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

NEW VALVE TECHNOLOGY

Urgent Field Safety Notice

Commercial name of the affected product: ALLEGRA Transcatheter Heart Valve

FSCA-identifier: 23-10

Type of action: Recall

Date: 06.07.2023

Attention:

Affected Devices: ALLEGRA THV 23

REF.: THV-AO0023G1RE **serial number:** n.a.

Basic UDI-DI ALLEGRA THV: 426050866THVAOXXXXG1REAC

Details to the affected products:

- Please refer to Appendix I for a list of affected devices by serial number.

Problem Description:

NVT has been informed that there has been a mix-up between an ALLEGRA THV 23 and an ALLEGRA THV 31.

If not identified prior to use, the mix up of an ALLEGRA THV size may potentially lead to complications, which could cause a serious deterioration in the patient's state of health.

An ALLEGRA THV 23 was found in the packaging of an ALLEGRA THV 31. Therefore NVT assumes that an ALLEGRA THV 31 is in an ALLEGRA THV 23 package. Based on the production data, the possibly affected products can be limited and identified (see Appendix 1). As a result, NVT has initiated a recall of the affected devices.

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

NVT GmbH
Lotzenäcker 17
72379 Hechingen I Germany
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www.nvt-med.com

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@biosensors.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.

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@biosensors.com, NVT GmbH

Disclosure of the information described here

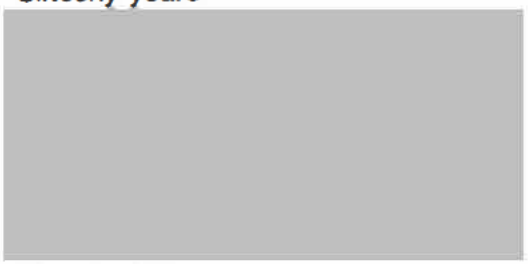
Please make sure that all users of the above products and other persons in your organization to be informed are aware of this urgent safety information.

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

Director QA&RA

Appendix I

Ref Number	Serial number
THV-AO0023G1RE	10017565
THV-AO0023G1RE	10017653
THV-AO0023G1RE	10017672
THV-AO0023G1RE	10017971
THV-AO0023G1RE	CXAX0109
THV-AO0023G1RE	CYBX0128
THV-AO0023G1RE	CYBX0130
THV-AO0023G1RE	CYBX0134
THV-AO0023G1RE	CYBX0196
THV-AO0023G1RE	CYBX0198
THV-AO0023G1RE	CYBX0200
THV-AO0023G1RE	CYBX0243
THV-AO0023G1RE	CYBX0245
THV-AO0023G1RE	CYBX0249
THV-AO0023G1RE	CYBX0250
THV-AO0023G1RE	CYBX0274
THV-AO0023G1RE	CYBX0294
THV-AO0023G1RE	CYBX0302
THV-AO0023G1RE	CYBX0380

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NEW VALVE TECHNOLOGY

Ref.: FSCA Number: 23-10

FSCA-Form

I hereby certify that I have read and understood the information in the urgent safety notice of 06.07.2023 regarding ALLEGRA THV 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@biosensors.com

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