Urgent Field Safety Notice (FSN)

For Attention of: End users and Distributors who may be in possession of affected products nominated hereafter.

DENTSPLY SIRONA is conducting a medical device voluntary recall for specific batch / Lot numbers of 3 different Endodontic file brands, listed below. A few sterile blisters may not guarantee sterility during the expected shelf life.

Information on Affected Devices

Date Issued: 12/2021

Commercial Name:
- PATHFILE STER 25MM/013
- PROGLIDER 6 FILE STERILE 25MM
- PROTAPER GOLD F1 21MM STER // F2 21MM STER // F2 25MM STER // F2 31MM STER

Primary Clinical Purpose of the Device: All those products are Endodontic instruments used during root canal treatment to shape the root canal system.

Affected productions:

Part Number	Description	LOT	UDI-DI (Unique Device Identifier)
A001522501303	**PATHFILE STER 25MM/013**	1734034	++J00310026DX
A0411221G0103	**PROTAPER GOLD F1 21MM STER**	1734130	++J00310031DQ
A0411221G0203	**PROTAPER GOLD F2 21MM STER**	1734012	++J00310031DQ
A0411225G0203	**PROTAPER GOLD F2 25MM STER**	1734128	++J00310031DQ
A0411231G0203	**PROTAPER GOLD F2 31MM STER**	1734126	++J00310031DQ
A092622500103	**PROGLIDER 6FILE STERILE 25MM**	1734001	++J00310030D

Reason for Field Safety Corrective Action (FSCA)

Description of the Product Problem: During regular internal testing, Dentsply Sirona has detected a sporadic sealing issue on a production of blisters. Some of these instruments may not guarantee sterility during the expected shelf life.

Hazard giving rise to the FSCA: Sterilisation has been performed by the manufacturer. Sterile barrier could not be fully guaranteed during the entire shelf life.

Probability of problem arising: Probability remains low.

Predicted risk to patient/users: Use of non-sterile instruments during root canal treatment could complicate root canal disinfection.

Background on Issue: Sterile barrier could not be fully guaranteed during the entire shelf life. All the necessary containments have been made and the concerned products have been identified. Preventive / corrective actions have already been taken to prevent recurrences.

Actions expected from End Users Customers (dentists)

Search in your Practice inventory.
Are you still in possession of any of the affected products listed above?

In case you are, please immediately segregate the products and return them to the Dealer who originally sold the products to you and you will be reimbursed.

Please acknowledge receipt of this notice by completing the reply form attached.
Thank you for your assistance.
We regret any inconvenience caused by this product issue.

Sincerely,

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