



Urgent Field Safety Notice
Amplatzer™ Steerable Delivery Sheath, 14F
Model ASDS-14F-075
GTIN 74185296345645

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

November 9, 2021

Dear Valued Customer,

Abbott is sharing important information about the use of the Amplatzer™ Steerable Delivery Sheath, 14F Model ASDS-14F-075 related to one (1) report of a patient experiencing an air embolism while the hemostasis valve was in the closed position. The hemostasis valve is an integrated valve designed to reduce blood loss during the procedure, while allowing for the passage of the dilator, guidewire and pigtail catheter when in the closed position. The hemostasis valve in the closed position is not fully sealed and additional steps are required to prevent air ingress. Abbott is providing instructions to reduce the potential for air ingress.

This product is not being removed from the field and does not need to be returned.

To date, there has been one (1) reported case of air embolism with the Amplatzer Steerable Delivery Sheath. The patient associated with this event experienced an air embolism while under conscious sedation, resulting in a cardiac arrest which rapidly responded to treatment without further complications. Air embolism is a known inherent risk of the procedure and is listed as a potential adverse event within the Instructions for Use.

Patients who have previously used the product are not affected by this notice and require no further action.

Procedural Instructions:

The following instructions are to be followed to reduce the potential for air ingress when using the Amplatzer Steerable Delivery Sheath, 14F Model ASDS-14F-075:

- Procedure-Related:
 - Maintain a continuous saline flush to the flushing port throughout the procedure, from the moment of sheath insertion until the sheath is removed from the patient.
 - Immediately connect the device loader in a fluid-to-fluid fashion after removal of the dilator and guidewire.
 - Do not aspirate from the sheath flushing port as this may result in air ingress.
- Additional Information:
 - The hemostasis valve in the closed position minimizes blood loss but does not prevent air ingress.
 - Capping of the bypass hub may not be sufficient to prevent air ingress.

Next Steps:

Customers who have already completed product training will be notified by the Abbott customer training system of additional required training emphasizing the information outlined above. New customers planning to use this product for the first time will receive all required product training to reduce the potential for air ingress.

What Action is Abbott Asking You to Take?

- Read this entire field safety notice.
- Complete the required training provided to you within the Abbott customer training system.
- Distribute this notice to those who need to be aware within your institution. We ask that you maintain a record of this notice to ensure effectiveness of the communication.

Additional Considerations:

Your current inventory of product is acceptable for safe use when following the directions above. There is no need to return any product to Abbott.

The appropriate regulatory agencies have been notified of this action.

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.

Sincerely,

Kara Carter
Divisional Vice President, Quality
Abbott Structural Heart