

FSN Ref: HHE-2022-03
FSCA Ref: HHE-2022-03



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

Date Issued: November 2022

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 number of Glyde Dose Pack, root canal conditioner listed below. The expiry date of the product is not correct.

Contact manufacturer:

Dentsply Sirona - Maillefer Instruments Holding Sarl
Chemin Du Verger 3 - CH 1338 Ballaigues - SWITZERLAND
Tel: +41218439200
E-Mail: Maillefer-Vigilance@dentsplysirona.com.

1. Information on Affected Devices

- **Device Type:** Glyde Dose Pack - Root Canal Conditioner
- **Commercial Name:** Glyde File Prep Doses Pack™
- **Primary Clinical Purpose of the Device:** Device in the form of a gel for use in the chemical and mechanical cleansing of the root canal preparation.
- **Affected product:**

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

2. Reason for Field Safety Corrective Action (FSCA)

- **Description of the Product Problem:** Dentsply Sirona has detected a wrong expiry date on Glyde products. Products have an expiry date of May 2024 instead of January 2024.
- **Hazard giving rise to the FSCA:** The full performance of the product cannot be guaranteed after January 2024.
- **Probability of problem arising:** Use of expired product after January 2024 cannot be excluded.
- **Predicted risk to patient/users:** Primary clinical purpose not fulfilled after January 2024 (ineffective product).
- **Background on Issue:** The full performance of the product cannot be guaranteed after January 2024. All the necessary containments have been made and the concerned products have been identified. Preventive / corrective actions have already been taken to prevent recurrences.

3. Actions expected from Users Customers: Return of products for credit note

Search in your Practice inventory. Are you still in possession of any of the affected product 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.

Note: The Competent (Regulatory) Authority of your country has been informed about this communication.

Sincerely,

Frédéric Mottier
QA / RC Director