JenaValve Technology GmbH

Guerickestraße 25
80805 Munich - Germany
Tel.: +49 89 55 27 908-0
Fax: +49 89 55 27 908-79
E-mail: info@jenavalve.de
www.jenavalve.de

Urgent: Field Safety Notice/ Field Safety Corrective Action

To all Health Care Facilities using the JenaValve Cathlete Plus Delivery System.

FSN: 20140904

05. September 2014

To whom it may concern:

This Field Safety Notice is to inform you that Jenavalve Technology GmbH has initiated a voluntary recall/ field safety corrective action for its marketed JenaValve Cathlete Plus Delivery System. This Field Safety Notice affects the following products:

Model Name	Model Number
JenaValve Cathlete Plus Delivery System - transapical	JV-1001-DSX – A
	JV-1001-DSX – B
	JV-1001-DSX – C

Our records indicate that your health care facility is potentially involved in this Field Safety Corrective Action. Please pay attention to the following Field Safety Notice and confirm its receipt.

Field Safety Notice:

The transapical Cathlete Plus Delivery System is designed to safely position and deliver the JenaValve Transcatheter Heart Valve (THV). The three (3) functional deployment steps are described in detail in the Instructions for Use for the Cathlete Plus Delivery System.

However, JenaValve Technology GmbH became aware of unintended and premature deployment of the JenaValve THV during step (1) of the deployment process.

The root cause analysis assumes that these reported cases of unintended

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deployment of the JenaValve THV during positioning were likely caused by a faulty spring in the safety button mechanism.

JenaValve Technology GmbH became aware of premature release of the JenaValve THV without activating the safety button release mechanism during positioning step 1, when the blue portion of the handle was quickly turned in clock- and/or counterclockwise direction. All related incidents are being thoroughly analyzed by the JenaValve Technology GmbH.

In order to avoid any potentially hazardous patient situations, JenaValve Technology GmbH decided to voluntarily recall all Cathlete Plus Delivery Systems from the market.

Potential Harm:

Jenavalve Technology GmbH is not aware of any deaths or severe injuries caused by the safety button problem. However, Jenavalve is aware of information suggesting a required conversion to surgical aortic valve replacement caused by a premature release of the JenaValve THV due to the described safety button problem.

There is no additional health risk for patients being implanted with a JenaValve THV. JenaValve THVs already implanted in patients can remain without any consequences, as these are not affected from this field safety corrective action!

Manufacturer's Corrective Action Items:

- Implementation of all identified corrective action items
- Recall of all Cathlete Plus Delivery Systems with the above identified reference numbers

Customer's Action Items:

Please support the below listed action items without any delay:

- Please pass this Field Safety Notice on to all required functions within your organization.

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- Please verify your Cathlete Plus Delivery System inventory and contact the JenaValve Customer Service to initiate a free of charge pick up for your inventory items.
- Please include your name, title, telephone number and signature on the return form.
- Return the completed form to JenaValve Technology GmbH by fax to confirm the receipt of this field safety notice.
- Please keep a copy for your records.

The applicable national Competent Authorities are being informed of this voluntary field safety corrective action.

In case of questions or other inquiries, please feel free to contact your JenaValve Technology GmbH field representative or Customer Service:

JenaValve Technology GmbH Customer Service
Guerickestraße 25
80805 Munich - Germany
Tel.: +49 89 55 27 908 -37
Fax: +49 89 55 27 908 -69
E-mail: customerservice@jenavalve.de

We appreciate your support for this measure.

With kind regards

Dr. Ulrich T. Opfermann

Digitally signed by Dr. Ulrich T. Opfermann
DN: cn=Dr. Ulrich T. Opfermann, o=JenaValve Technology GmbH, ou, email=opfermann@jenavalve.de, c=DE
Date: 2014.09.05 14:12:31 +02'00'

Safety Officer

JenaValve Technology GmbH

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FIELD SAFETY NOTICE FSN

JenaValve Cathlete Plus Delivery System

Return Form

☐ We confirm the receipt of this Safety Notification **FSN: 20140904**

☐ We confirm our intention to return all currently inventoried Cathlete Plus Delivery Systems identified below:

Model Name	Model Number
JenaValve Cathlete Plus Delivery System - transapical	JV-1001-DSX – A
	JV-1001-DSX – B
	JV-1001-DSX – C

Name/Address of Health Care Facility: _____

Name/Title (Please print): _____

Telephone #: _____

Signature/Date: _____