Urgent Field Safety Notice
Kryptonite Bone Cement
CA-11-030-FSCA-04202012
Updated Product Labeling

April 2012

Via certified mail and email

Dear Distributor,

Doctors Research Group, Inc., ("DRG") is providing this Field Safety Notice to provide new information regarding the mechanical properties of Kryptonite Bone Cement® ("Kryptonite") in all of its product configurations. DRG has manufactured and sold Kryptonite since 2007, during which time approximately 18,000 Kryptonite kits have been sold globally.

In December 2011, DRG became aware of a third-party evaluation of the device at body temperature, which noted characteristics of Kryptonite that differed from those observed in ambient-temperature preclinical testing conducted by DRG. DRG has investigated this issue at length and confirmed that both the strength and stiffness of Kryptonite at body temperature are approximately half that measured at ambient temperature. DRG believes that even at these lower strength and stiffness levels the product has mechanical characteristics substantially equivalent to similar commercially available products. DRG believes that this characteristic affects all Kryptonite product made to date.

Though DRG is aware of a small number of complaints noting product malleability observed during surgical interventions not reportedly related to Kryptonite implantation, based on a review of complaint data to date, DRG is not aware of any adverse events that are directly attributed to this issue.

DRG is taking the corrective action of notifying distributors of this new finding and providing an updated Instructions for Use (IFU) document. **Until notified otherwise, distributors should provide a copy of this Field Safety Notice and the updated IFU to all users who have received devices previously and in all future product purchases.** The updated IFU includes the new Precaution:

> *"The in situ stiffness and strength of fully cured product is approximately half that of the product at ambient conditions."*

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 (i.e product package insert).

Please contact DRG's US corporate headquarters at +1 203-262-9335 if you have questions.

Sincerely,

Luis Nesprido
Sr. Manager Regulatory & Quality Affairs
Doctors Research Group, Inc.