

## Advisory Notice

Dear customer,

With this advisory notice we would like to draw your attention to the fact that Wagner Klinikbedarf e.K. deviantly provided a product where the instructions for use were not included.

The following custom procedure pack is affected:

Product description	REF-No.	L/N
MIC* Gastrostomy Tube Care Kit 16	REF 104801701	FE21080134

Reason for this advisory notice:

This advisory notice has been issued, as the instructions for use are an important part of the product. The consultation of the instruction for use could be necessary for an adequate use of the custom procedure pack.

Risk assessment and necessary actions:

According to our traceability records your organization has received several product units of the affected lot. There is no immediate risk to the patient, as the product has a proven clinical use and the product can be used in a safe manner by medical professionals if the medical professionals are familiar with the usage of such sort of products. If there is the necessity to consult the instructions for use there is a link and a QR code on the package which lead to an electronic version of the instructions for use.

If your customers have to consult the instructions for use, there are the following possibilities to get a copy of the instructions for use (eIFU).

1. Use your smart device to scan the QR Code and consult the website.
2. Enter the URL in your browser (<https://www.eifu.online/AVA>) to get to the website

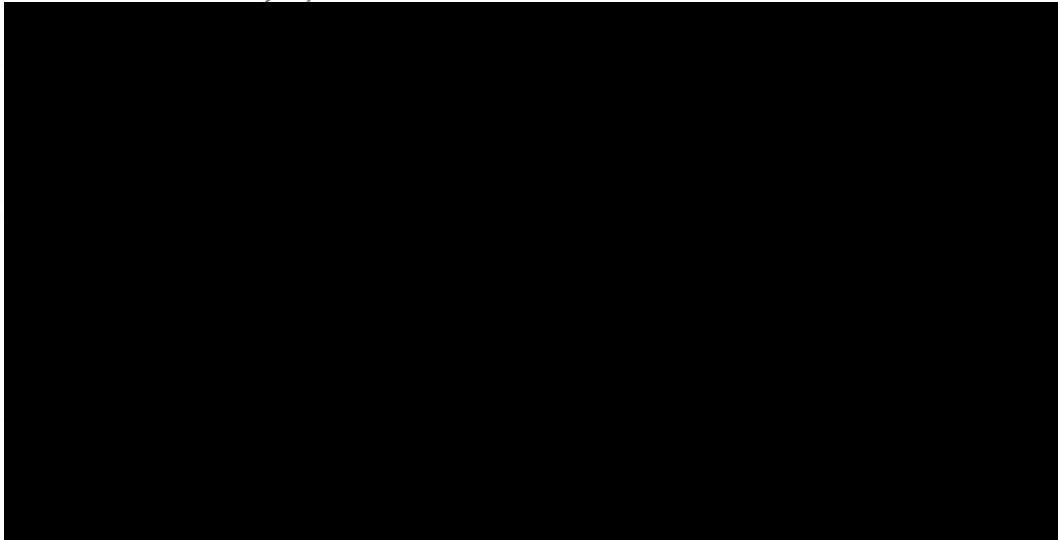
Please send the completed attachment 1 within 4 working days after receipt of this letter to the following address: info@wagner-klinikbedarf.de.

The competent authority will be informed about this advisory notice.

Please keep a copy of the letter for your records.

Wagner Klinikbedarf e.K. has undertaken the necessary corrective and preventive actions to prevent further occurrence and recurrence of such events.

We thank you for your support and apologize for any inconvenience this problem could have caused in your organisation.



Advisory Notice  
Attachment 1

## Customer Response Form

Please fill in, sign and send this form within 4 working days via email or fax to Wagner Klinikbedarf e.K. to the attention of Mr Ingo Wagner.

Fax: +49 2191-95163-29  
Email: info@wagner-klinikbedarf.de

According to our ERP records for traceability you have received the following product:

Product description	REF-No.	L/N
MIC* Gastrostomy Tube Care Kit 16	REF 104801701	FE21080134

Deviantly, the product does not contain the instructions for use. Nevertheless the product can be used in a safe manner if the users are informed on how to get access to the electronic version of the online IFU.

Please inform you customers accordingly and check your remaining product stock.  
If you still have product on stock please return the product to Wagner Klinikbedarf e.K., Inh. Ingo Wagner.

You hereby confirm that you have checked your product stock, returned the product to Wagner Klinikbedarf e.K. and informed your customers.

Customer name:	
Position:	
Date/Signature:	
Company stamp:	