

## 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,

Frédéric Mottier  
QA / RC Director

## **Urgent Field Safety Notice (FSN)**

### **Attachment 1: Distributor Recall Acknowledgement Form**

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

**FSN Date:** December 2021

Dear Valued DENTSPLY SIRONA Customer,

DENTSPLY SIRONA records indicate that the potentially impacted Endodontic Files (identified in the Table below) was shipped to your Distribution Facility.

Please complete this form to acknowledge that you have received and understand this Recall and will notify your customers who were potentially shipped the impacted products.

**Do you have affected product in your facility?**

Yes, we currently have one or more affected items in our facility.

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 facility (already sent to customers).

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

- 1) All items in stock mentioned in the table above have been returned to DENTSPLY SIRONA distributor for a full refund.
- 2) I have identified customers that received or may have received this device. Please could you provide DENTSPLY SIRONA a list of all customers (dentists) who purchased the product.
- 3) I have informed the identified customers of this FSN and I forwarded the End-user acknowledgement form to them.
- 4) I provide DENTSPLY SIRONA the confirmation of reply from all identified customers.

If your customer list is confidential, please provide written proof that:

- all our customers (dentist) having bought the products/batches in questions have been informed of the situation and requested to return their inventory of the items in question.

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 before this action is closed for your account. It is important that you complete this form and email a copy to [Maillefer-Vigilance@dentsplysirona.com](mailto: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
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A092622500103	PROGLIDER 6FILE STERILE 25MM	1734001	++J00310030D

## **Urgent Field Safety Notice (FSN)**

### **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:

<b>Part number</b>	<b>Model</b>	<b>LOT number</b>	<b>Quantity returned</b> (specify cases or items)
A001522501303	<b>PATHFILE STER 25MM/013</b>	1734034	
A0411221G0103	<b>PROTAPER GOLD F1 21MM STER</b>	1734130	
A0411221G0203	<b>PROTAPER GOLD F2 21MM STER</b>	1734012	
A0411225G0203	<b>PROTAPER GOLD F2 25MM STER</b>	1734128	
A0411231G0203	<b>PROTAPER GOLD F2 31MM STER</b>	1734126	
A092622500103	<b>PROGLIDER 6FILE STERILE 25MM</b>	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](mailto:Maillefer-Vigilance@dentsplysirona.com).

Appendix UDI (Unique Device Identifier) information :

<b>Part Number</b>	<b>Description</b>	<b>LOT</b>	<b>UDI-DI (Unique Device Identifier)</b>
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A092622500103	<b>PROGLIDER 6FILE STERILE 25MM</b>	1734001	++J00310030D