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Urgent Field Safety Notice

SET Aspirex[®]S 10F 110cm, LOT 190114
Straub Medical AG internal number FB199116, 2019-03-15
THE RETURN OF MEDICAL DEVICES TO THE MANUFACTURER

Date: **2019-03-19**

Attention: **Distributor of Straub Medical AG products**

Details on affected devices:

SET Aspirex[®]S 10F 110cm (REF 80232, LOT 190114)

Description of the problem:

The SET (LOT 190114) expiry date is 2022-07-31.

One of the four components (Aspirex[®]S 10 F x 110 cm catheter, LOT 190006) has a shorter expiry date (2022-01-10).

The expiry date of the SET must not be longer than the expiry date of any of the components in the SET. The correct expiry date of the SET should have been 2022-01-10.

There is **no risk of any deterioration to the state of health of the patient** as the products will be sterile at least until 2022-01-10. All the products will be recalled from the market significantly earlier. In addition, Straub Medical tested for sterility the products significantly older than three years and they were all still sterile.

Status 2019-03-15:

Of the 19 sets distributed in Europe of the affected LOT190114 **19 (ALL) are under control of Straub Medical AG or distributors.**

Advise on action to be taken by the user:

All products with the LOT 190114 must be quarantined and sent back to the manufacturer.

Transmission of this Field Safety Notice (if appropriate):

This notice needs to be passed on to all who need to be aware within your organization or to any organization where the potentially affected devices have been transferred (if appropriate).

Please transfer this notice to other organizations on which this action has an impact (if appropriate).

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action (if appropriate).

Contact reference person:

Mr. Radim Smitka

Telephone: +41 81 720 05 13

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A handwritten signature in blue ink, appearing to read "Radim Smitka", written over a horizontal line.

Signature and Stamp

