen micro-fractures are present, or if the injection occurs too close to a fracture line in the cortical shell. Leakage may cause tissue damage, and/or neurological or circulatory complications, including radiculopathy and pulmonary emboli. Injecting too much material (over-fill) or injecting the material too quickly may increase the risk of leakage. See Cortoss package insert.

When the anterior portion of the vertebral body is properly filled, slowly retract the Catheter toward the posterior wall of the vertebral body. Cortoss will fill the vertebra as this step is performed. If no leaks occur, the injection is continued until the desired fill has been achieved. Stop injecting Cortoss 1-3mm before the tip of the Catheter passes back into the needle.

**Warning:** If material does leak outside the vertebral body or in the circulatory system during the procedure, injection of the material should be stopped immediately. After the material hardens in the body after 2-4 minutes, delivery can be resumed if the physician determines the patient’s condition is suitable for additional injection. See Cortoss package insert.

When no leakage occurs but the injection of Cortoss through the initial Syringe takes more than 1.5 minutes after the preparation of the material, a small amount of Cortoss must be expressed from the Mix-tip before a second Syringe is filled. This ensures only freshly mixed Cortoss will be used and no unanticipated changes in setting times will occur.

Should Cortoss set in the Mix-tip or the Syringe/Catheter assembly, remove the item, discard it, and use a new one.

When using Cortoss, everyone involved in the procedure must be aware that Cortoss sets in 2-4 minutes at body temperature, 3.5-8 minutes at room temperature.

Average fill volume estimates:
- Thoracic level ~1.9cc’s
- Lumbar level ~2.6cc’s


Note: In order to prevent “pipe” formation, do not allow Cortoss to polymerize in the Catheter while in the body. Once the desired fill has been obtained, remove the Catheter from the Needle and replace the Stylet within the Needle prior to Cortoss hardening. If Cortoss has already polymerized, do not re-insert the Stylet. Rather, apply a gentle “twist and turn” of the Needle to break any connections between the Needle and the polymerized Cortoss. With the Needle removed, the soft tissue should be checked to ensure that material did not accumulate posterior to the vertebral body.

Alternatively, Cortoss can be delivered using the Plunger Delivery System.

Prime the Delivery System by attaching the Mix-tip directly to the Catheter and slowly squeezing the trigger to express a small amount of material from the distal end of the Catheter. The Catheter accommodates approximately 0.7cc of Cortoss.

After disengaging the Mix-tip, place the Catheter inside the Needle. Insert the Plunger into the Catheter and proceed with delivery as described previously.

Once Cortoss has polymerized, immediate full weight bearing is possible. Physiologic compressive strength, approximately 75% of cortical bone, can be achieved within 15 minutes.
Cortoss can be readily visualized on radiographic imaging because of the inherent radiopacity of the material. Visualization of the material is evident during the procedure under fluoroscopic guidance, and post-procedure on standard radiographs. 

Anterior (AP) x-ray showing the diffuse fill pattern of Cortoss.

Magnetic Resonance Image (MRI) with clear visualization of the implant.

Axial Computed Tomographic (CT) scan illustrating the dispersed and symmetrical distribution.
# Cortoss Technique Guide

## Product Portfolio

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Cortoss Bone Augmentation Material: Instructions for Use (IFU) 5334-0007 Rev. 03.

Actual fill volume depends on flow pattern and degree of compression.


Clinical Report 1100-0017 Rev. 00.

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