

Urgent Field Safety Notice

Commercial Name :

044.210 Drill 1, short, Ø 2.2mm, l 33.0mm, SS lot MG950 / LV463 / MG783 / MH027 / ML700

044.214 Drill 2, short, Ø 2.8mm, l 33.0mm, SS lot MJ330

044.215 Drill 2, long, Ø 2.8mm, l 41.0mm, SS lot MK547 / LV457

044.255 Twist Drill PRO Ø4.2mm, long, 41mm, SS Lot LV455

040.330 Starter Set, surg. instr., Ø 4.1mm, Lot MM191

FSCA identifier: **ER16-0238**

Type of Action: **Return for exchange**

Dear Customer (insert name)

We would like to inform you that the **above listed drills** which you have received from Institut Straumann **may not fit into the handpiece.**

Description of issue

The investigation of a received complaint has confirmed that the shaft diameter of a drill article number 044.215 lot LV457 is greater than the defined specification of Ø2.35mm in the area of the laser marking on the shaft. Further investigation has shown that the above listed articles and lots are also impacted. Testing with different handpieces shows that the drills can be inserted. However depending on the manufacturing tolerances of the handpiece that is used, these drills may not fit. The drills are multiple use instruments and are delivered non-sterile. In accordance with IFU 701124 they must be unpacked, disinfected, cleaned and sterilized before use. Additionally the IFU states that "Before every use, the device has to be carefully checked for proper function and damages." If the drills do not fit into the handpiece and there is not an alternative instrument available, then the the planned treatment will need to be re-scheduled.

If the parts are unpacked, the below listed component lot number on the drill itself is used to identify the impacted drills.

Article Number	Lot Number	Description	Component Lot Number (on drill)
040.330	MM191	Starter Kit	contains drill MF408
044.210	MG950	Drill 1, short, Ø 2.2mm, l 33.0mm, SS	MA219
044.210	LV463	Drill 1, short, Ø 2.2mm, l 33.0mm, SS	LE929
044.210	MG783	Drill 1, short, Ø 2.2mm, l 33.0mm, SS	LZ239
044.210	MH027	Drill 1, short, Ø 2.2mm, l 33.0mm, SS	MC041
044.210	ML700	Drill 1, short, Ø 2.2mm, l 33.0mm, SS	MF408
044.214	MJ330	Drill 2, short, Ø 2.8mm, l 33.0mm, SS	ME601
044.215	LV457	Drill 2, long, Ø 2.8mm, l 41.0mm, SS	LE976

044.215	MK547	Drill 2, long, Ø 2.8mm, l 41.0mm, SS	MF925
044.255	LV455	Twist Drill PRO Ø4.2mm, long, 41mm, SS	LF828

Institut Strauman has decided to voluntarily initiate a Field Safety Corrective Action to address this.

According to our records you have received **xx (enter quantity)** pieces of **(Insert article and lot number)**

Action to be taken:

1. Check your inventory for **the above listed article and lot numbers** and return all unused, packaged parts to the attention of **(insert employee's name)** for replacement as indicated on the **Customer Confirmation Form**
2. If you have already unpacked your drills, the lot number on the drill itself will be different. Please check your instruments for the Component Lot numbers listed above and return them to **(insert employee's name)** for replacement as indicated on the **Customer Confirmation Form**:
3. If you have already used and disposed of the listed articles, please complete the **Customer Confirmation Form**
4. For all cases complete and return the enclosed **Customer Confirmation Form** to **(insert contact details)**

Transmission of the Field Safety Notice

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

The competent authority of your country has been informed about this Field Safety Corrective Action.

We apologize for any inconvenience that this may cause.

Kind regards,

(insert name)