Asensus Surgical Italia S.R.L.
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20126 Milano, Italy
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www.asensus.com

FSCA Ref: FSCA-2023-000001

September 18, 2023

Urgent Field Safety Notice (FSN), Senhance Surgical System

Dear Valued Customer,

At Asensus Surgical the safety of all our products is a top priority. Unfortunately, with this letter Asensus informs you that a malfunction has been identified and may recur on the Senhance Surgical System. Below, Asensus provides a precise description of the situation and clear instructions to avoid any issue.

Information on Affected Devices

Device Type
Senhance Surgical System with Software (SW) version 2.7.4

Legal Manufacturer
Asensus Surgical Italia S.r.l.
Viale dell'Innovazione 3, 20126, Milano (MI) - Italy

Primary clinical purpose of device
The Senhance Surgical System is intended to assist in the accurate control of laparoscopic instruments for visualization and endoscopic manipulation of tissue including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrosurgery, suturing, mobilization, retraction, and sealing of vessels up to and including 5 mm in diameter in laparoscopic and thoracoscopic surgery. The system is indicated for adult and pediatric use. It is intended for use by trained physicians in an operating room environment in accordance with the Instructions for Use. Use of the device is limited to patients with a weight equal to or above 10 kg, who are suitable to be subjected to a conventional endoscopic technique.

Device part number
X9007708 Manipulator Arm, ISU Configuration
X9007696 Intelligent Surgical Unit
X9007707 Cockpit, ISU Configuration

Software version
2.7.4

Reason for Field Safety Corrective Action (FSCA)

Description of the product problem
Asensus Surgical has identified a malfunction that has occurred and may recur on the Senhance Surgical System. This issue presented itself as uncontrolled arm motion of the Laparoscope Instrument Actuator (LIA) where the LIA rotated continuously in one direction after the Surgeon removed the engagement of teleoperation on the Senhance System. There

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was no other uncontrolled arm motion observed. The Senhance System is designed with emergency stop capabilities to stop this issue if observed. There has been no patient impact or harm that has occurred due to this issue, however, the potential for an unacceptable outcome is possible (details below).

Hazard giving rise to the FSCA
Asensus Surgical has conducted a Health Hazard Evaluation and concluded that the potential severity for the outcome of uncontrolled arm motion is a harm of a "Critical" level. Specifically this issue may lead to a Critical Tissue Trauma (including but not limited to internal laceration).

Probability of problem arising
Asensus Surgical has conducted a Health Hazard Evaluation and concluded that the Probability of Occurrence of the issue is "Remote," meaning this event is likely to occur rarely during normal use.

Predicted risk to patient
Asensus Surgical has conducted a Health Hazard Evaluation and concluded that this issue poses a Moderate Risk to the patient. It is Asensus Surgical's policy that this risk must be reduced and thus action is being taken to address this issue in an urgent manner.

User actions to mitigate the risk

Asensus Surgical recommends stopping use of the Senhance Surgical System until software version 2.7.5 is installed.

Is follow-up of patients or review of patients' previous results recommended?
No follow-up on any patient is needed.

Is the FSN required to be communicated to the patient?
No

Is a reply required?
Yes, please complete the form in the last page and return it to regulatory@asensus.com

Asensus actions to mitigate the risk

A software upgrade will be performed by the Asensus Service Team.

Modifications to the Senhance software have been developed and verified. Software version 2.7.5 has been released as the latest software version to address this issue. If the malfunction occurs, SW 2.7.5 automatically triggers a power cut reproducing the emergency button trigger. This implementation will immediately stop the arm movement as no electric power is reaching the manipulator arm, triggering a service state that will force the user to reboot the arm.

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By when will the action be completed?
SW 2.7.5 installation will be performed by the Asensus Service team as soon as possible. You will be contacted by a Service Team representative to plan this activity.

General Information

FSN Type
First FSN

Further advice or information already expected in follow-up FSN?
No. Once SW version 2.7.5 is installed, the customer will be able to use the Senhance Surgical system again and the actions will be considered closed.

Transmission of this Field Safety Notice

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

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

I confirm that the Competent (Regulatory) Authority of your Country has been informed about this communication, together with the Italian Ministry of Health (CA where the manufacturer has its site). The Manufacturer Notified Body has also been duly informed.

Asensus Surgical apologizes for any inconvenience caused by this action.

If you have any questions on this notice, please contact:

[redacted]
Director, Global Quality/EMEA Regulatory
PRRC Person Responsible for Regulatory Compliance
Asensus Surgical Italia S.r.l.

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Field Safety Notice Customer confirmation receipt form
Please sign this form and return the signed copy to regulatory@asensus.com

Hospital Name and address

I, the undersigned, confirmed that this notice has been received and the information has been transmitted to the users of the device at my institution. Also, the content has been understood and all the actions requested by the FSN have been executed.

Print Name
Title
Signature
Date