Heraeus Kulzer
Mitsui Chemicals Group

Urgent Safety Information

Recall

concerning

GLUMA Desensitizer PowerGel

Hanau, April 22nd 2014

Heraeus Kulzer GmbH
Mitsui Chemicals Group

Dr. Albert Erdrich
Sicherheitsbeauftragter §30 MPG
Safety Manager Medical Devices
Grüner Weg 11
63450 Hanau
Germany

To all sales organizations, sales reps, dental wholesale dealers, dental material retail dealers and distributors as well as customers as dentists, dental surgeries, dental clinics and hygienists.

Identification of the involved medical device:

Hypersensitivity treatment:	***GLUMA Desensitizer PowerGel***
Article numbers:	66043451, 66052803
Syringe LOT:	**010103, 10104**
Expiry date:	**2015-09, 2016-06**
Assortment LOT:	**42, 43, 44, 45, 46, 47, 48, 49, 50, 51**
Expiry date:	**2015-09**

Please note that this recall does not affect GLUMA Desensitizer liquid or any other LOT of GLUMA Desensitizer PowerGel than mentioned above.

Description of the problem including the identified causes:

Backgrounds of the issue are complaints about single syringes of these LOT showing a more than usual jerky extrusion behavior. In one case this led to a fluid ejection from the syringe in front of a hygienist when pushing harder on the plunger rod outside the mouth. This near accident and further

complaint reports about the same issue resulted in an evaluation of the pastes' properties and primary packaging details.

These thorough evaluations make HKG aware that the used primary packaging, namely closing cap and plunger rod, in combination with a more liquid viscosity of these two syringes' LOT may have led to the unwanted behavior as described above.

Risk for patients, user and/ or any third party when using the product further on

If uncontrolled fluid ejection from the syringe occurs, especially the dental patient could be exposed to the gel reaching the mucosa, the face or even the eyes causing irritation, chemical burns and blistering of the tissues which is a medically reversible condition. This could happen to the users and any involved third person, too, when safety hints and precautions where disregarded using the gel product.

A serious injury may occur and cannot be excluded completely by the product warnings and the safety precautions such as the use of safety glasses and rubber dam during treatment as indicated in the Instructions for Use. In the best interest of HKG customers' safety, we are voluntarily recalling this product to minimize the risk of occurrence to a minimum. Up to now, Heraeus Kulzer did not receive any reports on incidents or a serious injury of a patient. Nevertheless, as responsible manufacturer of high quality medical devices, Heraeus Kulzer has decided to minimize any risk and to recall the concerned lots of those articles immediately. This is a truly prophylactic preventive action.

Which measures should be taken by the addressees of this information?

HKG asks for immediate assistance from anybody of the listed group of people by taking such following measures:

1. Search your inventory and immediately block any *GLUMA Desensitizer PowerGel* Assortments with the aforementioned LOT or any syringe samples with noted LOT; see numbers and images above.
2. Send all identified products to your dealer or directly to Heraeus Kulzer's address listed at the end and copy the delivery note of your return shipment to your dealer for replacement or credit. Please note that the replacement or credit can only be issued by the entity you originally bought and paid the product.
3. If you are a dealer identify any customers that *GLUMA Desensitizer PowerGel* of the mentioned LOT was distributed to. Please, identify each customer by name, phone number and address.

   As you distributed this product to end users you must contact each customer, instruct them to cease usage of this particular LOT with this Urgent Safety Information and return the product to Heraeus Kulzer either via your organization or directly to the address of Heraeus Kulzer listed below. Please be aware of measure 2.
4. If you are an end user of the product, please, identify any *GLUMA Desensitizer PowerGel* with the aforementioned LOT or any syringe samples in your surgery or clinic rooms with the noted LOT; see numbers and images above. If you identify any product cease usage of this product and send products to your dealer or directly to the address of Heraeus Kulzer listed below. Please be aware of measure 2.
5. If you as customer of a dental material supplier have forwarded this product to any other end users, please, follow the instructions of measure 3.
6. If you as end user of the product do not find any product of the affected LOT as described above, please, sign the attached form and either FAX it to Heraeus Kulzer +49 6181 35 39 79 or send it via E-mail to GSM@kulzer-dental.com

7. Please, return the aforementioned *GLUMA Desensitizer PowerGel* LOT either to your providing dealer, your local Heraeus Kulzer sales organization or directly to the following Heraeus Kulzer address in Germany:

   Heraeus Kulzer GmbH
   Return Recall GLUMA
   Alte Heerstraße
   Geb. B802
   41538 Dormagen
   Germany

Circulation of this written Urgent Safety Information

All informed addressees of this information shall circulate this information to anybody to whom they know that those might be concerned by this information or identify those to your next Heraeus Kulzer representative or sales organization to act for you.

Please, keep this information until all measures are completed which could be assumed at earliest in October 2014 – planned final report for this recall.

Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte) has got a copy of this Urgent Safety Information. In parallel, we have informed all concerned vigilance contact points about this preventive action.

Contact person:

Mr. Dr. Albert Erdrich
Tel: +49 6181 35 55 46
E-Mail: GSM@kulzer-dental.com

Thank you very much for your immediate attention to this matter and your kind understanding. We greatly appreciate your support during this preventive action and we regret deeply any inconvenience this might cause to your business.

22. April 2014,
i.V. Dr. Albert Erdrich

[redacted]

Heraeus Kulzer
Mitsui Chemicals Group

End User Statement

I have searched my inventory and DO NOT have any of the affected LOT of *GLUMA Desensitizer PowerGel* as described in the Urgent Safety Information from Heraeus Kulzer, dated April 22nd 2014.

The product and LOT in question:

Article numbers:	66043451, 66052803
Syringe LOT:	**010103, 10104**
Expiry date:	**2015-09, 2016-06**
Assortment LOT:	**42, 43, 44, 45, 46, 47, 48, 49, 50, 51**
Expiry date:	**2015-09**

Please sign below and FAX to Heraeus Kulzer at **+49 6181 35 39 79** or send the statement via E-mail to GSM@kulzer-dental.com.

Name of Dental Office: _____

Name of Signee: _____

Signature: _____

Date: _____

Heraeus Kulzer
Mitsui Chemicals Group

Dealer Statement – informed customers

I have circulated the Urgent Safety Information from Heraeus Kulzer, dated April 22nd 2014 to all my customers below which I have provided with the affected LOT of *GLUMA Desensitizer PowerGel*.

The product and LOT in question:

Article numbers:	66043451, 66052803
Syringe LOT:	**010103, 10104**
Expiry date:	**2015-09, 2016-06**
Assortment LOT:	**42, 43, 44, 45, 46, 47, 48, 49, 50, 51**
Expiry date:	**2015-09**

Please, fill in the customers and sign at the end. If you have more customers than space in the provided table, please use several forms.

FAX to Heraeus Kulzer at **+49 6181 35 39 79** or
send the statement via E-mail to GSM@kulzer-dental.com.

Surgery/ Clinic	Contact person	Phone number	Address

Name of the Company: _____

Name of Signee: _____

Signature: _____

Date: _____