

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

Customer
Address 1
Address 2
Code, Country

Breckerfeld, 07 November 2021

Field Safety Notice: Aadv Twist Drill \varnothing 4.6 mm

Dear customer,

Our records show that you received the following product:

Article Number	Description	LOT	Quantity	Invoice	Date
810395	Surgical Kit S				

Our quality management system revealed that the Aadv Twist Drill Short \varnothing 4.6 mm included in this kit, could have a too small diameter:



Several levels of inspection of the possibly affected batch did not show abnormalities, so we assume that it is a single error. At this moment in the investigation, a mix-up of an isolated \varnothing 4.6 mm drill with a \varnothing 3.9 mm drill in the manufacturing process seems a plausible cause.

Depending on whether a countersink drill is subsequently used in the surgical protocol, the placement of wide implants in hard or very hard bone without using a correct \varnothing 4.6 mm Twist Drill might lead to increased torque at implant insertion. Thereby, bone stress could be increased, impairing successful osseointegration.

Although the probability that you received a non-conforming product (with regard to drill diameter) and the resulting patient risks are very low, we are kindly asking you to return \varnothing 4.6 mm Twist Drill Short from the above specified kit to the GC Tech sales representative, who will contact you specifically for that purpose, and fill-in the attached confirmation form. Alternatively, you might send back possibly affected drill to us, if you

GC Tech.Europe GmbH
Harkortstr. 2
D-58339 Breckerfeld
Telefon +49 (0)2338/801-980
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

prefer this option. You will receive immediate replacement.

We apologize for the possibility that this error may have occurred and any potential inconvenience. If you have any questions, please contact us at: marc.wendland@gc.dental or +49 2338 801 982 or your local GC contact.

Adam Tomczak, Quality and Regulatory Affairs Manager

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Customer
Address 1
Address 2
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Safety Notice Receipt Confirmation: Aadva Twist Drill \varnothing 4.6 mm

Please send it by email to marc.wendland@gc.dental or by post to our address: Harkortstrasse 2, 58339 Breckerfeld, Germany.

Article Number	Description	LOT	Quantity	Invoice	Date
810395	Surgical Kit S				

Please mark as appropriate:

- I read and understood the safety notice dated 07 November 2021.
- I returned \varnothing 4.6 mm Twist Drill Short from the above surgical kit to GC Tech sales representative.
- I returned \varnothing 4.6 mm Twist Drill Short from the above surgical kit by shipment.
- I have further questions, please contact me at: _____

Date: _____

Name: _____

Signature: _____

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Customer
 Address 1
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Breckerfeld, 07 November 2021

Field Safety Notice: Aadva Twist Drill \varnothing 3.9 mm and \varnothing 4.6 mm

Dear customer,

Our records show that you received the following product:

Article Number	Description	LOT	Quantity	Invoice	Date
810395	Surgical Kit S				

Our quality management system revealed that the Aadva Twist Drill Short \varnothing 4.6 mm included in this kit, could have a too small diameter:



Several levels of inspection of the possibly affected batch did not show abnormalities, so we assume that it is a single error. At this moment in the investigation, a mix-up of an isolated \varnothing 4.6 mm drill with a \varnothing 3.9 mm drill in the manufacturing process seems a plausible cause.

Depending on whether a countersink drill is subsequently used in the surgical protocol, the placement of wide implants (\varnothing 5.0 mm) in hard or very hard bone without using a correct \varnothing 4.6 mm Twist Drill might lead to increased torque at implant insertion. Thereby, bone stress could be increased, impairing successful osseointegration.

A \varnothing 3.9 mm Twist Drill with too large diameter is very unlikely to occur, but cannot be excluded due to the above mentioned possibility of mix-up in the manufacturing process. This does not affect placement of regular implants (\varnothing 4.0 mm), unless a mismatching \varnothing 3.9 mm Twist Drill with too large diameter is used outside of

the recommended surgical protocol. Using a mismatching \varnothing 3.9 Twist Drill for wide implant placement (\varnothing 5.0 mm) might result in impaired chances of treatment success due to decreased implant insertion torque and not achieving primary stability in soft and standard bone.

Although the probability that you received a non-conforming product (with regard to drill diameter) and the resulting patient risks are very low, we are kindly asking you to return both \varnothing 3.9 mm and \varnothing 4.6 mm Twist Drill Short from the above specified kit to the GC Tech sales representative, who will contact you specifically for that purpose, and fill-in the attached confirmation form. Alternatively, you might send back possibly affected drills to us, if you prefer this option. You will receive immediate replacement.

We apologize for the possibility that this error may have occurred and any potential inconvenience. If you have any questions, please contact us at: marc.wendland@gc.dental or +49 2338 801 982 or your local GC contact.

Adam Tomczak, Quality and Regulatory Affairs Manager

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Safety Notice Receipt Confirmation: Aadva Twist Drill \varnothing 3.9 mm and \varnothing 4.6 mm

Please send it by email to marc.wendland@gc.dental or by post to our address: Harkortstrasse 2, 58339 Breckerfeld, Germany.

Article Number	Description	LOT	Quantity	Invoice	Date
810395	Surgical Kit S				

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- I returned \varnothing 3.9 mm and \varnothing 4.6 mm Twist Drill Short from the above surgical kit by shipment.
- I have further questions, please contact me at: _____

Date: _____

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A \varnothing 3.9 mm Twist Drill with too large diameter is very unlikely to occur but cannot be excluded due to the above mentioned possibility of mix-up in the manufacturing process. This does not affect placement of regular implants (\varnothing 4.0 mm), unless a mismatching \varnothing 3.9 mm Twist Drill with too large diameter is used outside of the recommended surgical protocol. Using a mismatching \varnothing 3.9 Twist Drill for wide implant placement (\varnothing 5.0 mm) might result in impaired chances of treatment success due to decreased implant insertion torque and not achieving primary stability in soft and standard bone.

Although the probability that you received a non-conforming product (with regard to drill diameter) and the resulting patient risks are very low, we are kindly asking you to return \varnothing 3.9 mm Twist Drill Short from the above specified kit to the GC Tech sales representative, who will contact you specifically for that purpose, and fill-in the attached confirmation form. Alternatively, you might send back possibly affected drill to us if you prefer this option. You will receive immediate replacement.

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