

Fälschungen von endodontischen Feilen: «ProTaper Universal»

Stand 17.09.2012

Die Firma „Dentsply Maillefer“ in Balaigues in der Schweiz hat Swissmedic über Fälschungen von endodontischen Feilen der Marke “ProTaper® Universal” informiert. Bei diesen Produkten handelt es sich um Feilen, die bei Wurzelbehandlungen von Zähnen eingesetzt werden.

Fälschungen wurden bisher im asiatischen Raum und im Mittleren Osten gefunden.

Es ist nicht auszuschliessen, dass gefälschte Produkte auch in der Schweiz und insbesondere über das Internet zum Kauf angeboten werden. Sofern Sie davon Kenntnis haben, ersuchen wir Sie dringend, Swissmedic darüber zu informieren.

Die gefälschten Feilen weisen eine schlechte Qualität auf. Gesundheitsschäden für den Patienten und den Zahnarzt sind bei ihrer Anwendung möglich.

Die bisher gefundenen Fälschungen haben Verpackungen, die einige leicht erkennbare Unterschiede zu den Originalverpackungen aufweisen. Diese Unterschiede sind im Anhang zusammengestellt. Eine Information von Dentsply Maillefer finden Sie ebenfalls im Anhang.

Kontakt:

Swissmedic, Abteilung Medizinprodukte
Hallerstrasse 7
CH-3000 Bern 9
Tel: 031 323 22 51, Fax: 031 322 76 46
e-Mail: medical.devices@swissmedic.ch

Weitere Informationen über Medizinprodukte finden Sie im Internet auf www.swissmedic.ch/md.asp

Institut suisse des Produits Thérapeutiques Swissmedic
Division Surveillance du marché
Attn. Mme Karoline Mathys
Hallerstrasse. 7
CH-3000 BERNE 9

Ballaigues, August 13, 2012

Re : Counterfeit DENTSPLY Maillefer's Products

Dear Sirs,

Our company belongs to the DENTSPLY group of companies ("DENTSPLY").

We discovered that the company Osakadental, Unit04,7/F,Bright Waytower NO.33 Mong KO Road, KOWLOON, HK. has recently sold copies of our PROTAPER® UNIVERSAL Files (see enclosed document describing the difference between our products and the counterfeits ones).

These activities clearly infringe DENTSPLY's intellectual property rights, in particular its trademark rights.

In addition, these products bear **false** :

- (i) **CE0459 mark**, as these products with bearing these labelling could not have been certified by G-MED
- (ii) **Reference numbers**, as the references indicated on these products do not match the size of the products as defined in the Dentsply Maillefer's internal procedures.
- (iii) **Lot numbers**, as the lot numbers indicated on these products do not match the Dentsply Maillefer's lot files **and**
- (iii) **Manufacturer's Name and address**, as Dentsply Maillefer never manufactured these devices.

Therefore, they are obviously not in conformity with the applicable legislation and may lead to vigilance issues.


We believe it is important to bring this issue to your attention and leave it to you to decide any measures you deem appropriate.

In any case, we remain at your disposal for any further information you may need.

We thank you in advance for your assistance and remain,

Yours sincerely,

Maillefer Instruments Holding Sàrl



Luc Etienne
QA/RA Director & Management representative

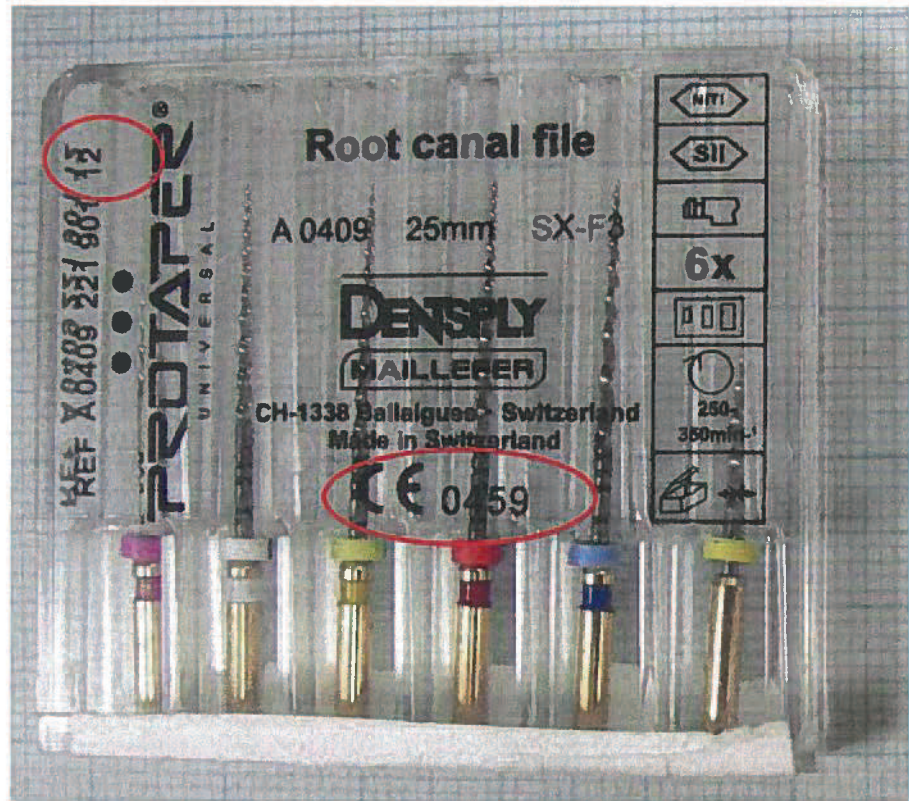
Maillefer Instruments Holding Sàrl



Dominique Legros
General Manager CEO



Fake primary packaging



COPIED ProTaper files

Counterfeit product has a ReOrder number ending in 12 and also carries a CE mark. DENTSPLY Maillefer does not produce such a product.



COPIED ProTaper files

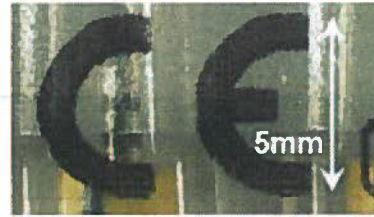


**WE
KNOW
ENDO.**

Fake versus original packaging



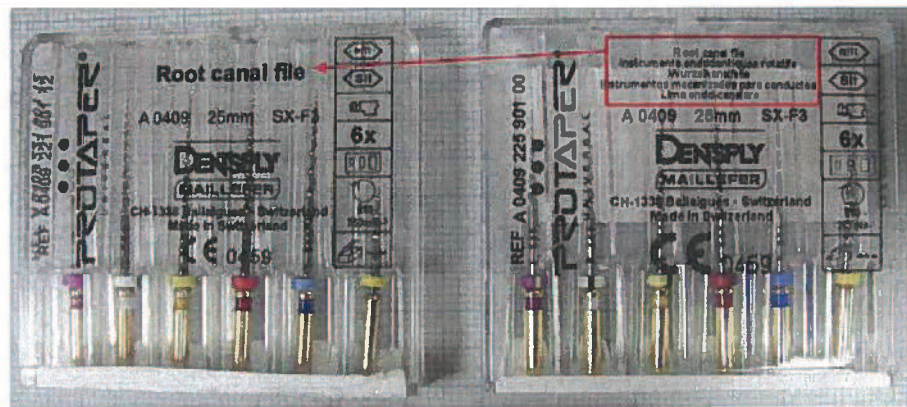
COPIED ProTaper files



ORIGINAL Dentsply Maillefer ProTaper files

The CE mark has to be 5mm high on the original labelling, whereas on the copied labelling the CE mark was only 3mm high.

This difference is visible by the practitioner without any magnification.



COPIED ProTaper files

ORIGINAL Dentsply Maillefer ProTaper files



COPIED ProTaper files

ORIGINAL Dentsply Maillefer ProTaper files

There was no sticker with the bar code at the rear of the copied boxes.

Fake versus original packaging

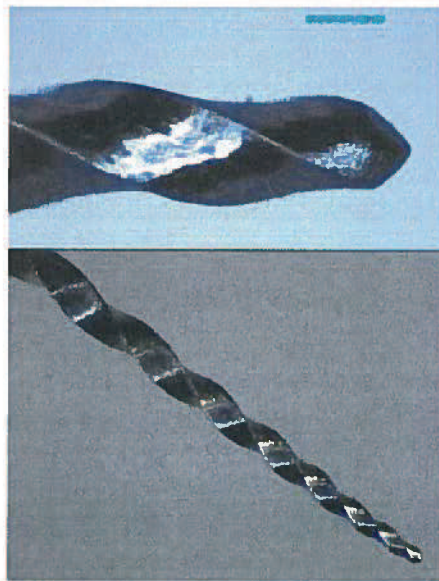


COPIED ProTaper files

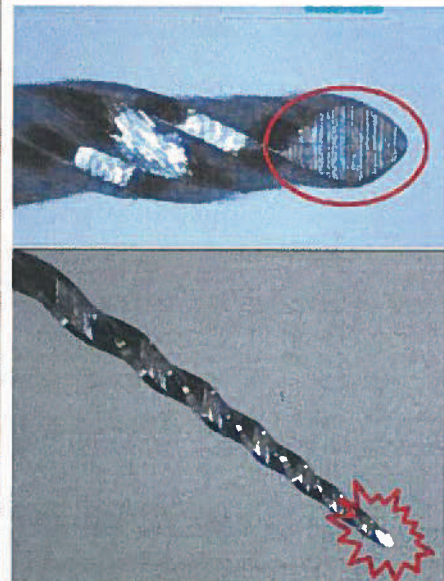


ORIGINAL Dentsply Maillefer ProTaper files

Fake versus original product



COPIED ProTaper files



ORIGINAL Dentsply Maillefer ProTaper files

The F3 Finisher has a tip with a bevel.

This bevel can be seen by the practitioner with a low magnification, because it reflects the light like a tinny shiny point at the tip end when once the files are rotated between the fingers.

The copied files had a standard conical tip.



**WE
KNOW
ENDO.**