



**Urgent Field Safety Notice**  
**DRG Kryptonite Bone Cement**  
**CA-12-011-FSCA-09112012**  
**Updated Product Labeling (IFU)**

September 2012

*Via certified mail and email*

Dear Distributor,

Several recent modifications have been made to the Instructions for Use (IFU) document for Kryptonite Bone Cement (KRYP-Z-10, KRYP-Z-05). As part of routine product recertification through DRG's Notified Body, the Notified Body requested a Field Safety Corrective Action (FSCA). This Field Safety Notice is provided to effectively communicate this latest safety information.

The updated English language IFU (DWG-2115 Rev 5) is provided as an attachment. Revisions to the IFU include the following:

1. Warning 5: Changed "Avoid mixing" to "Do not mix" and ... "as the effects are not known" to "as such use may adversely affect the physical characteristics of the product (including polymerization rate, strength and expansion)"
2. Warning 9: Added "Product misuse may result in expansion substantially greater than 100% and significant reduction in strength and stiffness".
3. Added hazard/precautionary statements and symbols pertaining to Component A.
4. Added instruction "Do not store above 25°C (77°F)"

Until notified otherwise, distributors should provide a copy of this FSN and the updated IFU to all users who have received devices previously and with all future product purchases.

Additionally, the FSN and updated IFU will be attached to the outer packaging of product shipped from DRG until such time that an updated multilingual IFU can be incorporated within the product packaging. Future production runs will also incorporate items 3 and 4 above within the product labeling.

As with all bone cement products, DRG recommends monitoring patients' post-surgical outcomes to evaluate their status with regard to the known risks associated with these devices, including all those listed in the IFU.

The relevant Competent Authorities have been advised of this FSCA. Please confirm receipt of this notice by completing the attached Acknowledgement of Receipt form and faxing (+1 203-262-9340) or emailing (blogsdon@doctorsresearchgroup.com) it to DRG. Please contact DRG's US corporate headquarters at +1 203-262-9335 if you have questions.

Sincerely,

A handwritten signature in black ink that reads "Joseph Jannetty". The signature is written in a cursive, flowing style.

Joseph Jannetty  
President and CEO  
Doctors Research Group, Inc.



## Acknowledgement of Receipt

I/we have received and reviewed the Urgent Field Safety Notice (CA-12-011-FSCA-09112012) pertaining to IFU modifications for Kryptonite Bone Cement.

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Distributor/Company Name

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\_\_\_\_\_

\_\_\_\_\_  
Distributor/Company Address

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name

Please complete this form and fax (+1 203-262-9340) or email ([blogsdon@doctorsresearchgroup.com](mailto:blogsdon@doctorsresearchgroup.com)) to Doctors Research Group.