



Urgent Safety Information: Field Safety Corrective Action (FSCA)

To: Distributors/Dealers, Medical Device Safety Officers

Please ensure that all users within your organization are made aware of this "Urgent Safety Notice."

Recall of Sterilely Packaged Saw Blades

Recall Number: RA_ 2026-01

Date: April 28, 2026

Manufacturer:

newbox medical GmbH

Euler Street 14-16

48155 Münster

Affected product

Item number	Description	GTIN	Lot	Best Before
CS82-19-127-S	Saw blade 90.0 x 19.0 x 1.27 mm, sterile	4059216045158	W01525	02/20/2036
CS82-23-127-S	Saw blade 90.0 x 23.0 x 1.27 mm, sterile	4059216078316	W01541	02/20/2036

Product description:

newbox medical saw blades are intended for use by qualified surgeons to cut and remove bone tissue during various surgical procedures

Description of the problem:

With the product mentioned above, the sterile barrier may open unintentionally due to insufficient strength of the seal. This can result in the product no longer being sterile.

Potential risks

There is a risk of infection.

What actions should the recipient take?

According to our records, you were supplied with the product mentioned above.

1. Please check immediately whether you have any units of the affected product in stock. Isolate the affected products to prevent their use.
2. Please return the signed response form to fsn@newbox-medical.com . A response is required even if you do not have any stock.
3. Upon receipt of your response, we will coordinate the replacement of the goods with you.
4. Please inform other parties about this **"Urgent Safety Notice"** if you have distributed the item.
5. If you are a retailer, please notify affected customers.

Please report all product-related incidents to the manufacturer, distributor, or local representative, and, if applicable, to the relevant national authority, as this constitutes important feedback.

If you have any questions or need to report an issue, please contact your designated contact person.

Contact Person

Name: Clint Schöppner

Position: PRRC

Email: fsn@newbox-medical.com

Phone: 0251 – 97824290

Fax: 0251 – 97284299

We confirm that the national authority in your country (EU) has been informed of this notice to customers.

We thank you for your support and apologize for any inconvenience caused.

Sincerely,

Clint Schöppner

newbox medical GmbH

Management, PRRC



Response Form

newbox medical GmbH
Euler Street 14-16
48155 Münster

Recall of Sterilely Packaged Saw Blades Recall Number:

RA_2026-01

Date: April 28, 2026

Please return the completed and signed form to us immediately—no later than April 30, 2026—by email to fsn@newbox-medical.com . By signing, you confirm that you have read and understood the “**Urgent Security Information**,” implemented the necessary measures, and made them available to all users.

Please select one option—a response is required

There are no units of the affected product in stock I am returning the following products for a free replacement

Item number	Description	Batch	Best Before Date	Quantity
CS82-19-127-S	Saw blade 90.0 x 19.0 x 1.27 mm, sterile	W01525	02/20/2036	
CS82-23-127-S	Saw blade 90.0 x 23.0 x 1.27 mm, sterile	W01541	02/20/2036	

Name of the facility	
Facility Address	
Name	
Email	
Phone	
Date	
Signature	

When sharing the articles with other parties and organizations

Name of the institution	
Address of the institution	
Quantity transferred	