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,

[redacted]

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Attachment 2: End user Recall Acknowledgement Form

FSN Reference number: HHE 2021-5 **FSN Date:** December 2021

Dear Valued DENTSPLY SIRONA Customer,

Our records indicate that you received the potentially impacted Endodontic Files (identified in the Table below).

Do you now have affected product in your office?

☐ Yes, we currently have one or more affected items in our office. Please indicate the quantity below:

Part number	Model	LOT number	Quantity returned (specify cases or items)
A001522501303	**PATHFILE STER 25MM/013**	1734034	
A0411221G0103	**PROTAPER GOLD F1 21MM STER**	1734130	
A0411221G0203	**PROTAPER GOLD F2 21MM STER**	1734012	
A0411225G0203	**PROTAPER GOLD F2 25MM STER**	1734128	
A0411231G0203	**PROTAPER GOLD F2 31MM STER**	1734126	
A092622500103	**PROGLIDER 6FILE STERILE 25MM**	1734001	

☐ No, we currently have no affected items in our office.

I hereby confirm the receipt, reading and understanding of the Field Safety Notice.

I confirm that all items in stock mentioned in the table above have been returned to my issuing Dealer.

By signing below, I acknowledge that the required actions have been taken in accordance with this recall notice, and that I will return affected product.

Printed Name: _____ **Signature:** _____

Title: _____ **Telephone:** ( ) ____-_____ **Date**____/____/____

Account No. _____ **Facility Name:** _____

Facility Address: _____

City:_____ **State:**_____ **ZIP:**_____

Note: This form must be returned to DENTSPLY SIRONA as soon as possible. It is important that you complete this form and email a copy to Maillefer-Vigilance@dentsplysirona.com.

Appendix UDI (Unique Device Identifier) information :

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