

Urgent Field Safety Notice

Eye dropper system ATS

Date: 01.07.2021

Sender:

Heinz Meise GmbH Medizintechnik – Im Gewerbepark 6 - DE- 58579 Schalksmühle - Germany
Phone: +49 (0) 23 55 / 90 95-50 / E-Mail: mail@meise.com

Address:

Customers and distributors

Dear Healthcare Professional and Customer,

Heinz Meise GmbH Medizintechnik has been alerted to an unusual discoloration of the ATS 36 eye drop systems by a customer report.

Description of the Problem: The eye dropper systems show inhomogeneous discoloration on some places (brown spots, please see appendix 1) in both the inner and outer surfaces. The discoloration is particularly noticeable on the cap of the applicator. The feed tubing is not affected.

Health risks:

The eye dropper systems are intended for the administration of autologous blood serum eye drops into the human eye.

In case of discoloration on the applicator, migration of the discolored material with the serum eye drop could occur.

Background information on the present investigations

Meise Medizintechnik has carried out analysis to determine the cause of the failure.

Based on the test performed so far, no chemical differences between the discolored area and the rest of the product were detected, as well as no biological residues.

Measures taken by the manufacturer:

- A 100% control of the warehouse stock for the eye drop systems was carried out.
- Affected products were sorted out and sent to the restricted warehouse
- Some of the products affected with this defect will be used for further investigation.
- The supplier of the component was immediately informed about this defect, a failure analysis was requested.

The following measures must be carried out:

Since the root cause of this unusual error has not yet determined and further error investigation is required, we expressly advice against the use of the eye dropper systems if they contain this error.

- Please check the products for discolorations before use. These are clearly visible.
- Do not use the affected eye dropper systems
- Please take note of the extended points, regarding the general advice, in the attached instructions for use for the eye drop systems.
- Please inform Heinz Meise GmbH Medizintechnik about the number of affected products

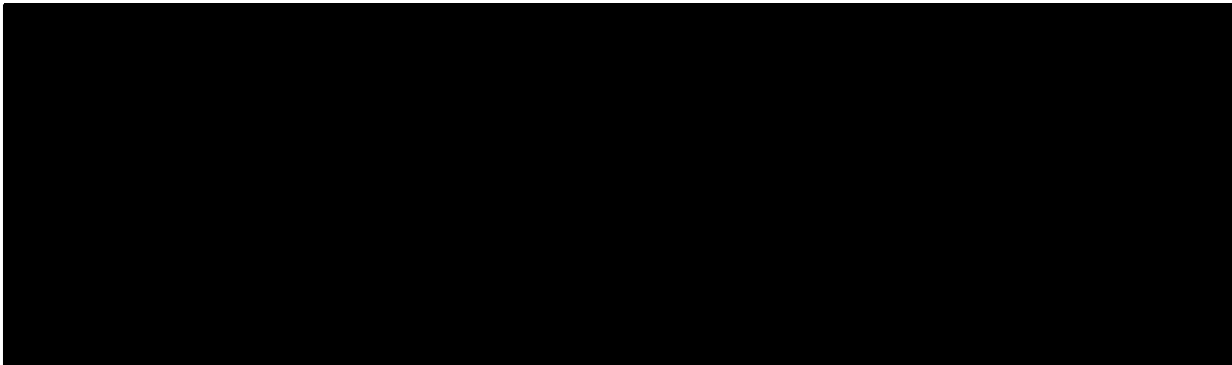
Urgent Field Safety Notice

Eye dropper system ATS

- We kindly request all receivers of this information to fill out the attached form completely, even if no affected products have been received
- Please return the completed form to Meise Medizintechnik. Your response is essential to monitor the effectiveness of this corrective action. (by mail or e-mail)
- Please forward this information to all persons in your organization and medical institutions who have the product in use.

Please accept our sincere apologies for any strain this puts on you or your patients.

Your sincerely,



Urgent Field Safety Notice
Eye dropper system ATS

Safety information response form
Eye drop system ATS

Please fill out the confirmation form and send it back to Heinz Meise GmbH Medizintechnik:

Are there any affected products in your organization?

Yes No

I have read the current instructions for use for the ATS eye drop systems and have taken note of the extension to the item "**Preliminary activities**" regarding testing for possible product impurities.

I have informed and trained all users about the above-mentioned amendment and also provided the current instructions for use.

Name: _____

Function: _____

Phone number: _____ E-Mail: _____

Name of the
institution: _____

Address of the institution: _____

Country: _____ State: _____

Signature

Date

PLEASE RETURN BY E-MAIL OR POST TO:

mail@meise.com

Meise Medizintechnik GmbH – Im Gewerbepark 6 - DE- 58579 Schalksmühle -Germany

Urgent Field Safety Notice
Eye dropper system ATS

Appendix 1

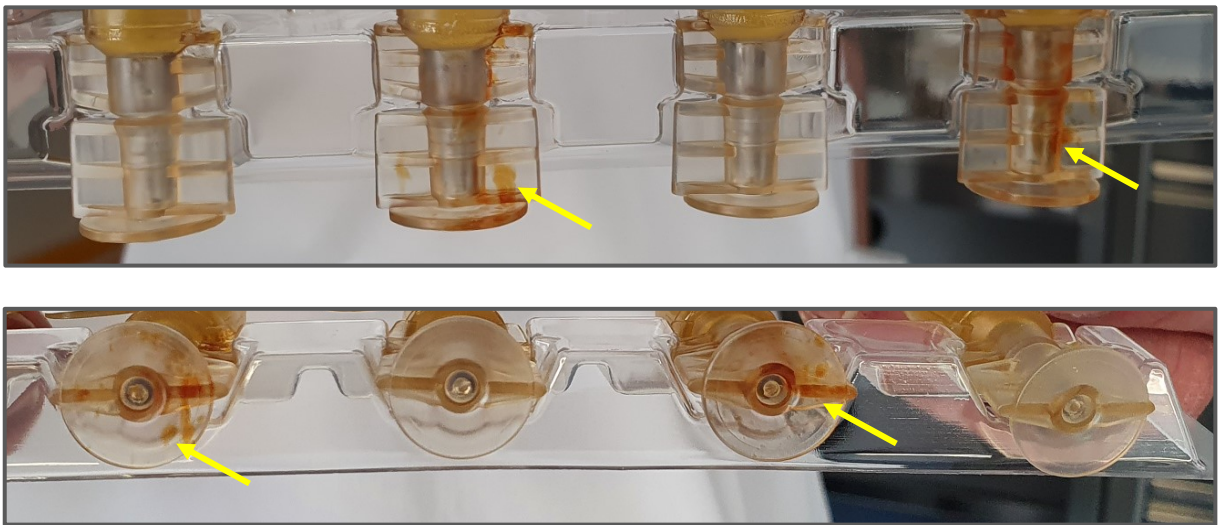


Fig.1: Discoloration of the applicator cap

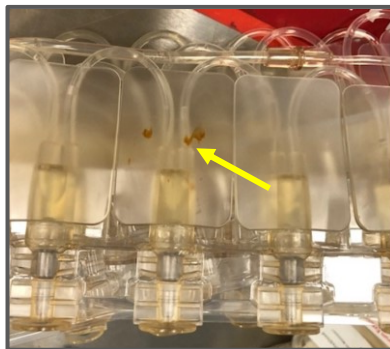


Fig.2: Discoloration on the back of the applicator