

Media release

Dental implant manufacturer banned from using ‘compatibility’ and ‘generic’ claims to sell cut-price imitations

- *German court stops imitator from marketing and guaranteeing products in combination with other systems*
- *Court ruling underlines that dentists must not mix/combine implant system components without specific certification of conformity*
- *Swiss court prohibits misleading use of ‘generic’*

Basel, 20 December 2012 – Straumann has won two important legal battles against a cut-price imitator who misleadingly claimed its implant components are compatible with, and equivalent to, Straumann originals. Courts in Germany and Switzerland found that neither conformity nor scientific tests had been conducted to support the claims made by DRS International GmbH (Dental Ratio Systems) and its former Swiss Distributor about its Oktagon® implant system.

Marketing of combination use banned; guarantee defunct

The District Court in Frankfurt am Main also found that ‘combined use’ (use of parts in combination with parts from third parties) was not stipulated in the CE Mark (Conformité Européenne) certification. As a result, the court ruled that the Oktagon implant system may neither be marketed nor sold by DRS for combination with system parts from other producers and that dentists must not use it in such a combination.

Because compatibility is not stipulated in the CE Mark certification, a second ruling by the Court forbids DRS from further claiming that a combination of Oktagon with other systems could be guaranteed. If a dentist or a laboratory mixes Oktagon or any components from other producers with Straumann components the Straumann guarantee is void.

The Court also prohibited DRS from advertising Oktagon as a ‘high quality copy’ of Straumann’s Standard Plus implant, noting that this improper claim, unfairly exploited Straumann’s good reputation and valued brand.

Labeling of dental implants as ‘generic’ misleading and illegal

In a separate action against ProImplant GmbH, the Swiss distributor of DRS, the Appeals Court in Basel struck down ProImplant’s misleading claim that the Oktagon implant is a ‘bioequivalent generic’. The Court found that the terms ‘generic’ and ‘bioequivalent’, which are used for pharmaceuticals, had been improperly and misleadingly applied to dental implants. The Court gave the following ruling:

The approval of medical devices follows a concept that differs from that of the approval procedure for pharmaceutical products. In the case of pharmaceuticals, it has to be demonstrated in a bioequivalence study that the generic and the reference product are essentially identical. The approval of medical devices, however, is based on a self-



declaration, by means of which the manufacturer declares that the 'basic requirements' are met.

Straumann's determined stand

"Dentists and patients have been misled into believing that lower-price imitations are the same as Straumann originals", said Beat Spalinger, President & CEO of Straumann. "They have also been hoodwinked by a misleading guarantee. Dental implants are not 'generic' or 'bioequivalent' and it is illegal to label them as such. Look-alikes and copycats are not manufactured to our standards nor have they undergone the extensive clinical testing that Straumann implants and abutments receive. Most importantly, without proven conformity they must not be used in combination with other systems. The court's ruling makes this clear and sends an important signal to imitators and dentists who buy their products. We are determined to take a strong, justified stand against rogue imitators, in the interest of patients."

About Straumann

Headquartered in Basel, Switzerland, the Straumann Group (SIX: STMN) is a global leader in implant and restorative dentistry and oral tissue regeneration. In collaboration with leading clinics, research institutes and universities, Straumann researches, develops and manufactures dental implants, instruments, prosthetics and tissue regeneration products for use in tooth replacement and restoration solutions or to prevent tooth loss. Straumann currently employs 2575 people worldwide and its products and services are available in more than 70 countries through its broad network of distribution subsidiaries and partners.

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