31 July 2026

URGENT: INITIAL FIELD SAFETY NOTICE

Device Commercial Name: **Trilogy® Delivery Catheter**

Models:	**TRILOGY-DC-S**	**| TRILOGY-DC-M**
UDI-DI:	**00850000898134**	**| 00850000898141**
LOT NO:	**DS-050626-002**	**| DS-042826-007**

Field Safety Corrective Action (FSA) Reference Number: FA26001

Manufacturer: JenaValve Technology, Inc.
4 Cromwell
Irvine, California 92618
United States

Single Registration Number (SRN):
US-MF-000023455

European Authorized Representative:
MDSS GmbH
Schiffgraben 41, 30175 Hannover,
Germany

United Kingdom Responsible Person:
MDSS UK
Parkway House, Palatine Rd,
Northenden, Wythenshawe,
Manchester M22 4DB
United Kingdom

Dear Valued Customer,

We are writing to make you aware that JenaValve Technology Inc. is initiating a voluntary recall (removal) of two (2) lots of Trilogy® Delivery Catheter. You are receiving this letter because our records indicate that you have received one or more Trilogy® Delivery Catheters from Lot Numbers: TRILOGY-DC-S: DS-050626-002 and TRILOGY-DC-M: DS-042826-007. The Trilogy® Delivery Catheter is part of the Trilogy® Transcatheter Heart Valve System and delivers the Trilogy® Transcatheter Heart Valve (THV) transfemorally through the Trilogy® Introducer Sheath.

Reason for the Field Safety Corrective Action
During the investigation of a complaint involving difficulty deploying the valve during an implant procedure, it was identified that the sleeve liner had separated, adding significant resistance to deployment. A root cause investigation has determined that, due to a manufacturing issue, some Trilogy® Delivery Catheters from certain lots may have an increased potential for sleeve liner separation that may result in difficulty or inability to deploy the Trilogy® Heart Valve. We are removing all devices of the affected lots, and you should not use Trilogy® Delivery Catheter from the affected lots.

Potential risks associated with this issue may include prolonged procedure time, extended fluoroscopy time, vascular complications, aortic dissection, access site complication, paravalvular or transvalvular regurgitation, bleeding, kidney injury, stroke, conversion to surgical aortic valve replacement (SAVR) and death. In the reported case, valve deployment occurred but paravalvular regurgitation exists and the patient will require a secondary intervention.

This recall does not affect patients who have successfully undergone previous Trilogy® Heart Valve implantation. No additional action is required for patients with a successfully implanted valve. These patients should continue to be monitored per your standard clinical follow-up procedures.

Actions to be Taken by the Customer / User

Review the information contained in this Field Safety Notice and ensure that anyone in your facility who needs to be aware of this notification reads this letter carefully. You may direct any questions regarding this notice to your JenaValve Field Representative and/or to Maria Jose Arana at (+1) 949-767-2110 (Extension 1154).

Examine your inventory immediately to determine if you have Trilogy® Delivery Catheters from the affected lots and quarantine the subject products. The affected TRILOGY-DC-S: DS-050626-002 and TRILOGY-DC-M: DS-042826-007.

JenaValve field team members will schedule a visit to retrieve the subject Trilogy® Delivery Catheters. If you prefer to return the products yourself, please contact us for an RGA number before shipping to:

JenaValve Technology Inc.
4 Cromwell, Irvine, California 92618 USA.
Attn: Quality Department. Reference: FA26001.

Complete and sign the Business Reply Form (BRF) and email it to customersupport.us@jenavalve.com or provide it to your JenaValve field representative. Upon receipt of the completed BRF and returned product, JenaValve will provide replacement products. Incomplete BRFs cannot be processed.

If any affected devices have been transferred to another facility, identify the receiving facility on the BRF, notify JenaValve, and provide this notice to the relevant personnel. Please ensure this notice is passed on to all organizations and individuals where the affected devices have been transferred or made available.

JenaValve is committed to ensuring the safety, effectiveness. and reliability of our products. Should you have any questions about this medical device recall (removal) or need additional support, please contact us at +1 866-588-8287 between the hours of 8:00 am and 17:00 (PST) Monday through Friday. Or via email at customersupport.us@jenavalve.com.

Maintain awareness of this notice and the resulting actions for an appropriate period to ensure the effectiveness of the Field Safety Corrective Action.

The relevant Competent Authorities have been informed of this Field Safety Corrective Action in accordance with applicable European Union Medical Device Regulation (EU) 2017/745 requirements. Healthcare professionals should continue to report suspected incidents involving this device in accordance with their national vigilance reporting requirements.

Sincerely,

Maria Jose Arana
Vice President of Quality and Compliance
JenaValve Technology, Inc.

JENAVALVE

BUSINESS REPLY FORM

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FSCA Reference Number: FA26001

Please complete this Business Reply Form within **5 business days** of receipt of this letter and email it to: customersupport.us@jenavalve.com. Attach a copy to your product return and keep a copy for your records.

☐ By checking this box, I acknowledge that I have read and understand the notification	
Your Name/ Title	
Signature	**Date**
Facility/ Institution Name and Shipping Address	
Telephone Number	

Select applicable boxes:

☐ We have products subject to this removal and have quarantined all affected products.

☐ We are returning the following devices:

Lot Number	Quantity to be Returned

Lot Number	Quantity to be Returned

☐ We have products subject to this removal that have been moved/ transferred to another facility/ location – **Complete Table Below**

Facility/ Institution Name and Address	Lot Number	Quantity Transferred

☐ We have no products subject to this removal for return.