

Fälschungen von endodontischen Feilen: K-FILE COLORINOX, K-REAMER und HEDSTROEM FILE COLORINOX

Stand 08.01.2013

Die Firma Dentsply Maillefer in Balaigues in der Schweiz hat Swissmedic über Fälschungen von endodontischen Feilen der Marken „K-FILE COLORINOX“, „K-REAMER“ und „HEDSTROEM FILE COLORINOX“ informiert. Bei diesen Produkten handelt es sich um Feilen, die bei Wurzelbehandlungen von Zähnen eingesetzt werden.

Fälschungen wurden bisher in Polen und in Litauen 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 und/oder Griffe, die einige leicht erkennbare Unterschiede zu den Originalverpackungen und/oder den Originalgriffen 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: materiovigilance@swissmedic.ch

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

Faelschung_Dentsply_Maillefer_Feilen_(df)_2013-01-08.doc

Geht an: <i>mep</i>	Post Eingang: 19. NOV. 2012
EDV eingetragt: <input type="checkbox"/>	KST/KTR/Produkt: <i>al</i>
	Dat.

**Institut suisse des produits
thérapeutiques Swissmedic
Division Dispositifs Médicaux
A l'attn. de M. Petitpierre
Hallerstrasse. 7
CH-3000 BERNE 9**

Ballaigues, le 15 novembre 2012

Avis de contrefaçon :

Monsieur,

Nous voudrions vous informer que nous avons identifié la présence de contrefaçons pour certains de nos produits.

Il s'agit en particulier de nos limes endo acier : K-FILE COLORINOX[®], K-REAMER[®] et les HEDSTROEM FILE COLORINOX[®]

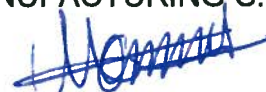
Ces produits sont des copies reproduisant nos nom, adresse, désignation, aspect général et CE.

Veuillez trouver ci-joint, pour complément d'information, quelques photos des ces produits comparés aux notres.

A ce jour ils n'ont été trouvés qu'en Pologne et en Lituanie, mais la mauvaise qualité de ces contrefaçons nous amène à craindre des problèmes notamment en ce qui concerne les déclarations d'incidents.

Je vous prie d'agréer, Monsieur, mes cordiales salutations.

MAILLEFER INSTRUMENTS
MANUFACTURING S.à.r.l



Glawdys Monnin
Assistante Affaires Réglementaires

Dentsply Maillefer

Chemin du Verger 3 - CH-1338 Ballaigues
Switzerland

Phone +41 (0)21 843 92 92

Fax +41 (0)21 843 92 93

www.dentsplymaillefer.com

Annexes : ment.

Institut suisse des produits
thérapeutiques Swissmedic
Division Dispositifs Médicaux
A l'attn. de M. Petitpierre
Hallerstrasse. 7
3000 BERNE 9
SUISSE

Ballaigues, 22 October 2012

Re: Counterfeit DENTSPLY Products

Dear Sirs,

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

We discovered that Osakadental, Unit 04, 7/F, Bright Waytower NO.33 Mong KO Road, KOWLOON, HK has recently sold copies of our K-FILE COLORINOX[®], K-REAMER[®] and HEDSTROEM FILE COLORINOX[®] (see enclosed document describing the difference between our products and the counterfeits ones).

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

- (i) **CE0459 mark**,
- (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



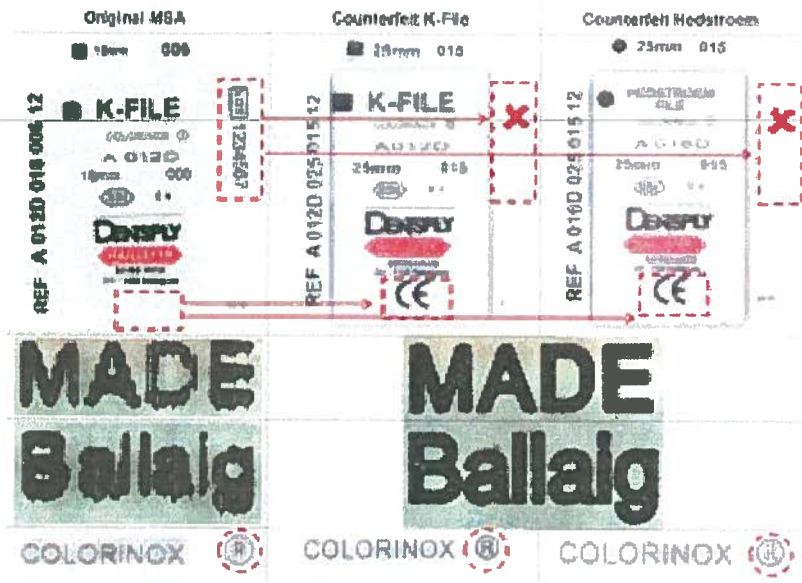
Luc Etienne
QA/RA Director & Management Representative

Maillefer Instruments Holding Sàrl



Dominique Legros
General Manager CEO

Fake primary packaging



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

Counterfeit products do not have a lot number.

Counterfeit product labeling has a better quality compared to the original one.

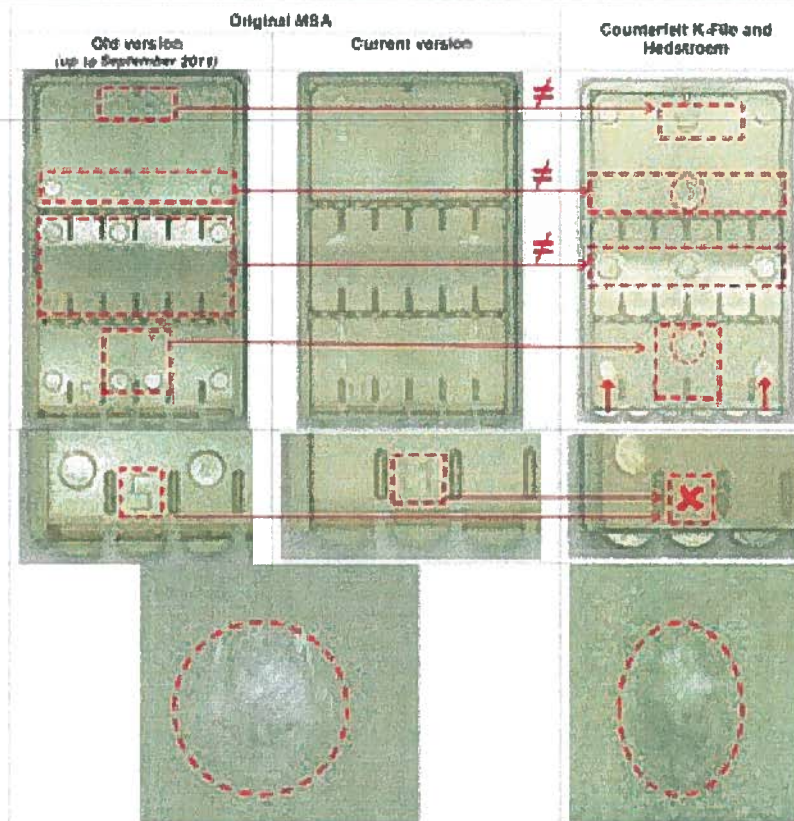
Counterfeit product has the R marking different.



The lot number reference n°2350190 refers to Reamer instruments dedicated to surgical practice but not to root canal files.

Replacement of the word DENTSPLY by KOREA and the word «Ballaigues» by KOREA.

Fake versus original packaging

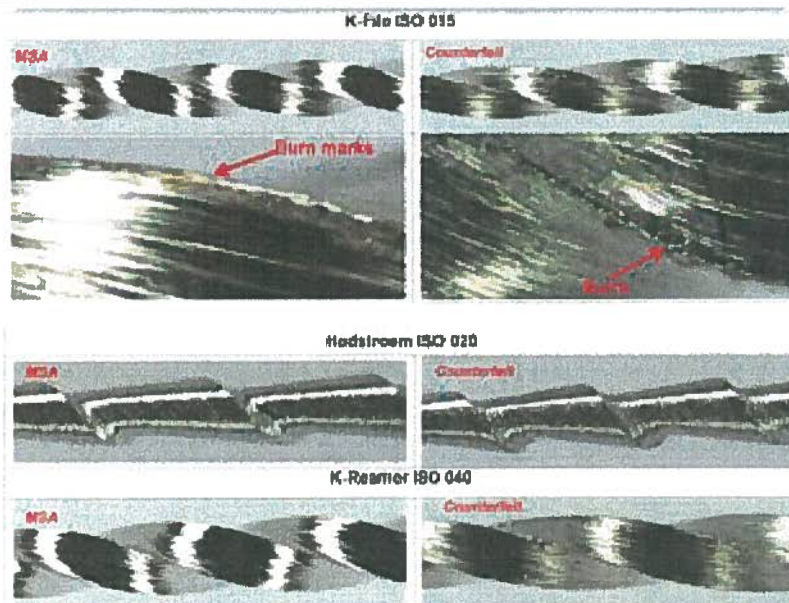


Ejection points are similar with the old Maillefer box version in terms of dimensions but their number and positions are different.

There is no identification number on the bottom inside the box.

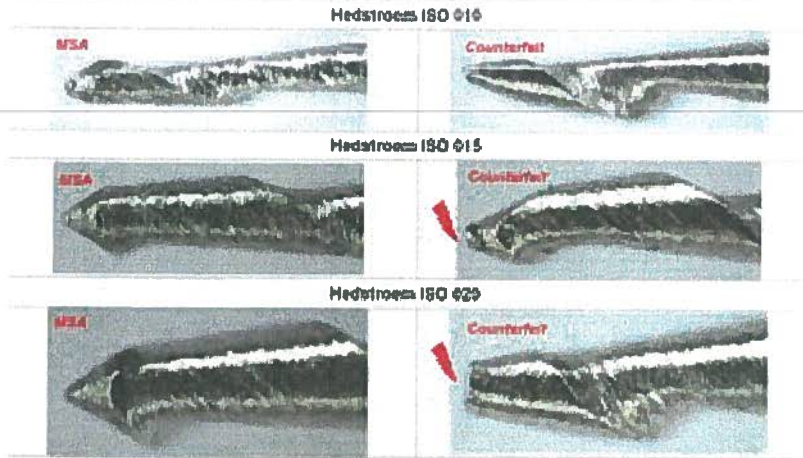
The box aspect is different in terms of shaping.

Fake versus original product



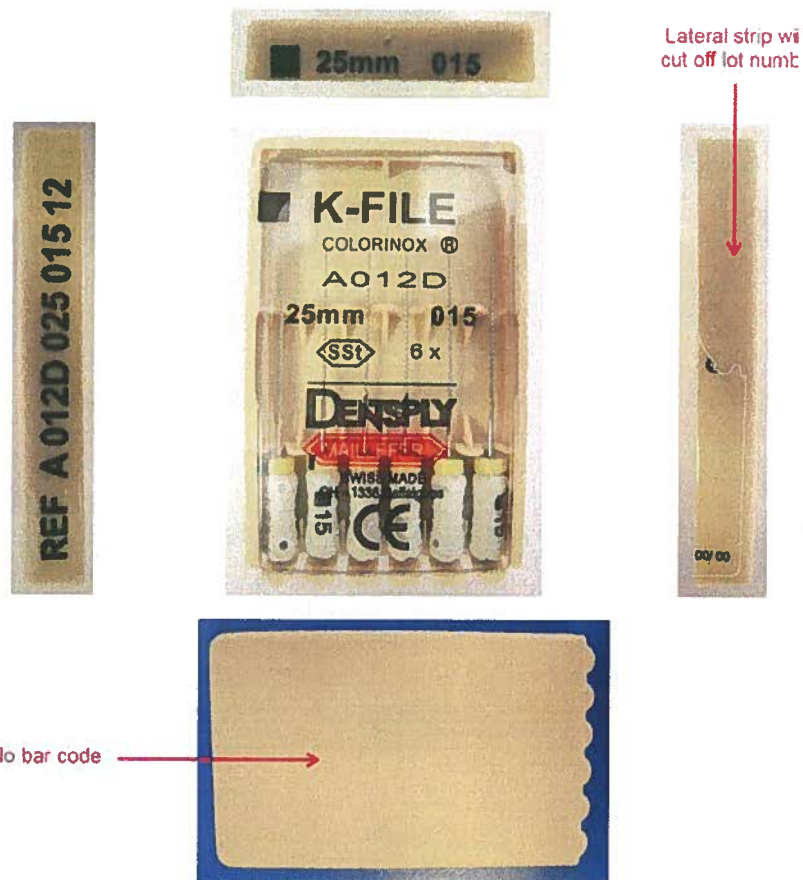
Counterfeit instruments had many burrs with punctual defect of twisting but they have the same face and flute number.

Fake versus original product



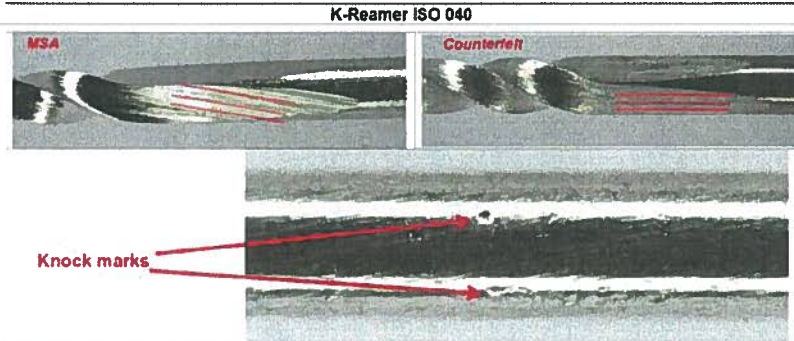
Counterfeit instruments show flattened tips with knock marks.

Fake versus primary packaging



Counterfeit products do not have a bar code. DENTSPLY Maillefer does not produce such a product.

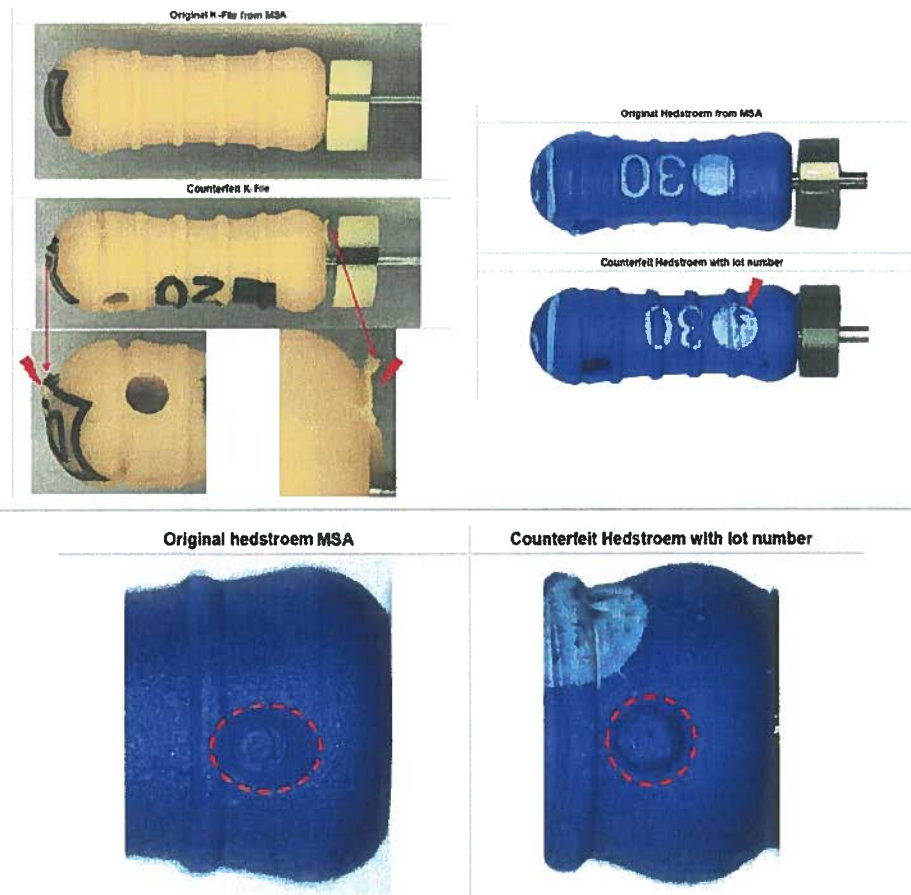
Fake versus original packaging (rear active part)



Counterfeit hedstroems have similar rear active part and similar grinding mark orientations.

Many marks are visible on the shaft.

Fake versus original product (handle)

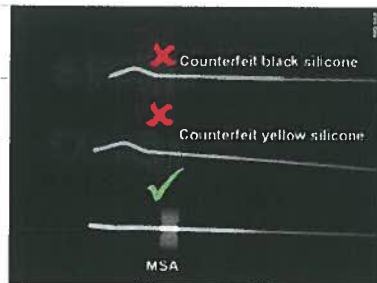


Counterfeit products had defect on the markings (oval injection point instead of round).

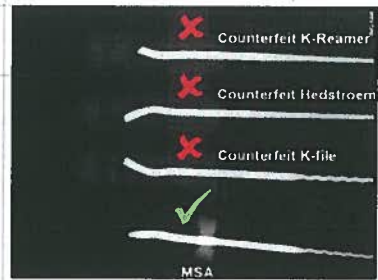
Counterfeit products had the same handle but with huge defect of injection.

Fake versus original product (silicon stops)

Counterfeit files without lot number



Counterfeit files with lot number



Counterfeit product s silicon stops were not radio-opaque at all, whereas Maillefer s silicon stop could be easily seen on the radiograph.