



**ALLOMATRIX™ INJECTABLE PUTTY, ALLOMATRIX™
CBONE PUTTY, ALLOMATRIX™ CUSTOM BONE
PUTTY, ALLOMATRIX™ DR BONE PUTTY,
AND ALLOMATRIX™ RCS BONE PUTTY**

**MIXING INSTRUCTIONS
150828-1**

The following languages are included in this packet:

English (en)

Deutsch (de)

Nederlands (nl)

Français (fr)

Español (es)

Italiano (it)

Português (pt)

Turkce (tk)

For additional languages, visit our website www.wright.com.

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

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contact the manufacturer or local distributor.**



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**ALLOMATRIX™ INJECTABLE PUTTY, ALLOMATRIX™ C BONE
PUTTY, ALLOMATRIX™ CUSTOM BONE PUTTY, ALLOMATRIX™
DR BONE PUTTY, AND ALLOMATRIX™ RCS BONE PUTTY**

MIXING INSTRUCTIONS

(150828-1)

FOR SPECIFIC PRODUCT INFORMATION

- A. ALLOMATRIX™ INJECTABLE PUTTY
- B. ALLOMATRIX™ C BONE PUTTY AND ALLOMATRIX™ RCS BONE PUTTY
- C. ALLOMATRIX™ CUSTOM BONE PUTTY
- D. ALLOMATRIX™ DR BONE PUTTY
- E. ALLOMATRIX™ DR BONE PUTTY OR ALLOMATRIX™ CUSTOM BONE PUTTY AS A SPINE GRAFT EXTENDER

NOTE: Do not add any substances to the putty that are not recommended within these mixing instructions. Using alternative mixing solutions and/or adding other substances to the mixture may alter the safety and effectiveness of this product.

A. ALLOMATRIX™ INJECTABLE PUTTY



- 1) Using sterile technique with gloves, empty powder into the mixing bowl.



- 2) Empty mixing solution into the bowl. If using the optional nozzle attachment, and for easier injection, add extra sterile fluids (saline or water) according to the table below.

Diluent Table for Nozzle Attachment

Kit Size	Additional Amount to Add
5cc	1cc
10cc	2cc
15.5cc	3cc
20cc	4cc



- 3) Mix with spatula and knead material against the side wall of the bowl until the desired consistency is achieved (approximately 30-60 seconds).



- 4) After achieving a putty-like consistency, the material can be handled digitally. Material maintains handling characteristics up to 10 minutes after mixing.



- 5) If injection through a syringe is desired, remove plunger from syringe, roll the putty into a cylinder-like shape and insert into syringe barrel. (Alternatively, the spatula may be used to fill syringe).



- 6) Attach nozzle to syringe, if desired. To attach nozzle, grip syringe tightly and twist nozzle onto the syringe. Note: Injection into the graft site may be performed with or without the nozzle attachment.



- 7) Re-insert plunger and inject into bone defect.



- 8) With nozzle in position, remove syringe by holding the nozzle and twisting off the syringe. Insert push rod to extrude the remaining material in the nozzle.

B. ALLOMATRIX™ C BONE PUTTY AND ALLOMATRIX™ RCS BONE PUTTY



- 1) Using sterile technique with gloves, empty powder into the mixing bowl. For the 12cc ALLOMATRIX™ RCS Bone Putty Product, empty both vials (powder and CALCIPLEX™ granules) into the mixing bowl.

- 2) Empty mixing solution into the bowl.

- 3) Mix with spatula and knead material against the side wall of the bowl until the desired consistency is achieved (approximately 30-60 seconds).

- 4) After achieving a putty-like consistency, the material can be handled digitally. Material maintains handling characteristics up to 10 minutes after mixing.

C. ALLOMATRIX™ CUSTOM BONE PUTTY

* See Section E if mixing with bone marrow aspirate.



- 1) Using sterile technique with gloves, empty powder into the mixing bowl.

- 2) Empty mixing solution into the bowl.

- 3) Mix with spatula and knead material against the side wall of the bowl until the desired consistency is achieved (approximately 30-60 seconds).

- 4) Blend the additional cancellous chips that are provided in the package until desired consistency is achieved. The 5cc volume requires approximately 20 – 30 seconds of kneading in order to obtain optimal handling characteristics. The 10 cc and 20 cc volume require approximately 30 – 60 seconds of kneading in order to obtain optimal handling characteristics.

- 5) After achieving a putty-like consistency, the material can be handled digitally. Material maintains handling characteristics up to 10 minutes after mixing.

D. ALLOMATRIX™ DR BONE PUTTY

* See Section E if mixing with bone marrow aspirate.



- 1) Using sterile technique with gloves, empty powder into the mixing bowl.

- 2) Empty mixing solution into the bowl.

- 3) Mix with spatula and knead material against the side wall of the bowl until the desired consistency is achieved (approximately 30-60 seconds).

- 4) The material will be very crumbly at this point.
IMPORTANT: This special formulation requires approximately 20-30 seconds of kneading in order to obtain optimal handling characteristics.



- 5) After achieving a putty-like consistency, the material can be handled digitally. Material maintains handling characteristics up to 10 minutes after mixing.

E. ALLOMATRIX™ DR BONE PUTTY OR ALLOMATRIX™ CUSTOM BONE PUTTY AS A SPINE GRAFT EXTENDER

ALLOMATRIX™ Custom Bone Putty or ALLOMATRIX™ DR Bone Putty may be used as a spine graft extender. These products can be mixed with the patient's own bone marrow aspirate (BMA) and local bone, see Table below. Instructions for obtaining BMA and mixing with the ALLOMATRIX™ Custom Bone Putty or ALLOMATRIX™ DR Bone Putty follow.

Table – Recommended Mixing Proportions

	Volume	Bone Marrow Aspirate	Autologous Local Bone
ALLOMATRIX™ Custom Bone Putty	5cc Kit	3cc*	5cc
	10cc Kit	6cc*	10cc
	20cc Kit	12cc*	20cc
ALLOMATRIX™ DR Bone Putty	3cc Kit	2cc*	5 cc

* It is suggested that the user begin with the amounts in the table, and add additional fluids (after addition of the autologous local bone) to achieve desired handling characteristics.

The following are suggested instructions* for obtaining Bone Marrow Aspirate:

- A. Prepare Site
Prep and drape site as for iliac crest graft harvest. Palpate the anterior iliac crest. Placement: 1cm posterior to the anterior superior iliac spine will avoid damage to the lateral femoral cutaneous nerve of the thigh.
- B. Insert needle
Introduce the aspiration needle into the central position of the crest taking care to avoid penetrating the lateral overhang lip.
- C. Prepare for aspiration
Remove the trocar and place the aspiration syringe onto needle.
- D. Aspirate bone marrow
Begin aspiration of red marrow. If marrow does not aspirate easily, reposition needle slightly. If marrow still does not aspirate, redirect needle by removing syringe, replacing the trocar and following steps A-D.
- E. Redirect, continue aspiration
Redirect needle every 5cc during aspiration to avoid aspirating peripheral blood.

* DISCLAIMER: Proper surgical procedures and techniques are the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of the procedure used based on personal medical training and experience. Although Wright Medical cannot recommend a particular surgical technique suitable for all patients, a detailed surgical technique is available for surgeon reference.



- 1) Using sterile technique with gloves, empty powder into the mixing bowl.



- 2) Add bone marrow aspirate into the bowl.

* Note: Optional diluent is included in the event that insufficient patient BMA is available, or if the surgeon determines that use of the included diluent is preferred based on individual patient needs and circumstances.



- 3) Add autograft bone.



- 4) With the spatula, mix material against the side wall of the bowl.

IMPORTANT



- 5) The 5cc volume requires approximately 20-30 seconds of kneading in order to obtain optimal handling characteristics.
- 6) Mix with spatula and knead material against the side wall of the bowl until the desired consistency is achieved (approximately 30-60 seconds).
- 7) With the spatula, mix material against the side wall of the bowl.
- 8) The 10cc and 20 cc volumes require approximately 30-60 seconds of mixing in order to obtain optimal handling characteristics.



- 9) After achieving a putty-like consistency, the material can be handled digitally.
Material maintains handling characteristics up to 10 minutes after mixing.

See package insert for additional information.

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