PAJUNK®
Trust Tradition. Experience Innovation.

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

Leon Green
NHS Supply Chain
West Way,
Coates Park Industrial Estate
Alfreton.
Derbyshire. DE55 4QJ

Geisingen, 2021-10-29

Urgent Field Safety Notice

RECALL OF SPROTTE® NRFit® 051163-29A Batch 1338, 1343

Manufacturer/ Sender

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

IDENTIFICATION OF AFFECTED DEVICES:

Trade Name:	**SPROTTE® NRFit®**
Item number(s):	**051163-29A**
BATCH	**1338, 1343**

Dear valued Customer,

PAJUNK® GmbH Medizintechnologie has received the information from the field that may affect 2 batches of the SPROTTE® NRFit® anaesthesia conduction needles identified above.

The needles type "SPROTTE® NRFit®" are used for puncture of the spinal space for regional anaesthesia.

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 the 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 packaging during the manufacturing of certain products.

Due to this problem, PAJUNK® GmbH Medizintechnologie cannot guarantee with sufficient certainty that the needle´s **specification identified in the label which is SPROTTE® NRFit® matches with the content.**

The problem could be identified and limited to the products listed in the attachment. To avert potential hazards, PAJUNK® GmbH Medizintechnologie has decided to recall the affected products.

Description of the potential consequences to patients:

In the case of failure to comply with this customer information there is a risk of using a puncture needle which afterwards cannot be used to a infusion device e. g. a syringe with a NRFit connector because the connection does not match. The procedure may be delayed or require re-puncture with a NRFit® needle (if available).

Action to be taken by the recipient

1. Identify the affected products (per Attachment 1) and quarantine!
2. Do not use any of the affected products!
3. 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.

Further actions planned by PAJUNK® GmbH Medizintechnologie

PAJUNK® GmbH Medizintechnologie has reviewed the packaging process, taken corrective action and will implement preventive actions to ensure the highest level of product safety and 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 "Urgent safety information: RECALL of a Medical Device".

Contact person logistics / customer service:

Ms. Nilüfer Sen
PAJUNK® GmbH Medizintechnologie
Karl-Hall-Strasse 1
78187 Geisingen
Baden-Wuerttemberg, Germany
Fon +49(0)7704-9291 ext. 647
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Mrs Dianne Chamberlain
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Unit C1, The Waterfront
Goldcrest Way
Newburn Riverside
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Phone:+44 (0)191 264 7333
Dianne.chamberlain@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

Item Number	LOT
051163-29A	1338
051163-29A	1343

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Attachment 2
Reply Form

Please return this form together with the original letter within 5 days of receipt of the urgent safety information 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 urgent safety information.

We have identified affected devices in our institution. (If multiple batches or multiple article numbers are involved, PAJUNK® GmbH Medizintechnologie requests that you kindly submit a detailed breakdown.)	[PLEASE FILL IN NUMBER+LOT]
Number of devices/ individual packs that we are immediately returning:	
Number of affected devices that have already been used on patients to date:	

SIGNATURE AREA

_____

Name/ position [BLOCK LETTERS] Date/ signature