PAJUNK®
Trust Tradition. Experience Innovation.

PAJUNK® GmbH Medizintechnologie | Karl-Hall-Straße 1 | 78187 Geisingen

USER FACILITY
USER FACILITY Street Address
12345 **USER FACILITY TOWN**
USER FACILITY COUNTRY

Geisingen, 2024-10-23

Field Safety Notice

Corrective Action of Rectus Sheath NRFit 0731163-49 Lot 1555

Manufacturer/ Sender

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

IDENTIFICATION OF AFFECTED DEVICES:

Trade Name:	**NRFit Rectus Sheath**
Item number(s):	**0731163-49**
BATCH:	**1555**

Dear valued Customer,

PAJUNK® GmbH Medizintechnologie has received information from the field that affects the batch 1555 of the Rectus Sheath NRFit item number **0731163-49.**

The Rectus Sheath NRFit products are used for rectus sheath block analgesia.

This letter is meant to inform you about the problem, explain the measures you have to take and the actions that PAJUNK® GmbH Medizintechnologie has in place to address this issue.

Affected products
The complete list of affected products including item number is attached to this letter (Attachment 1).

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Description of product problem

PAJUNK® GmbH Medizintechnologie received information from the field about a problem which has occurred in the assembly during manufacturing of a component of the products and batch identified above.

Due to this problem, PAJUNK® GmbH Medizintechnologie cannot guarantee with sufficient certainty that the products can be utilized as intended. The catheter cannot be connected to the ClampingAdapter and application of anesthetic agent is impossible.

The problem was identified and limited to the products listed in the attachment. To avert potential hazards, PAJUNK® GmbH Medizintechnologie has decided to inform you about this issue and provide functional ClampingAdapters to replace the faulty ones prior to intervention.

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, require a re-puncture or cannot be performed at all due to lack of a connector to an external infusion unit

<u>Action to be taken by the recipient</u>

1. Identify the affected products (per attachment 1) and quarantine!
2. If you are a distributor, please forward this information directly to the target users.
3. Do not use any of the affected products without contacting or being contacted by PAJUNK® GmbH Medizintechnologie
4. Representatives of PAJUNK® GmbH Medizintechnologie will contact every customer and will provide functional ClampingAdapters.
5. Please fill in and return the attached reply form (Attachment 2) to your contact point at PAJUNK® GmbH Medizintechnologie / your distributor of PAJUNK® GmbH Medizintechnologie devices.

Further actions planned by PAJUNK® GmbH Medizintechnologie

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

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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 "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.

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Contact person Managing Director:

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Unit D1, The Waterfront
Goldcrest Way
Newcastle upon Tyne, NE15 8NZ
Phone:+44 (0) 7766 078 949
Stephen.Brown@pajunk.co.uk

Contact person Regulatory Affairs / Safety Officer:

Christian G. H. Quass
Director Regulatory Affairs & Safety Officer for Medical Devices
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PAJUNK® GmbH Medizintechnologie | Karl-Hall-Straße 1 | 78187 Geisingen

Attachment 1

List of affected products

Product Description	Item Number	LOT
Rectus Sheath NRFit	0731163-49	1555

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Germany

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USt-IdNr.: DE 812493272
Sitz der Gesellschaft: Geisingen
Registergericht: Stuttgart HRB 450245
Geschäftsführung:
Simone Pajunk-Schelling, Martin Hauger

Bank:
Volksbank eG Villingen *IBAN:* DE14 6949 0000 0080 0577 09 | *BIC:* GENODE61VS1
Deutsche Bank Villingen-Schwenningen *IBAN:* DE72 6928 0035 0832 9333 00 | *BIC:* DEUTDE6F694
Commerzbank AG *IBAN:* DE72 6928 0035 0832 9333 00 | *BIC:* DRESDEFF692

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Attachment 2
Reply Form

Please return this form together with the original letter within 5 days of receipt of the Field Safety Notice by fax, letter or e-mail attachment to the person named in the cover letter, **info@pajunk.co.uk** or to **safety@pajunk.com**

Recipient:	Sender [stamp/physical address of institution]
PAJUNK® GmbH Medizintechnologie -Sicherheitsbeauftragter- Karl-Hall-Straße 1 **78187 Geisingen**	

We hereby confirm receipt of the aforementioned Field Safety Notice.

We have identified affected devices in our institution.	[PLEASE FILL IN NUMBER+LOT]
Number of affected devices that have already been used on patients to date:	

SIGNATURE AREA

_____

Name/ position [BLOCK LETTERS] Date/ signature