

# AGB ADJUSTMENT INFORMATION



In the performance of an adjustment on the gastric band the skin over the port is penetrated blindly, using a special needle for the purpose of instilling or withdrawing fluid from the band around the stomach in order to achieve stomach restriction and weight loss.

There are significant risks including, but not limited to: bleeding, infection (that may necessitate removal of the port or band with attendant risk of recurrence of morbid obesity), catheter, port and/or band damage that may require prolonged antibiotic treatment, anesthetic risks (including shock / death), cardio-respiratory arrest, damage to the port or catheter (resulting in its removal/replacement), band erosion, fistula formation, damage to nerves, blood vessels, skin, intra-abdominal or thoracic structures including the gastrointestinal system, liver, heart, lungs and pleura, intra-abdominal infection, band slippage, pouch dysfunction, dysphasia, esophageal dilatation or dysfunction, heartburn, gastritis, ulceration, gastric outlet obstruction, reflux esophagitis/inflammation/Barrett's esophageal cancer, esophageal motility problems, pain, scar, inability/difficulty eating certain types of food or pills, or a need for additional surgery or procedures.

The long-term consequences /risks of this device are unknown, and it is still considered experimental in the U.S.A. Unforeseen conditions may require additional procedures / surgery / investigations for which the patient assumes full responsibility/financial and otherwise. Further, the adjustable gastric band requires lifelong medical surveillance and modification of food choices including, but not limited to, the amount and frequency; as well as a life-long need for nutritional supplementation including, but not limited to, proteins, vitamins, minerals and fluids.

No warranty or guarantee has been given or implied to the patient with regard to the outcome. The patient will refrain from having this device adjusted by anyone other than these health-care providers who are qualified by education, training and experience to handle this device.

Port and/or tubing problems include leakage, breakage/disconnection of tubing, flipping or tipping of port, infection (minor to severe) which may result in removal of port, tubing, and/or band. X-ray may sometimes be needed in order to perform the adjustment of the gastric band. A procedure may be necessary to correct the position of the port.