



English

NAME OR TRADE NAME OF THE DEVICE


Liposuction Cannula Single Use, Sterile

DEVICE DESCRIPTION


Liposuction cannulas are specialized surgical instruments used primarily in liposuction procedures for the removal of subcutaneous fat. The use of liposuction cannulas specifically targets subcutaneous fat, and this is a key part of the indications for the procedure. Whether for aesthetic body contouring or medical treatments, the effectiveness of liposuction depends on its ability to remove or redistribute subcutaneous fat.

INTENDED PURPOSE

Liposuction cannulas Single Use, Sterile, used for harvesting and removing fat during Liposuction procedure. These procedures are indicated to treat “MEDICAL” conditions like lipoedema, body contour defects, scar tissue, breast reconstruction as well as “NON-MEDICAL” body contouring for aesthetic reasons, making it a “DUAL PURPOSE DEVICE”. Only the patient’s indications / intentions determine the “Medical” or “Non-Medical” use of the device. Consequently, the device is intended for Single-Procedure use within a given procedure.

 **Note – Follow the guidelines of this document with respect to “Medical” and “Non-Medical” use of the device.**


INTENDED USER & ENVIRONMENT

 This device shall not be used in private environments by lay persons. This device 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.

All staff involved in the procedure shall be trained and shall keep their knowledge of basic cardiac life support and in the checking of equipment and emergency drugs used for resuscitation purposes up to date. Medical doctors performing the procedure shall also be trained in advanced cardiac life support.

PATIENT TARGET GROUP

Patients aged over 18 years.


 **ACCIDENTAL OPENING OF STERILE BARRIER SYSTEM BEFORE USE**

In case of accidental opening of the Sterile Barrier System (SBS) before use, the product must be considered non-sterile. Do not use the product. Dispose of it according to local guidelines

MEDICAL CONDITIONS

- Lipoedema
- Scar Tissue repair / correction
- Lymphedema
- Gynecomastia
- Axillary Hyperhidrosis
- Adiposis Dolorosa
- Body contour defects
- Breast reconstruction
- Lipomas
- Lipodystrophy Syndrome
- Madelung’s Disease

INDICATIONS

 The indication for the use of liposuction cannulas extends to various medical and cosmetic applications.

Lipoedema - Lipoedema Management - Liposuction cannulas are indicated for the removal of abnormal fat deposits associated with lipoedema, particularly in the lower body. This helps reduce pain, improve mobility, and prevent the progression of the disease.

Body contour defects - They are used in liposuction / lipoplasty procedures aiming to improve body contour and symmetry.

Scar Tissue repair / correction - Fat Grafting - Cannulas are sometimes used to inject harvested fat in atrophic scars area or areas with contour irregularities to improve appearance and texture.

Breast reconstruction - In some breast reconstruction procedures, liposuction cannulas may be used to harvest fat for fat grafting, where fat is transferred to the breast area to improve contour and symmetry.

Lymphedema - Fat Removal in Lipolymphedema -In some advanced cases of lymphedema complicated by fat accumulation (lipolymphedema), liposuction cannulas may be used to reduce the fat component and alleviate symptoms.

Lipomas - Benign Fatty Tumours - Liposuction cannulas can be used to excise lipomas, particularly when they are large or located in areas where traditional surgical excision might be more invasive.

Gynecomastia - Male Breast Reduction – Liposuction Cannulas are used in the treatment of gynecomastia to remove excess fatty tissue in the male breast, often in combination with the removal of glandular tissue.


Lipodystrophy Syndrome - Abnormal fat accumulation can sometimes lead to discomfort, pain, or other symptoms. Liposuction cannulas can be used to alleviate these symptoms by reducing the fat deposits causing the issues.

Axillary Hyperhidrosis - Sweat Gland Removal - In some cases, liposuction cannulas are used to remove sweat glands in the underarm area to treat severe cases of axillary hyperhidrosis (excessive sweating).

Madelung’s Disease - Fat Removal - Liposuction cannulas are indicated for the removal of abnormal, symmetrical fat deposits around the neck, shoulders, and upper trunk in patients with Madelung’s disease.

Adiposis Dolorosa - Symptomatic Fat Removal - Liposuction cannulas can be used to remove painful fatty deposits associated with Dercum’s disease, providing relief from discomfort and improving the patient’s quality of life.

CONTRA INDICATIONS

 Liposuction cannulas are not recommended in areas where there is very little subcutaneous fat. Attempting to remove fat from such areas can lead to damage to underlying structures, irregularities, or unsatisfactory aesthetic outcomes.

Cardiovascular Disease - Patients with severe heart conditions (e.g., congestive heart failure, severe coronary artery disease) are at increased risk during surgery, including liposuction, due to the stress it places on the cardiovascular system.

Coagulopathy (Bleeding Disorders) - Patients with clotting disorders (e.g., hemophilia) or those on anticoagulant therapy may experience excessive bleeding during or after the procedure, making liposuction risky.

Diabetes - diabetes can impair wound healing and increase the risk of infection and other complications after liposuction.

Respiratory Conditions - Patients with severe chronic obstructive pulmonary disease (COPD) or other significant respiratory disorders may not tolerate general anaesthesia or the physical stress of surgery.

Immunocompromised State - Patients with a weakened immune system (e.g., due to HIV, chemotherapy, or corticosteroid use) are at higher risk for infections and poor wound healing post-liposuction.

Active Skin Infections - If there is an active infection in the area where liposuction is planned, the procedure should be postponed preventing the spread of infection and other complications.

Pregnancy - Liposuction is not recommended during pregnancy due to the risks it poses to both the mother and the fetus.

Breastfeeding – it is recommended to waiting until after breastfeeding is completed before undergoing liposuction to avoid potential complications and to ensure better results.

Excessive Fat Removal - Removing large volumes of fat (typically more than 5 Liters) in a single session increases the risk of complications such as fluid imbalance, blood loss, and adverse effects from anaesthesia. Such procedures are often contraindicated or should be performed with extreme caution.

Performance Characteristics

Material of Construction - Cannulas are made of biocompatible medical grade stainless steel AISI 304 and ABS plastic and are suitable for.

- Liposuction Aspiration.
- Liposuction Infiltration, including administration of tumescent solution.

Design & Size – Cannulas are available in various types and configurations to meet the user requirements.

Safety Features - Markings are provided on the components to allow surgeons to be mindful of where the ports are with respect to the Handle, Thread Hub or Luer Lock. The surface finish of the cannula is smooth to minimize tissue trauma during insertion and movement within the body. The smooth finish of the cannula reduces friction against tissues, which can help in achieving a more efficient and comfortable procedure. This is particularly important for minimizing repetitive strain and improving overall ergonomic performance.

Connection Compatibility / Function – all cannulas manufactured by the company are 100% verified to be compatible with their respective parts.

ERGONOMICS & COMMUNICATION

Handle Cannula - are designed to provide comfortable grip during use. A thumb impression is provided that helps with motion required during the procedure. The cannula ports are placed according to the thumb impression. The texture on the surface of the handle prevents slipping, ensuring a secure grip.

Thread Hub Cannulas – hexagonal shape of the connectors allows for easy connection with the respective part / suction unit.

Luer Lock – Standard Luer Lock helps in forming connection with the syringes or Luer Lock handles smooth and simpler. The hexagonal shape allows for easy rotation when connecting devices.

All cannulas are marked to guide the surgeon to be mindful of where the cannula ports are during the procedure.

All cannulas are marked with “Branding”, “Single Use Symbol” “Guide Arrow” and “CE Mark”

All cannulas have safety features with respect to accidental slips.

Sterility & Packaging

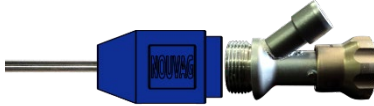
All cannulas placed on the market are in Sterile Condition using validated sterilization method with protective packaging inside.

Single-Use Packaging - Cannulas are individually packaged in sterile pouches to maintain sterility until use. The packaging is designed to withstand the sterilization process and protect the cannula from contamination.


Seals and Indicators - Packaging includes seals and indicators (e.g., chemical indicators) that change colour to show that the sterilization process has been completed.


Storage Conditions - Cannulas should be stored in a clean, dry environment to maintain their sterility. Proper storage conditions help prevent damage to the packaging and ensure that the cannulas remain sterile until use.


USABILITY INFORMATION - INSTALLATION

Type	Connection
Thread Hub Cannula	LipoSurg LipoPower and Infiltration system; LipoSurg Cart LipoSurg, Vacuson 60, Vexio Cart Vacuson 60 LP, LipoPower system
	REF 4390 - Liposuction handle for conventional cannulas REF 4391 - Liposuction handle with ventilation ports for conventional cannulas.
Connecting Part	

RESIDUAL RISK

 **Do not use if the product sterile barrier system or its packaging is compromised.**

 **Check cannula for any damage prior to and after use, in case of malfunction stop and replace the cannulas.**

 **The cannula should be able to connect to the respective part smoothly and completely, do not use if it does not.**

Handling – Usability

Aseptic presentation technique requires opening of the outer packaging by an assistant nurse. Sterile nurses or surgeons must not touch the surface of the outer packaging. The inner layer with the sterile product may be handled by sterile personnel. Product in inner layer can be placed on sterile surfaces.

Procedure

Step 1 Patient Preparation

Evaluation - The patient is evaluated to determine suitability for liposuction, including medical history, physical examination, and specific areas for fat removal.

Marking - The surgeon marks the areas on the patient’s body where fat is to be removed.

Step 2 Cannula Selection

The appropriate cannula size and type are selected based on the area being treated.

Extract the cannula from the Sterile pouches maintaining the sterility. Before starting the procedure, it’s essential to ensure that all parts of the cannula (such as the connection between the cannula and the syringe or suction pump) are securely assembled. This prevents any leaks or malfunctions during the procedure.

Step 3 - Incision

Small Incisions: Small incisions, usually around 2-5 mm in length, are made near the target area. These incisions are strategically placed to minimize visible scarring.

Step 4 – Site Preparation

Tumescent Solution Injection - A tumescent solution is injected through the incision into the fat layer using the ideal cannula to prepare site. This solution helps to numb the area, reduce bleeding, and make fat easier to suction.

Step 5 - Lipo-Aspiration

Connect the Cannula - Depending on the type of cannula, it can be connected to an empty syringe (for manual suction) or to a suction pump (for powered suction).

Insertion – A small incision allow the cannula to enter the subcutaneous fat layer where the tumescent solution has been injected.

The cannula is carefully inserted through the incision into the subcutaneous fat layer. The cannula is inserted atraumatically (without causing injury) into the fat layer.

Fat Harvesting - The fat is gently suctioned out using slight suction and careful, gentle movement of the cannula to ensure an even removal of fat without damaging surrounding tissues.

Step 6 – Lipo-Infiltration

Connect Prefilled - The cannula is connected to a suction or infiltration unit that has already been filled with harvested fat.

Puncture Access to Target Area - A small incision is made to insert the cannula into the area where fat is to be reinjected (e.g., for body contouring or reconstructive purposes)

Fat Injection: The fat is reinjected into the target area in thin strands (perl-strand-wise) with slight pressure. The cannula is moved continuously and in a fan-like pattern to create overlapping channels, ensuring that the fat is distributed evenly for a natural look.

Step 7 - Close Each Incision with Sutures

After the cannula is removed, the small incisions made for the procedure are closed with sutures to promote healing and reduce the risk of infection.

Step 8 - Compression Garment

A compression garment is applied to the aspirated areas. This garment helps reduce swelling, supports the treated tissues during healing, and aids in shaping the final contour of the body.

The patient will wear the compression garment during the recovery period, as instructed by the surgeon, to ensure the best possible outcome.

Step 9 - Disposal and Documentation

Disposal - Ensure that all single-use instruments, including the cannulas, are properly disposed of in accordance with medical waste disposal guidelines.















Document the Procedure - Record the details of the procedure, including the type of cannula used, the amount of fat removed, and any observations during the surgery.

Step 10 – Follow up

Schedule Follow-Up Visits - Arrange for follow-up appointments to monitor healing and assess the results.

Patient Instructions - Provide the patient with detailed post-operative care instructions and explain the signs of complications that would require immediate attention.

EXPLANATION OF SYMBOLS

Symbols	Explanation Title of Symbol	Symbols	Explanation Title of Symbol
	Indicates the need for the user to consult the instructions for use.		Caution - To indicate that caution is necessary when operating the device.
	Indicates the item is a medical device		CE Mark long with number from the notified body.
	Indicates the manufacturer’s catalogue number.		Indicates the manufacturer’s batch code.
Item Name with specifications	Item name and sizes are specified on the label.	00 Stk	Item quantity
	Date of manufacture Format YYYY-MM PK Representing the country of manufacturer.		Use-by date (Expiry Date) YYYY-MM
	Keep away from sunlight		Keep dry - Protected from moisture.
	Temperature limit 5 – 25 Degree Celsius.		Sterilized using ethylene oxide Single Sterile Barrier System with protective packaging inside
	Do not use if package is damaged and consult instructions for use Indicates a medical device that should not be used		Contains hazardous substances - Cobalt (Co) - Stainless steel may contain Cobalt (Co) more than 0.1% w/w which is a CMR



	if the package has been damaged or opened. "Do not use if the product sterile barrier system or its packaging is compromised".		substance and may result in an allergic reaction.
	Do not re-use Do not re-use" are "single use" and "use only once". Risk: Reuse of device can result in cross infection and injury to patient.		Do not re-sterilize Indicates a medical device that is not to be re-sterilized.
	Latex Free Product is declared as latex free.		Disposal - The device must be disposed of according to local regulations governing medical waste, rather than being thrown out with everyday trash.
	Unique Device Identifier Indicates a carrier that contains Unique Device Identifier information.		QR Code / Aztec Code - The code contains information regarding UDI-DI & UDI-PI
	Authorized representative in the European Union OBELIS S.A., Bd Général Wahis 53, 1030 Brussels, Belgium. Tel: +(32) 2 732-59-54 mail@obelis.net		
	Swiss Representative OBELIS SWISS GmbH Ruessenstrasse 12, 6340 Baar/ZG, Switzerland		
	Manufacturer - Ammad Surgical 41-B Commercial Area, Cavalry Ground, Cantt. Lahore, Pakistan. Post Code: 54000 info@ammadsurgical.com		
	Branding		
	St. Gallerstrasse 25, 9403 Goldach, Switzerland. Tel : +41 71 846 66 00 Email : info@nouvag.com Web : www.nouvag.com		

COMPLAINT & SUGGESTION

To register a complaint, suggestion, or malfunction of the device, please contact the distributor.

Users and/or patients must report serious incidents that have occurred in relation to the device to the manufacturer and competent authority of the member state in which the user or patient is established.

NON-MEDICAL

Intended Purpose (NON-MEDICAL)

Liposuction cannulas Single Use, Sterile, used for harvesting and removing fat during Liposuction procedure. In addition to "Medical" these procedures are intended for "NON-MEDICAL" body contouring for aesthetic reasons.

WARNINGS

- 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. Devices have not been validated for the treatment of clinically diagnosed obesity and therefore should not be used for such purposes. Do not be over forceful with the device that can result in rupture of the cannula.
- The volume of blood loss and endogenous body fluid loss may adversely affect intra and/or postoperative hemodynamic stability and the consumer's (End User) safety. The capacity of providing adequate, timely fluid management is essential for the consumer's safety.
- 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.
- Liver or cardiovascular dysfunction, such that the transient release of glycerol or free fatty acid, may be associated with increased risk.
- Devices intended for invasive use 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.
- The medical doctor or allied health professional responsible for anaesthetic management shall ensure appropriate monitoring of the consumer both during the procedure and after it. With respect to tumescent liposuction, appropriate post-procedure monitoring shall be in place as lidocaine levels have been found to rise for up to 16 hours post-delivery.

INDICATIONS FOR NON-MEDICAL

NO INDICATION FOR "NON-MEDICAL" USE OF THE DEVICE

CONTRA INDICATIONS FOR NON-MEDICAL

- Coagulant disorders, being treated with anticoagulant medications;
- Uncontrolled hypertension;
- Pregnancy;
- Medical conditions, such as heart, lung, or circulatory system disease;
- Skin infections and open lesions
- Elevated body temperature (pyrexia)
- Recent surgery (6 weeks);
- Incapability to understand the consequences, implications and risks of the medical procedures (for example liposuction, lipolysis, lipoplasty) where the devices are used;
- Extreme obesity (body mass index above 40);
- Phlebitis and vasculitis
- Age less than 18;
- Varicose veins in the area of treatment;
- Vascular fragility;
- Cancer or tumours
- Diabetes mellitus;

LIST THE BODY PARTS ON WHICH THE DEVICE CANNOT BE USED

- Nose
- Scalp
- Ears
- Shins
- Bony prominences (e.g., collarbone, spine)
- Tocs
- Forehead
- Knees (especially over the patella)
- Elbows
- Fingers
- Eyeballs and surrounding ocular structures

ADVERSE EFFECTS

- Hyper- or hypovolaemia;
- Bradycardia;
- Venous thromboembolism;
- Fat embolism
- Infection
- Fluid accumulation
- Skin erythema or panniculitis;
- Contour irregularities

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@ammadsurgical.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.