

Advisory Notice

Drill Extension for Astra Tech Implant System® REF 22520, Lot# 419645, Lot# 418469 and Lot# 417849

Date: 2019-04-05

Dear Dental Professional,

We regret to inform you that due to a manufacturing issue the above-mentioned product may not work as expected.

This advisory notice is intended to verify whether the delivery to you was affected by this issue and will also give you advice on how to act in case you received an affected product.

Details on affected devices:

Drill Extension
REF 22520
Lot# 419645, Lot# 418469 and Lot# 417849
www.dentsplysirona.com

Background

The Astra Tech Implant System is a dental implant system used to replace missing teeth. The concerned product: Astra Tech Implant System, Drill Extension, is used for extending the length of a drill shaft.

Description of the issue

Due to a manufacturing issue, it may happen that the **Drill Extension, REF 22520** will not work as expected. Specifically, in cases where an unfavorable combination of dimensional tolerances exists, the clamping functionality, which ensures that the attached drill is fixed in the drill extension, may be impaired.

Warning

When using the **Drill Extension, REF 22520** with reduced clamping functionality, there is the potential for the inserted drill to fall out of the drill extension during handling which presents an increased risk for swallowing or aspiration of the drill.

Advise on action to be taken by the user:

Based on the use of this product, two different scenarios are possible.

Scenario 1: In case you have unopened (in its original packaging) product: **Drill Extension, REF 22520, Lot# 419645, Lot# 418469 or Lot# 417849** in your stock:

Please return the product without delay to your Dentsply Sirona regional sales organization by including the completed and signed answer letter (page 3 of this document).

You will receive replacement shortly.

Scenario 2: In case you have already unpacked the product from the original packaging or the product has already been used clinically:

Please verify that the **Drill Extensions, REF 22520** in your possession and stored in the Surgical Tray or placed at any other storage in your office is working correctly by verifying the clamping function with different drills in your possession.

In case you identified a reduced clamping functionality, please return the product without delay to your Dentsply Sirona regional sales organization by including the completed and signed answer letter (page 3 of this document).

You will receive replacement shortly.

Independent from the result of your verification we would ask you to return the completed and signed answer letter (page 3 of this document) by email to

MoIndalSWE-ANR22520@dentsplysirona.com

Transmission of this Advisory 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 potentially affected product(s) have been transferred.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of this measure.

Contact data in case of questions:

Norbert Bergner
Medical Device Safety Officer (MPA EU)
Sirona Dental Systems
Fabrikstr. 31
D-64625 Bensheim
GERMANY
Phone: +49 6251 16 3775
E-mail: implants-safetyofficer@dentsplysirona.com

We sincerely regret the inconvenience this manufacturing issue may cause for you and your patients.

Answer Letter to Advisory Notice

Astra Tech Implant System, Drill Extension - REF 22520 - Lot# 419645, Lot# 418469 and Lot# 417849

Customer / User:

Customer ID: _____

Name: _____

Street: _____

Address _____

Phone: _____

Email: _____

or Practice Stamp

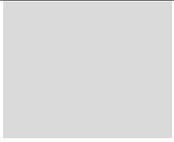
We hereby confirm that we have checked our stock in regard of the above-mentioned product and Lot-Numbers.

In addition, we followed the request and transferred this information to our organization or to any organization where the potentially affected product(s) have been transferred.

Date:

Signature:

For Scenario 1:

<p>Number of identified originally packed product Astra Tech Implant System, Drill Extension, REF 22520 Lot# 419645, Lot# 418469 or Lot# 417849 Items will be sent to our regional Dentsply Sirona Sales Organization for replacement Please include a copy of this Answer Letter to the delivery to ensure free replacement</p>	
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For Scenario 2:

<p>We have verified acc. to Advisor Notice that all Astra Tech Implant System, Drill Extension, REF 22520 in our possession and stored in the Surgical Tray or any other storage in our office show no reduced clamping functionality.</p>	
<p>Date:</p>	<p>Signature:</p>

This is the response to above mentioned Advisory Notice.

Please send the completed and signed response to MoInDalSWE-ANR22520@dentsplysirona.com

