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08.07.2021

Field Safety Notice

Recall concerning
Suction Polyp Trap 900334H

Dear Sir or Madam,

Kindly note that we need to recall our product 900334H:

Identification of relevant items:

LOT: **G2112528**

Quantity: **102 pieces**

Description of problem:

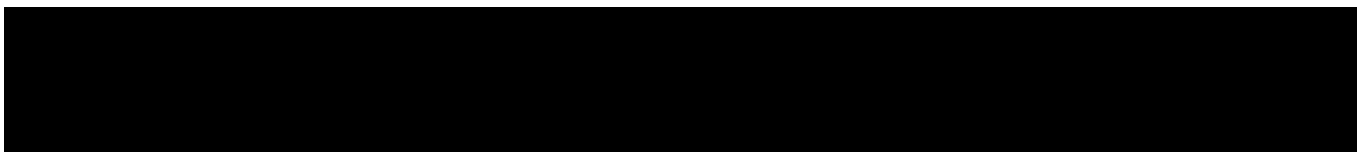
We were informed of a possible labelling error of the Suction Polyp Traps, which can affect the investigation results.

We were informed that the chambers on the Suction Polyp Traps within the above-mentioned lot-number shows an incorrectly labelling. The assignment of the labelling on the open position and the chambers has been changed. The labelling is visible and always located at the same place. Our internal investigation confirms that this error occurs.

Risk to patient:

The defect can be easily identified by the user in the required visual inspection for the integrity of the correctness of the labelling.

Otherwise, there is a patient's risk of an incorrect or impossible diagnosis caused by the use of a product where the labelling on the chambers is incorrect and the polyps fall into the collecting container of the Suction Polyp Traps instead of being collected separately in the individual chambers. This could possibly result in further interventions.



To date, no adverse effect has been reported on the health and safety of the patients that may be associated with this problem.

What measures need to be achieved by addressee?

Based on the traceability, we have determined that you received potentially affected products. For this reason we would like to ask you for the following assistance:

1. Please check if you still have products from the above-mentioned lot-number(s).
2. Please check the potentially affected lot-number(s) for the labelling of the open position and chambers – see photos:

Wrong:



purple number 0 on the chamber,
purple number 1, 2, 3, 4 at the open position

Correct:



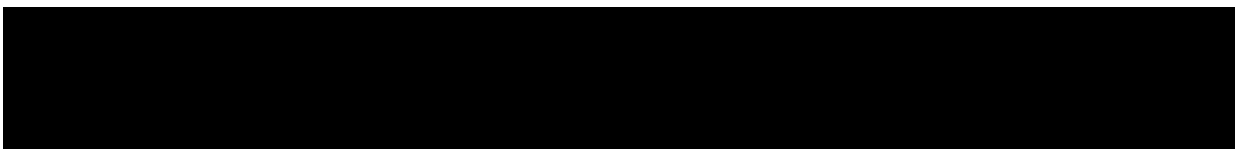
purple number 1, 2, 3, 4 on the chamber
purple number 0 at the open position

3. The correct labelled products can be used without risk.
4. The incorrectly labelled products must not be used and must be returned to us.
5. We kindly ask you to inform us as soon as possible how many products of the affected lot-number(s) have not been used and are damaged. Please send back these goods along with the filled in document.

Please return all unused products with incorrect labelling of this lot-number to the following **return address**:

ENDO-FLEX GmbH
Südring 21
46342 Velen-Ramsdorf

Please make sure that all relevant persons get to know of this urgent security information.



In case you've handed over above items to a third party please make sure to forward them this information and inform below mentioned contact person.

The authorities for drugs and medical items received a copy of this urgent security information.

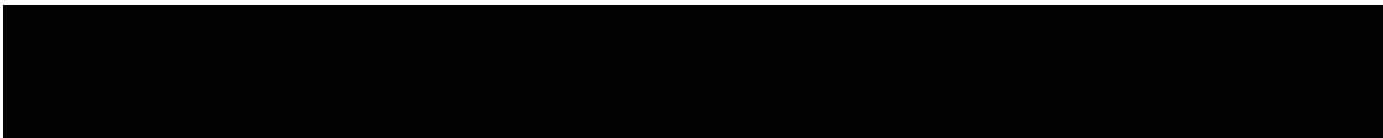
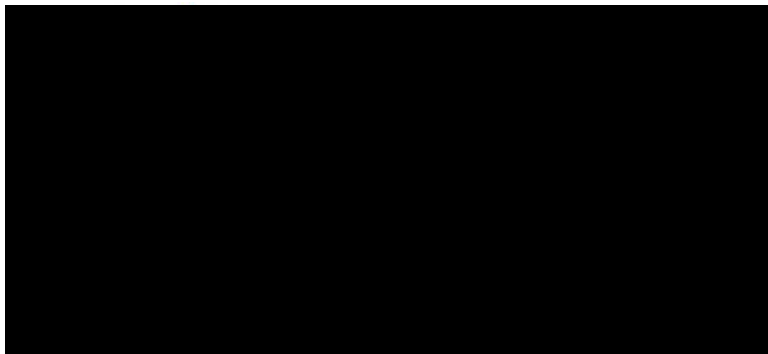
Contact person at ENDO-FLEX GmbH:

Ralf Fehrholz
Alte Hünxer Str. 115

46562 Voerde

Tel.: +49 281 94400-50
Fax: +49 281 94400-11
E-Mail: Fehrholz@endo-flex.de

Kind regards



Customer response form
FAX Number to reply +49 281 944 00-11
or by email to Vertrieb@endo-flex.de

Recall for ENDO-FLEX Suction Polyp Trap

Item number	900334H
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LOT:	G2112528
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☐ Following products are in our storage:
 (Don't use the products, return them to ENDO-FLEX please!)

Item number	LOT	Quantity
900334H	G2112528	

☐ No products in our storage.

Vendor:

Person
responding:

Tel. No.

Remarks:

Please follow the procedure:

- Please fill in this form completely, even if you have no more products in stock.**
- Please send the filled form to Fax No.: +49 281 944 00-11 or by email to Vertrieb@endo-flex.de**

date:

Signature / function

