



PRO-DENSE™ Bone Graft Substitute

Mixing Instructions

150839-2

The following language is included in this packet: English (en)



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***The CE-Marking of Conformity is applied per catalog number and appears on the outer label, if applicable.**



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NOTE: Do not add any additional substances to the graft. Using alternative mixing solutions and/or adding other substances to the mixture may alter the safety and effectiveness of this product. Some substances, such as bone marrow and blood, will prevent the graft from setting.

Preparation of Implant Site and Accessories

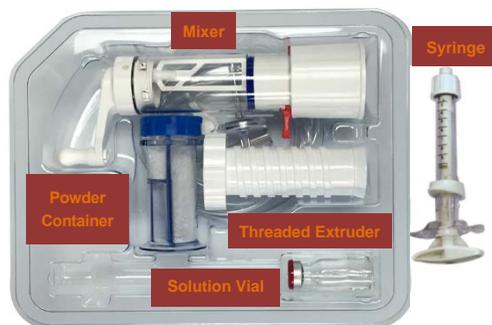
1. (OPTIONAL) Use bender (where supplied) to curve needle, allowing for precise material placement. There are two bending channels. HIGH: aggressive curvature, LOW: gentle curvature.

2. Pre-place needle in defect under fluoroscopic guidance.

3. Remove top from mixer and add all powder and solution.



4. Replace top and attach vacuum hose to the vacuum port. (Optional)



5a. **MIX** approximately 50 revolutions in 30 seconds (in one direction).



5b. **STOP** mixing and wait approximately 30 seconds before starting step 5c



5c. **MIX** approximately 25 revolutions in 15 seconds (in one direction).

Note: Inject paste in 3-5 min.



6. Disconnect vacuum hose (if connected), remove top, and scrape excess.



7. Remove red tab and rotate white base counterclockwise to expose syringe port.



8. Holding the mixer on its side, insert threaded extruder at an angle until completely seated and advance threaded extruder until graft just begins to enter syringe port as shown.



9. Remove syringe cap from the delivery syringe and press fit syringe barrel in a vertical orientation.



10. While holding mixer on its side, continue rotating/advancing extruder until syringe is full. Disconnect syringe and reconnect syringe cap.

(Note: For 20cc Kit, immediately repeat steps 9-10)



11. Dock syringe to pre-placed needle. Begin injecting with steady thumb pressure. **Avoid overfilling or pressurizing the treatment site.**

(Note: If injection becomes too difficult, see steps 11a-11b)



For Mechanical Assist:

11a. Slide and snap white collar to activate twist mechanism.

11b. Twist handle of plunger clockwise to continue injecting.



Note: The graft will set in ~ 20 – 30 min.