



URGENT FIELD SAFETY NOTICE

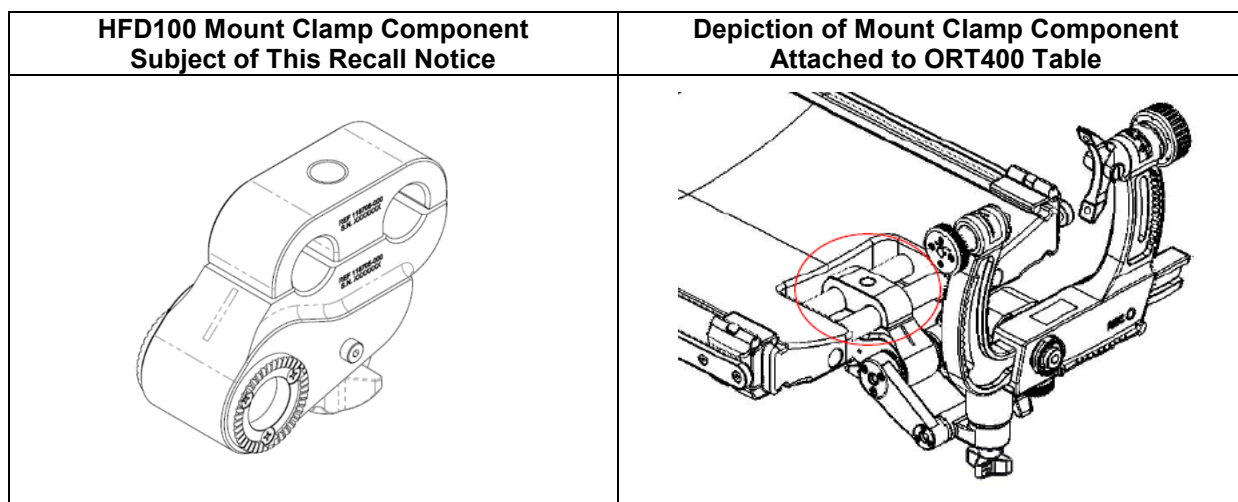
February 17, 2021

Subject: Field Safety Corrective Action to Replace Mount Clamp Component of the HFD100 Head Fixation Device Linkage used with ORT400 Operating Room Tables

Dear Customer,

IMRIS is conducting a Field Safety Corrective Action to address a potential risk associated with use of the HFD100 head fixation device linkage with the ORT400 operating room table, and will be completing corrective action to replace the mount clamp component, shown below, in affected HFD100 units at your location.

It has come to our attention that the 'mount clamp' component of the HFD100 linkage, which attaches to the parallel dowels embedded in the ORT400 table, may exhibit rotational movement or deflect under normal or foreseeable forces in clinical use. We have identified limitations in the current design that contribute to this potential hazard. Rotational movement at the table attachment point could result in HFD movement going unnoticed, which could result in a situation where surgical or medical intervention is necessary, a situation where navigation needs to be re-established, or a situation resulting in extended time under anesthesia for the patient. It may also be difficult to loosen the mount clamp component after use, potentially leading to ergonomic injury or a workaround during equipment teardown. IMRIS has not received reports of injury associated with this issue.



To minimize the potential risk of injury, IMRIS is taking the following corrective actions:

- The existing mount clamp component of the HFD100 used with ORT400 tables will be replaced with an improved design. The split block clamp and hand knob used for tightening the component onto the table are being improved to ensure rigid attachment of the HFD100 to the ORT400 table.

IMRIS has identified that your facility has one or more HFD100 mount clamp components that require replacement. Please confirm details on the last page of this letter and return your response to IMRIS. IMRIS Customer Service will contact you to facilitate replacement of this component at your facility.



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Until the HFD100 mount clamp component is replaced, IMRIS recommends these preventive actions:

- Ensure the instructions in the Operator Manual for proper HFD100 linkage assembly are followed to produce rigid fixation.
- Ensure there is no movement of the mount clamp component and of the HFD100 linkages prior to clinical use.

The appropriate regulatory agencies have been notified of this corrective action plan. IMRIS is committed to patient and user safety, and apologizes for any inconvenience that this may cause. Please contact our customer support team through our service line at 1-866-475-0525 or e-mail: customersupport@imris.com if you have any questions or concerns.

Sincerely,

A handwritten signature in black ink that reads "Tracy Brinkmeyer".

Tracy Brinkmeyer

Vice President, Quality & Regulatory



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Mount Clamp Component of HFD100 Head Fixation Devices used with ORT400 Operating Room Tables

IMRIS has identified that your facility has one or more HFD100 mount clamp components, used only with ORT400 tables, which require replacement. Please confirm the following information and return your response to IMRIS.

☐ Yes, our facility has the following HFD mount clamp component(s) at our facility:
☐ HFD mount clamp component serial number(s): _____

☐ If you have selected "Yes" above, please also select one of the following:
☐ Our HFD100(s) is currently in use with ORT400 table(s) at our facility.
☐ Our HFD100(s) is NOT currently in use with ORT400 table(s) at our facility. If this option is selected, please provide clarification below around why the HFD100(s) is NOT currently in use:

☐ No, our facility does not currently have an HFD100 in use with the ORT400 table at our facility; please indicate the reason it is no longer in use at your facility so that we can update our records:

Hospital Name:	
Name of person completing form:	
Title/Position of person completing form:	
Telephone Number and Email Address:	
Signature:	

All fields must be completed. Please return this form via mail, fax or email.

Address	IMRIS 5101 Shady Oak Road Minnetonka, MN 55343 USA
Fax	1-866-992-3224
Email:	customersupport@imris.com