

Urgent Field Safety Notice

Commercial Name : **040.447S Drill set long, drill stop compatible for D 4.8mm Implant Lot GY037, Lot HA443, Lot HE874, Lot HL216**

FSCA identifier: **(SB14/2014)**
Type of Action: **(Return product to manufacturer)**

Dear Customer (insert name)

We would like to inform you that the 040.447S Drill set long, drill stop compatible for D 4.8mm Implant which you have received from Institut Straumann may contain a green colour coded drill which is incorrectly D3.5mm in diameter instead of D4.2mm .

Description of Problem

Institut Straumann has received a customer complaint reporting that 040.447S Drill set long, drill stop compatible for D 4.8mm Implant lot GY037 contains a green colour coded drill which is incorrectly D3.5mm instead of D4.2mm. The investigation of this complaint has confirmed that the green colour coded drill is only D3.5mm. All other drills within the set 040.477s Drill set long, drill stop compatible for D 4.8mm Implant are correct.

The investigation determined that there are potentially two further Drill Sets 040.447S that contain an incorrect drill (D3.5mm / green colour coding) and that these Drills sets are in one of the listed lot numbers.

This issue is limited to article number 040.447S lot numbers GY037, HA443, HE874, HL216 only.

Risk Assessment

The 040.447S Drill set long, drill stop compatible for D 4.8mm Implant is used for preparing the implant bed for implantation of a D4.8mm implant. The green coding on the drill indicates that the drill is 4.2mm diameter and is used to widen the implant bed from D3.5mm to D4.2mm as preparation to insert a 4.8mm diameter implant. As this drill is only D3.5mm it is not possible to widen the D3.5mm implant bed hole to D4.2 mm. This will be detected at the latest during the check of the final preparation depth with the D4.2mm Depth gauge as it will not fit the implant bed.

If you do not have an alternative drill (either alternative drill set 040.477s or alternative sterilized multiple use drill 044.254 / 044.255) then the implant bed preparation cannot be completed for the 4.8mm diameter implant. The implant cannot be placed and the procedure cannot be completed.. There is no risk associated with drill sets that have already been used.

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 **040.447S Drill set long, drill stop compatible for D 4.8mm Implant Lot GY037, Lot HA443, Lot HE874, Lot HL216.**

Action to be taken:

1. If the article **040.447S Drill set long, drill stop compatible for D 4.8mm Implant Lot GY037, Lot HA443, Lot HE874, Lot HL216** is still in your inventory, return it to the attention of **(insert employee's name)** for credit or replacement as indicated on the **Customer Confirmation Form**
2. If you have used the **040.447S Drill set long, drill stop compatible for D 4.8mm Implant Lot GY037, Lot HA443, Lot HE874, Lot HL216** no additional action is required.

3. For both 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 within your organization who need to be made aware of this issue 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)