GUIDOR® easy-graft® CLASSIC alloplastic bone grafting system

GUIDOR® easy-graft® is a patented1 bone grafting solution from Sunstar offering a fully resorbable, synthetic bone graft substitute to clinicians who seek stability, osteoconductivity and control of placement. With over 250,000 applications worldwide2, GUIDOR easy-graft has established itself as a leading alloplastic bone grafting material for your ridge preservation and other bone regenerative needs.

**Designed to Make It Easy**
GUIDOR easy-graft is a complete system that helps clinicians provide more predictable clinical results. Each system is comprised of β-tricalcium phosphate (β-TCP) granules coated with a poly(lactide-co-glycolide) (PLGA) that are mixed with N-methyl-2-pyrrolidone (NMP) liquid activator called BioLinker® to form a permeable, moldable material which hardens to form a stable, porous scaffold.

This unique combination of materials in GUIDOR easy-graft provides the foundation for easy preparation, dispensing and shaping. The porosity of the granule supports material resorption and bone regeneration.

The system contains BioLinker® and a β-TCP granule with polymer coating.

When mixed, BioLinker softens the polymer coating creating a sticky surface that can be compressed and shaped.

BioLinker is flushed out of the material when in contact with body fluids.

GUIDOR easy-graft hardens in approximately one minute into a stable, porous scaffold of interconnected granules.

**Soft from the Syringe. Hard in the Defect.**

Placing bone graft material doesn’t have to be complex. In fact, a majority of clinicians surveyed said they use GUIDOR easy-graft because preparation and placement are simpler and faster than other bone graft materials3 and because use of GUIDOR easy-graft does not require a membrane in many cases.3

- Easy-to-handle; syringe directly into the defect
- Material hardens into a stable, porous scaffold in approximately one minute
- Ideal for ridge preservation and filling voids around immediate implant placements

1. US Patent: 7,731,756; 8,153,148; 8,163,030
Simple Steps for Minimally Invasive Ridge Preservation

**Prep.**
1. Atraumatic Extraction
2. **KEY STEP** Socket Preparation
   - Thoroughly clean alveolar walls.
   - Cause bleeding.
3. **KEY STEP** Socket Evaluation
4. Create Additional Retention
   - In mesial and distal walls.

**Dispense.**
5. Prepare BioLinker®
6. Introduce BioLinker
7. Wet Granules with BioLinker
8. Expel Excess BioLinker

**Shape.**
9. Inject Material into the Site
10. **KEY STEP** Compress Material Firmly
11. Shape and Contour
   - GUIDOR® easy-graft® hardens in contact with body fluids in minutes.

For more information including frequently asked questions, visit [http://us.guidor.com/techniqueguide/](http://us.guidor.com/techniqueguide/)

**Clinical Preferences** when using GUIDOR® easy-graft® CLASSIC alloplastic bone grafting system

<table>
<thead>
<tr>
<th>Indications Treated</th>
<th>% of Clinicians</th>
</tr>
</thead>
<tbody>
<tr>
<td>extraction site or ridge preservation</td>
<td>88%</td>
</tr>
<tr>
<td>immediate implant placement when additional bone regeneration is desired</td>
<td>8%</td>
</tr>
<tr>
<td>aid in the regeneration and integration of periodontal tissue components</td>
<td>1%</td>
</tr>
<tr>
<td>ridge augmentation</td>
<td>1%</td>
</tr>
<tr>
<td>other</td>
<td>1%</td>
</tr>
</tbody>
</table>

4. Data on File, DOF-0007

- Prior to placement of GUIDOR® easy-graft® CLASSIC, 95% of respondents cleaned the defect with mechanical devices, such as curette and burs.
- 52% of respondents did not cover the site with anything after placing GUIDOR® easy-graft® CLASSIC in the defect.
- 83% of respondents placed sutures over the site.
Opinions after use

An independent healthcare market research firm conducted a blind product evaluation, where 80 US dentists tried GUIDOR® easy-graft® CLASSIC Alloplastic Bone Grafting System for the first time. From 2014-2015, the respondents indicated they completed a total of 300+ cases with an average of 5 cases per clinician and provided feedback after 3 months (N=75) and 6 months (N=65).

90% of the respondents were satisfied with the clinical outcomes when using GUIDOR® easy-graft® CLASSIC.

### Satisfaction with Clinical Outcomes

<table>
<thead>
<tr>
<th>Clinical Outcome</th>
<th>% of Clinicians</th>
</tr>
</thead>
<tbody>
<tr>
<td>stability of the prosthesis/final restoration</td>
<td>90%</td>
</tr>
<tr>
<td>final aesthetic of the case</td>
<td>90%</td>
</tr>
<tr>
<td>healing of the soft tissue</td>
<td>88%</td>
</tr>
<tr>
<td>bone maturation</td>
<td>75%</td>
</tr>
</tbody>
</table>

### Agreement with Positive Statements

- 90% of the respondents confirmed that GUIDOR® easy-graft® CLASSIC simplifies bone grafting procedures.
- 95% of the respondents did not report any patient complaints after using GUIDOR® easy-graft® CLASSIC.
- 97% of the respondents did not report any signs of infection or inflammatory reactions after GUIDOR® easy-graft® CLASSIC.

Additional clinical references and scientific publication are listed at [http://us.guidor.com/egstudies](http://us.guidor.com/egstudies)
More Consistent, Predictable Results
If the ability to place an implant is your primary measure of success, GUIDOR® easy-graft® provides a predictable way to maintain alveolar bone for rehabilitation with dental implants after tooth extraction.5

Clinical Case: Rigid, Porous Scaffold of GUIDOR easy-graft Achieves Implant Success
A 23-year-old female patient without medical contraindication for implant therapy presented with a maxillary right second premolar that due to extensive caries could not be saved. The treatment plan included a delayed implant placement protocol.

Figures 1-12: Clinical Case

Figure 1: Pre-op Clinical View
Figure 2: Pre-op Radiograph
Figure 3: Atraumatic Extraction
Figure 4: Socket Filled with GUIDOR easy-graft

Figure 5: Clinical Result 3 Weeks Post-op
Gradual proliferation of the epithelium over the grafted site.

Figure 6: Clinical Result 4 Months Post-Op
Grafted area is covered with newly formed keratinized epithelium.

Figure 7: Newly Formed Bone at 4 Month Re-entry
Adequate preservation of ridge dimension can be seen.

Figure 8: Histological Analysis
GUIDOR easy-graft particles surrounded by newly formed bone. Key: EG = GUIDOR easy-graft, NB = newly formed bone

Figure 9: Implant Placement
Figure 10: Clinical Result After 4 Months Post-implant Placement
Figure 11: Clinical View After Crown Placement
Figure 12: Final Radiograph at 16 Months
No residual particles of the grafting material are detected and the implant seems surrounded by vital bone.

(Courtesy of Dr. Minas Leventis, DDS, MSc, PhD)

5. Leventis, Minas, DDS. Socket Preservation Using in situ hardening synthetic Bone Graft Substitute.
GUIDOR® easy-graft® Alloplastic Bone Grafting System

GUIDOR easy-graft is a fully resorbable bone grafting system that contains a syringe filled with coated granules and an ampule of the liquid activator, BioLinker®. Once mixed, GUIDOR easy-graft can be dispensed and shaped directly into the defect where it will harden into a stable, porous scaffold in approximately one minute.

<table>
<thead>
<tr>
<th>Product Size</th>
<th>Item #</th>
<th>Granule Size</th>
<th>Content</th>
<th>Color Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large</td>
<td>C11-008</td>
<td>500-1000µm</td>
<td>3 systems x 0.4ml</td>
<td></td>
</tr>
<tr>
<td>Medium</td>
<td>C11-078</td>
<td>500-1000µm</td>
<td>3 systems x 0.25ml</td>
<td></td>
</tr>
<tr>
<td>Small</td>
<td>C11-018</td>
<td>500-630µm</td>
<td>3 systems x 0.15ml</td>
<td></td>
</tr>
</tbody>
</table>

1 system = 1 syringe of GUIDOR easy-graft granules and 1 ampule of BioLinker®

Size Selector: The Amount of GUIDOR easy-graft needed to fill a socket

The following estimates are based on GUIDOR easy-graft placement in dentiform sockets. Material needs in clinical use may vary.

Indications for Use

GUIDOR easy-graft is indicated for the treatment of intraoral/maxillofacial osseous defects. Dental and maxillofacial indications may include:
- Extraction defects (alveolar ridge preservation)
- Periodontal defects
- Peri-implant defects
- Augmentation of deficient alveolar crest (e.g. Guided Bone Regeneration, GBR)
- Sinus floor augmentation
- Defects after surgical extractions
- Defects after removal of bone cysts
- Defects after root resection of apicoectomy
- Defects after removal of autologous bone

Contraindications

GUIDOR easy-graft should not be used in pregnant or nursing women.

Possible Adverse Effects

Possible adverse reactions associated with the use of the device include: eye, respiratory and skin irritation.

Refer to Instructions for Use at http://us.guidor.com/IFU

For More Information

- Contact your Sunstar or Dealer representative
- Call 1-877-484-3671
- Go to http://us.guidor.com

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