⚠ URGENT MEDICAL DEVICE RECALL NOTICE

February 11, 2022

Subject: Unintended Couch Motion Resulting in Contact Between Patient Couch and Nozzle

The purpose of this letter is to advise you that Mevion has voluntarily recalled Hand Pendants for S250 and S250i. All Hand Pendants have been inspected for an identified defect. The Hand Pendants that failed inspection have been removed from service.

Statement of Problem

An instance occurred at a customer site where a stuck motion button (see image below) on the Hand Pendant caused unintended Couch motion. Without noticing the stuck button, a therapist engaged the Motion Enable Bars on the Hand Pendant and observed the Couch unexpectedly move in the direction associated with the stuck button. This Couch motion resulted in contact between the Couch and the Nozzle. The therapist released the Motion Enable Bars which stopped the Couch motion. No patient contact or injury occurred.

Description of Potential Harm

Unintentional motion of the Couch may produce injury to a patient if the patient comes in contact with mechanical force with the Nozzle or other objects in the treatment room. Marginal to lethal harm to a patient could be sustained without operator intervention.

Determination of Cause

After a comprehensive engineering investigation, it was determined that the Hand Pendant involved had a stuck motion button. This button became lodged beneath a misaligned overlay label surrounding the buttons on the Hand Pendant, causing the button to be continuously depressed. A defective Hand Pendant may cause unintended Couch motion if a motion button is stuck and the Motion Enable Bars are simultaneously engaged.

Containment/Mitigation

A technical service bulletin (TSB0048) describing an inspection procedure to identify defective product has been released to and implemented by Mevion Service.

All Hand Pendants at customer sites have been inspected and those that do not conform to this TSB Mevion inspection have been replaced.

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DID: LIN220211 VID: 1

Mevion will update the manufacturing inspection criteria to include a visual inspection of the button overlay alignment with the plastic top cover button openings to ensure proper clearance. All future shipments will be subject to the updated inspection criteria.

Required User Action

No user action is required at this time (except for completing and returning the acknowledgement receipt at the bottom of this notice). Mevion Service has already implemented TSB0048. Mevion recommends the users to review the User's Manual for safe Couch operation and Hand Pendant use. Users are reminded to contact Mevion Service in the event of unexpected System behavior before proceeding.

Corrective Action

Mevion will conduct further review and investigation of the design and manufacturing process of the Hand Pendant.

Please contact Mevion Customer service (robyn.walker@mevion.com) with any questions or concerns.

Please distribute this notice to all users of the Mevion Medical Systems device at your organization who may be affected by this issue.

xxx

Customer acknowledges receipt of this notice:

I have read and understood the notice.

Signature:

Name:

Title:

Email:

Institution:

Please sign, print and return acknowledgement to Field Service or by email to: robyn.walker@mevion.com