

Date: 26thJanuary 2026

Field Safety Notification (FSN)
Aquasil putty Soft
Long setting time

1. **Attention to:** End users and Customers who may be in possession of affected products nominated hereafter.

2. **Purpose of this letter:**

The purpose of this letter is to advise you that Dentsply Sirona is voluntarily conducting a product Field Safety Notification on **ref. 60578320 and 60578321 Aquasil putty soft and ref. 60578332 and 60578333 Aquasil putty hard** for batches indicated in table 1. The product could be affected by a performance failure due to a long setting time. At the time of this information, the result of the long setting time has not resulted in any reported damages to health.

The affected products are reported in table 1:

Product code	Product name	Batch
60578320	AQUASIL PUTTY SOFT REG PACK 2X450ML	2311432656
60578320	AQUASIL PUTTY SOFT REG PACK 2X450ML	2403440087
60578320	AQUASIL PUTTY SOFT REG PACK 2X450ML	2407449110
60578320	AQUASIL PUTTY SOFT REG PACK 2X450ML	2410455771
60578320	AQUASIL PUTTY SOFT REG PACK 2X450ML	2501459563
60578320	AQUASIL PUTTY SOFT REG PACK 2X450ML	2502462412
60578320	AQUASIL PUTTY SOFT REG PACK 2X450ML	2502462422
60578320	AQUASIL PUTTY SOFT REG PACK 2X450ML	2502464285
60578320	AQUASIL PUTTY SOFT REG PACK 2X450ML	2505469777
60578320	AQUASIL PUTTY SOFT REG PACK 2X450ML	2505469779
60578320	AQUASIL PUTTY SOFT REG PACK 2X450ML	2505469797
60578321	AQUASIL PUTTY SOFT PACK4X(450+450ML)	2311432660
60578321	AQUASIL PUTTY SOFT PACK4X(450+450ML)	2401436295
60578321	AQUASIL PUTTY SOFT PACK4X(450+450ML)	2406445642
60578321	AQUASIL PUTTY SOFT PACK4X(450+450ML)	2407449112
60578321	AQUASIL PUTTY SOFT PACK4X(450+450ML)	2412458885
60578321	AQUASIL PUTTY SOFT PACK4X(450+450ML)	2502462412
60578321	AQUASIL PUTTY SOFT PACK4X(450+450ML)	2502463586
60578321	AQUASIL PUTTY SOFT PACK4X(450+450ML)	2502464183
60578321	AQUASIL PUTTY SOFT PACK4X(450+450ML)	2505469777
60578321	AQUASIL PUTTY SOFT PACK4X(450+450ML)	2505469779
60578321	AQUASIL PUTTY SOFT PACK4X(450+450ML)	2505469795
60578321	AQUASIL PUTTY SOFT PACK4X(450+450ML)	2505469797

60578332	AQUASIL PUTTY HARD FAST PACK 2X450ML	2405445155
60578332	AQUASIL PUTTY HARD FAST PACK 2X450ML	2501461092
60578332	AQUASIL PUTTY HARD FAST PACK 2X450ML	2502463608
60578332	AQUASIL PUTTY HARD FAST PACK 2X450ML	2504469709
60578333	AQUASIL PUTTY HARD PACK4X(450+450ML)	2405445157
60578333	AQUASIL PUTTY HARD PACK4X(450+450ML)	2504469709

Table 1

3. Reason for the Voluntary Field Safety Notification:

Aquasil putty soft is an Addition Silicone dental impression material. This voluntary Field Safety Notification is occurring due to a long setting time of the product indicated in table 1 exceeding the timing indicated in the labelling (the setting time could exceed 20 minutes).

4. Risk to Health:

The primary clinical purpose of the product cannot be fulfilled due to the long setting time of the product identified. No action is required for patients already treated with the affected lots.

5. Actions to be Taken by Users Customers: return to Dealer

We kindly ask to proceed with the following steps:

- Search in your Practice inventory. Are you still in possession of any of the affected product listed in table 1?
- In case you are, please immediately segregate the products.
- Please **return** the material to Dealer / Local Dentsply Sirona country organization who originally sold the products to you. Complete the **Notification Acknowledgement form** and send it to the following contact for the refund:

Field customized based on the local DS country organization

6. Dentsply Sirona Action:

Preventive / corrective actions have already been taken to prevent recurrences.

7. Transfer of Information:

This voluntary notification is being conducted to the clinical level and ought to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected products are located. Please transfer this notice to those organizations on which this action has an impact. Dentsply Sirona has notified the appropriate regulatory agencies of this action. Please ensure to report any product-related events to Dentsply Sirona, as this provides important feedback.



Reference Number: 9000-HHE-2025-23 [1]

8. Acknowledgement Information:

Complete the Notification, Acknowledgement Form (separate sheet) when the action has been completed and provide the information back to the following contact:

Field customized based on the local DS country organization

9. Dentsply Sirona Contact Information:

The following contact information is open for any questions or concerns.

Field customized based on the local DS country organization

We sincerely regret the inconvenience this issue may cause for you and your patients.