PAJUNK® GmbH Medizintechnologie | Karl-Hall-Str. 1 | 78187 Geisingen, Germany

# Urgent Field Safety Notice
# StimuLong Sono II Sets

FSCA-009-25_2025

For Attention of: Distributors, Hospitals or Users which received the following devices
Manufacturer: PAJUNK® GmbH Medizintechnologie
Karl-Hall-Str. 1
78187 Geisingen
Baden-Wuerttemberg, Germany

## 1. Identification of Affected Devices

| Device Trade Name | Item Number | Batch Number |
|---|---|---|
| StimuLong Sono II NanoLine® | 521187-32C | 1591 |
| StimuLong Sono II NanoLine® | 531187-32A | 1590 |
| StimuLong Sono II NanoLine® | 531187-32C | 1591 |

## 2. Reason for Field Safety Corrective Action (FSCA)

PAJUNK® GmbH Medizintechnologie received information from the field on a manufacturing problem of the products and batch identified above.

Due to this, PAJUNK® GmbH Medizintechnologie cannot guarantee that the products can be used as intended. The affected components cannot be connected to the Clamping Adapter and a subsequent application of anesthetic agent is impossible.

The above stated issue was identified and limited to the products listed in the attachment. To avoid potential hazards, PAJUNK® GmbH Medizintechnologie has decided to inform affected customers about this issue and to recall the affected StimuLong Sono II NanoLine® sets.

Description of the Potential Consequences to Patients:

In the case of failure, the affected products do not comply with their specifications. The procedure of injection of anesthetic may be delayed, or cannot be performed at all due to lack of a compatible connector to an external infusion unit.

## 3. Action to be Taken by the User

a. Identify the affected products (per Attachment 1) and quarantine!
b. Do not use any of the affected products!
c. Please fill in and return the attached reply form (Attachment 2) accompanied by the affected products to your contact point at PAJUNK® GmbH Medizintechnologie / your distributor of PAJUNK® GmbH Medizintechnologie devices.

## 4. Further Actions Planned by PAJUNK® GmbH Medizintechnologie

PAJUNK® GmbH Medizintechnologie has reviewed the production process, taken corrective action and will implement preventive actions to ensure the highest level of patient safety, product safety and product quality.

## Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organization. Please transfer this notice to any organization on which this action has an impact or inform below mentioned contact person about third parties where the affected products have been transferred to. Please retain this information at least until the measure has been completed by PAJUNK® GmbH Medizintechnologie. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

**Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate.**

Your national Competent Authority has received a copy of this Urgent Field Safety Notice.

We apologize for any inconvenience this may have caused. If there are any questions regarding this issue, please contact one of the contact persons listed below.
Thank you for your understanding and support in advance.

**Contact Person Quality Management:**

**Jelena Juric**

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## Attachment 1

## Affected devices

| Device Trade Name | Item Number | Batch Number |
|---|---|---|
| StimuLong Sono II NanoLine® | 521187-32C | 1591 |
| StimuLong Sono II NanoLine® | 531187-32A | 1590 |
| StimuLong Sono II NanoLine® | 531187-32C | 1591 |

**Attachment 2**
**Reply form**

Please return this form together with the original letter within 5 days of receipt of the urgent field safety information by fax, letter or e-mail attachment to above mentioned contact person or to safety@pajunk.com.

| Recipient: |
|---|
| PAJUNK® GmbH Medizintechnologie<br>Karl-Hall-Straße 1<br>**78187 Geisingen** |

| Customer Details: | |
|---|---|
| Healthcare Organisation Name | |
| Organisation Address | |
| Contact Name | |
| Telephone number | |
| Email | |

| Customer Actions Undertaken | | |
|---|---|---|
| I confirm receipt of the Field Safety Notice and that I read and understood its content. | ☐ Yes | ☐ N/A |
| I performed all actions requested by the FSN. | ☐ Yes | ☐ N/A |
| The information and required actions have been brought to the attention of all relevant users and executed. | ☐ Yes | ☐ N/A |

| | | Quantity | Batch Numbers | Date of Action |
|---|---|---|---|---|
| ☐ | I have returned affected devices - enter number of devices returned and date complete. | | | |
| ☐ | I have destroyed affected devices – enter number destroyed and date complete. | | | |
| ☐ | Devices have already been used on patients / no return or destruction possible. | | | |

**SIGNATURE AREA**

Name/ position [BLOCK LETTERS] Date/ signature