

name  
address

Country

Neustadt, 31th July 2018

**Urgent safety information**

**Recall of item FE-D1812WB - Cytology Brush - LOT: 20170415**

Dear Sir or Madam,

FENDO MedizinTechnik take through to the above-mentioned product a product recall. Since you also got the cytology brush with the above-mentioned LOT from us, do not continue using these products or to put on the market and if still in stock, send them back to us immediately or if necessary recall them back from your customers and then send all your stock balance of this product to us.

If you or your customer have already used the products you do not need to do anything except to answer the answer form completely which you will get by post and sent back to us.

**problem:**

More than 2100 products of this LOT have been sold and were used without any problems. Now the head of **one** cytology brush is during a surgery aborted and left in the patient's lungs, attempts to retrieve failed so far.

**Safety measures to be taken by the user / distributors immediately:**

- Please immediately ensure that the product with the above mentioned Lot number will be no longer used under any circumstances!
- Please ensure that the other products of this LOT will be immediately transferred to the quarantine storage! Please ensure that all relevant employees (users, incoming goods, employees returns processing, customer service representatives, etc.) are informed immediately!
- Please ensure that all customers are notified immediately, who have purchased this product from you!

### **action plan**

FENDO MedizinTechnik will analyze exactly how this incident occurs and if necessary we will induce the OEM manufacturer to modify the design of the product to ensure patient safety.  
All cytology brushes which are still in your warehouse will be taken back on our costs and you'll receive a credit note.

The BfArM as well as the Notified Body were informed about this product recall.

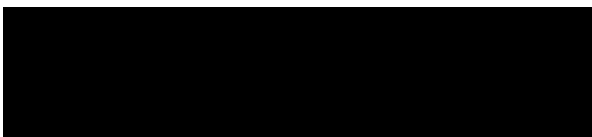
Please return the attached form completely filled to us within 3 days.

We apologize for the inconvenience,  
thank you for your support and understanding!

For further information about the reshipment and questions, please contact us here are the contact data:

Email: [h.fehling@fendo-medizintechnik.de](mailto:h.fehling@fendo-medizintechnik.de)  
Tel. 05032/9 58 22 05

Kind regards



**ANTWORTFORMULAR / ANSWER FORM**
**Rückruf des Artikels FE-D1812WB – Zytologiebürste - LOT: 20170415 /  
 Recall campaign item no. FE-D1812WB – Cytology Brush – LOT: 20170415**

Bitte vollständig ausfüllen und innerhalb von 3 Tagen per Email oder Fax zurück an FENDO MedizinTechnik senden: / *Please fill in completely and send it back within 3 days to FENDO MedizinTechnik by e-mail or fax:*

[t.fehling@fendo-medizintechnik.de](mailto:t.fehling@fendo-medizintechnik.de) – Fax. 0 50 32 / 9 58 22 03

Name der Firma / of the company - der Klinik / of the clinic - des Arztes / of the doctor:	
Kunden-Nr.: / Cust. No.:	
Adresse / address:	
Telefon / phone:	
Email:	
AnsprechpartnerIn/ Contact person	

Bitte kreuzen Sie das zutreffende Kästchen an / *Please tick the appropriate box:*

**Alle betroffenen Produkte wurden schon verbraucht. /**  
*All affected products have already been consumed.*

**Wir senden den betroffenen Lagerbestand zurück,  
 wir haben noch ..... (Menge) auf Lager. /**  
*We'll send all affected products we've on stock back,  
 We've ..... (quantity) on stock.*

**Mit dieser Unterschrift bestätigen wir den Erhalt dieses Schreibens und akzeptieren  
 den Rückruf und garantieren die Einhaltung der Sicherheitsmaßnahmen /**  
*With this signature we confirm the receipt of this letter and accept  
 the recall and guarantee compliance with the security measures.*

.....  
 Ort, Datum, Name, Funktion im Unternehmen, Firmenstempel /  
*Place, date, name, function in the company, company stamp*

Wir erhielten dieses Schreiben mit den Sicherheitsinformationen am: .....  
*We received this letter with the safety informations on: Datum / Date*