



URGENT FIELD SAFETY NOTICE
Revised Surgical Technique – RSP Impaction Block Fixture

September 23, 2015

DJO Surgical

Dear [REDACTED]

A DJO Global Company

We would like to inform you of a revision to our current Surgical Techniques for the use of the RSP Monoblock Fixture (part number 804-03-053)

9800 Metric Boulevard

Austin, TX 78758-5445

T 512.832.9500

DJOglobal.com

It has been discovered that during use, material from the impaction fixture may be transferred to the HA coating of the humeral stems. This updated technique will provide instructions on how the current fixture can be used without a risk of the material transfer.

Provided with this notification is a field bulletin that addresses the specific techniques to be followed for the RSP Monoblock fixture. Also provided is a newly revised Surgical Technique for RSP that also includes these new instructions.

Instructions:

- 1. Please become familiar with these new techniques and notify all of your applicable users of the RSP Monoblock stems of these revised methods.**
- 2. When each user has been notified of these new techniques, please ask them to complete the form that has been provided with this notification indicating that they have been informed of these changes and understand the new methods. If you do not have surgeons who implant RSP Monoblock, please indicate that on the form and return.**
- 3. Return the completed forms to Desiree Wells at desiree.wells@djoglobal.com.**

The relevant National Competent Authorities have been advised of the FSCA.

Agency	DJO UK
Agency ID	150 EUR
Address	1a Guildford Business Park, Guildford, Surrey GU2 8XG, United Kingdom
Contact Person	Ben Whiting
Contact Number	441483459659
Qty	4

If you have any questions, please contact Teffany Hutto by phone at (512) 834-6255 or by email at teffany.hutto@djoglobal.com or MDSS GmbH by phone: +49-511-62628630 or email: vigilance@mdss.com

Thank you for your prompt action in this matter.

Together in Motion™