

Richard Wolf GmbH • Postfach 11 64 - 65 • 75434 Knittlingen, Germany

Department: Customer Service
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Your reference • Your correspondence dated • Our reference QM700024802 • Date June 11, 2025

Emergency safety notice

Affected products:

Product number: 2260021 FOOTSWITCH 2 PEDALS, L 5 M

Our reference no.: QM 700024802
Actor ID/SRN: DE-MF-000007048

Dear Sir / Madam,

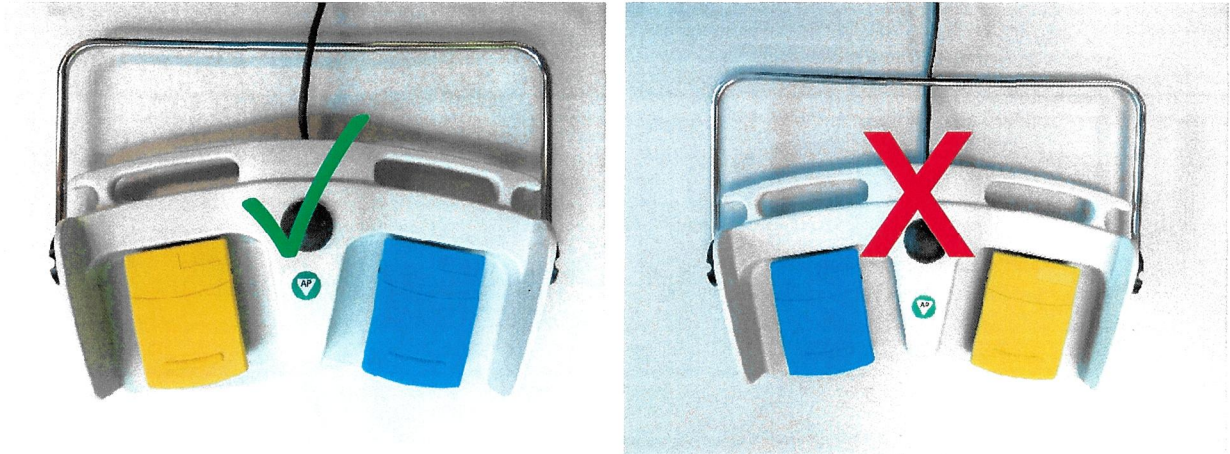
As part of our continuous product monitoring procedure, our attention has been drawn to a potential defect.

According to our records, you operate the potentially affected product. The procedure for rectifying the defect is set out in this letter.

Material	Serial number		
2260021	SN00377	SN00387	SN00395
	SN00380	SN00388	SN00396
	SN00381	SN00389	SN00397
	SN00382	SN00390	SN00398
	SN00383	SN00391	SN00399
	SN00384	SN00392	SN00400
	SN00385	SN00393	

The problem

Richard Wolf has identified an assembly error in a batch of the FOOTSWITCH 2 PEDALS L 5 M. The color coding on the pedal caps is the wrong way round.



According to the instructions for use (GA-A339) and the specifications in standard IEC 60601-2-2, the left pedal cap should be yellow (indicating cutting) and the right pedal cap should be blue (indicating coagulation). On the affected products, the color coding is the wrong way round, however: the left is blue (cutting) and the right is yellow (coagulation). The electrical functionality is assigned correctly; it is solely the colored caps that do not meet the requirements set out in the relevant standard.

This deviation from the established color coding represents a relevant product risk. In a typical operating situation, the OR staff often rely on the color coding of the footswitches, particularly in hectic or emergency situations when decisions have to be made quickly. Potential confusion regarding the pedal function cannot be ruled out in these circumstances, particularly as the user will primarily be directing their attention toward the operating site and the acoustic signals of the device. Even if the acoustic signals are correct and the electrical functionality is achieved, the incorrect visual guidance provided by the colored caps must be assessed as critical.

We want to pre-empt this situation by implementing this measure.

Measures to be taken by the addressee

Read through both this letter and the attached reference documents (see list of attachments) and keep them on file until the measure has been implemented.

Please follow the steps below:

1. Check your inventory for the material and serial numbers listed above.
2. If you have an affected footswitch, take it out of service immediately.
3. Within your organization, make sure that all users of the product referred to here and any other persons who require this information have been made aware of this emergency safety notice. If

you have passed on this product to third parties, please forward a copy of this notice and inform the contact persons stated below accordingly.

4. Make sure that this notice is retained within your facility until all the in-house measures required have been implemented.
5. To verify that you have received this emergency safety notice, we require you to return the enclosed **response form by June 30, 2025**. You can send this to us **via e-mail to FSCA700024802@richard-wolf.com**. We also ask that you complete this form even if you no longer have the product in stock. In doing so, you will be confirming receipt of this safety notice and you will not receive any further reminders from Richard Wolf.
6. Please inform Richard Wolf GmbH of any adverse events.

Based on our delivery records, Richard Wolf will automatically send you the right number of replacement parts over the coming days. A description of how to connect the footswitch is provided in the instructions for use.

The faulty footswitch must be destroyed by cutting through the connection cable at the housing outlet. To prove that the product has been destroyed, we require you to provide a photograph that clearly shows the type plate and the cut cable.

The relevant national authorities have been informed of this **emergency safety notice**.

Your contact for

Questions concerning safety:

Mr. Martin Senger
Head of Quality Engineering Department

Tel.: +49 7043 35 4011
E-mail: FSCA700024802@richard-wolf.com

Questions concerning the procedure:

Mr. Thilo Musikant
Head of Customer Service Department and Service Center

Tel.: +49 7043 35 4189
E-mail: thilo.musikant@richard-wolf.com

Please accept our apologies for any inconvenience caused by this measure. On behalf of Richard Wolf GmbH, thank you in advance for your support in ensuring its timely implementation.

Yours faithfully,
Richard Wolf GmbH

Martin Senger
Head of Quality Engineering Department

Thilo Musikant
Head of Customer Service Department and Service Center

Annexes:
Response form

Response form

by e-mail to FSCA700024802@richard-wolf.com

Emergency safety notice concerning:

2260021 FOOTSWITCH 2 PEDALS L 5M

Our reference no.: QM 700024802

Please read this document together with emergency safety notice QM700024802 and complete, sign, and return this document as soon as possible – no later than **June 30, 2025** – by e-mail to FSCA700024802@richard-wolf.com.

Please check the boxes as applicable.	
<input type="checkbox"/>	We confirm that we have received, read, and understood the emergency safety notice.
<input type="checkbox"/>	We are an active healthcare facility .
<input type="checkbox"/>	We are no longer using the affected products.
<input type="checkbox"/>	We have the affected products in stock and are continuing to use them.
<input type="checkbox"/>	We have informed all affected users about this emergency safety notice.
<input type="checkbox"/>	We are or were a dealer of these products.
<input type="checkbox"/>	We have forwarded this emergency safety notice to all customers who have received the affected products from us.

Company

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Dept./Name

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Address

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Tel./Fax

.....

E-mail

.....

Place/date

.....

Signature/

stamp

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Richard Wolf GmbH would like to thank you for your understanding and cooperation. Please accept our apologies for any inconvenience caused.