

PRO-DENSE® Bone Graft Substitute Mixing Instructions

135703-3

The following languages are included in this packet:

English (en) Deutsch (de) Nederlands (nl) Français (fr)
Español (es) Italiano (it) Português (pt) 中文-Chinese (sch)

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



PRO-DENSE® Bone Graft Substitute (135703-3)

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.



4. Add **all** powder.



6. Replace top and attach vacuum hose to the vacuum port.



5. Add all solution.

7. Mix vigorously, approximately 50 revolutions in 30 seconds (one direction).

8. Disconnect vacuum hose, remove top, and scrape excess.

Note: Inject paste in 3-5 min.



10. Rotate white base to expose the syringe port.





9. Remove red tab.

11. Holding mixer on its side, insert threaded extruder at angle until completely seated.



12. Holding mixer on its side, advance threaded extruder until graft just begins to enter the syringe port as shown.



- 13. Remove syringe cap from delivery syringe.
- 14. Press fit syringe barrel in a vertical orientation.



- 15. While holding mixer on its side, continue rotating/advancing extruder until syringe is filled.
- 16. Disconnect syringe and reconnect syringe cap. (Note: For 20 cc Kit, immediately repeat steps14-17 for additional syringe.)





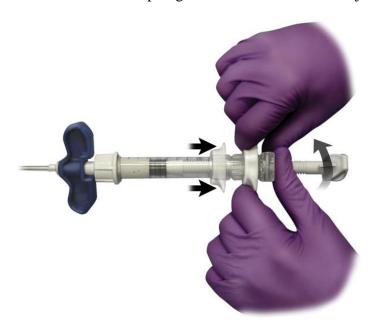
17. Dock syringe to pre-placed needle. Begin injecting with steady thumb pressure. Avoid overfilling or pressurizing the treatment site. **Note:** If injection becomes too difficult, see steps 18a-18b.



For Mechanical Assist:

18a. Slide and snap white collar to activate twist action.

18b. Twist handle of plunger clockwise to continue injecting.



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

NOTE: Residual material may be left in syringe. The amount of remaining material is relative to user's adherence to the mixing and ejecting times outlined in these instructions.

CAUTION: The paste should be allowed to set prior to definitive hardware placement. Do not disturb while curing.