



PRO-DENSE™ BONE GRAFT SUBSTITUTE

MIXING INSTRUCTIONS

150836-1

The following languages are included in this packet:

English (en)	Deutsch (de)	Nederlands (nl)	Français (fr)
Español (es)	Italiano (it)	Português (pt)	Türkçe (tk)

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Then click on the **Prescribing Information** option.

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CE 0086*

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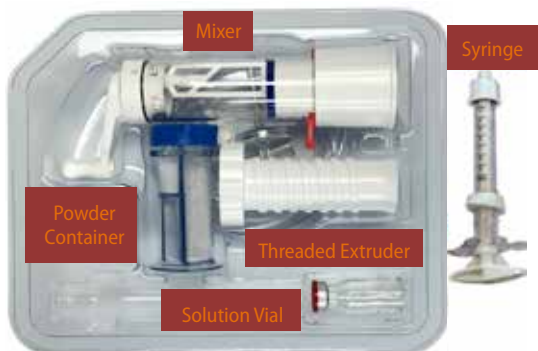
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Rx ONLY

Jan 2017
Printed in U.S.A.



PRO-DENSE™ BONE GRAFT SUBSTITUTE (150836-1)

EN

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, effectiveness and setting of this product.

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.

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.