URGENT FIELD SAFETY NOTICE

PLEASE READ THOROUGHLY

Recall of a

lot of the device component listed below

from manufacturer Encore Medical LP (also operating as Enovis DJO)

COMPONENT (COMMERCIAL NAME)	PART NO.	LOT NUMBER
Reverse Shoulder Prosthesis (RSP) Humeral Socket Insert	508-01-032	859C1190

FSN Ref: MDD23.189

FSCA Ref: MDD23.189

NO OTHER PRODUCTS ARE AFFECTED

BY THIS FIELD SAFETY NOTICE

9800 Metric Boulevard
Austin, Texas 78758
United States

(800) 456-8696 Toll Free
(512) 834-6300 Fax
enovis.com

AUGUST 10, 2023

Dear Madam or Sir,

The purpose of this communication (also referred to below as "Field Safety Notice") is to inform you that Encore Medical LP (also operating under the tradename "Enovis DJO"; SRN US-MF-000025365) has voluntarily initiated a global Field Safety Corrective Action for the lot of the device identified below ("affected device"), of which Encore Medical LP is the manufacturer.

COMPONENT (COMMERCIAL NAME)	PART NO.	LOT NUMBER
Reverse Shoulder Prosthesis (RSP) Humeral Socket Insert	508-01-032	859C1190

The manufacturer's shoulder devices (including RSP Humeral Socket Insert) are intended for treatment of patients who are candidates for shoulder arthroplasty per the Indication for use. While total shoulder replacements are not intended to withstand activity levels and loads of normal healthy bone, they are a means of restoring mobility and reducing pain for many patients.

Only the lot number identified above is affected by this Field Safety Notice.

REASON FOR FIELD SAFETY CORRECTIVE ACTION:

Enovis DJO has identified through an internal review that the lot of the implant component identified above was not subjected to final sterilization before shipment.

WHAT IS ENOVIS DJO DOING?

We are continuing our investigation. When we became aware of this issue, we immediately reached out to all implanting surgeons directly by telephone to make them aware of this issue so that they are prepared to manage their patients who received affected components. Enovis DJO also immediately contacted all of its distribution partners with remaining affected components in their possession, custody, or control and requested that they quarantine all affected components. At this time, there are no remaining affected components in the field and surgeries with other Enovis product may proceed without concern.

This Field Safety Corrective Action is being performed with the knowledge of and in cooperation with the Federal Institute for Drugs and Medical Devices (BfArM, Germany).

RISK TO HEALTH:

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Although cleaned and packaged in a clean-room environment, Enovis DJO has determined that the identified lots of components are not sterile. Product that is not properly sterilized may lead to a varying degree of infection, sepsis and could, thus evolve into a serious clinical condition requiring further medical intervention. At this time, Enovis DJO has not received any reports of patient illness, injury, or infection associated with the affected lot.

INSTRUCTIONS TO IMPLANTING SURGEON:

We ask that you reach out to you patient who was implanted with the affected component as identified above and consider whether it may be appropriate for your patient to be monitored more closely to watch for signs and symptoms of acute or chronic infection.

We have also provided a patient letter for you to provide to your patient who was implanted with an affected component.

Please make the hospital where you implanted the components aware of this action, as appropriate, by providing a copy of this communication.

Please make any healthcare institutions or implanting surgeons that may have had possession of the affected component aware of this action by providing a copy of this communication.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Please review and complete the enclosed **Field Safety Notice Response Form within 10 (ten) days after receiving this communication**.

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CONTACT DETAILS OF THE MANUFACTURER:

If you have any questions or need help completing these actions, please contact us at:

ENCORE MEDICAL LP

Metric Boulevard 98000 TX 78758 Austin, United States

Att. Sherri Mellingen

Email: sherri.mellingen@enovis.com.

Telephone: (952) 913-6383

We deeply regret this inconvenience, but we greatly appreciate your understanding as we take actions to ensure patient safety and customer satisfaction.

Sincerely,

Sherri Mellingen

DIRECTOR, REGULATORY AFFAIRS |SURGICAL

sherri.mellingen@enovis.com

Enclosures:
Patient Letter
Field Safety Notice Response Form

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Field Safety Notice Response Form

Please assist us in making this corrective action process as efficient and convenient for you as possible by completing and returning this form **within 10 (ten) days after receiving this communication**. This will serve as confirmation that you have received and understand the notification.

Please complete this Field Safety Notice Response Form and return it to us by one of following routes:

By facsimile to:	**+1 512 834 3539**
By email to	**julie.baker@enovis.com]**
By regular mail to:	**Julie Zorka-MacCloskey** **9800 Metric Boulevard** **Austin, Texas 78758** **United States**

Summarized below is the identification of the device encompassed by this field safety notice. Our records indicate that you received one (1) unit of this device.

COMPONENT (COMMERCIAL NAME)	PART NO.	LOT NUMBER
Reverse Shoulder Prosthesis (RSP) Humeral Socket Insert	508-01-032	859C1190

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Please complete/confirm as appropriate:

Customer Details	
Healthcare Organisation Name	
Organisation Address	
Contact Name	
Telephone number	
Email	

Customer action undertaken:		
☐	I confirm receipt of the Field Safety Notice (FSN) and that I read and understood its content.	
☐	I performed all actions requested by the FSN.	
☐	The information and required actions have been brought to the attention of all relevant users and executed.	
☐	I have reached out my patient and discussed his/her care.	
	I have provided the patient letter to my patient.	
☐	I have a query please contact me	*Please provide contact details if different from above and brief description of query*

Thank you for assisting us with this field action.

It is important that your organization takes the actions detailed in the FSN and confirms that you have received the FSN. Your reply is the evidence we need to monitor the progress of the corrective actions.

Person Completing Form		
Name	**Signature**	**Title**
Phone number	**Email**	**Date**