Urgent!
Customer information
Corrective action (Field Safety Notice, FSN)

NEW VALVE TECHNOLOGY

FSCA Number: 21-01 2021-06-25

FSCA Title: Voluntary Recall of ALLEGRA Delivery System TF

Affected Devices: ALLEGRA Delivery System TF

REF.: DSL-AO18G1RE1150 serial number: n.a.

Basic UDI-DI: n.a.

Details to the affected products:

- Affected are devices with Lot number between 1189056 (including) and 1213540 (including)
- Please refer to Appendix I for a list of affected devices by lot number.

Problem Description:

In specific production lots of the affected device, NVT has received reports of Inflow Cover Tip cracking prior to or during implantation procedures.

If not identified prior to use, the Inflow Cover Tip cracking may potentially lead to treatment delays or complications, which could cause a serious deterioration in the patient's state of health.

As a result, NVT has initiated a voluntary recall of the affected devices.

NVT has linked the problem of the Inflow Cover Tip to a change of supplier location and has already implemented additional controls. Therefore, the lot numbers of the affected products can be precisely narrowed down and identified (please refer to Appendix I).

This issue is related exclusively to the ALLEGRA Delivery System TF. Patients who have already been treated with an affected device are not impacted by this action.

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www.nvt-med.com

Authorized Representatives:
Thomas K. Graham, Jure Brecko
Seat of the company: Hechingen
District Court Stuttgart HRB 735335
Ust-IdNr.: DE 274108111

Sparkasse Zollernalb
IBAN DE86 6535 1260 0134 0315 50
BIC/SWIFT SOLADES1BAL

Required Actions:

- Please identify and quarantine any devices in your inventory that appear in Appendix I.
- For any affected devices in your possession, please complete the enclosed Field Safety/Corrective Action (FSCA) response form **immediately** and return it by fax to +49 7471 989 79-222 or by email to complaint@nvt-med.com.
- Upon receipt of the completed FSCA response form, a company representative will contact you to arrange for the return of the affected devices and the provision of replacement devices.
- If you have any questions or concerns, please contact your company representative, or contact our Customer Service team by email at: customercare@nvt-med.com.

Additional Actions for Distributors

- Provide a copy of this FSN and the FSCA response form to all customers who may have received affected devices.
- Assist these customers with the required actions listed above.
- Confirm to NVT that you have completed the required activity for all of your impacted customers.
- Forward all completed FSCA response forms received from customers to NVT at the addresses listed above.

Contact Reference Person

Holger Sigg, Director QA&RA, **complaint@nvt-med.com**, NVT GmbH

Disclosure of the information described here

Please make sure that all users of the above products and other persons in your organization to be informed are aware of this urgent safety information.

Please read and sign the attached confirmation form and return it to the contact address provided.

The Federal Institute for Drugs and Medical Devices as well as your national competent authority has received a copy of this urgent safety information.

We regret any inconvenience you or your patients may experience as a result of this situation. If you have any questions regarding this action, please contact the company representative responsible for your institution or NVT GmbH directly.

Sincerly yours

NVT GmbH

Holger Sigg

Director QA&RA

NEW VALVE TECHNOLOGY
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Anlagen:

List of affected devices

FSCA form

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Ref Number	Lot Number		Ref Number	Lot Number
DSL-AO18G1RE1150	1189056		DSL-AO18G1RE1150	1203481
DSL-AO18G1RE1150	1190650		DSL-AO18G1RE1150	1205260
DSL-AO18G1RE1150	1190651		DSL-AO18G1RE1150	1205261
DSL-AO18G1RE1150	1190652		DSL-AO18G1RE1150	1205262
DSL-AO18G1RE1150	1190653		DSL-AO18G1RE1150	1205263
DSL-AO18G1RE1150	1190654		DSL-AO18G1RE1150	1205264
DSL-AO18G1RE1150	1191695		DSL-AO18G1RE1150	1205265
DSL-AO18G1RE1150	1191696		DSL-AO18G1RE1150	1205990
DSL-AO18G1RE1150	1191698		DSL-AO18G1RE1150	1205991
DSL-AO18G1RE1150	1192473		DSL-AO18G1RE1150	1205992
DSL-AO18G1RE1150	1192474		DSL-AO18G1RE1150	1205993
DSL-AO18G1RE1150	1192475		DSL-AO18G1RE1150	1205994
DSL-AO18G1RE1150	1192476		DSL-AO18G1RE1150	1205995
DSL-AO18G1RE1150	1193447		DSL-AO18G1RE1150	1206763
DSL-AO18G1RE1150	1193448		DSL-AO18G1RE1150	1206764
DSL-AO18G1RE1150	1193449		DSL-AO18G1RE1150	1206765
DSL-AO18G1RE1150	1193450		DSL-AO18G1RE1150	1206766
DSL-AO18G1RE1150	1193451		DSL-AO18G1RE1150	1206767
DSL-AO18G1RE1150	1193452		DSL-AO18G1RE1150	1206768
DSL-AO18G1RE1150	1193453		DSL-AO18G1RE1150	1207570
DSL-AO18G1RE1150	1193454		DSL-AO18G1RE1150	1207571
DSL-AO18G1RE1150	1196793		DSL-AO18G1RE1150	1207572
DSL-AO18G1RE1150	1196794		DSL-AO18G1RE1150	1207573
DSL-AO18G1RE1150	1196795		DSL-AO18G1RE1150	1207574
DSL-AO18G1RE1150	1196796		DSL-AO18G1RE1150	1207575
DSL-AO18G1RE1150	1196797		DSL-AO18G1RE1150	1209910
DSL-AO18G1RE1150	1196798		DSL-AO18G1RE1150	1209911
DSL-AO18G1RE1150	1196799		DSL-AO18G1RE1150	1209912
DSL-AO18G1RE1150	1196800		DSL-AO18G1RE1150	1209913
DSL-AO18G1RE1150	1196801		DSL-AO18G1RE1150	1209914
DSL-AO18G1RE1150	1196802		DSL-AO18G1RE1150	1209915
DSL-AO18G1RE1150	1199078		DSL-AO18G1RE1150	1209916
DSL-AO18G1RE1150	1199079		DSL-AO18G1RE1150	1209917
DSL-AO18G1RE1150	1199080		DSL-AO18G1RE1150	1209918
DSL-AO18G1RE1150	1199081		DSL-AO18G1RE1150	1209919
DSL-AO18G1RE1150	1199082		DSL-AO18G1RE1150	1211779
DSL-AO18G1RE1150	1199861		DSL-AO18G1RE1150	1211780
DSL-AO18G1RE1150	1199862		DSL-AO18G1RE1150	1211781
DSL-AO18G1RE1150	1199863		DSL-AO18G1RE1150	1211782
DSL-AO18G1RE1150	1199864		DSL-AO18G1RE1150	1211783
DSL-AO18G1RE1150	1200385		DSL-AO18G1RE1150	1211784
DSL-AO18G1RE1150	1200386		DSL-AO18G1RE1150	1211785
DSL-AO18G1RE1150	1200387		DSL-AO18G1RE1150	1211786
DSL-AO18G1RE1150	1200388		DSL-AO18G1RE1150	1211787
DSL-AO18G1RE1150	1200389		DSL-AO18G1RE1150	1211788
DSL-AO18G1RE1150	1200390		DSL-AO18G1RE1150	1213537
DSL-AO18G1RE1150	1200391		DSL-AO18G1RE1150	1213538
DSL-AO18G1RE1150	1203479		DSL-AO18G1RE1150	1213539
DSL-AO18G1RE1150	1203480		DSL-AO18G1RE1150	1213540

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Ref.: FSCA Number: 21-01

FSCA-Form

I hereby certify that I have read and understood the information in the urgent safety notice of 25.06.2021 regarding ALLEGRA Delivery System TF and that I have taken or will take the recommended measures.

Hospital name, city / distributor (in block capitals):

Name (in block capitals):

Title and department:

Contact information:

Tel.-No./Fax-No./Email:

Signature:

Date:

☐ We do not have any of the affected devices listed in Appendix I of the Field Safety Notice

☐ We have the following in Appendix I affected devices:

Product Reference	Lot Number	Amount	Stock location

Note: Please use separate sheets, if necessary

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Upon receipt of this completed form, a company representative will contact you to arrange the return and replacement of affected devices.

Please complete this form even if you do not have any affected product and return by:

Fax: +497471 989 79-222

E-Mail: complaint@nvt-med.com

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