

Urgent Field Safety Notice (FSN)
Glyde File Prep Doses Pack™
Wrong Expiry Date

Attachment 1: Distributor Recall Acknowledgement Form

FSN Reference number: HHE 2022-3

FSN Date: November 2022

Dear Valued DENTSPLY SIRONA Customer,

DENTSPLY SIRONA records indicate that the impacted products (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 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		
			Quantity	Unit of sales (boxes of 35 doses)	Number of doses
A09050000000	Glyde Doses Pack	1779021		<input type="checkbox"/>	<input type="checkbox"/>

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/batch in question 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.

Appendix UDI (Unique Device Identifier) information :

Part Number	Description	LOT Number	EU UDI-DI (Unique Device Identifier)
A090500000000	Glyde Doses Pack	1779021	+J003A0905000000002