



aap Implantate AG · Lorenzweg 5 · 12099 Berlin · Germany

KUNDE
NAME
STRASSE Nr.
PLZ, ORT

Field Safety Notice

- user information as field safety corrective action -

XX.03.2023

Reference Number: FSCA_2023-001

Addressees: Users, operators

Identification of affected medical devices:

Medical device: Instrument with color marking

Product Description: Instruments for the insertion of trauma implants

Product-/Articelnr.: all instruments with color marking

Lot code: all lots

Dear users and customers,

due to defects of color markings in the field, we hereby inform you about important instructions for use and inspection. which help to minimize potential secondary risks. The color markings are used to simplify the assignment of the marked instruments in a system. The basic intended use of the instruments is not affected by the color marking.

Warnings and notes on the use of instruments with color marking already included in the instructions for use:

- Reusable products can wear out as a result of use and lose their function. The integrity of the products must therefore be checked before each use. Worn out or functionally impaired devices must be disposed of immediately.¹
- Any elements that may affect the structure, functionality and device identification (e.g. unnecessary vibration, strain, moisture, heat and UV radiation) must be minimized by the user.¹
- Damaged devices should not be used. aap is only liable for the devices as supplied. Any unintended modification will result in a new medical device for which the operator (clinic, practice, etc.) then becomes liable.¹
- aap does not accept any liability for damage caused by a lack of or by irregular checks on the devices, in particular the drill.¹
- Color markings are to be checked for damage within the specified checks. Instruments with defective or missing color markings must be discarded (compare "Important information" chapter 5.2.6).²

5.2.6 INSTRUMENTS WITH COLORED RINGS

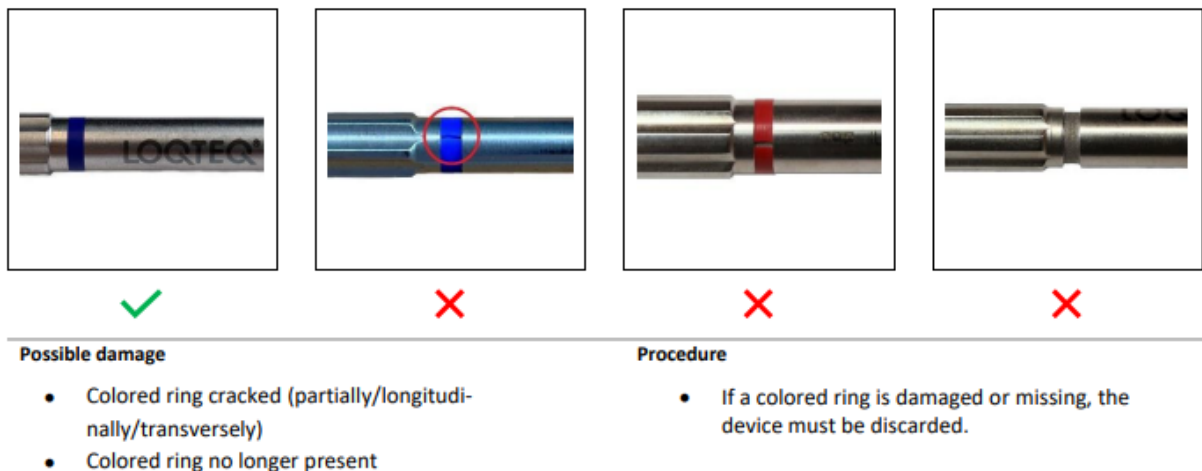


Figure 1: Excerpt "Important information" chapter 5.2.6

¹ current Instruction for use WM 7001-00_Rev 14

² Important Informations WI 1000-00_Rev 01

The remaining risks from the further use of the products concerned were examined and evaluated by means of a corresponding risk analysis.

Risk assessment:

The loss of the color ring is associated with the possible risk that parts of the color ring could enter the patient during an operation. If parts of the color marking remain, secondary reactions in the patient cannot be completely excluded at this time. So far, aap has not become aware of any case. The color marking is visible in the image control (X-ray).

In compliance with the above-mentioned instructions, there is no increased risk for patients, users and third parties.

Decision:

Taking into account the risks mentioned, the decision is made to send the users a Field Safety Notice with important user instructions to be taken into account in order to avoid further occurrences in the field. This also includes the document "Important information" (WI 1000-00_Rev 01), which contains instructions for use and inspection.

Please take the following actions immediately:

1. please read the instructions for use and control received with this letter.
2. acknowledge receipt, acknowledgement and understanding of the instructions.

Forwarding the Notice:

Please ensure that all users of the named products within your organization, as well as any other stakeholders, receive this Field Safety Notice information. If products have been passed on to third parties, please also send them a copy of the Field Safety Notice or inform our contact person.

Please keep this information.

The national authorities will be informed about this Field Safety Notice.

If you have any questions, please do not hesitate to contact us.

Contact:

For queries please contact:

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Best regards
aap Implantate AG

Thomas Batsch
PRRC- Vigilance

To
aap Implantate AG
Attn: Quality Management
Lorenzweg 5
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Germany

E-Mail: incident@aap.de
FAX: +49 (0) 30/750 19 111

Confirmation form

for the receipt, knowledge as well as comprehensibility of the instructions for the use and control of instruments with color marking.

Product: all instruments with color marking

Please return this confirmation form to us immediately by fax, e-mail or post.

- We confirm receipt, acknowledgement and understanding of the instructions for use and control of instruments with color marking.

Health facility / User/

Distributor: _____

Address: _____

Name in block letters: _____

Telephone number: _____

Signature/Date/Stamp: _____