RICHARD WOLF

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Department: Service
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Your reference.	Your correspondence dated	Our reference	Date
		QM 700015934	01.04.2021

Emergency safety notice

Affected products:	**Optical Fibers Reusable & Disposable**
Product numbers:	**87501200 Laser fiber 200 µm, reusable** **87501272 Laser fiber 272 µm, reusable** **87501550 Laser fiber 550 µm, reusable** **87501800 Laser fiber 800 µm, reusable** **875011000 Laser fiber 1000 µm, reusable** **875013650 Laser fiber 365 µm, reusable** **87502200 Power laser fiber 200 µm, reusable** **487501200 Laser fiber, 200 µm, disposable** **487501272 Laser fiber, 272 µm, disposable** **487501550 Laser fiber, 550 µm, disposable** **487501800 Laser fiber, 800 µm, disposable** **4875011000 Laser fiber, 1000 µm, disposable** **4875013650 Laser fiber, 365 µm, disposable** **487502200 Power laser fiber, 200 µm, for single use**
Lot-Number:	**all LOTs with production date after 01/01/2016**

Dear Sir or Madam,

we have been informed by our supplier that some discrepancies have been found in the ETO sterilisation process for the products listed above.

According to our records, you operate at least one of these affected products, or at least one product from the affected production period was delivered to you.
This letter provides you with the following information on the procedure for rectifying the defect.

The following procedure is absolutely safe for you and your patients and has been agreed with our Notified Body (0124), as well as our competent national authority (BfArM).

Facts:
The products described above were sterilised by a sub-supplier, who had to cease operations due to discrepancies in the process chain and whose certification has since been withdrawn.
Due to the ongoing proceedings, it is not yet possible for us to narrow down the non-conformities to individual production batches.
We cannot currently guarantee with certainty, that the affected products are sterile.

With this measure, we would like to take preventive action against this situation.

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Measures by the addressee:
Read this letter and its reference documents (see list of attachments) completely and keep these reference documents until the recommended action has been completed.

Please carry out the following steps:

1. Check your new stock of laser fibres from Richard Wolf GmbH according to the type numbers and the date of manufacture stated on them.

   NOTE: Reusable laser fibres that already have been used are not affected by this situation and can therefore continue to be used in accordance with the instructions for use.

2. Ensure that no direct use of original packaged and sterile labelled laser fibres is made until they have been reprocessed in house or on your behalf prior to first use.

   NOTE: Our disposable laser fibres must only be reprocessed for the first time before first use and are still not suitable for multiple use.

   NOTE: For our reusable fibres, the only change is that they have to be reprocessed for the first time before being used by you on site or on your behalf. This does not affect the further use and preparation to which you are already accustomed.

3. In order to be able to use the sterile laser fibres supplied, they must be reprocessed by the user before they are used for the first time.

   NOTE to users: To do this, remove all packaging and carry out the cleaning and sterilisation process specified in the enclosed instructions for use (GA-A346) for non-sterile laser fibres.

   This process specified in the instructions for use GA-A346 for non-sterile, reusable laser fibres can also be used **once** for single-use laser fibres as well as for our reusable laser fibres within the scope of this FSCA.

4. If it is not possible for you, as the user of the sterile disposable fibres, to reprocess the laser fibres or to have this done by a qualified service provider, the laser fibres must be scrapped.

   NOTE: If reprocessing is only not possible because no reprocessing basket for laser fibres (type 85843030) specified in accordance with GA-A346 is available, please contact our customer service hotline on tel. no. +49 (0)7043 35 4389 so that we can provide you with an appropriate reprocessing basket. In this case, you can avoid scrapping and remain able to act, at least for the time being.

5. Ensure that all users of the product and other persons to be informed are made aware of this emergency safety information. If you have given the product to third parties, please forward a copy of this information and inform the contact persons listed below.

6. Ensure that this notice is observed in your institution until the measures described have been completed for the affected stock.

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7. Inform Richard Wolf GmbH, if affected products have been passed on to other facilities. If so:

   a) Please provide us with the contact details, so that Richard Wolf GmbH can inform the recipients accordingly.

   b) As a dealer please note, that you are responsible for notifying the affected customers.

8. For proof of receipt of this urgent safety information, we require the enclosed **reply form**, which you are kindly requested to return to us by fax to **+49 7043 351360**, or by email to **FSCA700015934@richard-wolf.com**, by April 16th 2021 the latest. Please also complete this form if you no longer have the products in stock. By doing so, you acknowledge receipt of this emergency safety information and avoid receiving further reminders from Richard Wolf GmbH.

9. Inform Richard Wolf GmbH of any adverse events that occur during the use of the products in question.

10. Follow all national regulations for reporting adverse events to the appropriate national or local regulatory authority in your country.

The affected laser fibres must NOT be used without prior reprocessing action.

This emergency safety information will be sent to all affected customers.

It is not necessary to return the affected products to us; the reprocessing carried out by you, as well as the destruction, must be confirmed using the attached reply letter.

The competent national authorities (including the responsible authority in your country) have been informed of this **emergency safety information**.

We are making every effort to provide affected customers with free replacements as quickly as possible. However, the current supply bottlenecks unfortunately remain.
Affected customers will receive a separate letter from us informing them about future availability and supply arrangements.

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Geschäftsführer/Managing Directors: Jürgen Pfab, Jürgen Steinbeck

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Your contact for

Questions concerning the procedure:

Mr Thilo Musikant
Head of Service Department
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e-mail: thilo.musikant@richard-wolf.com

Questions concerning safety:

Mr Oliver Ehrlich
Safety Officer for Medical Devices
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Fax: +49 7043 35 4300
e-Mail: vigilance@richard-wolf.com

We would like to apologise for the inconvenience this measure will cause you and, on behalf of Richard Wolf GmbH, thank you in advance for your support in implementing it in a timely manner.

We are convinced that this procedure is absolutely safe on the one hand and hope that we can at least somewhat alleviate the gaps in supply that have already occurred with the alternative solutions offered. We would like to assure you that Richard Wolf GmbH does everything in its power to ensure that only products that meet our strict quality criteria are on the market.

Yours faithfully,
Richard Wolf GmbH

Thilo Musikant (authorized signatory)
Head of Service Department

p.p. Oliver Ehrlich
Safety Officer for Medical Devices

Attachment:
- Response form
- GA-A346