



February 12, 2022

Dear AspireAssist Patient,

Aspire Bariatrics, Inc. regrets to inform you that we are winding down all operations at the Company. As a result, we are withdrawing the AspireAssist from the market, effective April 8, 2022. Due to the financial impact of the COVID-19 pandemic, we can no longer afford to continue operations at the Company.

Please note that our withdrawal of the AspireAssist from the market is entirely the result of economic factors, not the result of safety or effectiveness issues associated with or reported with the product. The safety and effectiveness profile of the AspireAssist, as has been found subsequent to when the product received FDA approval (known as a “PMA”) , is consistent with the safety and effectiveness profile of the product when it received FDA approval in June 2016.

In accordance with federal law, AspireAssist supplies may no longer be distributed in interstate commerce once we withdraw the AspireAssist from the market effective April 8, 2022. Up until, April 7, 2022, we will provide **free of charge**, AspireAssist accessories to your physician’s facility (or directly to you with a prescription from your physician) as long as such supplies last. We will no longer supply **any** AspireAssist supplies after April 7, 2022. Orders for AspireAssist supplies with an accompanying prescription from your physician must be received by April 1, 2022.

As you may have noticed, AspireAssist supplies, with the exception of the Carry Bag, have an expiration date. The latest expiration date of the AspireAssist supplies (except for the Companion) is ranges between November 1, 2023 and December 17, 2023. The expiration date of Companion is June 2023.

You and your physician need to discuss whether you should continue Aspiration Therapy after we withdraw the AspireAssist from the market. Clearly, once the AspireAssist supplies are no longer available or are past their expiration date, you will need to cease Aspiration Therapy. Once you cease Aspiration Therapy, there is only risk and no benefit to keeping your A-Tube in. In particular, there is some risk that you may regain weight after you cease Aspiration Therapy. Weight regain, while the A-Tube is in your body, can lead to the potentially serious complication of a buried bumper. We recommend that you discuss with your physician the risk of weight regain and timing of explantation of your A-Tube. Table 1 on the next pages lists the risks associated with keeping your A-Tube in vs. removal.

Your doctor has been given instructions on how to inform us if he/she notices any problems with your device. If you visit a different doctor to have your A-Tube explanted, please inform him or her that the A-Tube cannot be “yanked out”, but rather must be removed endoscopically and to contact us for instructions on how to remove the A-Tube. The publicly available 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.

	Risk Associated with Leaving A-Tube In	Risks associated with Removing the A-Tube
Weight Regain	You may regain weight when you can no longer aspirate. (see Section 12.3 Of User Guide). Weight gain can lead to health complications.	You may regain weight when you can no longer aspirate. (see Section 12.3 Of User Guide). Weight gain can lead to health complications.
Risk Associated with Weight Regain	Your skin-port may become tight causing the A-Tube to pull into the stomach wall. This could cause a buried bumper. A buried bumper is a potentially serious complication and requires immediate medical attention (see Section 5.2 of User Guide)	N/A
Risk Associated with Stomal	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 your stomach causing a hole or tear in your A-Tube and leakage of gastric contents. Leakage of gastric contents can cause significant swelling, irritation, and even infection in the skin around your Skin Port. (see Section 13.5 of User Guide)	N/A
Risks associated with endoscopic procedures	Your 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 any endoscopic procedure, (see Table 6.2 of Patient Guide)	Although not seen in the studies, there are risks associated with any endoscopic procedure (see Table 6.2 of Patient Guide)
Risks associated with stoma not closing without treatment when the A-Tube is removed	There is a risk of your stoma not closing after A-tube removal without additional interventions. This risk is increased if the A-Tube has been in place for more than 12 months. Additional intervention during or after the removal procedure may be necessary to reduce this risk.	There is a risk of your stoma not closing after A-tube removal without additional interventions. This risk is increased if the A-Tube has been in place for more than 12 months. Additional intervention during or after the removal procedure may be necessary to reduce this risk.
Risks associated with gastric leakage after A-Tube removal	The stomal area may become irritated after A-Tube removal due to gastric leakage. To minimize this risk, your physician may prescribe a proton pump inhibitor until the stoma tract is healed completely. You should avoid over distending the abdomen and strenuous activities during the healing process.	The stomal area may become irritated after A-Tube removal due to gastric leakage. To minimize this risk, your physician may prescribe a proton pump inhibitor until the stoma tract is healed completely. You should avoid over distending the abdomen and strenuous activities during the healing process.

We will continue to provide telephonic and email support, if you have any questions, after we withdraw the AspireAssist from the market. Our website (<http://www.aspirebariatrics.com>), 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. You or your physician may direct any questions that arise at questions@aspirebariatrics.com or at (610) 590-1568.

Sincerely,

ASPIRE BARIATRICS, INC.



Katherine D Crothall
President/ CEO