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Department: Service
Administrator: Thilo Musikant

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Your reference.	Your correspondence dated	Our reference	Date
		QM 700015728	2021-05-31

Emergency safety notice

Affected products: **Instructions for use for Morce Power Plus / Motor Control Unit 2307**

Article number: **GA-A245**
(see attachment for detailed article list)

Dear Sir / Madam,

On December 30, 2020, FDA issued new guidance entitled “Product Labeling for Laparoscopic Power Morcellators”.

According to our records, you operate at least one of the affected products. This letter aims to inform you about the measures you will need to take as a result.

Situation:
The guidance that has now been published replaces the FDA guidance document entitled “Immediately in Effect Guidance Document: Product Labeling for Laparoscopic Power Morcellators” which was issued in November 2014.
Richard Wolf incorporated the previous guidance into the current instructions for use in 2015; the new guidance means that our instructions for use require a further update. This has been confirmed to us following consultation with authorities including our national authority – the German Federal Institute for Drugs and Medical Devices (BfArM).

This guidance contains recommendations concerning the content and format for certain labeling information for laparoscopic power morcellators (LPMs). In the view of FDA, the recommendations in this guidance reflect the state of the science and available technology regarding use of LPMs and are being made in light of scientific information. A number of publications suggest that the use of these devices contributes to the dissemination and upstaging of an occult uterine malignancy in women undergoing laparoscopic gynecologic surgery for presumed fibroids. FDA is also recommending that manufacturers incorporate into the labeling for these devices information providing greater specificity regarding the risk of use as it relates to age, information regarding the risk of spreading malignant and benign uterine tissue, and information regarding the use of containment bag systems. These labeling recommendations are intended to enhance, but not replace, the physician-patient discussion of the benefits and risks of use of LPMs that uniquely pertain to individual patients. FDA believes this effort will promote the safe and effective use of LPMs when used for gynecologic surgeries.

Measures to be taken by the addressee:

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

Please follow the steps below:

1. Read through the enclosed information sheet BB-A245-4 carefully and pay attention to the contra-indications and warnings regarding the use of the morcellator.

2. Enclose information sheet BB-A245-4 with your existing copy of instructions for use GA-A245. If you no longer have a copy of GA-A245, please contact our service hotline.

3. Remove and destroy information sheet BB-A245-3, if present.

4. Make sure, within your organization, that all users of the aforementioned product and other persons to be informed have received knowledge 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 person stated below accordingly.

5. Make sure that this notice is retained within your facility for as long as the affected product is in use.

6. Notify Richard Wolf GmbH if the affected product has been passed on to other facilities. If so:

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

    b) Please note that you, as a dealer, are responsible for notifying the customers concerned.

7. Please confirm receipt of this emergency safety notice by returning the attached **Response form** by fax to **+49 7043 351360** or by e-mail to **FSCA700015728@richard-wolf.com on or before 2021-06-18**. 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 GmbH.

8. Notify Richard Wolf GmbH about any adverse events occurring during use of the affected products.

9. Observe all national regulations for reporting adverse events to the competent national or local supervisory authorities in your country.

The emergency safety notice is being sent to all affected customers.

The competent national authorities (including the Federal Institute for Drugs and Medical Devices in Bonn) have been informed about this **emergency safety notice**.

Your contact for

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Questions concerning the procedure:

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Questions concerning safety:

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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.

We would like to assure you that Richard Wolf GmbH makes every effort to guarantee that only those products meeting our stringent quality criteria are available on the market.

Yours faithfully,
Richard Wolf GmbH

Thilo Musikant
Head of Service Department and Service Center

Marco Bruxmeier
Head of Quality Engineering Department

Attachments:
- Article list
- Response form
- BB-A245-4