FIELD SAFETY NOTICE

iCLAS™ Cryoablation System (Catheter and Console)
Medical Device Modification

20th May 2022

FSCA Reference: R-22-001

Dear valued customer,

Adagio Medical, Inc. is initiating a voluntary medical device Field Safety Corrective Action (FSCA) of the iCLAS™ Cryoablation System (Catheter and Console) indicated for the treatment of Atrial Fibrillation (AF). Although, the reported incident occurred during the pre-market clinical study of the non-CE marked iCLAS™ Cryoablation System, we emphasize our steadfast commitment to patient safety by initiating this voluntary FSCA to further improve the safety profile of the Adagio iCLAS Cryoablation System.

ISSUE DESCRIPTION

During the pre-market clinical study of the non-CE marked iCLAS™ Cryoablation System conducted in the US (IDE G180263), there was a serious adverse event (SAE) at Baylor St. Luke's Medical Center on October 13th, 2021 (gas embolism and expiration) of a patient undergoing an AF ablation procedure using the Adagio Medial iCLAS™ Cryoablation System. This SAE was reported to the FDA on November 3rd, 2021, and a voluntarily temporary study pause was placed until the investigation was completed. The investigation results and the required corrective actions taken to mitigate recurrence was reviewed and approved by the FDA, the pre-market study was approved to resume on April 13, 2022.

SAE NARRATIVE SUMMARY

The procedure was performed with the Biosense Webster VIZIGO™ Guiding Sheath and the Adagio iCLAS™ Cryoablation Catheter which successfully completed 20 freeze cycles. The catheter was removed for post-mapping after completion of the 20th successful freeze cycle. The catheter was re-inserted into the patient post-mapping without completing the functional test freeze. After re-positioning of the iCLAS™ Cryoablation Catheter, the freeze application was initiated followed by the console alert for a system error. The patient's heart rate declined rapidly and presence of nitrogen in the left atrium was confirmed with ICE (Intracardiac Echocardiography). The catheter was not immediately removed from the patient or disconnected from the console after the console reported the error and went into safe abort.

INVESTIGATION CONCLUSION

The damaged VIZIGO™ Guiding Sheath (Kinked and exposed braid wire) caused severe damage to the iCLAS™ Cryoablation Catheter. The catheter electrode band #20 caught the exposed braid wire in

the kinked segment of the sheath, combined with the obstruction caused by the deformation of the pull wire ring encroaching inside the guiding sheath. During catheter removal, the force applied to retract the catheter caused the catheter electrode band to skive/cut into the catheter freezing element and severed the two layers of high-pressure tubes containing the cryogen (catheter built in safety layers). This resulted in an external gas (Critical Nitrogen) leak into the patient leading to air/gas embolism and expiration.

ROOT CAUSE

Investigation of the reported SAE confirmed the following root causes:

- Insufficient Study Materials (Study Protocol, IFU, & Investigator Brochure): The list of compatible steerable sheaths was communicated to all participating investigators during study training, but it was not documented in the study materials.
- Insufficient Training: The training did not specify excessive insertion/retraction force and troubleshooting for catheter resistance observed during catheter insertion/retraction.
- User Oversight: The catheter functional test freeze was not performed prior to catheter re-introduction into the patient as indicated in the Warning section of the IFU.

RISK ASSESSMENT

As identified above, a damaged iCLAS™ Cryoablation Catheter when used in a patient can lead to serious injury as it can potentially leak nitrogen from the system into patient bloodstream. This can result in air/gas embolism and consequently, severe injuries such as heart attack, stroke, or death.

The above SAE was reported in the clinical pre-market study conducted in the US. Adagio Medical concluded the investigation and determined necessary corrective actions to prevent recurrence of similar events. The corrective actions were accepted by the US FDA (Food Drug Administration) and implemented in all investigation sites.

There has been no other similar SAE's reported to date in Europe either with the non-CE-marked investigational or the CE-marked commercially available iCLAS™ Cryoablation System. However, Adagio Medical is committed to ensure patient safety across the regions where the device is available, we have voluntarily initiated this FSCA to implement the corrective actions to the CE-marked commercially available products in Europe.

ACTIONS TO BE TAKEN BY CUSTOMERS

There are no device modifications, changes, or device return required for the Adagio iCLAS™ Catheter. However, the iCLAS™ Cryoablation Console will need to be upgraded with a software update to further improve the safety profile of the Adagio iCLAS™ Cryoablation System. The revised labeling, software update, and physicians training will be provided by Adagio Representatives prior to the next iCLAS™ Cryoablation Procedures.

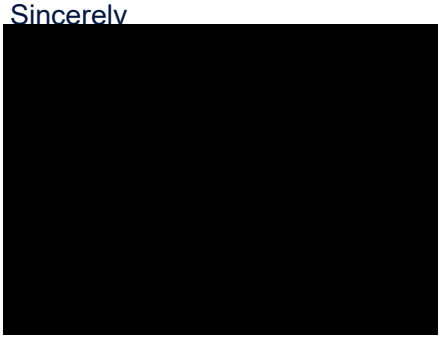
The Adagio Representative will reach out to schedule a meeting / visit to ensure:

- Training to the revised labeling
- Console software update
- Inventory update with the revised labeling

Please sign and populate this form and then email the completed form to complaints@adagiomedical.com or fax to 001-949-348-1866 or hand to your Adagio Representative within 30 days of receiving this notice.

Adagio Medical, Inc. will notify the Competent Authority of your country of this field safety corrective action. We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Adagio Representative. Thank you for your cooperation and immediate assistance.

Sincerely



DETAILS ON AFFECTED DEVICES

iCLAS™ Cryoablation Console (109-0010-001) Affected Lot/Serial Number (SN)

Software Version 106-2015-001 Rev.02

Lot No	SN	MFG Date	Lot No	SN	MFG Date
F020-01167	16 and 35	15-Jun-20	F021-01168	40	15-Jun-21
F020-02169	14	17-Jun-20	F021-01230	44	18-Aug-21
F020-03169	15, 19, 22, 23, 24, 26, and 37	17-Jun-20	F021-01257	46	14-Sep-21
			F021-06323	50	19-Nov-21

iCLAS™ Cryoablation Catheter (109-0013-001) Affected Lot/Serial Number

Lot#	SN	Manufacturing Date	Expiration Date
F021-01179	01, 02, 03, 04, and 06	28-Jun-21	28-Jun-22
F021-01181	03, and 04	30-Jun-21	30-Jun-22
F021-01193	02, 03, 08, and 09	12-Jul-21	12-Jul-22
F021-01203	01, 02, 03, 05, and 07	21-Jul-21	21-Jul-22
F021-02193	01 and 02	12-Jul-21	12-Jul-22
F021-01207	01, 03, and 07	26-Jul-21	26-Jul-22
F021-01210	08	29-Jul-21	29-Jul-22
F021-01228	05, 06, 07, and 08	16-Aug-21	16-Aug-22
F021-01232	01, 02, and 03	20-Aug-21	20-Aug-22
F021-02223	02 and 07	11-Aug-21	11-Aug-22
F021-01233	05	21-Aug-21	21-Aug-22
F021-01236	01, 03, 04, and 05	24-Aug-21	24-Aug-22
F021-02250	01, 04, 05, and 09	07-Sep-21	07-Sep-22
F021-01264	02, and 07	21-Sep-21	21-Sep-22
F021-01301	01, 02, 03, 04, 05, 06, and 07	28-Oct-21	28-Oct-22
F021-02301	01, 02, 03, 04, 05, 07, 08 and 09	28-Oct-21	28-Oct-22
F021-02302	01, 02, 03, 04, 05, 06, 07, and 08	29-Oct-21	29-Oct-22
F021-01321	01, 02, 03, 04, 05, 07, 08 and 10	17-Nov-21	17-Nov-21
F021-01337	01, 02, 03, and 04	03-Dec-21	03-Dec-22
F021-04288	01, 02, 03, 04, 06, and 07	15-Oct-21	15-Oct-22

FIELD SAFETY NOTICE – RESPONSE FORM

iCLAS™ Cryoablation System (Catheter and Console)

FSCA Reference: R-22-001

Please sign and populate this form and then email the completed form to complaints@adagiomedical.com or fax to 001-949-348-1866 or hand to your Adagio Representative within 30 days of receiving this notice.

Your signature on this form acknowledges that you have read and understand this Medical Device Field Safety Notice for the iCLAS™ Cryoablation System (including Catheter and Console). Please ensure that all users of the iCLAS™ Cryoablation System at this facility have been notified accordingly.

Please provide the required information and signature below.

Signature: _____ Date (mm/dd/yyyy): _____

Name: _____ Email: _____

Title: _____ Department: _____

Facility Name: _____

Facility Address: _____