

Date: 26th January 2026

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

1. Attention to: Distributors 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 Action / Recall 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 Dealer: Scrap the material and complete the Notification Acknowledgement form

Dealer in possession of the affected products in the inventory or returned from users should proceed with the following steps:

- Please immediately segregate the products and proceed with the scrap
- Please complete the **Notification Acknowledgement form** for the refund and return it to the following contact:

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:

Dealer should transfer the information as reported in the steps below:

- Please identify customers that received or may have received the devices indicated in table 1
- Please inform the identified customers of this FSN / Recall notice sending to **the FSN / recall notification for user.**

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.

8. Acknowledgement Information:

Please complete the attached 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.