



Urgent Field Safety Notice

Vereinigte Papierwarenfabriken GmbH, Industriestrasse 6, 91555 Feuchtwangen

FSN Ref: FSN-2023-06-A

FSCA Ref: FSCA-2023-06-29

Date: 04.07.2023

Urgent Field Safety Notice
Recall of Stericlin® see-through reels made of paper and film
with partially incomplete seal

For Attention of:

Person responsible for regulatory compliance of medical devices, or head of central sterilisation supply department (CSSD)

Contact details of manufacturer:

Vereinigte Papierwarenfabriken GmbH
Dr. Jürgen Wirtz
Industriestrasse 6
D-91555 Feuchtwangen


+49 (0) 9852 901 134
regulatory@vp-group.de



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Recall of Stericlin® see-through reels made of paper and film
with partially incomplete seal

1. Information on Affected Devices	
1	1. Device Type(s) Stericlin® see-through reels flat made of paper and film Reel width 15 cm, 200 m on a reel non-sterile supply, for sterile packaging of terminally sterilised medical devices 
1	2. Commercial name(s) Stericlin® see-through reels flat made of paper and film
1	3. Unique Device Identifier(s) (UDI-DI + UDI-PI) GTIN (UDI-DI): 54009445230059 UDI-PI: 27093030501683FKFS230110
1	4. Primary clinical purpose of device(s) It is a premanufactured sterile barrier system for use in packaging systems for terminally sterilized medical device, where the primary purpose of the packaging systems is to enable sterilisation, physical protection, sterility maintenance and aseptic presentation of the medical device. The intended user is the trained specialist staff in the processing units of the health care facilities. There is no direct patient contact with the product.



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1	5. Device Model/Catalogue/part number(s) 3FKFS230110
1	6. Affected serial or lot number range(s) Article number: 3FKFS230110 Description: See-through reels flat made of paper and film Size: 15 cm / 200 m Lot number: 3050168 Box number: 2023 to 2073, reels 4045 to 4145 packaged within aforementioned boxes. Only such reels with an additional marking „position 5“ are assumed to be potentially affected (for this marking, refer to the illustration in the attachment to this document)

2 Reason for Field Safety Corrective Action (FSCA)	
2	1. Description of the product problem On the reels concerned, one of the two sealing seams is missing over a length of about 25 cm, or the foil and paper adhering to one another just very slightly. All three grooves of the groove sealing are affected on the aforementioned length. The incompleteness of the seal is visually recognizable, and the seal seam is open or will open at a very slight stress level. The defective seal is repeating in the affected reels regularly after about every meter within the roll.
2	2. Hazard giving rise to the FSCA It cannot be ruled out that such defect seals could also have occurred on other rolls of the identified lot number (3050168) in the limited range of certain roll numbers (4046 to 4145). If such reels were to be used, it could not be ruled out



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	that the defective sealing seam could go unnoticed. In this case, the integrity of the sterile barrier packaging formed by the paper film reel respectively the sterility of the packaged medical product would not be guaranteed.
2	<p>3. Background on Issue</p> <p>The problem became known when the reels with the reel numbers 4140 and 4145 of the affected lot 3050168 were complained about with the defect of seals as described. The error was noticed by the users in the hospitals before using the material. Due to the quality checks carried out by the manufacturer during the production of lot 3050168, it was possible to narrow down the probability of error to certain reels. According to this limitation, only reel numbers from 4046 to 4145 can be affected by the defect. These reels were supplied – with two reels in one box – with the box numbers 2023 to 2073 in the time period until December 2022.</p>

	3. Type of Action to mitigate the risk	
3	<p>1. Action To Be Taken by the User</p> <p> <input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input type="checkbox"/> Other <input type="checkbox"/> None </p> <p>Affected product (please refer to the instructions as provided in section 1.6 „Affected lot number range“) will be picked-up by us. A refund will happen after your feedback concerning identification of affected products. Please do not destroy any product without prior consultation with us.</p>	
3	2. By when should the action be completed?	immediately (identification and quarantine of products) by 21.07.2023 (return of products)
3	3. Is customer Reply Required? <i>(If Yes, please use the Customer Feedback Form as attached to this FSN)</i>	Yes
3	<p>4. Action Being Taken by the Manufacturer</p> <p> <input checked="" type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> IFU or labelling change <input type="checkbox"/> Other <input type="checkbox"/> None </p>	
3	5. By when should the action be completed?	21 July 2023



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4. General Information	
4	1. FSN Type New Field Safety Notice
4	2. Further advice or information already expected in follow-up FSN? No
4	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)
	a. Company Name Vereinigte Papierwarenfabriken GmbH
	b. Address Industriestrasse 6 D-91555 Feuchtwangen
	c. Website address www.vp-group.de
4	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.
4	5. List of attachments/appendices: <ul style="list-style-type: none">• Customer feedback form• Illustration of labels inside of the cores of the reels• Illustration for better identification of position #5 in a roll
4	6. Name/Signature 

Transmission of this Field Safety Notice	
	<p>This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.</p>



Attachment to Urgent Field Safety Notice

Vereinigte Papierwarenfabriken GmbH, Industriestraße 6, 91555 Feuchtwangen

FSN Ref: FSN-2023-06-A

FSCA Ref: FSCA-2023-06-29

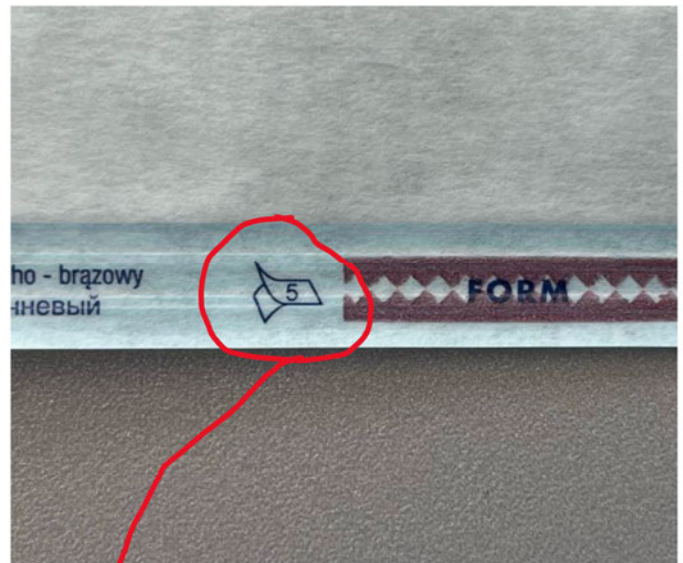
Date : 04.07.2023

Attachment to Urgent Field Safety Notice
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with partially incomplete seals



Batch/LOT number: 3050168

Reel – number: 4046 to 4145



Only the reels of the position #5 are affected (identifying digit within the peel symbol)

Presumably affected reels* from the number range according to limitation:

4050, 4055, 4060, 4065, 4070, 4075, 4080, 4085, 4090, 4095
4100, 4105, 4110, 4115, 4120, 4125, 4130, 4135, 4140, 4145

* All reels from reel no. 4046 to reel no. 4145 have to be checked for the number of position. All reels with position identifier „5“ are potentially affected, while any reels with identifiers „1“, „2“, „3“ or „4“ are not affected



Important Customer Feedback

Vereinigte Papierwarenfabriken GmbH, Industriestrasse 6, 91555 Feuchtwangen

**Please return this 2-page form sheet filled and signed
latest by 14.07.2023 to**

**Vereinigte Papierwarenfabriken GmbH
Regulatory Affairs
attn. Dr. Jürgen Wirtz
Industriestrasse 6
D-91555 Feuchtwangen**

alternativ E-Mail contact:
regulatory@vp-group.de

1 Safety relevant product information (FSN – Field Safety Notification)

Date: 04.07.2023
Article number: 3FKFS230110
UDI (Unique Device Identification) 54009445230059 (UDI-DI resp. GTIN)
27093030501683FKFS230110 (UDI-PI)
Batch number: 3050168
Box number: 2023 to 2073

Reference: *Our letter from 04.07.2023 "Urgent Field Safety Notice - Recall of Stericlin® see-through reels made of paper and film with partially incomplete seals"*

2 Customer

Name of the Organisation	
Address	
Name of Contact Person	
Title / Function	
Telephone	
E-Mail	
Other Information:	



Important Customer Feedback

Vereinigte Papierwarenfabriken GmbH, Industriestrasse 6, 91555 Feuchtwangen

3 Confirmations (please place crosses accordingly)

- I herewith confirm receipt of the product-safety relevant information (report) as referenced in section 1. I have completely read this information and understood the content.
- At the time of receipt of this report all concerned products have completely been used up by our organization.
- At the time of receipt of this report not all concerned products have been used up by our organization.
 - The products concerned by this report and not completely used up by our organisation have already been returned to Vereinigte Papierwarenfabriken GmbH, Industriestrasse 6, 91555 Feuchtwangen.
 - The products concerned by this report and not completely used up by our organisation are still in blocked inventory and will be immediately returned to Vereinigte Papierwarenfabriken GmbH, Industriestrasse 6, 91555 Feuchtwangen.
 - Products concerned by this report and not yet used in our production have been finally disposed already. We herewith confirm their destruction. Please also tell us the quantity in pieces, running meters or rolls that have been destroyed.

Destroyed Quantity:

- Other additional actions taken (please specify):

Date, signature	
Name in capital letters, title, or function possibly company stamp	