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Directorate General of Health Services
Ministry of Health and Family Welfare
Government of India
(Medical Devices and Diagnostics Division)

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Food & Drugs Administration Bhawan,
Kotla Road, New Delhi.

F.No.29/Misc/03/2022-DC (248)

Date: 29th Dec 2022

MEDICAL DEVICE ALERT

DEVICE

MitraClip™ G4 Clip Delivery System and MitraClip™ NTR/XTR Clip Delivery System

Description and Identification of the Incidence

- The MitraClip Clip Delivery System is a heart valve repair device that is intended to treat mitral regurgitation. The increased rate of reports is for clips failing to “Establish Final Arm Angle” (EFAA) and for events of “Clip Opening While Locked” (COWL).
 - EFAA is a procedural step where the user intentionally attempts to open a locked Clip to verify that the locking mechanism is engaged. EFAA steps occur during device preparation and prior to Clip deployment. An EFAA failure occurs if the Clip opens during this verification step.
 - COWL describes when the Clip Arm angle increases post-deployment. In these cases, users observe a slippage in the lock, resulting in an Arm angle greater than 10 degrees from the angle observed at deployment. This change in arm angle after deployment can be identified through fluoroscopy
- When the clip is locked, the locking mechanism is designed to more fully engage as the Grippers push down on the clip Arms. The constant force applied by the Grippers secures the leaflets within the clip. During a COWL event, the lock slips as the Clip Arms open by a given degree. In any case where significant residual MR is observed after Clip deployment, a second clip should be considered and implanted in accordance with the IFU

Who May Be Affected

- Any person with mitral regurgitation who has to be treated with the use of MitraClip™ G4 Clip Delivery System and MitraClip™ NTR/XTR Clip Delivery System

- Health care providers who treat people with mitral regurgitation using the affected MitraClip™ G4 Clip Delivery System and MitraClip™ NTR/XTR Clip Delivery System

Important Note: CDSCO have not received any complaints from the market on this issue.

FURTHER DETAILS & CONTACTS

M/s St. Jude Medical India Pvt. Ltd. had issued a Medical Device Safety Notice which is attached herewith this alert.

M/s St. Jude Medical India Pvt. Ltd

D.No.- 168/B/1, Plot 18 & 19,
Laxmi Nager, Behind T B Hospital,
MCH Circle-5, Mandal, Hyderabad,
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URGENT MEDICAL DEVICE CORRECTION
MitraClip Delivery System

Abbott

September 8, 2022

Commercial Name: MitraClip™ G4 Clip Delivery System, MitraClip™ NTR/XTR Clip Delivery System (reference Appendix A for model numbers)

FSCA-Identifier: Clip Delivery System September 8, 2022

Manufacturer: Abbott Vascular Santa Clara, CA

Type of Action: Advisory Regarding the Use of the Device

Attention: Healthcare Professional, Implanting Physician

Dear Valued Customer,

Abbott is sharing information about the use of the MitraClip™ Delivery System. Abbott has observed an increase in complaints regarding Clip locking malfunctions. This communication is to bring awareness, share the actions Abbott is taking, and emphasize the relevant steps of the Instructions for Use (IFU) to aid in optimal function of the Clip locking mechanism.

Your current inventory of product may be used with the guidance described in the attached materials. There is no need to return any product to Abbott.

Description and Identification of the Incidence

The increased rate of reports is for clips failing to "Establish Final Arm Angle" (EFAA) and for events of "Clip Opening While Locked" (COWL).

- EFAA is a procedural step where the user intentionally attempts to open a locked Clip to verify that the locking mechanism is engaged. EFAA steps occur during device preparation and prior to Clip deployment. An EFAA failure occurs if the Clip opens during this verification step.
- COWL describes when the Clip Arm angle increases post-deployment. In these cases, users observe a slippage in the lock, resulting in an Arm angle greater than 10 degrees from the angle observed at deployment. This change in arm angle after deployment can be identified through fluoroscopy (see example in Appendix A, Figure 1).

Table 1 shows the estimated rate of EFAA Failure and COWL reports as function of MitraClip use.

Table 1 Global Rate of MitraClip reported events over estimated clip usage

Global Rate	EFAA Failure Rate	COWL Rate
February 2021 – January 2022	0.51%	0.28%
February 2022 - July 2022	0.80%	0.50%

Potential Patient Risk

Table 2 shows the outcomes and associated rates of EFAA failure and COWL events observed during MitraClip procedures.

Table 2: Observed rates during a MitraClip™ procedure (February 2022 – July 2022)

Patient Outcomes	Observed EFAA failure	Observed COWL
No consequence to patient	0.74% of total implants (91.7% of EFAA cases)	0.30% of total implants (60.4% of COWL cases)
Intraprocedural MR recurrence	0.06% of total implants (7.7% of EFAA cases)	0.19% of total implants (36.8% of COWL cases)
Other ¹	0.005% of total implants (0.6% of EFAA cases)	0.01% of total implants (2.8% of COWL cases)

¹Depending on clinical status, treatments may include medical management, usage of an additional clip, catheter snaring technique or vascular surgery to remove embolized clip, or non-urgent surgical valve replacement/repair.



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In mitral regurgitation (MR) patients with multiple comorbidities and who are not surgical candidates, an unsuccessful MitraClip procedure, recurrence of severe MR, device embolization, or tissue injury may lead to hospitalization, worsening congestive heart failure, cardiogenic shock, or death. However, while there has been a recent increase in reported EFAA failure and COWL events, the acute procedural success² rate remains consistent with historical data. Further, EFAA failure or COWL most often results in no adverse patient outcomes. COWL may lead to less MR reduction, which is often treated with the use of one or more additional clips. There is a low incidence of required additional interventions, and:

- Zero (0) immediate open surgical conversions have been observed as a result of EFAA/COWL events.
- 0.53% of EFAA/COWL events have resulted in non-urgent open surgical conversions based on clinical decisions by the treating physician, such as, to treat significant residual MR.

The MitraClip™ therapy continues to provide a significant benefit to patients, and performance remains within the anticipated risk levels for these therapies.

Clip Mechanism and What to Do if the Issue Occurs

When the Clip is locked, the locking mechanism is designed to more fully engage as the Grippers push down on the Clip Arms. The constant force applied by the Grippers secures the leaflets within the Clip. During a COWL event, the lock slips as the Clip Arms open by a given degree. In any case where significant residual MR is observed after Clip deployment, a second Clip should be considered and implanted in accordance with the IFU.

What Action Abbott is Asking You to Take

- Please read through this customer letter and share this information with personnel associated with MitraClip procedures in your organization.
- Please continue to follow the steps of the IFU (eifu.abbottvascular.com) as summarized in Appendix A. It details the most relevant steps to aid in optimal function of the Clip locking mechanism, thereby reducing the probability of EFAA failure and COWL to occur.
- Complete and return the provided Acknowledgement Form.
- If you have transferred MitraClip products to other centers, inform those centers of this notice.
- Report any product incidents, regardless of procedure or patient outcome, to Abbott. When available, return any product related to an incident to Abbott for investigation.

Action Abbott is Taking

- Abbott has identified a contributing cause of EFAA/COWL events as a change in the material properties of one of the Clip locking components. Abbott is working on producing new lots with updated manufacturing processing and raw material to mitigate EFAA/COWL events.
- It is also known that certain use conditions can contribute to EFAA/ COWL events. As such, Abbott is using this communication to emphasize the most relevant sections of the IFU that can reduce occurrence, referenced in Appendix A.

Abbott has notified and is working with FDA on this issue. Report any adverse reactions or quality problems experienced with the use of these products to your local Abbott representative or Customer Service Department at 1-800-544-1664. Reports may also be sent to the FDA's MedWatch Adverse Event Reporting program by completing Form FDA 3500 online at www.FDA.gov, calling 1-800-FDA-1088, or Fax to 1-800-FDA-0178.

Thank you for your attention to this matter. Abbott is committed to providing high-quality products and partnering with you to ensure the safety of each patient. Please address any questions you may have with your local Abbott representative or Customer Service Department at 1-800-544-1664.

Sincerely,

Christopher Gallivan
Divisional Vice President, Quality
Abbott Structural Heart

² Acute Procedural Success is defined as cases with successful implantation resulting in MR that is 2+ or less as reported at the time of the procedure.



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Appendix A:

Example of imaging

An example of a Clip opening by 17 degrees is shown in Figure 1.

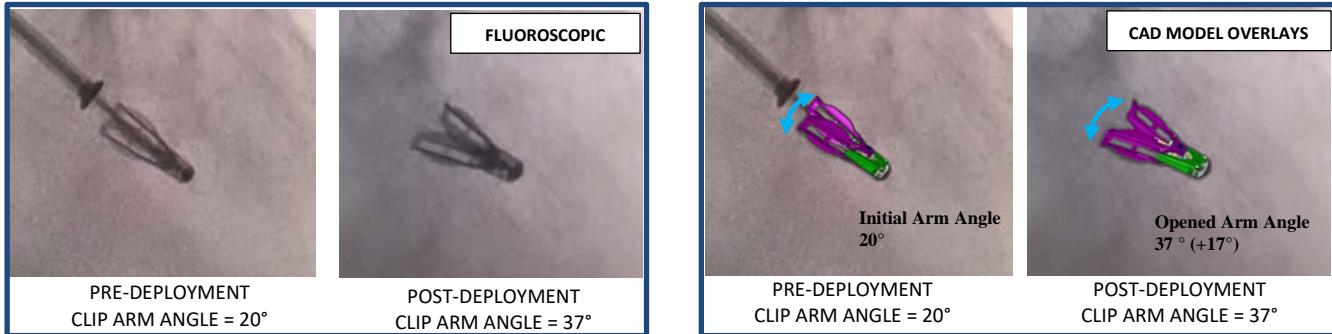


Figure 1: Fluoroscopic imaging of a Clip opening while locked (COWL) at deployment (left) with CAD model overlay super-imposed (right)

Steps relevant to Clip lock mechanism

The following information consist of the relevant steps of the Instructions for Use (IFU) and physician training materials with additional explanations to aid in optimal function of the Clip locking mechanism.

1. **Unlocking the Clip During Device Preparation and Intraprocedural**

- Rotate the Lock Lever outward and then retract the lever until the mark on the lever is fully exposed. Rotate the Lock Lever inward to engage the lever.
- Warning: DO NOT retract the lever forcefully. It may result in the inability to lock or unlock the Clip.
- If Clip does not unlock and Clips Arms fail to open visibly, use the following techniques:
 - Stop and return the Arm Positioner to Neutral. Retract the Lock Lever farther, then turn the Arm Positioner farther in the "Close" direction before turning in the 'Open' direction. Advance the lock lever just enough so that the mark on the lever is still fully exposed.
 - Turn the Arm Positioner to Neutral, then incrementally iterate the amount of Arm Positioner rotation in the "Close" direction followed by rotation in the "Open" direction. Iterate until Clip opens or until it is no longer possible to rotate the Arm Positioner in the "Close" direction. Advance the lock lever just enough so that the mark on the lever is still fully exposed.
 - Turn the Arm Positioner to Neutral, iterate the amount of Lock Lever retraction past the mark in 5 mm increments, and rotate the Arm Positioner fully in the "Close" direction, before rotating in the "Open" direction, until Clip opens. Advance the lock lever just enough so that the mark on the lever is still fully exposed.

Explanation: Forceful retraction of the Lock Lever involves retraction of the Lock Lever beyond the mark on the Lock Lever. This can inadvertently cause Harness deformation which can prevent the lock from functioning properly.

2. **System Positioning**

- Initial Positioning in the Left Atrium: Position the Clip centrally over the valve with respect to anterior-posterior and medial-lateral directions. Align the Clip so the DC Shaft is perpendicular to the plane of the mitral valve.
- Final system positioning: Raise the Grippers, Unlock the Clip and Open the Clip Arms to approximately 180 degrees. Adjust the system to reposition the Clip as necessary, rotate the DC handle to align the Clip Arms perpendicular to the line of coaptation.
- Warning: Do confirm that the Clip Arms are perpendicular to the line of coaptation. Failure to do so may result in loss of leaflet capture and insertion.

Explanation: If the Clip Arms are not perpendicular to the line of coaptation, or the Delivery Catheter (DC) is not perpendicular to the mitral valve plane during leaflet grasping, asymmetric tension on the leaflets may result in Clip rotation-post deployment and/or potential increase in MR. The Clip rotation could be interpreted as a change in Clip Arm angle.



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3. Locking Sequence (After Satisfactory Leaflet Grasp)

- Close the Clip until the Clip Arm Angle is approximately 60 degrees. Release tension on the DC and secure the DC Fastener.
- After verifying leaflet insertion and confirming the grasp is satisfactory, lock the Clip and slowly close the Clip just until the leaflets are coapted and MR is sufficiently reduced.

Explanation: After leaflet capture and insertion confirmation, locking the Clip at Clip Arm angle >60 degrees is to ensure that there is enough room for the harness to center in a locked configuration. Adequate leaflet insertion is necessary to maintain the leaflets within the Clip.

4. Establish Final Arm Angle (EFAA)

- With the Lock Lever fully advanced, and the Arm Positioner to Neutral (note the orientation of the blue line on the Arm Positioner), turn the Arm Positioner 1 turn in the “Open” direction (confirm blue line has returned to the original orientation). The Clip Arms may open slightly (~5°) and then remain in a stable position.
- If continued opening of the Clip Arms is noted, reconfirm that the Lock Lever is completely advanced. Close the Clip Arms, and Establish Final Arm Angle.
- Warning: DO NOT turn the Arm Positioner more than 1 turn in the “Open” direction from neutral. Failure to stop turning the Arm Positioner at 1 turn in the “Open” direction past neutral may result in Clip opening or device damage which could cause the Clip to become non-functional and lead to embolization and / or conversion to surgical intervention.
- If Failure to Establish Final Arm Angle continues and the Clip lock does not hold, do not continue with deployment steps and replace the CDS.

5. Lock Line Removal

- Pre-deployment Clip Assessment: Confirm DC Handle is secure, perform EFAA, turn the Arm Positioner to the “closed” side of the neutral position
- Deployment step 1: Lock line removal: While holding the ends of the Lock Line remove the Lock Lever Cap and “O” ring. Unwrap the two ends of the Lock Line in a counterclockwise direction. Separate the ends of the Lock Line and remove the plastic cover from the lines so that no twists or knots are present. Grasp one of the free ends of the Lock Line, confirm the line moves freely, and slowly remove the Lock Line. Pull the Lock Line coaxial to the Lock Lever. If resistance is noted, stop and pull on the other free end to remove the Lock Line.
- Perform EFAA.

Explanation: When the Lock Line is removed, the locking mechanism may be disrupted and can cause the Clip Arms to open. Turning the Arm Positioner to the “close” side of neutral pulls the Clip Arms in the closed direction, which prevents the Clip Arm from opening during Lock Line removal. Therefore, post-Lock Line removal EFAA confirms the Clip did not unlock during Lock Line removal.



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MitraClip™ G4 Clip Delivery System and MitraClip™ NTR/XTR Clip Delivery System Model Numbers
All MitraClip lot numbers are within scope of this Correction Notice.

Part Number	Product Description	GTN/UDI
CDS0701-NT	MitraClip G4 Clip Delivery System NT US	08717648230943
CDS0701-NTW	MitraClip G4 Clip Delivery System NTW US	08717648230967
CDS0701-XT	MitraClip G4 Clip Delivery System XT US	08717648230981
CDS0701-XTW	MitraClip G4 Clip Delivery System XTW US	08717648231001
CDS0601-NTR	MitraClip NTR Clip Delivery System US	08717648226342
CDS0601-XTR	MitraClip XTR Clip Delivery System US	08717648226366
CDS0704-NT	MitraClip G4 CDS NT REPAIR-MR Clinical	08717648234576
CDS0704-NTW	MitraClip G4 CDS NTW REPAIR-MR Clinical	08717648234590
CDS0704-XT	MitraClip G4 CDS XT REPAIR-MR Clinical	08717648234583
CDS0704-XTW	MitraClip G4 CDS XTW REPAIR-MR Clinical	08717648234606