

ENDO-FLEX GmbH, Alte Hünxer Straße 115, 46562 Voerde, Germany

**KUNDE**

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24.02.2022

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**Field Safety Notice**

Recall concerning

**FNA-B01-2218** SonoFlex EBUS – Nitinol Nadel

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Dear Sir or Madam,

With this letter we would like to inform you about a recall of our product **FNA-B01-2218** SonoFlex EBUS – Nitinol Needle and ask you to take note:

Identification of the medical devices concerned:

Artikel number (REF)	Batch number (LOT)	Quantity
Artikelnummer eintragen	LOT Nr. eintragen	Anzahl eintragen
Artikelnummer eintragen	LOT Nr. eintragen	Anzahl eintragen
Artikelnummer eintragen	LOT Nr. eintragen	Anzahl eintragen
Artikelnummer eintragen	LOT Nr. eintragen	Anzahl eintragen

*Bitte nur die Artikel und Mengen eintragen, die der jeweilige Kunde auch erhalten hat!  
Nicht Zutreffendes bitte entfernen!*

**Description of the problem:**

We have been informed of a qualitative problem regarding the above-mentioned product, which could no longer guarantee a possible safe treatment of the patient.

Although the investigation results so far do not show a clear cause, we are conducting a precautionary recall for the potentially affected batches.

**Patient risk & recommendation for further action:**

The safety and performance of the product cannot be fully guaranteed. Based on the current state of knowledge, we advise against its use.

### What measures are to be taken by the addressee?

Upon tracing, we have determined that you have received affected products. For this reason, we ask you for the following support:

1. please check if you still have products in stock from the above batch numbers (LOT).
2. Set the use of all affected lot numbers (LOT) in your possession.
3. Separate the batch numbers concerned (LOT) to avoid unauthorized access
4. forward this "**Urgent Safety Information**" to all persons in your institution who need to be informed. If you have passed on the product, please identify the facilities/departments concerned and forward this notification to them immediately.

Please keep this information at least until the measure has been completed. The Federal Institute for Drugs and Medical Devices has received a copy of this "**Urgent Safety Information**".

5. Please complete the attached **reply form** and return it by fax or email **immediately, but no later than 31.03.2022**, in order to be able to offer you an alternative as quickly as possible or to coordinate the return shipment of the affected items.

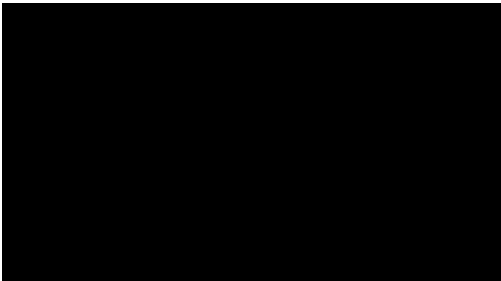
Please do not hesitate to contact us if you have any questions.

### Contact person at the company ENDO FLEX:

Stefanie Schaal  
Medi-Globe-Straße 1-5  
83101 Achenmühle

Fax: +49 8032 973 334  
E-Mail: [Schaal@medi-globe.de](mailto:Schaal@medi-globe.de)

Kind regards



## Reply form

FAX number for reply +49 281 9 44 00-11  
 or by e-mail to Vertrieb@endo-flex.de

### Artikelbezeichnung

We have the following number of affected products in stock:  
 (Please do not continue to use products and return them to ENDO FLEX!)

Artikel number (REF)	Batch number (LOT)	Quantity
Artikelnummer eintragen	LOT Nr. eintragen	
Artikelnummer eintragen	LOT Nr. eintragen	
Artikelnummer eintragen	LOT Nr. eintragen	
Artikelnummer eintragen	LOT Nr. eintragen	

*Bitte nur die Artikel und Chargen eintragen, die der jeweilige Kunde auch erhalten hat! Nicht Zutreffendes bitte entfernen!*

We do not have any affected product in our inventory.

Sender:

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Contact person:

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Tel. no.:

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Remark:

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Date:

Signature / Function

Please proceed as follows:

1. Complete the reply form in full, even if you no longer have any products in stock.
2. Please fax the completed reply form to the following fax number: +49 281 9 44 00-11 or to the following e-mail address: Vertrieb@endo-flex.de