FIELD SAFETY NOTICE

UPR Form A NITI

Manufacturer: GC Orthodontics Europe GmbH
Harkortstrasse 2
58339 Breckerfeld
Germany

Date of FSN: 26.07.2023

FSN Ref: FSN-01-23-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 the UPR FORM A NITI. Our records indicate that the affected devices have been shipped to your account.

1. **Information on affected devices:**

Device type	Single-use, non sterile Superelastic NiTi Archwire Maxillary
Product name	UPR FORM A NITI
Unique Device Identifier(s) (UDI-DI)	+E53577A0U0212514
LOT/Batch	212162
Primary clinical purpose of device(s)	Orthodontic treatment
Device Model/Catalogue/part number(s)	77-A0U0-2125 (NITI FORM A 21X25 U PK 10)

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

Description of the problem:

Product contains different variety of device and is wrongly labelled (wrong product description).

While the Article number of the device (77-A0U0-2125) is correct, the product description (UPR FORM B NITI) and the product contained in the package do not correspond to the article number.

The device contained in the package has a different size.

Potential Risk to the patient/users/other persons:

If device contained in the package, which has higher size than the type identified by article number, would be used, this could result into patient mistreatment with possible consequent unexpected extension of the dental arch. Although this extension is reversible, patient could, by result, require prolonged treatment.

3. Type of Action to mitigate the risk

Actions to be taken by the user:

☒ Return

- 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.
- Return all unused affected devices to Orthodontics Europe GmbH.
- 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.

Action(s) taken by the manufacturer:

☒ Product Removal

- 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.

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.

[redacted]

[redacted]

FIELD SAFETY NOTICE REPLY FORM

Field Safety Notice (FSN) information	
FSN Reference Number	FSN-01-23-GCOE
FSN Date	26.07.2023
Product name	UPR FORM A NITI
Unique Device Identifier(s) (UDI-DI)	+E53577A0U0212514
LOT/Batch	212162

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: 11. August 2023

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):

- ☐ No affected devices are available for return.
- ☐ 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:

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.
- Return a copy of this completed form with the returned product to our address stated above or Sales Representative

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.