



URGENT FIELD SAFETY NOTICE
Amplatzer™ Steerable Delivery Sheath
Model: ASDS-14F-075
GTIN: 05415067036025

Abbott Structural Heart
Abbott Medical
5050 Nathan Lane
Plymouth MN 55442 USA

June 2023

Dear Abbott Customer,

Abbott is voluntarily recalling the Amplatzer™ Steerable Delivery Sheath (Model ASDS-14F-075) (“ASDS product”) due to the potential for air embolism during normal use conditions. Our records indicate that your institution received the ASDS product, and we are requesting that you return any unused ASDS product to Abbott.

Why the Product is Being Recalled

Abbott has observed an overall reported incidence rate of 0.77% related to observed or potential air embolism during procedures in which the ASDS product was used. Within those cases, customers have reported air emboli having resulted in transient ST segment elevation resolving spontaneously and, less commonly, hemodynamic instability requiring medical intervention. There have been no reported cases of permanent injury or fatality due to air embolism.

The Instructions for Use indicate that “the hemostasis valve in the closed position minimizes blood loss but does not prevent air ingress” and provides instructions which reduce the potential for air ingress. Due to the continued occurrence of air ingress events, Abbott has decided to recall the ASDS product pending the approval and release of a modified steerable product. Importantly, please note that this issue is specific to the hemostasis valve of the ASDS product and does not impact the Amplatzer™ Amulet™ Left Atrial Appendage Occluder implant.

Steps Abbott is requesting you to take:

- Return any remaining unused ASDS product to Abbott. Your Abbott representative can assist you in returning these devices.
 - Continue to use the fixed curve Amplatzer™ Amulet™ delivery system for future Amplatzer™ Amulet™ Left Atrial Appendage Occluder implants.
- Complete and return the accompanying Acknowledgment Form to Abbott.

Abbott is informing all applicable regulatory agencies about this matter. Please report any adverse reactions or quality problems experienced with the use of these products to Abbott.

We sincerely apologize for any inconvenience that this may cause. Please know that Abbott is committed to providing the highest level of support, and we thank you for assisting with this process. Please contact your local Abbott representative with any questions on this notification.

Sincerely,

A handwritten signature in black ink, appearing to read 'C. Gallivan'.

Christopher Gallivan
Divisional Vice President, Quality
Abbott Structural Heart