



URGENT FIELD SAFETY NOTICE
RSP Monoblock & Turon Impaction Block Fixtures

February 14, 2017

DJO Surgical

Dear Mr. Ben Whiting,

A DJO Global Company

DJO Surgical is committed to providing safe and effective products to all of our customers around the world. The purpose of this letter is to advise you that DJO Surgical is executing a voluntary field action of the RSP Monoblock (part # 804-03-053).

9800 Metric Boulevard

Austin, TX 78758-5445

Description of Issue

T 512.832.9500

- It was discovered that during Turon assembly, the impaction forces can cause the polymer material from the Turon Impaction Fixture to wear off on the lateral surface of the Humeral Stem titanium plasma spray coating. This issue was also reported with the RSP Monoblock shell and the polymer material of the RSP Impaction Fixture.
- In 2015, a modified Surgical Technique was developed for both the Turon and RSP Monoblock Stems to prevent transfer of the polymer to the plasma coat. The revised surgical technique was distributed to the field.
- This recall includes the following parts. Do NOT use the affected product!
 - RSP Monoblock Impaction Fixture, part # **804-03-053, ALL lots**
- The impaction fixtures can be found in the following instrument trays (see attachment for photos):
 - ✓ FA RSP GLENOID
 - ✓ FA RSP MONOBLOCK LTD RELEASE

DJOglobal.com

DJO Sales Agents Action:

DJO Surgical requires that you do the following actions by **March 17, 2017:**

1. **This notice needs to be passed on to all those within your organization or to any organization where the potentially affected product has been transferred.**
2. **If your surgeon uses the impaction fixtures, email Valerie Moulton at Valerie.Moulton@djoglobal.com to place a replacement order and receive an RMA number.**
3. **Return all affected devices (quantities listed below) using the RMA number provided by DJO Surgical.**
4. **Sign the Acknowledgment and Receipt Form and email form to Desiree Wells at desiree.wells@djoglobal.com.**

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

Agency	DJO UK
Agency ID	N/A
Address	1A Guildford Business Park Rd, Guildford GU2 8XG, UK
Contact Person	Ben Whiting
Email	Ben.whiting@djoglobal.com
Affected Part	804-03-053 (RSP Monoblock)
Quantity	4

If you have any questions, please contact Neeta Sharma by phone at (760) 734-3551 or by email at Neeta.Sharma@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™