



Carl Zeiss Meditec AG 07740 Jena

Carl Zeiss Meditec AG
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07745 Jena
Germany
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Division/Dept.: MED-Q
Your contact: Laura Allan

Your ref.:
Yours of:
Our ref.: R2019-002
Date: 02/04/2019

ACTION REQUIRED: FIELD SAFETY NOTICE

Product Affected: 003500-0026-893 Visthesia 1.0% batch 140692AA

Dear Customer,

You are using the ZEISS Ophthalmic Viscosurgical Devices (OVDs). As you know, high quality and innovation is our main goal, but the safety of your patients is our first priority. To ensure that you are able to continue reliably using our products, Carl Zeiss Meditec is issuing a Field Safety Notice regarding the product listed above.

With this letter, we would like to inform you that we have received one report from the field that an OVD has been found, whose 27G Cannula was not the correct shape. Our initial investigation has identified a supplier manufacturing error which has resulted in a small number of cannula not being correctly bent and we have identified excess Silicone Oil coating on the tip of the cannula. Silicone Oil is biocompatible and a thin coating layer is part of the specification. In order to eliminate potential risk to the patient, any such cannulas should not be used.

Actions to be taken:

Please check the cannulas of Visthesia 1.0% batch 140692AA before use and discard them, if they are not properly bent. Your Zeiss representative will contact you shortly to arrange a visit and replace affected OVDs.

Affected Products:

Product: Visthesia 1.0%®
Lot Number: 140692AA
Expiry Date: 2021-02
Ref: A090004

Chairman of the Supervisory Board:
Dr. Michael Kaschke

Address of Record:
Goeschwitzer Str. 51-52
07745 Jena, Germany
Tel.: +49 36 41 220-0

Deutsche Bank Jena
Account: 624536900 (BIC 820 700 00)
S.W.I.F.T.-Code: DEUT DE 8EXX
IBAN: DE90820700000624536900

Commercial Register:
Local Court Jena HRB 205623
VAT-ID. No. DE 811 922 737
WEEE-Reg.-Nr. DE55298748

Board of Management:
Dr. Ludwin Monz, President and CEO
Jan Willem de Cler
Justus Wehmer

Address for Delivery:
Carl Zeiss Meditec AG
Carl-Zeiss-Promenade 10
07745 Jena, Germany

Commerzbank Jena
Account: 258072800 (BIC 820 400 00)
S.W.I.F.T.-Code: COBADEFFXXX
IBAN: DE31820400000258072800

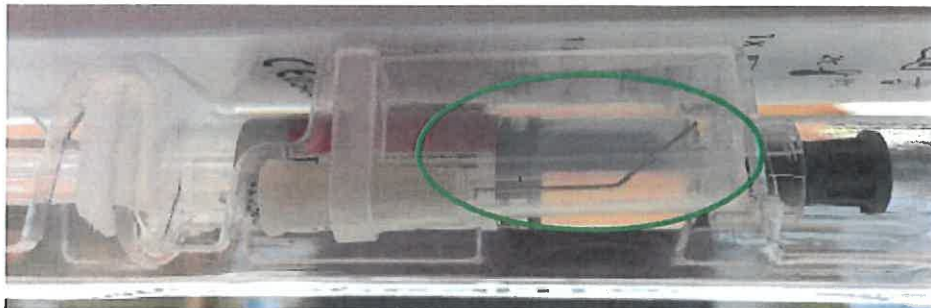


Order Code: 003500-0026-893

Incorrect shape (Needle does not have a 35° angle 9mm from the tip):



Correct shape:



We understand that this notification is highly inconvenient for you. We would like to apologize and thank you in advance for your support with regards to this Field Safety Notification. Please be assured that we are investigating the non-conformity along with our supplier to determine root cause and will implement the necessary corrective actions to prevent this from happening again.

We thank you very much for your attention, your consequent verifications and your continuous support.

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

Best regards

Carl Zeiss Meditec AG

i.V.

Colin Blair
Quality Management Representative

i.V.

Christina Jakob
Director Product Management Cataract Implants &
Consumables