GC Orthodontics Europe GmbH - Harkortstraße 2 · 58339 Breckerfeld · Germany

Zentrale / Head Office
Harkortstraße 2 · 58339 Breckerfeld · Germany
Tel +49.2338.801.888 · Fax +49.2338.801.877
info.gco.germany@gc.dental · www.gc.dental/ortho

FIELD SAFETY NOTICE

Experience Mini Metal Rhodium

Manufacturer:	GC Orthodontics Europe GmbH Harkortstr. 2 58339 Breckerfeld Germany	**Date of FSN:**	01.02.2024
		FSN Ref:	FSN-01-24-GCOE

Type of Action: ☒ Field Safety Notice
☐ Recall

For Attention of: *Enter name of customer*

Dear Valued Customer,

GC Orthodontics Europe GmbH has initiated a field safety action for Experience Mini Metal Rhodium brackets. Our records indicate that the affected devices have been shipped to your account.

1. **Information on affected devices:**

Device type	Single-use, non-sterile metal orthodontic bracket
Article number, Product name, UDI-DI, LOT/Batch, Manufacturing date	REF 24-2120-0010 EXMMRH ROTH 022/UR2 8T 9A UDI-DI: 14062762008772 LOT A325270 manufacturing date 28.09.2023
	REF 24-2120-0020 EXMMRH MBT 022/UR2 10T 8A UDI-DI: 14062762008789 LOT A325266 manufacturing date 26.09.2023
Primary clinical purpose of device(s)	Orthodontic treatment

2. **Reason for Field Safety Corrective Action (FSCA):**

Description of the problem:

Package contains wrong product.

Packages for REF 24-2120-0010 EXMMRH ROTH 022/UR2 8T 9A for batch number A325270 (manufacturing date 28.09.2023) incorrectly contain MBT products.

Packages for REF 24-2120-0020 EXMMRH MBT 022/UR2 10T 8A for batch number A325266 (manufacturing date 26.09.2023) incorrectly contain ROTH products.

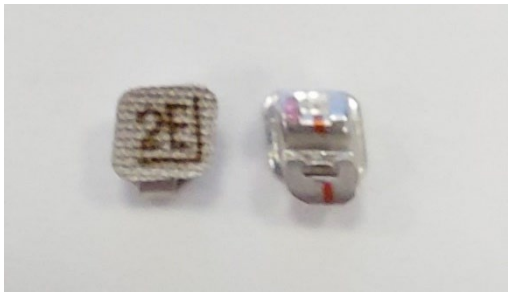
MBT and ROTH represent two different techniques in bracket application and the brackets are programmed with different values for torque and angulation.

Correct identification:

The products can be correctly identified by their base ID. MBT products have an additional "E" printed on the base ID.

ROTH:

MBT:



Potential Risk to the patient/users/other persons:

The wrong product applies different values in torque and angulation:

24-2120-0010 TQ 8°, ANG +9° (SLOT .022", ROT 0°)

24-2120-0020 TQ 10°, ANG +8° (SLOT .022", ROT 0°)

Depending on the orthodontic wire used in combination with the brackets, there might be a minimal change in treatment outcome. This is reversible, but might require a prolonged treatment.

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AG Hagen - HRB 9197
Geschäftsführer:
Josef Richter,
Katrin Langer
St-Nr.: 341/5702/0831

Commerzbank AG Hagen
IBAN: DE72450400420355078700
SWIFT: COBADEFFXXX
BLZ: 450 400 42
KTO: 355 07 87 00
Ust-Nr.: DE285268399

Märkische Bank eG Hagen
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3. Type of Action to mitigate the risk

Actions to be taken by the user:

☒ Identify Device
☒ Return Device (optional)
☒ Follow patient management recommendations
☒ Quarantine Device
☒ Destroy Device (optional)

- We request you to immediately stop using devices from affected lots.
- Report any occurrence of product performance issues or patient adverse events to GC Orthodontics Europe GmbH.
- If you are not the end user, please forward this notice to whom you have distributed the product to.
- Upon receipt of this letter please review your inventory, complete and return the provided "Field Safety Notice Reply Form" to the address, fax number or e-mail address on the form, even if you don't have the affected product.
- If you assume that some of the incorrect products have been used, please evaluate if to implement an appropriate patient follow-up and act accordingly.
- You may either return all unused affected devices to GC Orthodontics Europe GmbH or dispose them according to the applicable National Regulations.

Action(s) taken by the manufacturer:

☒ Product Removal

- GC Orthodontics Europe GmbH has taken immediate action to stop shipping devices from affected lots.
- The initial investigation has determined there are no other affected products or lots in distribution other than the one specified in this FSN.
- We will implement appropriate corrective actions to ensure product performance.
- Our Customer Service Team/ Sales Representative will work with you to replace your inventory or provide a credit note, as applicable.
- The appropriate regulatory agencies have been notified of this incident.

4. General Information

FSN Type	New
Further advice or information already expected in follow-up FSN?	Not planned yet

We regret any inconvenience this may cause you and appreciate your patience and understanding. If you have any questions, please contact your local GC representative or Customer Service at: info.gco.germany@gc.dental or +49 2338 801 888.

The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

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Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

B/O Christian Spotti
General Manager Quality Assurance
GC Europe AG

B/O Mario Minale
PRRC, Head of Regulatory Affairs
GC Europe N.V.

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FIELD SAFETY NOTICE REPLY FORM

Field Safety Notice (FSN) information	
FSN Reference Number	FSN-01-24-GCOE
FSN Date	01.02.2024
Product name	Experience Mini Metal Rhodium
Article number, **Product name,** **UDI-DI,** **LOT/Batch,** **Manufacturing date**	REF 24-2120-0010 EXMMRH ROTH 022/UR2 8T 9A UDI-DI: 14062762008772 LOT A325270 manufacturing date 28.09.2023
	REF 24-2120-0020 EXMMRH MBT 022/UR2 10T 8A UDI-DI: 14062762008789 LOT A325266 manufacturing date 26.09.2023

Kindly complete and return this form and any affected devices to GC Orthodontics Europe GmbH as per the instructions stated below.

Deadline for returning the FSN Reply form: **22.02.2024**

Customer Details	
Organization Name:	
Account Number:	
Contact Name:	
Address:	
Telephone Number:	
Email:	

Please indicate all that apply:

- ☐ I have read and understood the contents of this Field Safety Notice and have forwarded it to all affected parties
- ☐ A thorough search for all affected devices has been completed and no affected units remain in inventory. No devices will be returned.
- ☐ The affected devices have been identified and are being returned.

Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):

- ☐ The affected devices have been identified and are being destroyed.

Qty:	Lot/Serial Number:	Date Returned(DD/MM/YY):

- ☐ No affected devices are available for return/ destruction
- ☐ Other Action (Define):

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☐ I do not have any affected devices.

☐ I have a query please contact me (e.g. need for replacement of the product).

Please enter contact details if different from above and brief description of query:

Name/Designation	Signature	Date

Please return the filled in form and any affected products to GC Orthodontics Europe GmbH using any one of the following methods:

- Scan and email this form to info.gco.germany@gc.dental or fax to +49 2338 801 777.
- If returning product, please send the devices by shipment to our address GC Orthodontics Europe GmbH, Harkortstrasse 2, 58339 Breckerfeld, Germany or hand it over to our Sales Representative. In this case, please attach a copy of the completed form for identification of the returned articles.

It is important that your organization takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organization's reply is the evidence we need to monitor the progress of the corrective actions.

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