



acumed®

Callos® Bone Void Filler and Autograft Extender

Manufactured by Skeletal Kinetics®

Surgical Technique



A COLSON ASSOCIATE

Acumed® is a global leader of innovative orthopaedic and medical solutions.



We are dedicated to developing products, service methods, and approaches that improve patient care.



Callos® Bone Void Filler and Autograft Extender, Manufactured by Skeletal Kinetics®

Callos Bone Void Filler is a synthetic calcium phosphate cement. It offers high compressive support for host bone that has been compromised.¹ Synthetic calcium phosphates form a scaffold to allow bony ingrowth to occur through a cell-mediated remodeling process. In the cell-mediated remodeling process whereby host bone gradually replaces the synthetic calcium phosphate along with adjacent bone.² Callos Bone Void Filler exhibits high compressive strength throughout the remodeling process.³

Callos Bone Void Filler is radiopaque to facilitate its use during surgery. This allows proper placement in the reduced fracture and ensures the cancellous defect has been completely filled. Once mixed and placed into the bone void, it can be contoured to fill the defect. Callos Bone Void Filler does not "wash out" and is designed to set quickly in a warm, aqueous environment. In addition, Callos permits drilling and hardware insertion. Callos Bone Void Filler can be drilled and inserted with a screw to facilitate its use with hardware when treating periarticular fractures.

Indications for Use

Callos Bone Void filler is indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Callos Bone Void Filler is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The product provides a bone void filler that resorbs and is replaced by bone during the healing process.

	Definition
Warning	Indicates critical information about a potential serious outcome to the patient or the user.
Caution	Indicates instructions that must be followed in order to ensure the proper use of the device.
Note	Indicates information requiring special attention.

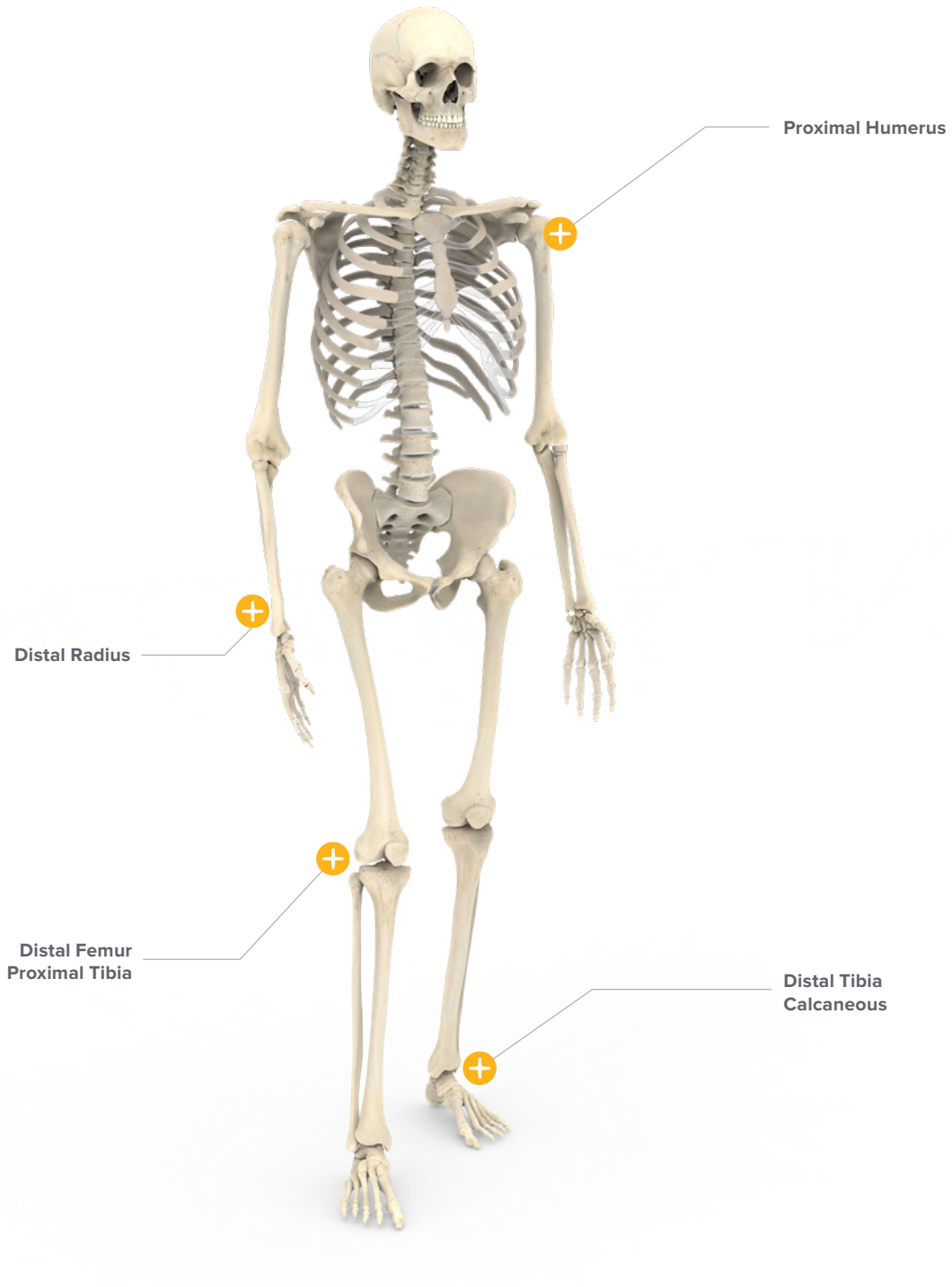


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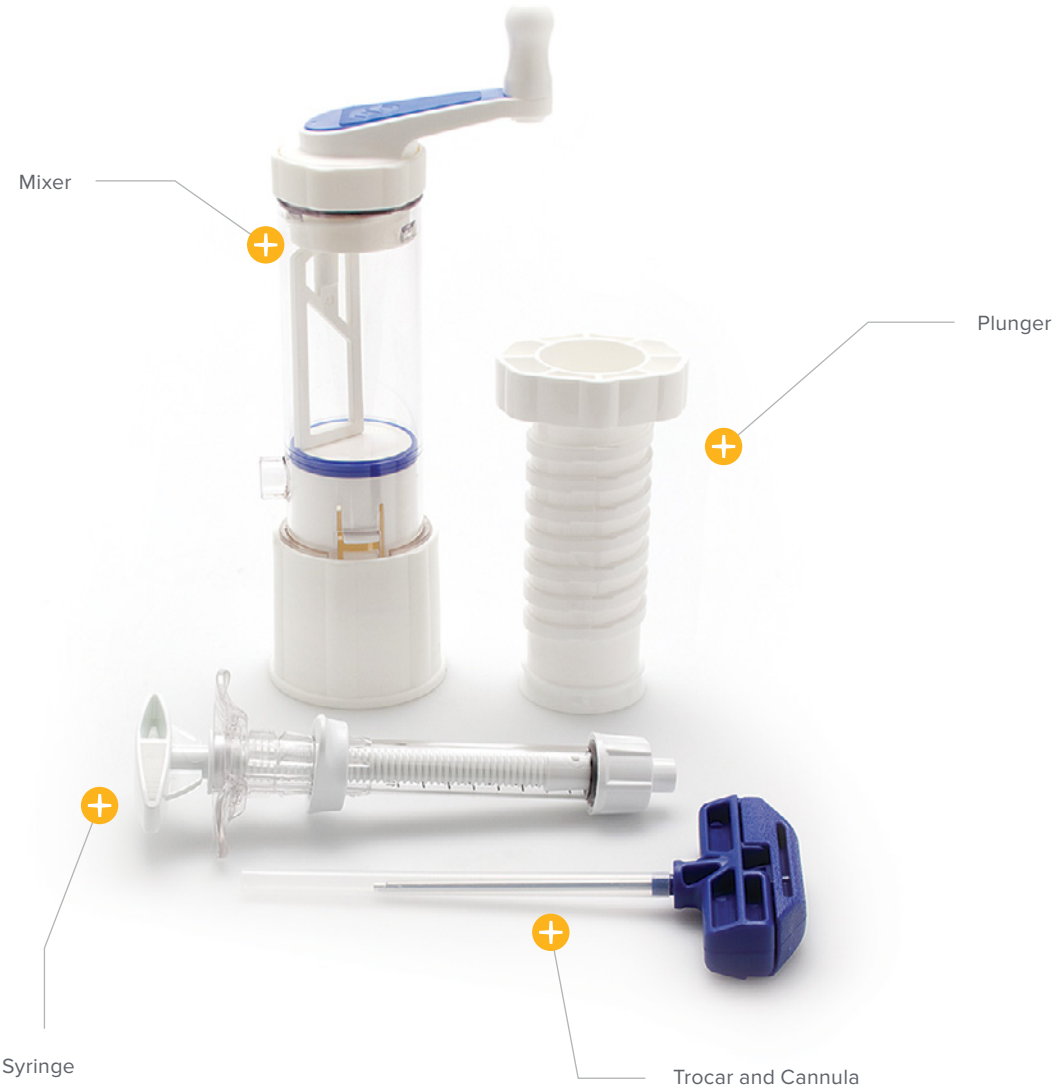
System Features

Potential Uses



System Features [continued]

Callos Inject Kit



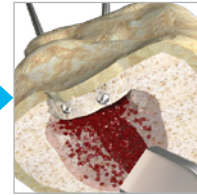
Surgical Technique Overview

Callos Basic
Surgical Technique

Fracture
Assessment
and Planning



Reduction and
Stabilization



Callos Impact
Mixing Instructions

Preparing Materials



Mixing Materials



Removal from
Mixer



Callos Inject
Mixing Instructions

Preparing Materials



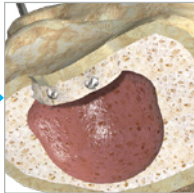
Mixing Materials



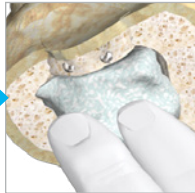
Preparation for
Dispensing



Void Preparation



Callos Implantation



Syringe Attachment



Preparing Bone Void Filler for Injection



Injection



Callos Basic Surgical Technique

1 Fracture Assessment and Planning

Preoperatively assess the fracture's characteristics. Determine the approximate volume of Callos needed based on the predicted shape and location of the fracture void after reduction.



Figure 1

2 Reduction and Stabilization

Reduce and stabilize the intraarticular and extraarticular fracture fragments. Visually verify fracture reduction with an appropriate imaging technology.

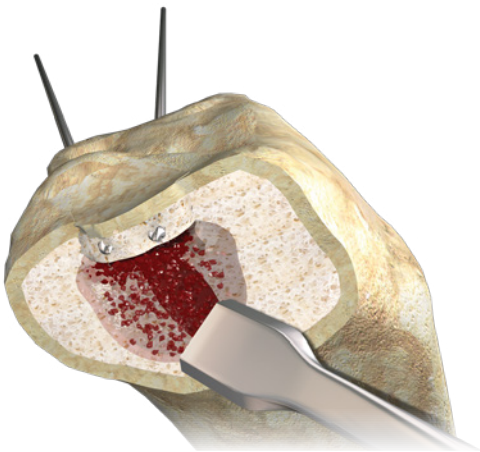


Figure 2

Callos Basic Surgical Technique [continued]

3 Void Preparation

Proper fracture reduction and void preparation are important to provide an optimal cement fill. To assure optimal fill, the fracture void should be irrigated and debrided to remove any clots, organized tissue, and/or loose bone debris.

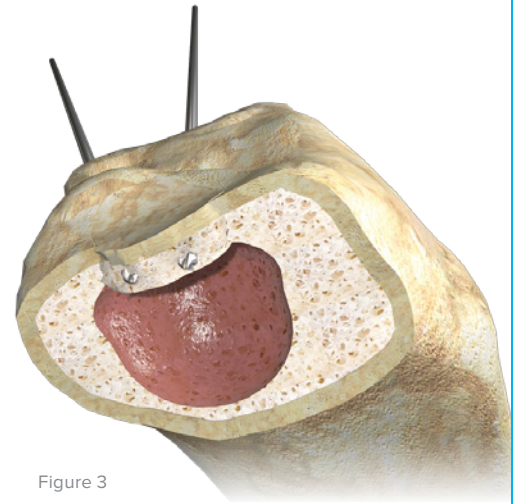


Figure 3

4 Callos Implantation

After mixing Callos Bone Void Filler according to the appropriate instructions and timing charts, inject or impact Callos Bone Void Filler into the reduced fracture void.

With Callos Inject, best practice is to inject the product in a retrograde fashion, filling the void from back to front.

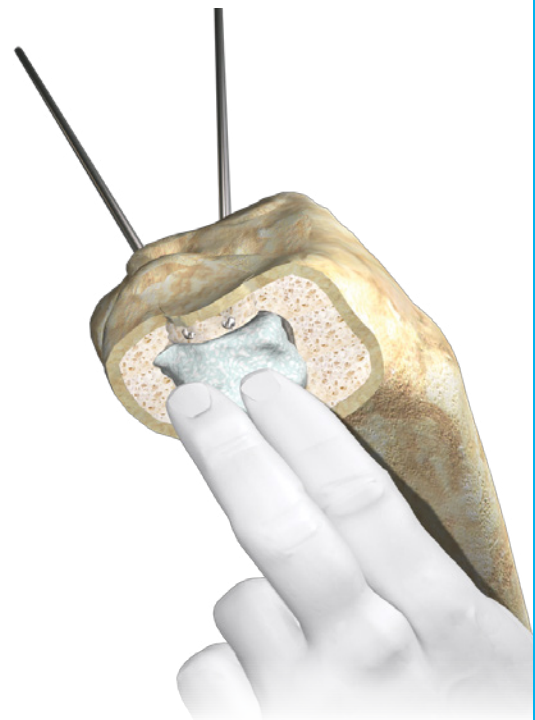


Figure 4

Callos Impact Mixing Instructions



Figure 1



Figure 2

1 Preparing Materials

Unpack all components of the Callos Impact kit. Ensure the base of the mixer is rotated all the way up by rotating clockwise until the blue line is above the side port. Unscrew the top of the mixer and pour Callos Bone Void Filler liquid first into the mixing chamber. Second, pour Callos Bone Void Filler powder into the mixing chamber.



Figure 3

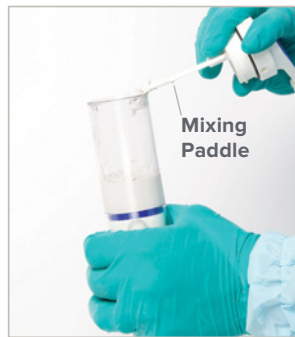


Figure 4

2 Mixing Materials

Screw the top of the mixer back on and rotate the handle briskly in a clockwise direction for 1 minute (100+ revolutions). Remove the top from the mixer and scrape the mixed Callos Bone Void Filler on the mixing paddle back into the mixer.

Caution: Do not mix with left hand (counterclockwise) this cause the base to loosen from the mixing chamber.



Figure 5



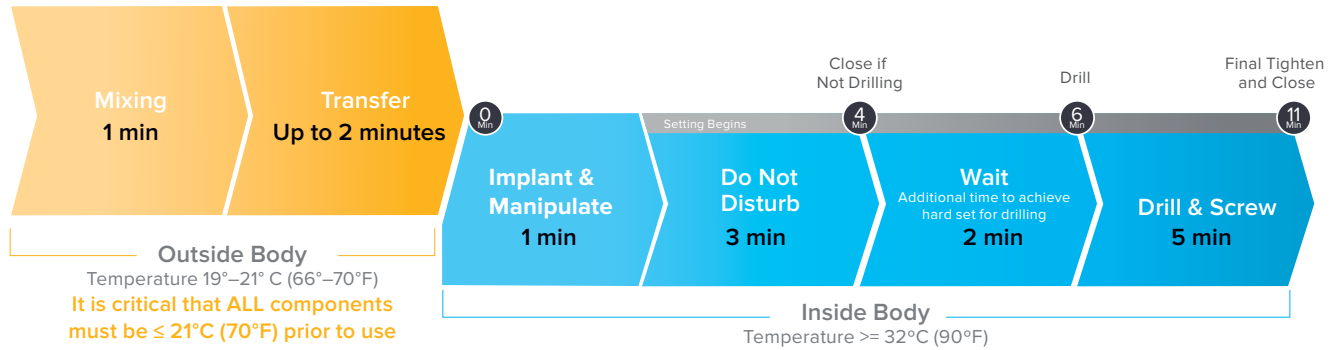
Figure 6

3 Removing Bone Void Filler From Mixer

Use the spatula to scoop Callos Bone Void Filler out of the mixer, scraping the sides of the mixer with the straight edge of the spatula. Form the putty into the desired shape. Callos is now ready for placement into a bone void. Follow Callos Bone Void Filler timing charts for working time during and after mixing.

Callos Impact Mixing Instructions [continued]

Callos Impact Timing Chart



Operating Room Guidelines

Temperature:

- ▶ Operating room temperature should be between 19°–21°C (66°–70°F).
- ▶ The temperature of the Callos powder and liquid inside the vials should be less than or equal to 21°C (70°F).
- ▶ Callos needs warm body temperature (above 32°C/90°F) and a wet environment (e.g. blood) to set properly.
- ▶ If the tourniquet cannot be lowered, apply warm (body temperature) saline over the Callos or on the wet lap sponges covering the Callos area.
- ▶ Higher temperatures will speed up setting.
- ▶ Lower temperatures will slow down the setting.

Drilling Callos

- ▶ Drill only after the hard setting period (see Timing Chart).
- ▶ Drills must be fluted or threaded.
 - Caution:** Do not drill Callos with K-wires.
- ▶ Do not force drill into Callos; let the drill do the work.
- ▶ Allow an additional five minutes after initial screw insertion before final two-finger tightening of screws.

Callos Inject Mixing Instructions



Figure 1



Figure 2

1 Preparing Materials

Unpack all components of the Callos Inject kit. Ensure the base of the mixer is rotated all the way up by rotating clockwise until the blue line is above the side port. First, unscrew the top of the mixer and pour Callos Bone Void Filler liquid into the mixing chamber. Second, pour Callos Bone Void Filler powder into the mixing chamber.



Figure 3



Figure 4

2 Mixing Materials

Screw the top of the mixer back on and rotate the handle briskly clockwise for 1 minute (100+ revolutions). Remove the top from the mixer and scrape the mixed Callos Bone Void Filler on the mixing paddle back into the mixer.

Caution: Do not mix with left hand (counterclockwise). This will cause the base to loosen from the mixing chamber.



Figure 5



Figure 6

3 Preparation for Dispensing Into Syringe

Rotate the base of the mixer counter-clockwise all the way into the down position. The bottom of the base will be at the halfway line of the port. Insert the plunger and rotate down clockwise until the Callos Bone Void Filler starts extruding out of the port.



Figure 7



Figure 8

4 Syringe Attachment

Remove the cap from the syringe. Attach the syringe to the port on the mixer.

Callos Inject Mixing Instructions [continued]

5 Dispensing Bone Void Filler Into Syringe

Rotate the plunger down clockwise to extrude Callos Bone Void Filler into the syringe. Do not grip the body of the syringe while rotating the plunger during extrusion. Remove syringe from port and reattach cap.



Figure 9



Figure 10

6 Preparing For Bone Void Filler Injection

Remove the trocar from the cannula. Attach the cannula to the syringe. Callos Bone Void Filler is now ready for placement into a bone void. Follow Callos Bone Void Filler timing charts for working time during and after mixing.

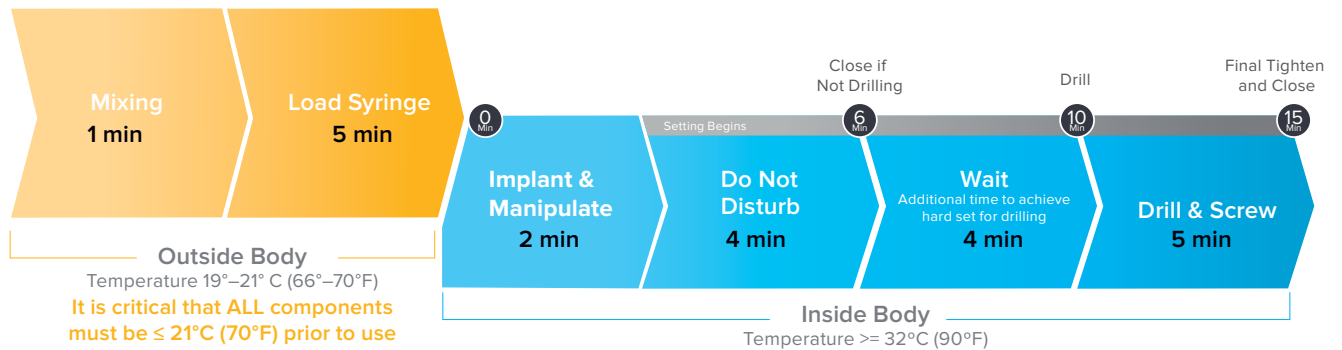


Figure 11



Figure 12

Callos Inject Timing Chart



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Temperature:

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Ordering Information

Callos Bone Void Filler			
Callos Inject 3 cc Sterile	65-0003-S	Callos Impact 5 cc Sterile	65-0105-S
Callos Inject 5 cc Sterile	65-0005-S	Callos Impact 10 cc Sterile	65-0110-S
Callos Inject 10 cc Sterile	65-0010-S		

Note: To learn more about the full line of Acumed innovative surgical solutions, please contact your authorized Acumed distributor, call 888.627.9957, or visit www.acumed.net.

References

1. McDonald E, Chu T, Tufaga M, et al. Tibial plateau fracture repairs augmented with calcium phosphate cement have higher *in situ* fatigue strength than those with autograft. *J Orthop Trauma*. 2011;25(2),90-95.
2. Barrere F, van Blitterswijk CA, de Groot, K. Bone regeneration: molecular and cellular interactions with calcium phosphate ceramics. *Int J of Nanomedicine*. 2006;(3):317-332.
3. Yetkinler D, Delaney D, Constantz B. In vitro and in vivo evaluation of two calcium phosphate cements. *Orthop Res Society Trans*. 2004;29.



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