

October 11, 2019

**URGENT: Field Safety Notice**  
**LEVÓ ARM**

**RESPONSE IS REQUIRED**

To whom it may concern:

The Levó Head Positioning System is an accessory specifically designed to work with two Mizuho OSI spinal surgery tables, the Trios Table System and the Modular Table System. Between January 2018 and July 2019, your organization purchased one of the following Levó Head Positioning System packages:

- 7887-100: Levó Prone Package
- 7887-200: Levó Cervical Package
- 7887-300: Levó Standard Package
- 7887-400: Levó Premium Package

Each of these packages includes a Levó Arm (7887-050) that provides the primary positioning and locking capabilities of the system. Recently, we became aware of the potential for fluid ingress resulting from unapproved cleaning techniques. Examples of incorrect cleaning could include submersion or exposure of the unit to direct fluid flow. This may result in fluid entering the unit, rendering the internal electronics inoperable and leading to a failure of the Arm's locking mechanism in isolated situations.

Effective with units manufactured as of July 1, 2019, we have implemented an enhanced design to the Levó Arm to address the likelihood of fluid ingress, and thus, the potential for the Arm to be unlocked when not intentionally engaged. Once an updated unit is available, your Levó Arm will be exchanged for the latest model at no charge.

## WHAT YOU NEED TO DO

You may continue to use the existing Levó Arm until a replacement Arm is provided. If either of the following two scenarios apply to your device, please cease use immediately and contact the Mizuho OSI Service Department:

- You believe the Levó Arm has been exposed to excessive fluids at any point while in use
- You notice any slipping of the Arm while properly installed for its intended use

We ask that you refer to the Levó Owner's Manual for specific instructions on how to properly clean all modules of the Levó Head Positioning System, including the Arm. These instructions, found in Section 13 of the manual, are also provided here for your reference.

## CLEANING AND DISINFECTING INSTRUCTIONS

### *Device Exterior*

After each use, surface disinfect the Levó™ Head Positioning System using a quaternary disinfectant compound according to manufacturer's directions for use. Wipe dry with a soft lint-free cloth. Ensure the solution is labeled for use as a surface disinfectant.

**NOTE:** *Failure to dry the surface thoroughly after cleaning and disinfecting may result in rust. Take care to avoid exposing the device to excessive moisture. Do not use flooding, fogging, or steam cleaning methods to clean the device.*



**CAUTION:** Never pour any liquid directly onto the Levó™ Head Positioning System. Never subject the Levó™ Head Positioning System to an equipment washing machine or any pressurized stream of water.

If blood or other fluids are allowed to remain on the device for a long period of time, they will require special cleaning to remove.

**NOTE:** *Use of iodophors will cause staining. Avoid the use of alcohol, bleach, or other highly concentrated chemicals.*



**CAUTION:** Damage to the device due to improper care, handling, and cleaning may cause harm to the patient, healthcare professional, and the device. It may decrease the product lifetime and void the warranty.

As part of a general function check, we also ask that prior to every surgery, you engage the Levó Arm Release Handle, press the Unlock button, and verify that the Arm moves smoothly throughout its range. For further details, please consult Sections 5 and 6 of the Levó Owner's Manual. If any unexpected motion is observed, contact the Mizuho OSI Service Department.

## EXCHANGE PROGRAM

Mizuho OSI has decided to proactively replace your Levó Arm. Please follow the instructions below regarding the Exchange Program.

- Mizuho OSI will provide a replacement Levó Arm at no charge. The timing of this replacement will be based upon product availability and is expected to be completed within 16 weeks.
- A Mizuho OSI Sales or Service member will assist you with the packaging and return of your existing Levó Arm(s) upon your receipt of the upgraded model.

## PRODUCT IDENTIFICATION

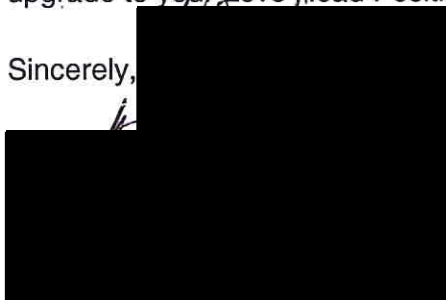
**Levó Arm:**  
7887-050  
7887-050R



The affected units of the Levó Arm, 7887-050, are those with serial numbers ranging from 201 to 452.

As noted, a Mizuho OSI Sales or Service member 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.

Sincerely,



**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](mailto:notice@mizuhosi.com).
2. For any questions about the Levó Arm exchange plan, call our Service Department at +1-510-429-1500, Option 2 or contact your Mizuho OSI sales representative.

**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 \_\_\_\_\_