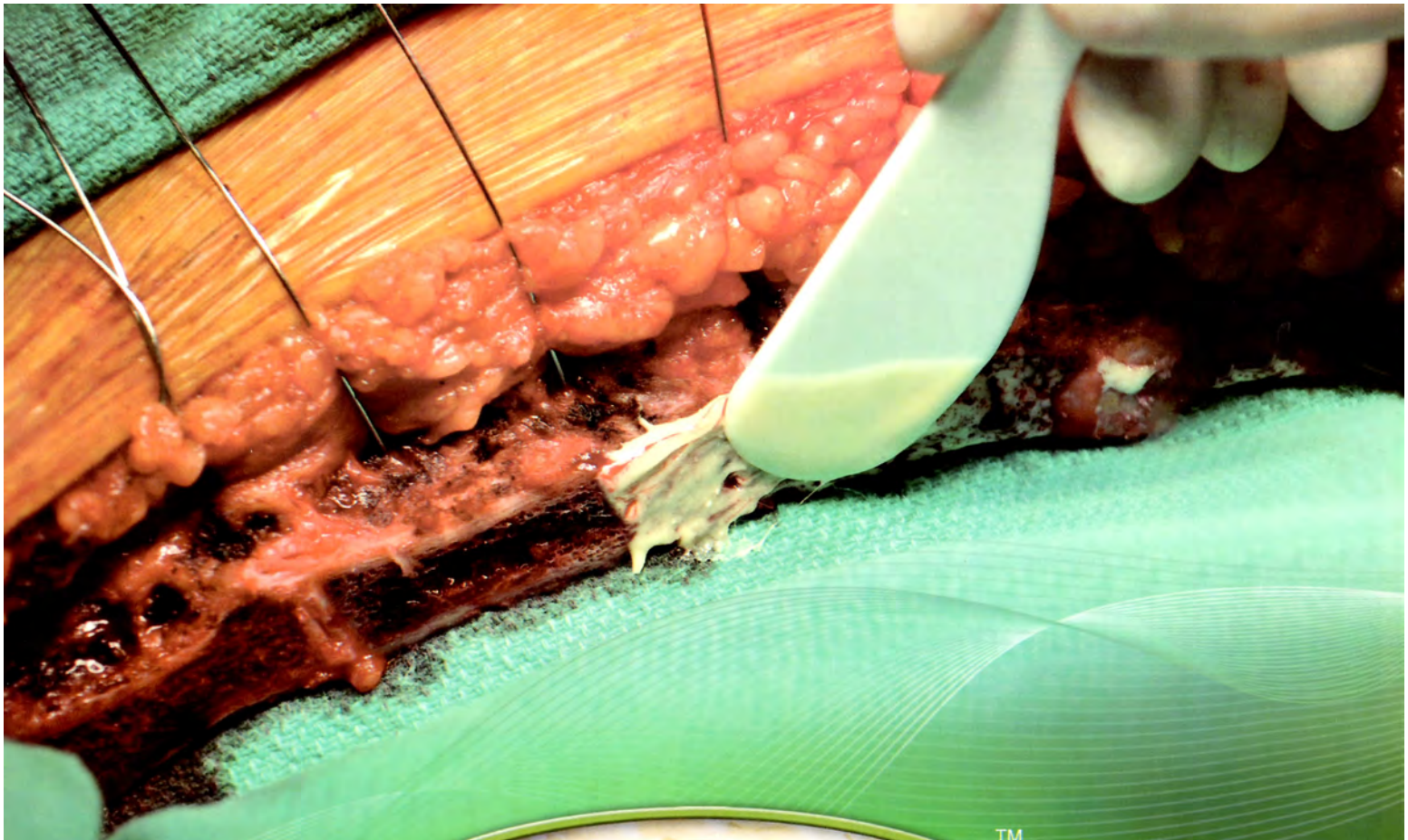

Kryptonite™

Sternal Closure System

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Surgical Technique Guide for Sternal Closure

using Kryptonite™ Osteoconductive Adhesive

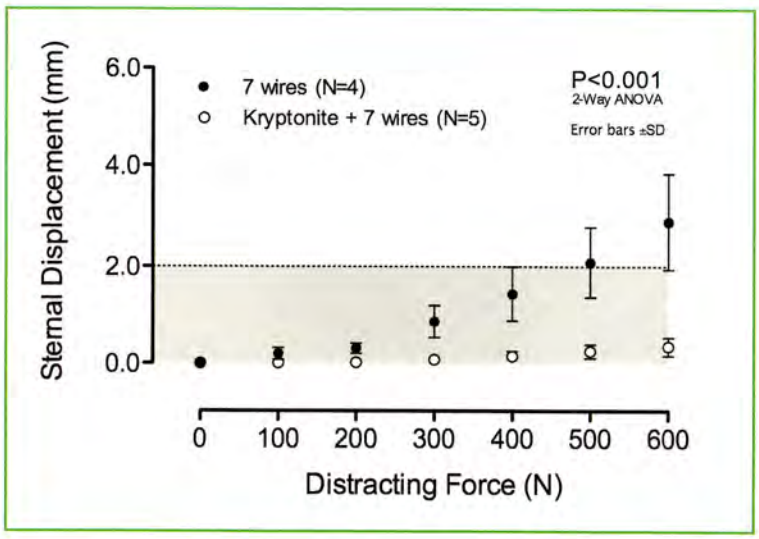
Intended for International Distribution Only

Introduction

Kryptonite™ Sternal Closure System

This guide provides an overview of the surgical technique for repairing a median sternotomy using the Kryptonite™ Sternal Closure System and is not intended as a substitute for training. Training is available through your local sales representative. See package insert for additional information. The contents of this manual are only a guide and are not intended to set a standard of care.

The Kryptonite™ Sternal Closure System gives the patient a mechanically unified, solid, stable sternum at 24-48 hours post-sternotomy. Repairing a median sternotomy with the Kryptonite™ Sternal Closure System reduces the motion measured between the sternal halves compared to wiring alone.[1]



1. Fedak P, Kolb E, Borsato G, et al., 2010. Kryptonite Bone Cement Prevents Pathologic Sternal Displacement. Ann Thorac Surg. 90: 979-85.

Kryptonite™ Sternal Closure System

The Kryptonite™ Sternal Closure System enhances a traditional multi-wire sternotomy repair by incorporating a structural adhesive to substantially reduce or eliminate post-operative motion between the sternal halves. Application of the cement takes only minutes.

The system comprises:

- 5 cc kit of Kryptonite™ Osteoconductive Adhesive
- Sterile brush for preparing the bone surfaces

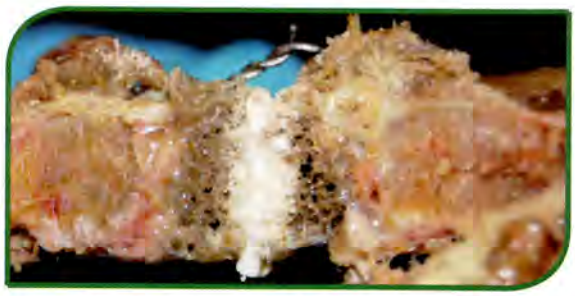
Kryptonite™ Osteoconductive Adhesive

Kryptonite™ OA is adhesive, osteoconductive, non-toxic, possesses bone-like mechanical properties, and is composed of castor oil based polyols, a reactive component and calcium carbonate. It is provided in three component parts that are mixed in the operating room and applied to the surgical site as a viscous liquid, an adhesive taffy or a moldable putty. When fully polymerized the material takes a porous, rigid structure that allows osseointegration.




Adhesive to Bone – Reactive components within Kryptonite™ Osteoconductive Adhesive allow it to chemically bond to bone, providing a secure and permanent interface.

Osteoconductive – The polymerization process releases carbon dioxide, forming internal pores in the range of 50 to 300 µm in diameter, which comprise approximately 50% of Kryptonite™ Osteoconductive Adhesive's final volume. Animal studies have shown that bone grows onto and into this porous structure[1] and that localized osteoclast activity resorbs the material and provides further access for bone growth.[2]



Cadavar Sternum held together with Kryptonite™Osteoconductive Adhesive

Mimics Cancellous Bone – In mechanical testing, the porous structure of Kryptonite™ Osteoconductive Adhesive mimics the stiffness and strength of healthy cancellous bone.

Low Exotherm – The material reaches a peak temperature of approximately 43°C (110°F) during its polymerization. A low exotherm can substantially reduce the risk of local tissue necrosis during polymerization.

Non-toxic – The biocompatibility, safety and stability of Kryptonite™ Osteoconductive Adhesive has been evaluated in accordance with FDA/ISO10993 guidelines and the product was found to be non-toxic and safe to use with no special precautions for either the patient or the operating room staff.

1. Adams DJ, Barreo M, Jiang X, Rowe DW, "Persistent osteoconductivity of calcium triglyceride bone cement in osteoporotic bone", Transactions of the 54th Annual Meeting of the Orthopedic Research Society, San Francisco, Mar 2-5, 2008, 33:1711.
2. Data on file at Doctors Research Group.

Surgical Technique

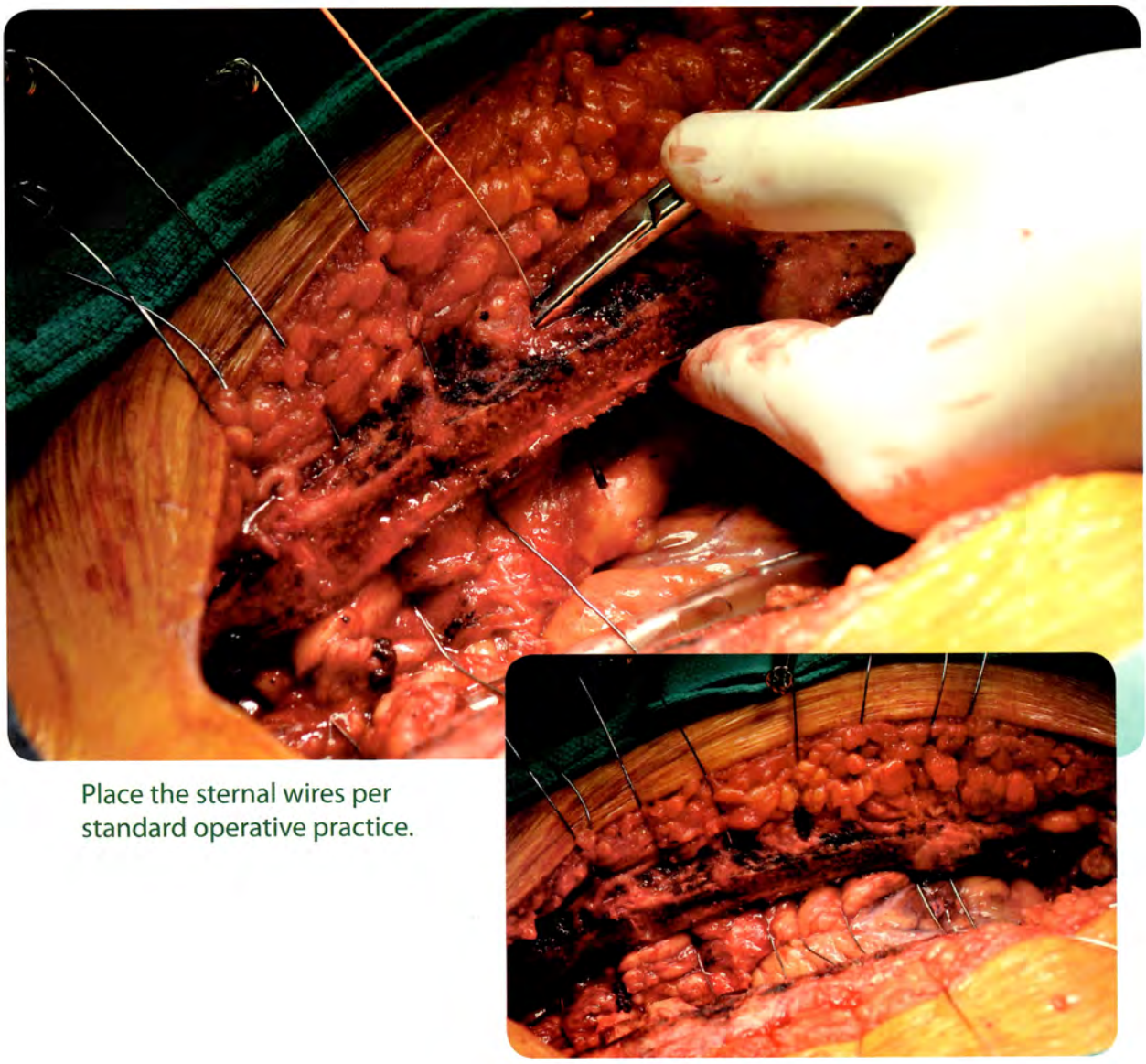
Step 1: Place Sternal Wires

Place 6-8 sternal wires trans-sternally or para-sternally using standard technique.

STERNAL WIRES MUST BE USED.

- *Kryptonite™ Osteoconductive Adhesive requires at least 24 hours to fully polymerize. Application without sternal wires may not provide adequate fixation to maintain stability.*

- *The safety and efficacy of using fewer than 6-8 wires has not been tested and is not advised.*



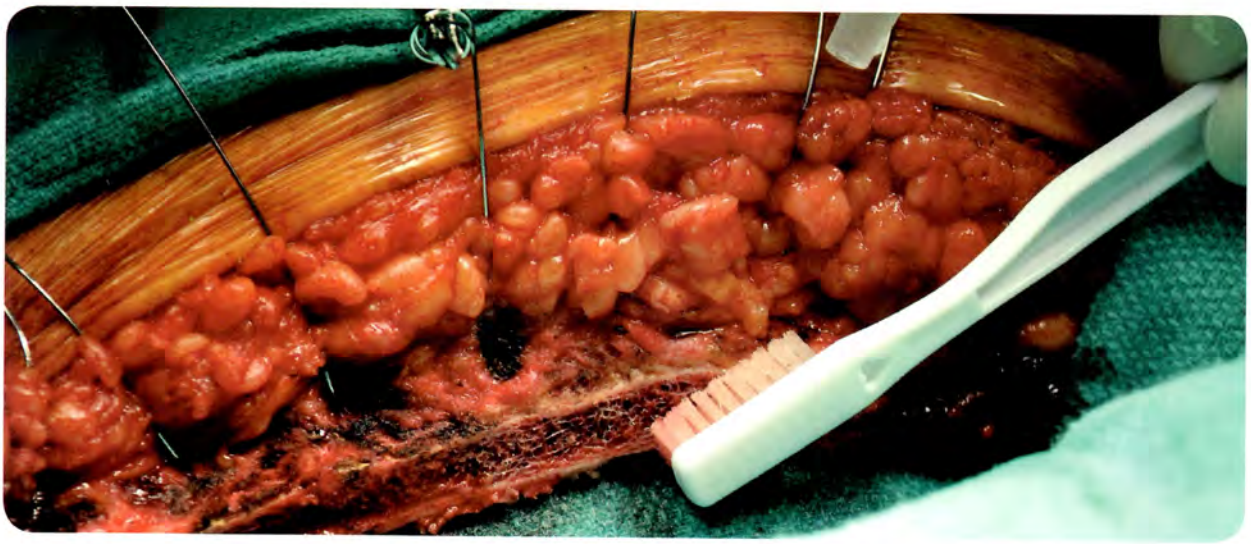
Place the sternal wires per standard operative practice.

Step 2: Clean and Dry Bone Surfaces

Use the sterile brush and saline irrigation to clean the cut surfaces of the sternal halves and expose the inner trabeculae. Then thoroughly dry the surfaces with a sponge or gauze.

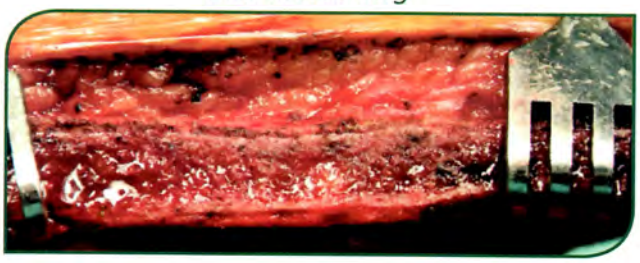
- *Exposing the trabeculae enhances penetration and adhesion of the cement.*
- *Avoid bone wax and other haemostatic agents as they may limit the adhesive potential of Kryptonite™ Osteoconductive Adhesive.*
- *Consider cautery to manage bleeding.*
- *Maintain a dry field. Contaminants (blood, fat or saline) may compromise adhesion and final mechanical properties of the cured cement.*

In cases of excessive bleeding, Kryptonite™ Osteoconductive Adhesive should not be used. Instead, close the chest using standard wire closure .



Clean the bone

Before cleaning



After cleaning

Step 3: Prepare the Kryptonite™ Osteoconductive Adhesive

Dispense components A, B and C into the mixing dish and start a timer. Mix until a homogeneous consistency is achieved (approximately 1 minute). Then allow the material to prepolymerize in the mixing dish for 3 additional minutes.

- *Allow the components to reach room temperature prior to use.*
- *Dispense entire contents of syringes and glass vial.*
- *Mixing order does not matter.*
- *Fully incorporate all of the powder and break up clumps larger than 1 mm with the spatula.*

Note the time that you start mixing.

Insufficient mixing

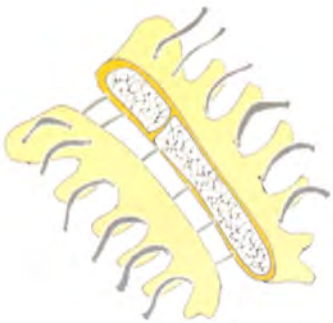
Fully mixed

Step 4: Apply the Kryptonite™ Osteoconductive Adhesive

Use the spatula to apply a thin layer of Kryptonite™ OA to the cancellous bone surfaces along the entire length of both sternal halves.

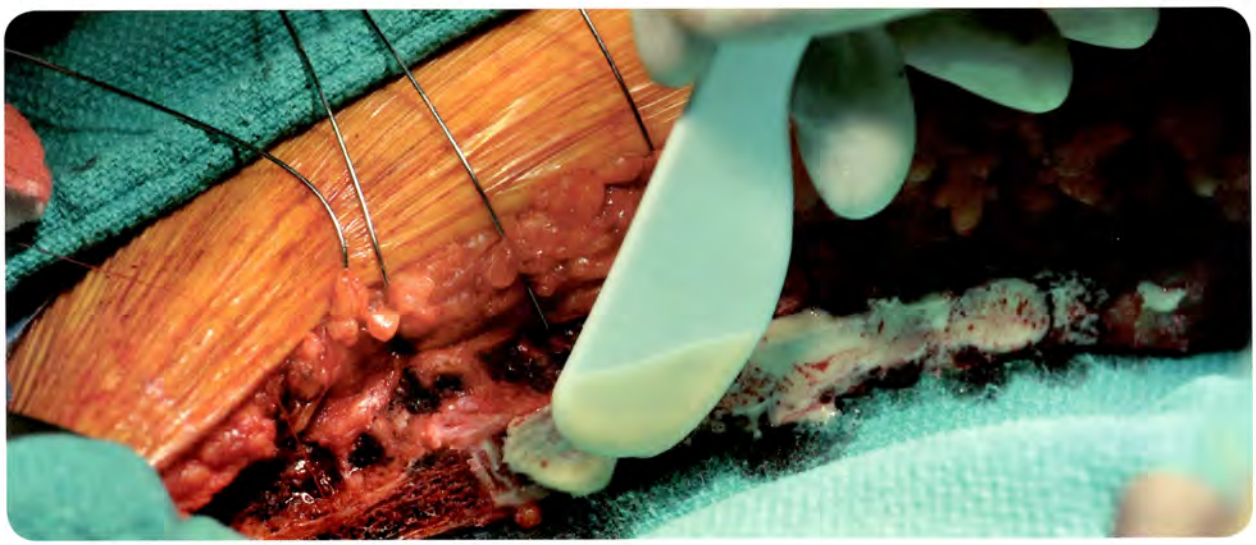
- *Begin to apply the material at 4 minutes. Application should be completed by 6 minutes. Application prior to 4 minutes may allow material to flow off of sternal bone.*
- *The 5 cc volume of material should be split evenly between the two sternal halves.*
- *'Less is More' - The material will expand in situ, so only a thin layer of material is required. In some cases less than 5 cc is appropriate and in other cases with large gaps (e.g. osteoporosis, trauma) more than 5 cc may be appropriate (use clinical judgment).*

Note: Kryptonite™ Osteoconductive Adhesive can adhere to plastic chest tubes. Strategies to reduce this risk include placing anterior mediastinal tube away from underside of sternum or applying a layer of gelfoam between the sternum and chest tube.



Wires in place and cancellous bone clean and dry

Thin layer of cement applied to both cut surfaces



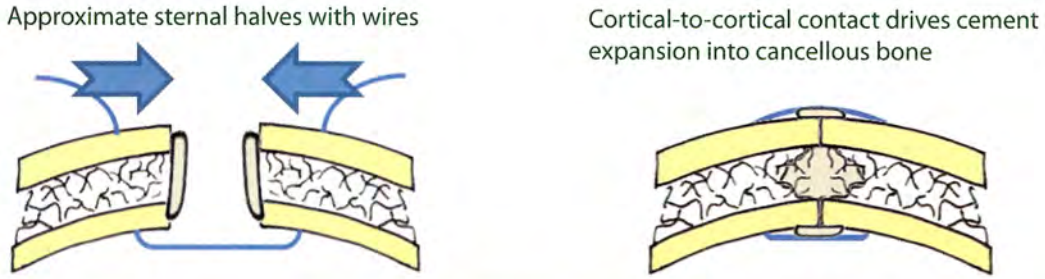
Apply the Kryptonite™ Osteoconductive Adhesive

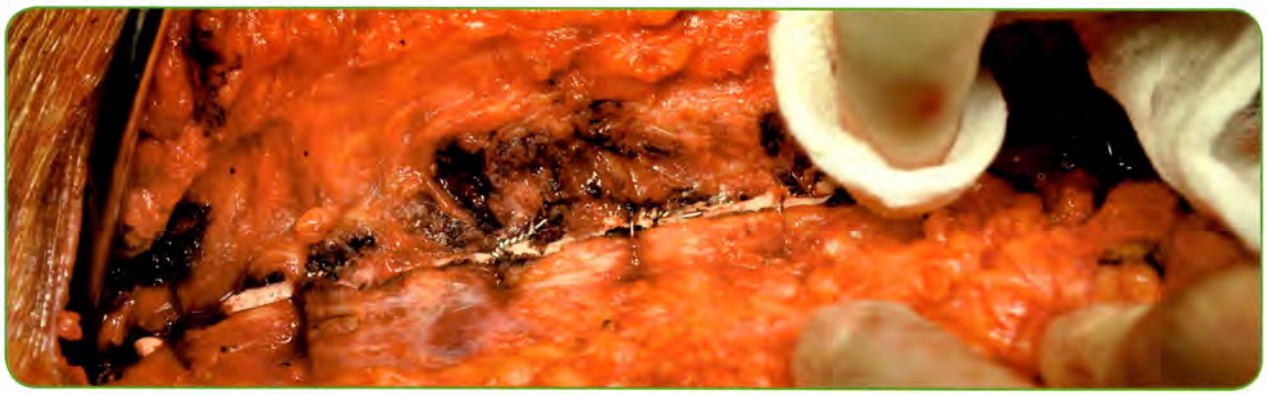
Step 5: Close the Sternum

Approximate the bone edges by tightening the sternal wires using standard technique.

- *Tighten the wires sufficiently to displace cement from between the cortical-to-cortical contact surfaces.*
- *Work quickly to achieve cortical-to-cortical contact, so as expansion occurs, the cement is driven into the cancellous bone.*
- *Use a sponge to remove excess material along the anterior surface of the sternum.*
- *Coating the anterior surface with Kryptonite™ Osteoconductive Adhesive is not recommended as it does little to enhance construct stability.*

Note: After the case immediately clean instruments coated with Kryptonite™ Osteoconductive Adhesive with alcohol or acetone.





Remove excess Kryptonite™ Osteoconductive Adhesive

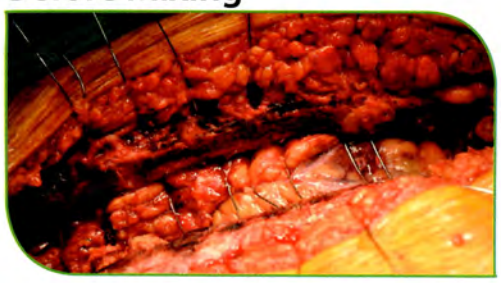
Step 6: Post-Op Care Considerations

In addition to the chemical adhesion to bone, Kryptonite™ Osteoconductive Adhesive will expand into the trabeculae to form a solid mechanical interlock . This expansion occurs over the first hour of product use. The material will take at least 24 hours to fully polymerize.

Emergency Re-entry: For the first 1-2 hours after closure the chest may be opened by cutting the wires and pulling the sternal halves apart. After several hours it will be necessary to use a sternal saw. A sterile sternal saw should be made available in the ICU. Education of ICU staff is warranted.

Mixing and Surgical Technique Overview

Before Mixing

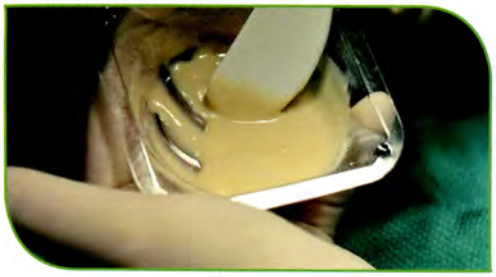


Place 6-8 sternal wires.

0-1 Minute

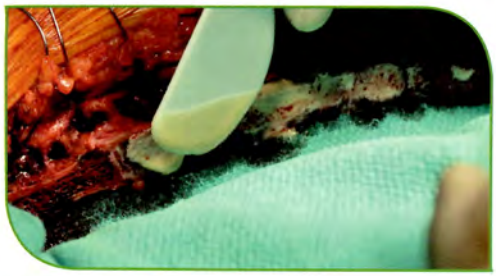
Empty component "C" into the bowl and add components "A" and "B". Mix until lumps are gone.

1-4 Minutes



Let mixture stand for initial polymerization or load into a delivery system.

4-6 Minutes



Liquid Phase: Apply KRYPTONITE™ Osteoconductive Adhesive to the sternum.

After Application

Close the sternum using standard technique.

Product Codes

Kryptonite™
Sterile · Non-radiopaque · With Calcium Carbonate

5cc	KRYP-Z-05
10cc	KRYP-Z-10

Kryptonite™ Sternal Closure System
Sterile · Non-radiopaque · With Calcium Carbonate · Sterile Brush

5cc	KRYP-SC-Z-05

Kryptonite™ X Radiopaque
Sterile · Radiopaque · With Calcium Carbonate and Barium Sulphate

5cc	KRYP-X-05
10cc	KRYP-X-10

Kryptonite™ 2X Radiopaque
Sterile · Radiopaque · With Barium Sulphate Only

5cc	KRYP-2X-05
10cc	KRYP-2X-10

Kryptonite™ Precision Delivery Syringe
Sterile · Threaded for Pressurized Delivery · 10cc Volume

Delivery Syringe	KRYP-DS

Kryptonite™ Mixing System
Sterile · Enclosed Mixing and Loading System · 40cc Maximum Capacity

Mixing System	KRYP-MM

Kryptonite™ Demo Kit
Non-sterile · Non-radiopaque · With Calcium Carbonate

Demo	KRYP-A-3

Product availability may be limited in certain areas.

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Kryptonite™

KRYPTONITE™ material has received a CE mark for use in Europe as a self-setting bone filler for bony voids or gaps that are not intrinsic to the stability of the bony structure. KRYPTONITE™ material is a resinous material for the repair of bony defects that may be shaped and gently applied to cranial defects. KRYPTONITE™ material has regulatory clearance in Australia (TGA) and in Canada (Health Canada Approved). KRYPTONITE™ material has obtained marketing authorization from the United States Food and Drug Administration as a bone cement with indications for use as a resinous material for filling cranial defects.

Kryptonite™ material has not been approved for sternal closure in the United States or Canada.

EC REP

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