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

Geisingen, 2019-09-02

Urgent Field Safety Notice

RECALL OF CERTAIN BATCHES

of

SPROTTE® lumbal with Introducer

SENDER:

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

RECIPIENT:

Xxx
Xxx
xxx

IDENTIFICATION OF AFFECTED DEVICES:

Trade Name:	**SPROTTE® Lumbar with Introducer**
Item number(s):	**see ATTACHMENT I**
BATCH	**BATCH 1240 - 1313**

Dear valued Customer,

PAJUNK® GmbH Medizintechnologie has internally identified a packaging problem that may affect certain batches of the SPROTTE® lumbar puncture cannulas with introducer listed in Attachment 1.

The cannulas type "SPROTTE®" are used for diagnostic lumbar puncture / puncture of the spinal space for CSF collection.

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This letter is meant to inform you about the problem, explain the measures you have to take and the actions that PAJUNK 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).

Description of product problem

PAJUNK® GmbH Medizintechnologie received information about a problem which has occurred in the packaging sealing process during the manufacturing of certain products.

Due to this problem, PAJUNK® GmbH Medizintechnologie cannot guarantee with sufficient certainty that the sterilized medical devices to which this safety measure applies remain reliably sterile during their defined storage and shelf life.

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 non-sterile product on the patient.

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®/ your distributor of PAJUNK®-devices.

Further actions planned by PAJUNK® GmbH Medizintechnologie

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

PAJUNK® GmbH Medizintechnologie will replace the returned devices subject to this recall free of charge and without any additional order within 2 – 5 weeks.

PAJUNK® GmbH
Medizintechnologie
Karl-Hall-Straße 1 · D-78187 Geisingen
Telefon +49 (0) 77 04/92 91-0
Telefax +49 (0) 77 04/92 91-600
info@pajunk.com · www.pajunk.com

Sitz der Gesellschaft: Geisingen
Registergericht:
Stuttgart, HRB 450245
Geschäftsführer:
Simone Pajunk-Schelling,
Martin Hauger

Volksbank eG Villingen
BIC: GENODE61VS1 · IBAN: DE14 6949 0000 0080 0577 09
Deutsche Bank Villingen-Schwenningen
BIC: DEUTDE6F694 · IBAN: DE73 6947 0039 0022 7389 00
Commerzbank AG
BIC: DRESDEFF692 · IBAN: DE72 6928 0035 0832 9333 00

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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 organisation. Please transfer this notice to any organisation 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, Swissmedic, Hallerstrasse 7, CH-3000 Bern 9, has received a copy of this "Urgent safety information: RECALL of a Medical Device".

Contact person logstics / customer service:

Ms. Nilüfer Sen
PAJUNK® GmbH Medizintechnologie
Karl-Hall-Strasse 1
78187 Geisingen
Baden-Wuerttemberg, Germany
Fon +49(0)7704-9291 ext. 647
Fax +49(0)7704-9291 ext. 600
Niluefer.sen@pajunk.com

Contact person Regulatory Affairs / Safety Officer:

Christian G. H. Quass
Director Regulatory Affairs & Safety Officer for Medical Devices
PAJUNK® GmbH Medizintechnologie
Karl-Hall-Strasse 1
78187 Geisingen
Baden-Wuerttemberg, Germany
Fon +49(0)7704-9291 ext.586
Fax +49(0)7704-9291 ext.602
christian.quass@pajunk.com
www.pajunk.com

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Attachment 1

List of affected products

Item Number	LOT
331151-30C SPROTTE Lumbal	1240 to 1313
331151-30C SPROTTE Lumbal	1240 to 1313
321151-30C SPROTTE Lumbal	1240 to 1313
321151-31C SPROTTE Lumbal	1240 to 1313
341151-30C SPROTTE Lumbal	1240 to 1313
321151-31A SPROTTE Lumbal	1240 to 1313
331151-31A SPROTTE Lumbal	1240 to 1313
331151-31B SPROTTE Lumbal	1240 to 1313
341151-31A SPROTTE Lumbal	1240 to 1313

PAJUNK® GmbH
Medizintechnologie
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Commerzbank AG
BIC: DRESDEFF692 · IBAN: DE72 6928 0035 0832 9333 00

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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 or to **sibe@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.)

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