Urgent Field Safety Notice (FSN)

Product Name: GLOBAL APG+ 2.5mm Breakaway Guide Pin

Type of Action: Field Safety Notice

Date: April 2014

FSCA Identifier: DVA-108588

Attention: Orthopaedic Surgeons who use GLOBAL APG+ 2.5mm Breakaway Guide Pin

Model names: GLOBAL APG+ 2.5mm Breakaway Guide Pin

Product Code: 223000019

DePuy Orthopaedics, Inc. is issuing a voluntary device correction for the GLOBAL APG+ 2.5mm Breakaway Guide Pin (single-use shoulder instrument). The Field Safety Notice is being issued to inform users about the possibility of the pin breaking and potentially being left in the patient. Information regarding the affected instrument's use will be included in the following surgical techniques:

Title	Reference Number
GLOBAL® APG+ Surgical Technique	061213509
DELTA XTEND™ Reverse Shoulder System Surgical Technique	061253505

Recommendations
The company would like to emphasize technical points regarding the use of the GLOBAL APG+ 2.5mm Breakaway Guide Pin (single-use shoulder instrument) to be included in the surgical techniques.

- "The grooves on the 2.5mm Breakaway Guide Pin are exclusively used for the breakaway feature and are not intended to indicate the depth to which the pin should be inserted."
- "The pin is designed to break at the grooves. Be aware that it may break unintentionally if subjected to too much bending force."

- "After use of the guide pin is complete, confirm that all sections (totaling the full length of the original, unbroken pin) have been removed."

Affected Single-Use Shoulder Instrument:

Product Code: 223000019 (Figure 1)
Lot Numbers: All Lots
Barcode GTIN Information (Figure 2)

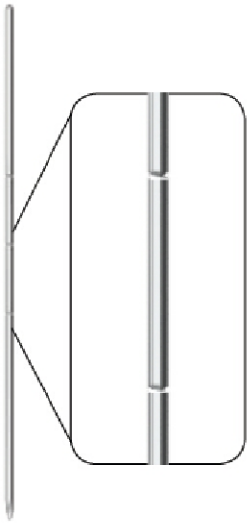

Figure 1: Image of GLOBAL APG+ 2.5mm Breakaway Guide Pin from the GLOBAL® APG+ Design Rationale and Surgical Technique

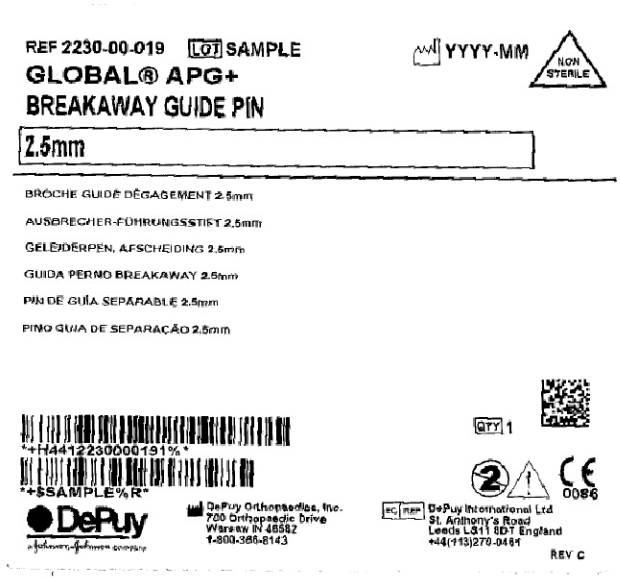

Figure 2: Product Code 223000019 Barcode GTIN – Outer Label

Intended Use

The GLOBAL APG+ 2.5mm Guide Pin is a single-use instrument that is used to assist the surgeon in the orientation of the cannulated reamers and cannulated central drills in the preparation of the glenoid surface. The GLOBAL APG+ 2.5mm Guide Pin is validated for use with the GLOBAL APG+ and DELTA XTEND Systems.

The guide pin is scored in three locations, which allows the surgeon to select a desired pin length. The single-use shoulder instrument is made from 316L Stainless Steel.

Reason for Device Correction
There have been two complaints received; one in 2012 and one in 2013. In the 2012 complaint the broken pin was located and removed. In the 2013 complaint the pin was left in the patient and retrieved in a second surgery.

Units Affected
Since September 30, 2009, there have been 28,558 GLOBAL APG+ 2.5mm Guide Pins manufactured. In [J&J Affiliate to add country] there have been [J&J Affiliate to add quantity supplied to users] sales of the affected single use shoulder instruments from 2009 through to February 2014. This device correction does not affect any other shoulder instruments.

Depth of Device Correction
This Field Safety Notice provides instructions for Surgeons and Users. The purpose of this device correction is to inform Surgeons and Users regarding the updates to the Surgical Techniques.

Clinical Implications
If not observed during surgery, the possible clinical implications related to this issue may include:

- Pain
- Adverse tissue reaction if the broken piece of the GLOBAL APG+ 2.5mm Guide Pin were to completely break free and cause irritation to the surrounding tissue
- Potential for significant damage to vital organs

The clinical implications above may potentially require additional surgical procedure(s), possibly including revision surgery. Following are general examples of possible risks/hazards of revision surgery:

1. Infection
2. Additional scarring
3. Neural and vascular damage
4. Additional pain to the patient
5. Functional problems resulting from items 1 – 4 above
6. Anesthesia-associated risks

The company suggests that if there are any doubts of broken or missing pieces during the procedure, or when inspecting the instruments during or directly after surgery, then radiographs (X-Rays) should be taken with proper techniques to ensure there are no pieces left in the patient. Once this is complete, the patient should continue to be treated per the standard of care.

Steps to take:
Please review all information provided regarding the use and care of the GLOBAL APG+ 2.5mm Guide Pins. The purpose of this communication is to inform you of this device correction and provide information relevant to the treatment of your patients. Contact your DePuy Sales Consultant for copies of the updated surgical techniques, as needed.

Please complete the attached form, this form needs to be completed and returned to [J&J Affiliate to add contact details of local DePuy/J&J FSCA co-ordinator].

Alan O' Sullivan (DePuy)
Recall Coordinator
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Tel no - +353 21 4914149

This FSN has been notified to the appropriate Regulatory Agency.

[redacted]

[redacted]

WW VP Medical Affairs

This Letter acknowledges receipt of the Field Safety Notice [ref.DVA-108588] dated [INSERT DATE] issued by DePuy Orthopaedics.

(Please check as appropriate)

☐ Yes I have received the FSN

Please fax or e-mail this completed document to [INSERT DePuy Marketing Company/Affiliate contact details]

Print Name: _____

_____

Signature

_____

Hospital Name

_____

Country

_____

City,

_____

Telephone Number or e-mail address