February 7, 2022

Dear Doctor:

Aspire Bariatrics, Inc. regrets to inform you that we are winding down all operations at the Company and, as a result, are withdrawing our FDA premarket approval (PMA) for the AspireAssist, effective April 8, 2022. Unfortunately, COVID-19 and its reemergence have wreaked havoc with our plans and we can no longer afford to continue operations at the Company. In accordance with federal law, AspireAssist supplies may no longer be distributed in interstate commerce once we withdraw our PMA, effective April 8, 2022.

Please note that our withdrawal of our PMA is entirely the result of economic factors, not the result of safety or effectiveness issues associated with or reported with the product. Indeed, the safety and effectiveness profile of the AspireAssist, as has been found in the field, is consistent with the safety and effectiveness profile as reported in our Clinician Guide and as reported in the literature[1].

Up until, April 5, 2022, we will provide ***free of charge***, AspireAssist accessories to your facility (or directly to your patients with a prescription) as long as such supplies last. We will no longer supply ***any*** AspireAssist supplies after April 7, 2022. Orders for AspireAssist supplies must be received by April 1, 2022. The AspireAssist Installation Tool Kit is provided to facilitate Skin Port placement and removal.

Please note that AspireAssist supplies, with the exception of the Carry Bag, have an expiration date. For your and your patients' planning purposes the following table lists the latest expiration date of each of the AspireAssist accessories:

Product Name	**Part Number**	**Latest Expiration Date**
Companion	100-0037-US	6/4/2023
Skin Port	200-0011-US	11/1/2023
Connector	200-0019-US	11/28/2023
Tubing Set	100-0016	12/17/2023
Lanyard	100-0020	12/2/2023
Skin-Port Sleeve Multipack	100-0007	7/30/2023
Carry Bag	100-0021	No Expiration Date
Emergency Clamp	100-0029	12/10/2023
Installation Tool Kit	200-0021-US	11/5/2023
A-Tube	100-0011-US	2/20/2023

The decision of whether a patient should continue Aspiration Therapy post PMA withdrawal is between you and your patient. Clearly, once the requisite supplies are no longer available or are past their expiration date, the patient will need to cease Aspiration Therapy. Once the patient ceases Aspiration Therapy, there is only risk and no benefit to keeping the A-Tube in. In particular, there is some risk of weight regain when patients cease Aspiration Therapy and weight regain can lead to the

[1] Jirapinyo P, Kumar N, Saumoy M, Copland A, Sullivan S. Association for Bariatric Endoscopy systematic review and meta-analysis assessing the American Society for Gastrointestinal Endoscopy Preservation and Incorporation of Valuable Endoscopic Innovations thresholds for aspiration therapy. Gastrointestinal Endoscopy, Vol , No 2020. https://doi.org/10.1016/j.gie.2020.09.021.

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potentially serious complication of a buried bumper. We recommend that you discuss with your patients the risk of weight regain and timing of explantation of their A-Tubes. The table below explains the risks of leaving the A-Tube in after ceasing Aspiration Therapy versus the risks of removing the A-Tube.

	Risk Associated with Leaving A-Tube In	**Risks associated with Removing the A-Tube**
Weight Regain	Patients may regain weight when they can no longer aspirate. (see Section 12.3 Of User Guide). Weight gain can lead to health complications.	Patients may regain weight when they can no longer aspirate. (see Section 12.3 Of User Guide). Weight gain can lead to health complications.
Risk Associated with Weight Regain	The skin-port may become tight causing the A-Tube to pull into the stomach wall, leading to a buried bumper. A buried bumper, a potentially serious complication, requires immediate medical attention (see Section 5.2 of User Guide)	N/A
Risk Associated with Stoma	There is a risk of irritation, redness, discharge, pain, or infection around the skin underneath the Skin-Port. If the cause of the condition is not treated it could result in tissue damage. (see Section 5.1 of the User Guide)	N/A
Risks Associated with A-Tube Deterioration	The A-Tube may start to break down as a result of microorganisms which normally live in the stomach causing a hole or tear in the A-Tube and leakage of gastric contents. Leakage of gastric contents can cause significant swelling, irritation, and even infection in the skin around the Skin Port. (see Section 13.5 of User Guide)	N/A
Risks associated with endoscopic removal procedure	The A-Tube will ultimately need to be removed because of deterioration, requiring an endoscopy. Although not seen in the studies, there are risks associated with an endoscopic procedure, (see Table 6.2 of Patient Guide)	Although not seen in the studies, there are risks associated with an endoscopic procedure (see Table 6.2 of Patient Guide)
Risk of persistent fistula	There is a risk of persistent fistula after tube removal and this risk is increased if the A-Tube has been in place for more than 12 months. Additional intervention during the removal procedure, including placement of an endoscopic clip, may be necessary to reduce this risk.	There is a risk of persistent fistula after tube removal and this risk is increased if the A-Tube has been in place for more than 12 months. Additional intervention during the removal procedure, including placement of an endoscopic clip, may be necessary to reduce this risk.
Risk of peristomal irritation from gastric leakage	Prophylactic treatment with a proton pump inhibitor is recommended until the stoma tract is healed completely. Patients should avoid over distending the abdomen and strenuous activities during the healing process.	Prophylactic treatment with a proton pump inhibitor is recommended until the stoma tract is healed completely. Patients should avoid over distending the abdomen and strenuous activities during the healing process.

The Clinician Guide discusses A-Tube removal and the A-Tube Instructions for Use (https://www.aspirebariatrics.com/patient-guides/) provides instructions for A-Tube removal. Specifically, as provide in Section 9 of the A-Tube Instructions for Use:

WARNING: A-Tube removal must be performed under **direct endoscopic visualization**. The A-Tube should be removed via an endoscopic method (after removal of the Skin-Port), utilizing a snare to pull the tube out through the mouth.

1. Place the patient in a supine position and administer sedation.
2. Introduce the endoscope, distend the stomach, and perform a complete examination of the upper gastrointestinal (UGI) tract (esophagus, stomach, proximal duodenum).
3. Insert a snare through the endoscope and navigate into the stomach.
4. Utilize the snare to grasp the A-Tube gastric segment near the end of the tube (1/3 or less of the distance to the internal bumper). Avoid placing the snare around an aspiration hole. Grasp the A-Tube in between the holes to ensure that the entire circumference of the A-Tube is secured in the snare.

Improper Placement

Correct Placement

5. Remove the Skin-Port by cutting the tube externally with scissors.
6. Withdraw the tube through the esophagus. Make sure the bumper and excess tube do not fold over or overlap, which will increase the width of the extracted device and thereby increase the risk of gastroesophageal trauma.
7. Remove the scope and snare out of the mouth, pulling the A-Tube out in tow.

If the A-Tube has been in place for more than 12 months, the internal ostomy site should be treated with argon plasma coagulation (APC), irritated with a cytology brush, and then closed with an endoscopic clip or overstitch to enhance fistula closure. To minimize peristomal irritation from gastric leakage and to help closure, prophylactic treatment with a proton pump inhibitor is recommended until the stoma tract is healed completely. It is also recommended to instruct the patient to avoid over distending the abdomen and strenuous activities during the healing process, and always maintain good skin care practices at the stoma site.

After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

In order to comply with FDA requirements and to ensure an orderly withdrawal, we request the following actions:

1. We have enclosed a letter to send to your patients explaining our market withdrawal. Please send the attached "Letter to AspireAssist Patients" to all AspireAssist patients who have not had their A-Tubes explanted. Please follow-up with a phone call to your patient to discuss our market withdrawal.

2. Please kindly keep records of when each current AspireAssist patient was contacted and when you contacted such patient. We, on behalf of the FDA, will ask you to confirm that you have contacted, or attempted to contact, all current AspireAssist patients.

3. Please kindly keep records of each AspireAssist patient whom you have prescribed the AspireAssist A-Tube and date of explanation. We may ask you to for this information in the future for reporting to the FDA and to inform future decisions regarding availability of product-specific information.

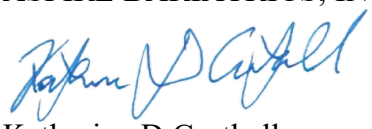
4. Please continue to report adverse events of potential relevance to the long-term safety monitoring of the device to us that you may observe during your routine visits with patients. Please continue to report significant adverse events or problems with the device through FDA's MedWatch Online Voluntary Reporting, available at https://www.accessdata.fda.gov/scripts/medwatch/ and within the reports please include as much detailed information as possible. In addition, please inform your patients that they can directly report their own adverse events or problems with the device through MedWatch.

We intend to keep our website, email addresses, Facebook page, and telephone numbers active for as long as patients have the AspireAssist A-Tube implanted so both clinicians and patients can continue to direct questions to us.

Please direct any questions you may have regarding this letter to Audrey Finkelstein at email: audrey.finkelstein@aspirebariatrics.com or by phone at (914) 589-9620 or me at kathy.crothall@aspirebariatrics.com or at (610) 316-7778.

Sincerely,

ASPIRE BARIATRICS, INC.



Katherine D Crothall
President/ CEO

Enclosure: Letter to Patients