Asensus Surgical Italia S.R.L.
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www.asensus.com

FSCA Ref: FSCA-2023-000002

November 29, 2023

Urgent Field Safety Notice (FSN), RADIA

Dear Valued Customer,

At Asensus Surgical the safety of all our products is a top priority. Unfortunately, with this letter Asensus informs you that an issue has been identified on a specific lot of Radia Effectors.

Below, Asensus provides a precise description of the situation and clear instructions.

Information on Affected Devices

Device Type
PN X9007738 - RADIA Effector Universal Needle Holder - Box of 5

Lot
230504003

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

Primary clinical purpose of device
RADIA Effectors are accessories for use with the Senhance® Surgical System to provide an articulating instrument. The RADIA Effectors are sterile, single-use, disposable components. Each RADIA Effector is contained within a device carrier for easy attachment to the RADIA Shaft. The entire RADIA Effectors, with exception of the device carrier, are patient contacting.
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.

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Reason for Field Safety Corrective Action (FSCA)

Description of the product problem
RADIA Effector part number X9007738 lot 230504003 was released to market, but the scheduled dose audit was not performed to confirm the validity of the gamma sterilization process. Potentially, the sterility of this lot is affected and cannot be guaranteed.

Hazard giving rise to the FSCA
Asensus Surgical has conducted a Health Hazard Evaluation and concluded that the potential severity for the usage of an Effector with compromised sterility is a harm of a "Critical" level.

Probability of problem arising
Asensus Surgical has conducted a Health Hazard Evaluation and concluded that the Probability of Occurrence of the issue is "Improbable".
The likelihood of the hazardous situation occurring is unlikely to occur ("Improbable") as certificates of sterility were properly received and archived, thus the product has been exposed to Gamma Sterilization according to defined and validated process parameters and the minimum required dose is significantly below the sterilization dose.

Predicted risk to patient
Asensus Surgical has conducted a Health Hazard Evaluation and concluded that this issue poses a Low 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 segregating and not using PN X9007738 - RADIA Effector Universal Needle Holder - Box of 5, lot 230504003 until further notice.

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

Asensus will conduct sterility testing on samples of the same lot (X9007738, lot 230504003)

By when will the action be completed?
Sterility testing will be conducted as soon as possible; once sterility is confirmed, you will be entitled to use the affected lot again.

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General Information

FSN Type
First FSN

Further advice or information already expected in follow-up FSN?
Yes. Once sterility testing will be executed, if sterility is confirmed the user will be advised to resume usage of lot 230504003 (PN X9007738). If from testing results, sterility is compromised, a recall of the lot will be executed.

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:

Luisa Mella
Director, Global Quality/EMEA Regulatory
PRRC Person Responsible for Regulatory Compliance
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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