Urgent Field Safety Notice (FSN)

FINGER SPREADERS 25MM D

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 numbers of Finger Spreaders 25mm D, listed below. A few Finger Spreaders have been manufactured with a diameter wider than it should be at the tip of the operating part.

Information on Affected Devices

Date Issued: 02/2020

Commercial Name: FINGER SPREADERS 25MM D

Primary Clinical Purpose of the Device: Finger Spreaders are instruments used in the context of a dental root canal obturation. Fingers Spreaders are conical flat end pluggers used for lateral compaction of the Gutta-Percha.

Affected productions:

Model	Catalog	Batch
FINGER SPREADERS 25MM D	A0182 025 004 00	1600468
FINGER SPREADER STERILE 25MM ASSORTMENT x4	A0182 025 900 03	1601919

Conform Finger Spreader

Non-conform Finger Spreader

Reason for Field Safety Corrective Action (FSCA)

Description of the Product Problem: During a domestic inspection, Dentsply Sirona has detected a sporadic dimensional issue on a production of Finger Spreaders D 25mm. Some of these instruments have a diameter wider than it should at the tip of the operating part.

Hazard giving rise to the FSCA: An incomplete / incorrect root canal obturation may occur by using such oversized instruments. Equally, there is potential risk of root fracture if the user tries to reach the expected working length by pressure on the oversized instrument.

Probability of problem arising: Probability remains low. The issue should be detected by most of the practitioners upon starting the obturation procedure. Moreover, the dimensional issue statistically impacts only 1.27% of the lot. Around thirty instruments already distributed on the market should be concerned by the issue.

Predicted risk to patient/users: An infection of the treated tooth due to an insufficient tightness of the root canal obturation or due to the presence of fissures may occur. This could lead to a health impact on the patient in short or medium term (root canal retreatment or tooth extraction in worth cases).

Background on Issue: Root causes which have conducted to the dimensional issue are being investigated. All the necessary containments have been made and the concerned productions have been verified. Preventive / corrective actions have been taken to prevent recurrences.

Actions expected from End Users

Verify in your inventory If you could be still in possession of any affected products listed above.

In this case, please immediately segregate the products and return them to the following address:

DENTSPLY SIRONA
Maillefer Instruments Holding Sàrl

For the attention of: complaint department

Chemin du Verger, 3
CH-1338 Ballaigues
SWITZERLAND

Please acknowledge and fill the reply form (see attachment).
Thank you for your assistance. We regret any inconvenience caused by this product removal.

Sincerely,

Frédéric Mottier
QA Manager