

GC Tech.Europe GmbH, Harkortstr. 2, 58339 Breckerfeld

Customer
 Address 1
 Address 2
 Code, Country

Breckerfeld, 31 August 2022

Field Safety Notice: Aadva™ Tapered Implant Narrow 8 mm 810248 LOT 22206

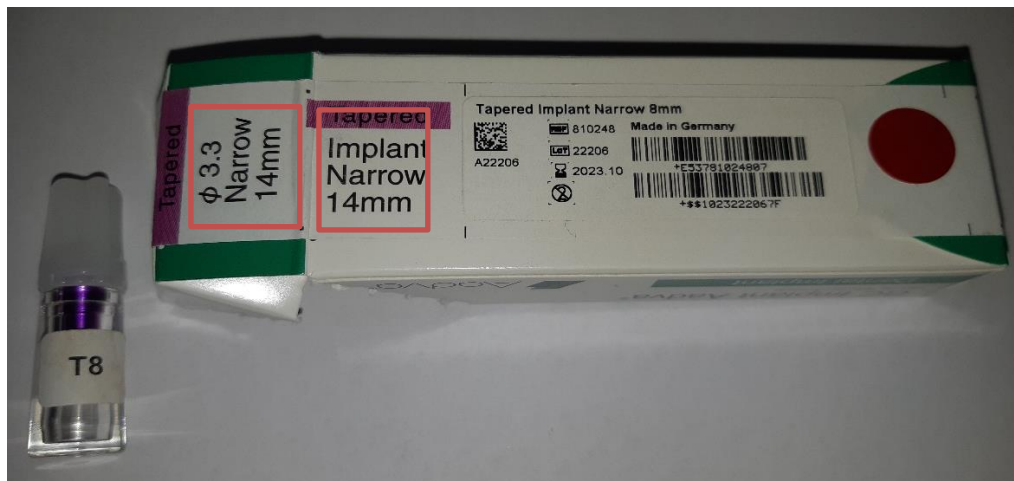
Dear customer,

Our records show that you received the following product:

Article Number	Description	LOT	Quantity	Invoice	Date
810248	Aadva™ Tapered Implant Narrow 8 mm	22206			

Our quality management system revealed that the Aadva Tapered Implant Narrow 8 mm (REF: 810248) could have a potential labelling error.

The product packaging consisted of the Tapered Implant – Type: Narrow, **Length: 8mm**, Diameter: 3.3. The label on the packaging (REF: 810248; HIBC code: +E53781024807; LOT: 22206) reflected the actual product inside the packaging (8mm implants). The blisters on the sterile product also provided the actual product information (8 mm implants). However, an auxiliary label placed on the packaging showed **incorrect product information (14 mm implants)** than the actual content inside.



Several levels of inspection of the possibly affected batch did not reveal any mislabelling, so we assume that the depicted case might be an insulated error.

We apologize for the possibility that this error may have occurred and any potential inconvenience. We kindly ask you to return the above-specified implant to your GC Tech sales representative and to fill in the attached confirmation form. Alternatively, you might send back the possibly affected implant to us, if you prefer this option. Once after your return of the implant, you will receive a replacement or a credit note.

If you have any questions, please contact us at: marc.wendland@gc.dental or +49 2338 801 982 or your local GC contact.

Christian Spotti,
General Manager GA and RA

Murat Aydin
Director Quality Assurance & GQM

Mario Minale
PRRC / Head of Regulatory
Affairs – GCE NV

GC Tech.Europe GmbH
Harkortstr. 2
D-58339 Breckerfeld
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Fax +49 (0)2338/801-985

AG Hagen - HRB 9769
Geschäftsführer:
Frank Rosenbaum,
Josef Richter
Ust-Nr.DE296619561
St-Nr.: 341/5706/1453

Commerzbank AG Hagen
IBAN: DE76 4504 0042 0355 0860 00
SWIFT: COBADEFFXXX
BLZ: 450 400 42
KTO: 355086000

Customer
Address 1
Address 2
Code, Country

Safety Notice Receipt of Confirmation: Aadva™ Tapered Implant Narrow 8 mm 810248 LOT 22206

Please return this confirmation receipt by email to marc.wendland@gc.dental or by post to our address: GC Tech.Europe GmbH, Harkortstrasse 2, 58339 Breckerfeld, Germany, or return it to your GC Tech sales representative.

Article Number	Description	LOT	Quantity	Invoice	Date
810248	Aadva™ Tapered Implant Narrow 8 mm	22206			

Please mark as appropriate:

- I read and understood the safety notice dated 31 August 2022.
- I returned the above specified Aadva™ Tapered Implant Narrow to GC Tech sales representative.
- I returned the above specified Aadva™ Tapered Implant Narrow by shipment.
- I have no products on stock
- I have further questions, please contact me at: _____

Date: _____

Name: _____

Signature: _____

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