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, 2024-12-09

Field Safety Notice

Recall of DeltaCut Biopsy 315S120280 Lot 1542, 1546, 1548, 1551, 1554

Manufacturer/ Sender

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

IDENTIFICATION OF AFFECTED DEVICES:

Trade Name:	**DeltaCut Biopsy**
Item number(s):	**315S120280**
BATCH:	**1542, 1546, 1548, 1551, 1554**

Dear valued Customer,

PAJUNK® GmbH Medizintechnologie has received information from the field that affects the batches 1542, 1546, 1548, 1551 and 1554 of the DeltaCut Biopsy item number 315S120280.

The DeltaCut Biopsy products are used for extraction of tissue specimens from soft tissue.

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).

Description of product problem

PAJUNK® GmbH Medizintechnologie received information from the field about detaching hubs of the biopsy needles during use. This potential failure pattern has been confirmed by internal investigation and further occurrence cannot be excluded.

Due to this problem, PAJUNK® GmbH Medizintechnologie cannot guarantee with sufficient certainty that the products can be utilized as intended. The DeltaCut biopsy needle hub can detach from the cannula tube and therefore a biopsy cannot be taken as intended/ the specimen cannot be used.

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 recall the products.

Description of the potential consequences to patients:

In case of failure, the affected products do not comply with their specifications. The procedure may be delayed, require a re-puncture or cannot be performed at all.

<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!
4. 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 processes, 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 "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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PAJUNK® GmbH Medizintechnologie | Karl-Hall-Straße 1 | 78187 Geisingen

Contact person customer service:

Nilüfer Sen

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Karl-Hall-Strasse 1
78187 Geisingen
Baden-Wuerttemberg, Germany
Fon +49(0)7704-9291 ext. 647
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Niluefer.sen@pajunk.com

Contact person Regulatory Affairs:

Christian G. H. Quass
Director Regulatory Affairs & PRRC-RA 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
DeltaCut Biopsy	315S120280	1542
DeltaCut Biopsy	315S120280	1546
DeltaCut Biopsy	315S120280	1548
DeltaCut Biopsy	315S120280	1551
DeltaCut Biopsy	315S120280	1554

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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 or to **safety@pajunk.com**

Recipient:	Sender [stamp/physical address of institution]
PAJUNK® GmbH Medizintechnologie Quality Management -PRRC-Q- Pajunkstrasse 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 devices/ individual packs that are immediately returning:	
Number of affected devices that have already been used on patients to date:	
Number of affected devices that have been disposed:	

SIGNATURE AREA

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Name/ position [BLOCK LETTERS] Date/ signature