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

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FIELD SAFETY NOTICE

Legend Medium Roth

Manufacturer:	GC Orthodontics Europe GmbH Harkortstr. 2 58339 Breckerfeld Germany	**Date of FSN:**	26.03.2025
		FSN Ref:	FSN-01-25-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 Legend Medium Roth orthodontic 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 32-2110-0010 LME ROTH 022/UR1 12T 5A UDI-DI: 14062762015473 LOT A325752 manufacturing date 2023-10-03
Primary clinical purpose of device(s)	Orthodontic treatment

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

Description of the problem:

Package contains wrong product.

The packages of the affected batch A325752 are labelled with article number 32-2110-0010 (LME ROTH 022/UR1 12T 5A / for first upper right tooth) but incorrectly contain products 32-2120-0010 (LME ROTH 022/UR2 8T 9A / for second upper right tooth).

Potential Risk to the patient/users/other persons:

The wrong product applies different values in torque and angulation:

Product as intended for the package	Wrong product contained in the package
32-2110-0010	32-2120-0010
for first upper right tooth	for second upper right tooth
TQ 12°, ANG +5° (SLOT .022“, ROT 0°)	TQ 8°, ANG +9° (SLOT .022“, ROT 0°)

Each bracket is provided with a colored marking, which is always found in the same place (disto-gingival) (Fig.1), indicating the intended quadrant of teeth for the bracket. As the brackets are intended for the same quadrant, they have the same color coding (in this case yellow).

However, there is a clear difference in size and shape between the two brackets. The product is intended for professional users only. It is very likely that they would immediately notice the difference in size and shape during fitting of the brackets, as the two corresponding teeth are right next to each other. In addition, the usual size difference between the brackets for the upper lateral and central incisors is also present in the second quadrant, i.e. in the brackets for teeth 22 and 21, which are also located (on the opposite side) directly next to the corresponding teeth (Fig.2).

If the brackets 11 and 12 are nevertheless interchanged, this will result in the tooth acquiring an incorrect angulation in the dental arch, due to the difference between the programmed torque and angulation values as described above. This error can be corrected during orthodontic therapy by replacing the corresponding brackets. This may result in an unintended extension of the therapy duration.

Figure 1

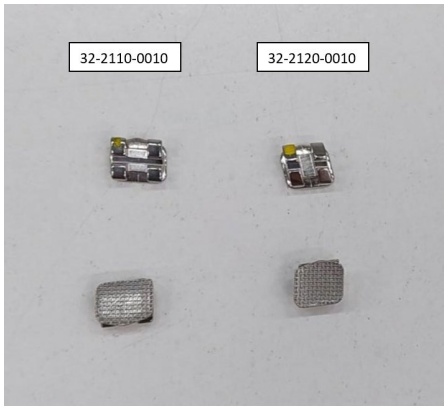

Figure 2

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

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

Märkische Bank eG Hagen
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BLZ: 450 600 09
KTO: 65 98 41 00

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
Director 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-01-25-GCOE
FSN Date	26.03.2025
Product name	Legend Medium Roth
Article number, **Product name,** **UDI-DI,** **LOT/Batch,** **Manufacturing date**	REF 32-2110-0010 LME ROTH 022/UR1 12T 5A UDI-DI: 14062762015473 LOT A325752 manufacturing date 2023-10-03

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: **25.04.2025**

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):
- ☐ 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:

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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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