

Surgical Technique





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.



ProModel® Bone Void Filler

ProModel Bone Void Filler is a synthetic bone graft made from a proprietary matrix of calcium phosphate, calcium sulfate and pore-generating fillers that is indicated for bone voids or gaps of the skeletal system that are not intrinsic to the stability of the bone structure. ProModel Bone Void Filler resorbs and is replaced by bone during the healing process. In an animal study conducted on sheep, the addition of the calcium sulfate to calcium phosphate provided a more porous construct at 4 and 12 weeks assessment, while still maintaining the structural geometry of the implant.¹

ProModel Bone Void Filler undergoes two stages en route to remodeling into natural cancellous bone. The first stage, approximately 15 to 60 days after implantation, consists of dissolution of the porogens, resulting in a macroporous calcium phosphate construct.¹ During this stage, the macropores allow the patient's natural bone remodeling cells (osteoclasts and osteoblasts) a greater surface area to begin remodeling the product into bone. The second stage consists of cell-mediated remodeling of this macroporous calcium phosphate construct and can take 12 to 24 months.¹

Indications for Use

ProModel is indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, posterolateral spine, and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. ProModel 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.

1. Skeletal Kinetics, Technical REP# 12088-AC, An in vivo evaluation of Calcium Phosphate-Calcium Sulfate Bone Void Filler, Delaney, D; He, K; April 2012 (submitted for publication).

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ProModel Inject® Mixing Instructions

1 PREPARATION OF MATERIALS

Unpack all components of the ProModel 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. Unscrew the top of the mixer and pour ProModel Bone Void Filler liquid first into the mixing chamber. Second, pour ProModel Bone Void Filler powder into the mixing chamber.



2 MIXING OF MATERIALS

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



3 PREPARATION FOR DISPENSEMENT INTO SYRINGE

Rotate base of mixer counter clockwise all the way into the down position. Insert plunger and rotate down clockwise until the ProModel Bone Void Filler starts extruding out of the port.



4 SYRINGE ATTACHMENT

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



5 DISPENSING BONE VOID FILLER INTO SYRINGE

Rotate plunger down clockwise to extrude ProModel Bone Void Filler into syringe. Remove syringe from port and reattach cap.

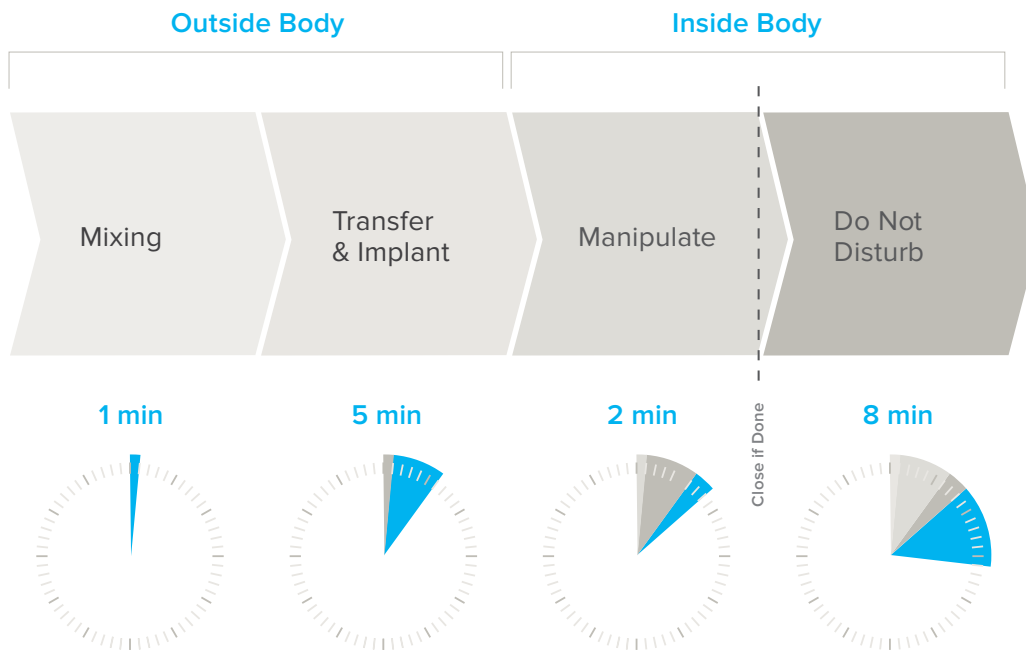


6 PREPARATION FOR BONE VOID FILLER INJECTION

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



ProModel Inject® Timing Chart



ProModel Impact® Mixing Instructions

1 PREPARATION OF MATERIALS

Unpack all components of the ProModel 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. Unscrew the top of the mixer and pour ProModel Bone Void Filler liquid first into the mixing chamber. Second, pour ProModel Bone Void Filler powder into the mixing chamber.



2 MIXING OF MATERIALS

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

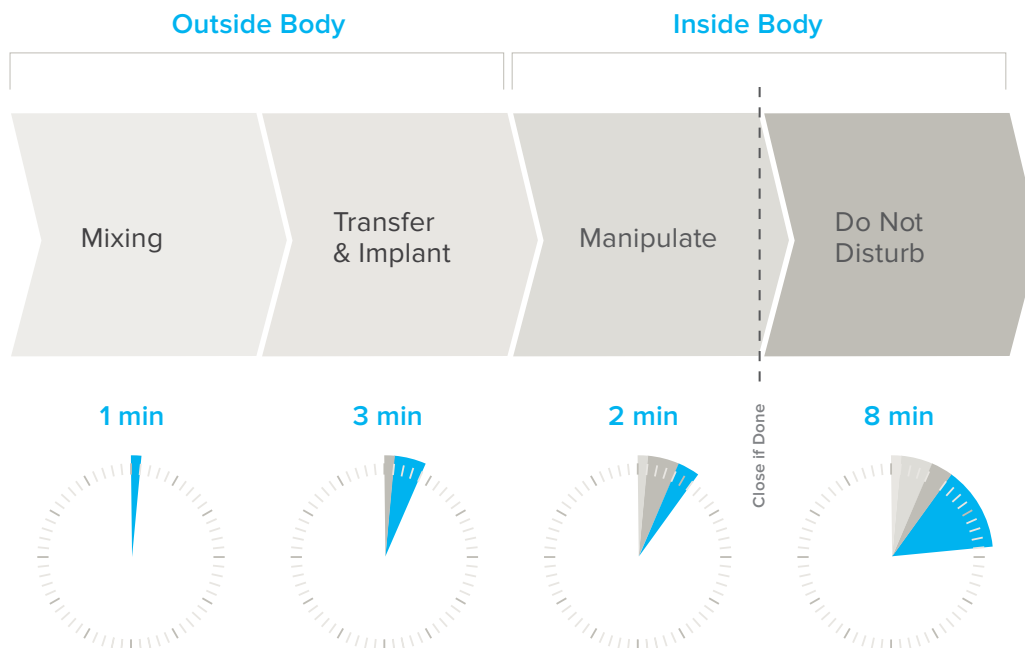


3 REMOVAL OF BONE VOID FILLER FROM MIXER

Use spatula to scoop ProModel Bone Void Filler out of the mixer. Form putty into desired shape. ProModel is now ready for placement into a bone void. Follow ProModel Bone Void Filler timing charts for working time during mixing.



ProModel Impact® Timing Chart



ProModel® Basic Surgical Technique



1 FRACTURE ASSESSMENT AND PLANNING

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



2 REDUCTION AND STABILIZATION

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



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.



4 IMPLANTATION OF PROMODEL

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

Ordering Information

ProModel®

ProModel® Inject® 5 cc Sterile	65-1005-S
ProModel® Inject® 10 cc Sterile	65-1010-S
ProModel® Impact® 5 cc Sterile	65-1105-S
ProModel® Impact® 10 cc Sterile	65-1110-S



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