MIZUHO | OSI®

30031 Ahern Avenue
Union City, CA 94587

Phone: 510-429-1500
Fax: 510-429-9945

mizuhosi.com

FSCA Ref: FSCA 2022-11-11 (New)

November 22, 2022

URGENT: Field Safety Notice
LEVÓ ARM

RESPONSE IS REQUIRED

For Attention of Operating Room Equipment Manager:

The Levó Head Positioning System is an accessory specifically designed to work with the Trios Table System and the Modular Table System manufactured by Mizuho OSI. Your organisation purchased the following Levó Head Positioning System product: 7887-400 Levó Premium Package.

This package includes a Levó Arm (7887-050) that provides the primary positioning and locking capabilities of the system. The purpose of this letter is to advise you that Mizuho OSI is voluntarily recalling the Levó Arm. The Competent (Regulatory) Authority of your country (Swissmedic) has been informed about this communication to customers.

Recently, we became aware of unexpected corrosion and shorting in one unit of the Levó Arm. The corrosion and shorting may render the internal electronics inoperable and may lead to a failure of the Arm's locking mechanism and ultimately unwanted motion of the unit. A patient's head could move unexpectedly with the potential of a patient injury.

We have implemented an enhanced design to the Levó Arm to address the unexpected corrosion and shorting. Once an updated unit is available, your Levó Arm will be exchanged for the updated design at no charge.

WHAT YOU NEED TO DO

While it is unlikely to occur, if you notice any slipping or unexpected behavior of the Arm while properly installed for its intended use, please cease use immediately and contact the local distributor.

30031 Ahern Avenue
Union City, CA 94587

Phone: 510-429-1500
Fax: 510-429-9945

mizuhosi.com

FSCA Ref: FSCA 2022-11-11 (New)

EXCHANGE PROGRAM

Mizuho OSI has decided to proactively replace your Levó Arm. Please note the following regarding the Exchange Program.

- Mizuho OSI will provide a replacement Levó Arm at no charge. Mizuho OSI is making every effort to replace these quickly, but it may be several weeks before your unit can be replaced.
- A Mizuho OSI Sales team member or local distributor will contact you when your replacement Arm is available and will assist you with the packaging and return of your existing Levó Arm upon your receipt of the upgraded model.

PRODUCT IDENTIFICATION

Levó Arm:
7887-050

Unique Device Identifier: 00842430104992

AFFECTED UNIT

The following serial number is being recalled in Switzerland: 507

MIZUHO | OSI®

30031 Ahern Avenue
Union City, CA 94587

Phone: 510-429-1500
Fax: 510-429-9945

mizuhosi.com

FSCA Ref: FSCA 2022-11-11 (New)

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)

Please transfer this notice to other organisations on which this action has an impact. (As appropriate)

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.

As noted, a Mizuho OSI Sales member or local distributor will assist you at your facility with the exchange of your Levó Arm unit once it arrives. We appreciate your patience as we provide this upgrade to your Levó Head Positioning System for your surgical staff and patients.

We apologize for any inconvenience that this recall may cause and appreciate your cooperation with our request. Should you have any inquiries, please do not hesitate to contact your Sales team member or local distributor.

Thank you for your immediate attention to this important matter.

Sincerely,

Mark DeSilets
Vice President, R&D/RA

MIZUHO | OSI®

30031 Ahern Avenue
Union City, CA 94587

Phone: 510-429-1500
Fax: 510-429-9945

mizuhosi.com

FSCA Ref: FSCA 2022-11-11 (New)

INSTRUCTIONS FOR RESPONDING TO THIS MEDICAL DEVICE RECALL:

1. Confirm receipt and understanding of this notice by signing and returning this page to our Regulatory Department at: FAX number +1-510-429-9945 or email notice@mizuhosi.com.
2. For any questions about the Levó Arm exchange plan, contact your Mizuho OSI sales team member or the local distributor.

CONTACT DETAILS OF LOCAL DISTRIBUTOR:
Fumedica AG
Luzernerstrasse 91
CH-5630 Muri
Schweiz
Phone: +41 (0)56 675 91 00
Email: fumedica@fumedica.ch

CUSTOMER RESPONSE CHECKLIST:

☐ I acknowledge and understand this Medical Device Recall.

☐ I understand that a Completed Certificate of Disinfection must be completed and placed in the shipping box with the RMA # clearly marked for the returned Levó Arm upon receipt of the upgraded unit.

Signed _____

Print Name _____ Facility _____

Email Address _____ Phone _____