Abbott Medical
5050 Nathan Lane
Plymouth, MN 55442, USA

Medical Device Notification

Amplatzer ™ Amulet™ Left Atrial Appendage Occluder

September 2026

Dear Valued Customer

Abbott is writing to inform you about forthcoming changes to the Instructions For Use (IFU) for the Amplatzer™ Amulet™ Left Atrial Appendage Occluder (referred to as Amulet) to bring attention to the risk of perforation of the pulmonary artery. Pulmonary artery injury is a serious adverse event that can result in pericardial effusion, cardiac tamponade, and potentially death.

Amulet is a transcatheter, self-expanding device intended for use in preventing thrombus embolization from the left atrial appendage. Our records indicate that you may have ordered or are a user of this product. Refer to Appendix A for list of models in scope. This notification is associated with an update to labeling. Product does not need to be returned.

Actions Abbott is Taking / has Taken

The current Amulet IFU contains a contraindication against use “where placement of the device would interfere with any intracardiac or intravascular structures.” Abbott is updating this contraindication to specifically identify the pulmonary artery as one of the adjacent structures. In addition, Abbott is updating the IFU to include additional guidance about assessing the distance between the device landing zone and the pulmonary artery. Abbott recently completed additional physician training on this subject.

Actions to be Taken by the Customer

Abbott asks that physician users continue to follow all procedural steps that have already been provided via training as presented below:

- After the landing zone has been identified, assess the closest distance to the pulmonary artery.
- A distance ≤1.5 mm represents significant risk for a pulmonary artery injury; a distance between 1.5 and 3.0 mm represents a theoretical risk for a pulmonary artery injury; and a distance >3.0 mm represents a lower risk for a pulmonary artery injury.
- To reduce the risk of pulmonary artery injury, consider an alternative landing zone or device orientation when clinically appropriate and device placement criteria can still be met.
- If the risk of pulmonary artery injury cannot be adequately minimized, the physician should carefully consider whether to proceed with device implantation.

Updated Instructions for Use will be available as per local requirements.

Steps Abbott is Requesting You to Take

- Review and share this notice with applicable personnel within your institution.
- Complete and return the accompanying Acknowledgement Form to Abbott.

Abbott is informing all applicable regulatory agencies about this matter. Adverse events or quality problems experienced with the Amulet device may be reported directly to Abbott.

If you have any questions, please contact your local Sales Representative.

Thank you very much for your attention to this letter and for your cooperation in completing the requested actions. Please know that Abbott is committed to providing the highest level of support, and we thank you for assisting us with this process.

Sincerely,

Christopher Gallivan
Divisional Vice President, Quality
Abbott Medical

Appendix A. List of Product, Models, UDI

Product	Model Number	UDI
Amplatzer™ Amulet™ Left Atrial Appendage Occluder	9-ACP2-007-016	00811806013459
	9-ACP2-007-018	00811806013466
	9-ACP2-007-020	00811806013473
	9-ACP2-007-022	00811806013480
	9-ACP2-010-025	00811806013497
	9-ACP2-010-028	00811806013503
	9-ACP2-010-031	00811806013510
	9-ACP2-010-034	00811806013527