



**URGENT FIELD SAFETY NOTICE**  
**RSP Monoblock & Turon Impaction Block Fixtures**

March 3, 2017

DJO Surgical

Dear Mr. Benjamin Kirschbaum,

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) and Turon Impaction Fixtures (part # 804-15-102).

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**Description of Issue**

- 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!
  - Turon Impaction Fixture, **part # 804-15-102, ALL lots**
  - 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
  - FA TURON HUMERAL HEAD 2010

**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](mailto: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](mailto:desiree.wells@djoglobal.com).**

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

Agency	SPEETEC GmbH - a DJO Global Company
Agency ID	N/A
Address	Merzhauser Straße 112, 79100 Freiburg, Deutschland
Contact Person	Benjamin Kirschbaum
Email	Benjamin.Kirschbaum@djoglobal.com
Affected Part	804-03-053 (RSP Monoblock), 804-15-102 (Turon)
Quantity	2 RSP, 4 Turon

If you have any questions, please contact Neeta Sharma by phone at (760) 734-3551 or by email at [Neeta.Sharma@djoglobal.com](mailto:Neeta.Sharma@djoglobal.com) or MDSS GmbH by phone: +49-511-62628630 or email: [vigilance@mdss.com](mailto:vigilance@mdss.com)

Thank you for your prompt action in this matter.

*Together in Motion™*