

Heraeus Kulzer GmbH
Heraeus Dental
Grüner Weg 11
D-63450 Hanau

Heraeus Kulzer GmbH · Grüner Weg 11 · 63450 Hanau

Address

Safety Manager Medical Devices
Contact person: Dr. Albert Erdrich
Telefon + 49 (0) 6181.35-5546
Fax + 49 (0) 6181.35-3979
albert.erdrich@heraeus.com
www.heraeus-dental.de

Urgent Safety Information - Recall of a Medical Device -

08.09.2010

Relevant Products: SOPIRA Carpule Needles

Art. Nr.	Needle Type	Length	Lot #	Expiry Date
65323474	G27, Ø0.4x38mm	38 mm	E0012L	2015/03
65481657	G27, Ø0.4x35mm	35 mm	A0013K	2015/03
65481657	G27, Ø0.4x35mm	35 mm	A0007K	2015/02
66008939	Free Flow - G27, Ø0.4x38mm	38 mm	E0014L	2015/03
66008939	Free Flow - G27, Ø0.4x38mm	38 mm	E0008L	2015/02

Dear ...

Unfortunately, we found among the listed articles and lot numbers of *SOPIRA Carpule Needles* with a probability of 5 to 35 % superficial corrosion traces. First analyses show that these are bloom defects of ferric oxides and chlorides.

According to our actual evaluation these coverings have no health hazard; especially they are nontoxic. The canulae are still sterile. Furthermore, the defect of the products is simply to recognize due to the corroded brown appearance of the needles. Until today we have received no information about intricacies with a health effect to patients.

Seite 2

Nevertheless, as responsible manufacturer of high quality medical devices Heraeus Kulzer has decided to exclude any risk and to recall the concerned lots of those articles immediately. This is a truly prophylactic action.

Therefore, please, if you have products of the listed lots on stock, we would like to ask you to return those for exchange at our expense to our distribution center:

***Heraeus Kulzer GmbH
Geb. B802
Alte Heerstraße
41538 Dormagen***

Please inform additionally all your customers and those you have delivered the canulaes about this recall and ask for the return of the faulty needles. We take pains to correct the insufficiency and to replace the needles by flawless ones as soon as possible.

Thank you very much for kind understanding and we appreciate your support during this corrective action. We regret the inconvenience this might cause to your business.

In parallel, we have informed the German health authorities (BfArM) and they and we will inform your local authorities about this preventive action.

Yours sincerely,

Dr. Albert Erdrich
Safety Manager Medical Devices
Heraeus Kulzer GmbH