

OSTEOSET[®] Resorbable Bead Kits and Mini-Bead Kits Mixing Instructions

135040-3

The following languages are included in this packet:

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

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

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

For additional information and translations please contact the manufacturer or local distributor.



Wright Medical Technology, Inc. P.O. Box 100 Arlington, TN 38002 U.S.A.

|--|

Wright Medical EMEA Krijgsman 11 1186 DM Amstelveen The Netherlands

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

R ONLY November 2009 Printed in U.S.A.

Mixing instructions for the $Osteoset^{\$}$ resorbable bead kit $(135040\mathcharcmatrix)$

- 1. Mix according to directions listed in Steps 1-5.
 - Note: Do not add any additional substances to the paste. Using alternative mixing solutions and/or adding other substances to the mixture may alter the setting time significantly. Some substances, such as bone marrow and blood, will prevent the paste from setting altogether.



Step 1

- Add powder to mixing bowl
- Add all of diluent
- Allow to sit
 - Standard kit: 1 minute
 - Fast-cure kit: 30 seconds

Step 2

- Mix thoroughly for 30 45 seconds
- DO NOT over mix
- When the consistency of the mixture is paste-like (i.e. sticks to the spatula), it is ready to apply to mold





Step 3

• With spatula apply an even coat of calcium sulfate paste to the Wright Bead Template bottom half (shown), ensuring complete filling of each bead cavity. Each OSTEOSET[®] Resorbable Bead Kit contains enough material to fill two bead templates.



Step 4

- Apply mold top and firmly press together (excess material will extrude from vents on the top of the mold). Allow to sit:
 Standard Kit: approximately 15-20 minutes
 Fast Cure Kit: approximately 3-5 minutes
- Carefully separate the mold



Step 5

• Flex the mold to facilitate bead removal

- 2. Gently pack the molded implants into the treatment site. Avoid overfilling the bone void or compressing the treatment site.
- 3. Remove excess material from the treatment site. Cover the opening of the bone void with cortical bone window and/or healthy periosteum or other soft tissues. Close the site using standard closure techniques.
- 4. Discard any unused OSTEOSET[®] Resorbable Bead Kit material and the mixing tools.

MIXING INSTRUCTIONS FOR OSTEOSET[®] MINI RESORBABLE BEAD KIT

1. Mix according to directions listed in Steps 1-5.

Note: Do not add any additional substances to the paste. Using alternative mixing solutions and/or adding other substances to the mixture may alter the setting time significantly. Some substances, such as bone marrow and blood, will prevent the paste from setting altogether.

Step 1

- Add powder to mixing bowl
- Add all of diluent
- Allow to sit
 - Standard kit: 1 minute
 - Fast-cure kit: 30 seconds

Step 2

- Mix thoroughly for 30 45 seconds
- DO NOT over mix
- When the consistency of the mixture is paste-like (i.e. sticks to the spatula), it is ready to apply to mold



Step 3

- With spatula apply an even coat of OSTEOSET[®] paste to only one half of the supplied mold
- Ensure complete filling of each bead cavity. NOTE: Each kit contains enough material to fill only one half of the supplied mold, which totals approximately 5cc final volume.
- After completely filling the mold half, tap on a flat surface to remove air bubbles.

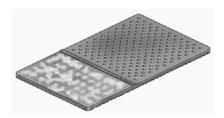




Step 4

Allow to sit:

- Standard Kit: approximately 15-20 minutes
- Fast Cure Kit: approximately 3-5 minutes



Step 5

• Flex the mold to facilitate bead removal



- 2. Gently pack the molded implants into the treatment site. Avoid overfilling the bone void or compressing the treatment site.
- 3. Remove excess material from the treatment site. Cover the opening of the bone void with cortical bone window and/or healthy periosteum or other soft tissues. Close the site using standard closure techniques.
- 4. Discard any unused OSTEOSET[®] Mini Resorbable Bead Kit material and the mixing tools.