



ANNEX FOR THE PATIENTS

Liposuction, lipolysis and lipoplasty are not reliable methods for weight reduction. Consideration should be given to exercise and dietary as well as lifestyle modification, both as alternatives to liposuction and lipolysis and in order to maintain any reduction in adipose tissue which these procedures may achieve. Careful consideration shall be given to consumer suitability with respect to medication which has the potential to cause bradycardia or hypotension as this has been reported as the cause of death in a number of consumers undergoing tumescent liposuction. Consumers taking drugs such as beta-adrenergic antagonists, non-dihydropyridine calcium-channel blockers, cardiac glycosides, and centrally acting alpha-adrenergic agonists shall be subject to very careful consideration as deaths have been reported due to bradycardia and hypotension. The procedure has to be preceded by a medical consultation which has to be documented and during which chronic disease and drugs taken by patient need to be considered. Consumers may experience extended post-operative analgesia (for example for 24 hours or more) which may result in reduced sensation in the areas infiltrated and therefore consumers shall be warned to protect themselves from injury.

USER & ENVIRONMENT

Appropriate training on the safe use of liposuction cannulas is essential for healthcare professionals to perform the procedure effectively and safely. This training should be comprehensive, covering everything from device mechanics to patient selection, surgical technique, and emergency preparedness. Ensuring that users are well-trained helps to reduce the risk of complications, improve patient outcomes, and maintain high standards of care.

Device(s) are intended for invasive use and shall only be used in an appropriate medical environment by appropriately trained medical doctors who are qualified or accredited in accordance with national law. The medical doctor who carries out the procedure shall be assisted by at least one medical doctor or allied health professional who is qualified or accredited in accordance with national law.

INFORMATION ON WHEN AND HOW TO REPORT UNDESIRABLE SIDE-EFFECTS TO THE MANUFACTURER

Unexpected or Unlisted Side Effects - Unexpected tissue damage, severe pain, or unusual post-operative complications.

Severe or Life-Threatening Side Effects - Any severe adverse events, such as significant bleeding, infection, nerve damage, or complications requiring hospitalization, should be reported immediately.

Device Malfunction or Failure - If the liposuction cannula malfunctions during the procedure (e.g., breaks, bends, or fails to operate as intended), leading to patient harm or an unsuccessful procedure, this must be reported.

Complications Related to Cannula Design - If the design of the cannula contributes to side effects (e.g., excessive tissue trauma due to sharp edges or inappropriate size for the procedure), this information is important to report.

HOW TO REPORT UNDESIRABLE SIDE-EFFECTS

Document the Adverse Event

Record all relevant details about the adverse event, including:

- Patient information (age, sex, medical history relevant to the event).
- A detailed description of the side effect or adverse event.
- The type and size of the cannula used.
- The date and location of the procedure.
- Any steps taken to manage the side effect.

Include Supporting Documentation

If possible, include any relevant supporting documents, such as medical records, photographs of the affected area, and any other evidence that can help the manufacturer understand the nature and severity of the side effect.

CONTACT THE MANUFACTURER

The company manufacturers Liposuction Cannulas, Single Use Sterile and can be directly contacted via email in case of any adverse or undesirable side effects due to the use of the device.

Send a detailed report via email to the manufacturer's designated reporting address.



AmmaD Surgical

41-B, Commercial Area, Cavalry Ground,
Cantt-Lahore, Pakistan.

Email: info@ammadurgical.com

REPORT TO REGULATORY AUTHORITIES

In addition to reporting to the manufacturer, adverse events should also be reported to the relevant regulatory authority in the Member State where the device has been used.

- **In Europe:** Reporting can be done through national competent authorities or the European Medicines Agency (EMA).
- **In the United States:** The FDA's MedWatch program (through their website or by submitting Form FDA 3500).
- **In other regions:** Follow the specific guidelines set by the local health authority.

Report Without Delay - Adverse events should be reported as soon as they are identified to ensure prompt action can be taken to mitigate further risks.

RECOMMENDATION TO UNDERGO A MEDICAL CONSULTATION, INCLUDING A DIAGNOSTIC EXAMINATION, OF THE AREAS INTENDED FOR THE TREATMENT

Before undergoing any procedure involving liposuction cannulas, it is highly recommended that patients undergo a thorough medical consultation and diagnostic examination of the areas intended for treatment. This recommendation is crucial for ensuring the safety and efficacy of the procedure.

PURPOSE OF THE CONSULTATION

Assessment of Patient's Overall Health - A comprehensive evaluation of the patient's medical history, including any chronic conditions, previous surgeries, medications, and allergies, is necessary to determine suitability for liposuction.

Understanding Patient's Goals - The consultation allows the patient to discuss their aesthetic goals with the surgeon, ensuring that expectations are realistic and achievable.

Identification of Contraindications - The consultation helps identify any contraindications to liposuction, such as cardiovascular issues, bleeding disorders, or poor skin elasticity, which may affect the outcome or safety of the procedure.

DIAGNOSTIC EXAMINATION OF THE TREATMENT AREAS

Physical Examination - A detailed physical examination of the areas targeted for liposuction is essential. This includes assessing the distribution and consistency of subcutaneous fat, skin elasticity, and any existing scars or abnormalities.

Skin and Tissue Assessment: The surgeon will evaluate the condition of the skin and underlying tissues to determine if the patient is a good candidate for liposuction and to plan the appropriate technique and cannula size.

DISCUSSION OF RISKS AND BENEFITS

Informed Consent - The consultation includes a detailed discussion of the potential risks and benefits of the procedure, ensuring that the patient is fully informed before proceeding.

Alternative Treatments - The surgeon will discuss any alternative treatments or procedures that may be more appropriate based on the patient's specific condition and goals.

CUSTOMIZED TREATMENT PLAN

Procedure Planning - Based on the consultation and examination, the surgeon will develop a customized treatment plan, including the selection of specific liposuction techniques, types of cannulas, and areas to be treated.

Preoperative Instructions - Patients will receive instructions on how to prepare for the procedure, including guidelines on diet, medication adjustments, and lifestyle changes.

EVALUATION OF PATIENT EXPECTATIONS

Realistic Outcomes - The surgeon will ensure that the patient has realistic expectations regarding the outcomes of the procedure, including the potential need for additional treatments or procedures to achieve the desired results.