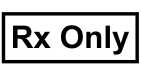
Implantech®

Superior Patient Aesthetics

INSTRUCTIONS FOR USE – CANADIAN PHYSICIANS ONLY

SILICONE FACIAL IMPLANTS

Symbol Definition – Refer to label for symbols applicable to your device.

	Caution, Consult Instructions for Use			Sterilized Using Steam or Dry Heat
	Do Not Reuse, "Single Use Only"			Sterilized Using Irradiation
	Catalog Number			Non-Sterile
	Batch Code, "Lot"			Manufactured By
	Use By			Manufacture Date
	U.S. Federal law restricts this device to sale by or on the order of a physician.			Medical Device

IMPLANTECH ASSOCIATES, INC.
PHYSICIAN'S INFORMATION DATA SHEET

Designed for use in cosmetic or reconstructive surgery, Implantech's facial implants are constructed of medical grade silicones and are available in a wide range of designs and sizes.

INDICATIONS FOR USE

1. *Chin and Mandibular Implants*
   To augment or reconstruct underdeveloped or traumatized mandibular regions.
2. *Malar, Submalar® & Midfacial Implants*
   To augment or reconstruct underdeveloped or traumatized malar regions.
3. *Nasal Implants*
   To augment or reconstruct underdeveloped or traumatized bony cartilaginous frame.
4. *Specialty Products*
   Individualized, carvable block used to augment or reconstruct under developed or traumatized facial areas.
5. *Conform® Implants*
   To augment or reconstruct underdeveloped or traumatized malar or chin regions. Designed to more easily conform to the facial skeleton in the malar or chin region.
6. *Temporal Shell Implant*
   To augment or reconstruct underdeveloped areas of the temporal fascia region of the face.

CONTRAINDICATIONS

- Lack of sufficient tissue covering.
- Known allergies to silicone materials.
- Active infection.
- Compromised circulation to the skin and soft tissues in areas to be implanted.
- Severe medical problems relating to the areas to be implanted.

NOTE: EVERY PATIENT SHOULD BE MADE AWARE OF THE FOLLOWING FACTS.

Facial (including chin, mandibular, malar and nasal) augmentation surgery can provide satisfaction to patients. Nevertheless, it is not without potential complications and risks. Facial (including chin, mandibular, malar and nasal) implantation surgery is an ELECTIVE PROCEDURE and the patient should be well counseled on the risk-benefit relationship. The possibility of explant surgery taking place at any time after implantation should also be discussed with the patient.

IMPLANTECH ASSOCIATES, INC. RELIES ON THE SURGEON TO ADVISE THE PATIENT OF THE COMPLICATIONS AND RISK ASSOCIATED WITH BOTH THE IMPLANT AND THE SURGERY ITSELF.

COMPLICATIONS AND WARNINGS

Resorption of bone underlying the implant can occur.

Inadequate tissue covering, inadequate size surgical pocket or too large an implant can result in tissue necrosis and extrusion of the implant.

Displacement or shifting of the implant can occur from too large a pocket.

Formation of a fibrous tissue capsule surrounding the implant is a normal physiologic response to any foreign body. Contracture of the fibrous tissue capsule can result in firmness, implant displacement or buckling, discomfort, or pain.

Utmost care should be taken to avoid damage to the implant during handling or in surgery. Avoid contact with sharp objects, such as surgical instruments or suture needles. Avoid undue handling with blunt instruments or manipulation.

Complications associated with all surgical procedures should be discussed with the patient (e.g. infection; poor reaction to medication/surgical procedures; poor wound healing; hematoma; serous fluid accumulation; nerve damage or irritation; neuralgia; loss of sensation; patient intolerance to any foreign implant).

Due to the wide variety of patients' physical responses to implant surgery and the differences in surgical techniques and medical treatments, as well as the possibility of complications or trauma, PATIENTS SHOULD BE ADVISED THAT THESE SHOULD NOT BE CONSIDERED LIFETIME IMPLANTS AND EXPLANT SURGERY MAY BE INDICATED AT ANY TIME. IMPLANTECH ASSOCIATES, INC. MAKES NO REPRESENTATIONS FOR THE TERM OF IMPLANTATION OF THE DEVICE.

Implants are intended for single patient use only.

WARNING: UNDER NO CONDITIONS SHOULD AN EXPLANTED PRODUCT BE REIMPLANTED! This is because recommended recleaning and resterilization may not adequately remove biological residues such as blood, tissue, and other matter, which could retain resistant pathogens.

INSTRUCTIONS FOR USE

SURGICAL PROCEDURE

Proper surgical procedures and techniques are the responsibility of the medical profession. Each surgeon must evaluate the suitability of the procedure based upon current accepted techniques, individual judgment, and experience.

Proper size and shape of implants must be determined for the individual patient by the surgeon. Sizer kits are available from Implantech for the convenience of the surgeon.

SUPPLIED STERILE OR NON-STERILE

(See label for method of sterilization.)
Implants supplied in sterile form are processed by a validated, strictly controlled cycle. Sterility is verified in accordance with AAMI / ANSI / ISO Standards. Sterility of the implant is maintained only if the package is intact and undamaged.

If the sterile implant becomes contaminated prior to implantation, it may be recleaned and resterilized by autoclaving according to procedures described below. The implant should not be resterilized by ethylene oxide gas, since excessive accumulation of ethylene oxide residuals may cause adverse tissue reaction.

Implants supplied in non-sterile form, must be sterilized by autoclaving before use. (SEE STERILIZATION INSTRUCTIONS.)

PACKAGING

Sterile product is supplied in a sealed double package. Sterility is not guaranteed if the package has been damaged or opened.

Non-sterile product is supplied in a sealed, single package.

A tear-off patient chart record is provided on both sterile and non-sterile packages.

TO OPEN STERILE PRODUCT:

1. Peel open outer package under clean aseptic conditions.
2. Invert outer package over sterile field, allowing sealed inner package to fall on field.
3. Using aseptic precautions, peel open inner package and retrieve implant.

NOTE: Attach patient record portion of the label to patient's chart.

NON-STERILE PRODUCT AND SIZER KITS

1. If sterilization or resterilization is required, the following cleaning and sterilization techniques have been found effective.
2. Remove implant from its package in a clean environment using gloved hands. Do not sterilize in the packaging system supplied. Utmost caution should be taken to avoid contamination as lint, fingerprints, talc, and other surface contaminants can cause foreign body reactions.

3. TO CLEAN: Wash thoroughly in a hot water-soap solution. Use a mild non-oily soap. Rinse thoroughly in hot water followed by distilled water and sterilize.

   DO NOT USE SYNTHETIC DETERGENTS!!
   DO NOT USE OIL BASED SOAPS!!

4. Sterilize per STERILIZATION INSTRUCTIONS below.

NOTE: Attach patient record portion of label to patient's chart.

STERILIZATION INSTRUCTIONS

The Sterilization Instructions provided are to be used only as a guide. We recommend that the efficacy of the specific autoclaving cycle employed be established by appropriate methods such as the use of commercially available chemical or biological monitors. **DO NOT USE ETHYLENE OXIDE STERILIZATION.**

Wrap implant in a clean, lint-free material and place in a clean, open autoclaving tray. Sterilize by the following gravity displacement autoclaving cycle:

1. Minimum of 15 minutes at 270°F, 30 psi.

When steam auto claving, the user should verify that the sterility procedure will produce a sterility assurance level of 10-6 by using an appropriate biological indicator and validation program as specified in Chapters 1035 and 1211 of the United States Pharmacopeia pages 1284-1285 and pages 1347-1348.

When using autoclaves for sterilization, it has to be strictly ensured that the steam used is absolutely free of foreign substances. (Note: Do not exceed 12 cumulative autoclaving cycles.)

Storage: After autoclaving, the autoclaved device should be stored in such a way as to maintain the sterility of the device until ready for use.

WARNING: IMPLANTS SHOULD BE ALLOWED TO COOL THOROUGHLY AFTER AUTOCLAVING.

PRODUCT EXAMINATION AND HANDLING

1. Prior to implantation, products should be visually examined for any evidence of particulate contamination or damage. DAMAGED PRODUCTS SHOULD NOT BE IMPLANTED. Do not attempt to repair damaged products.
2. The implant should be kept submerged in sterile normal saline prior to implantation to prevent contact with airborne and surgical field particulate contaminants.
3. Care must be taken to prevent possible surface contamination by talc, dust, and skin oils which might adversely affect the suitability of the implant.

WARRANTY, LIMITATION OF LIABILITY AND DISCLAIMER OF OTHER WARRANTIES.

Implantech Associates, Inc. warrants that reasonable care was used in the manufacture and production of the product. Because Implantech Associates, Inc. has no control over the conditions of use, patient selection, surgical procedure, post-surgical stresses, or handling of the device after it leaves our possession, Implantech Associates, Inc. does not warrant either a good effect or against an ill effect following its use. Implantech Associates, Inc. shall not be responsible for any incidental or consequential loss, damage, or expenses directly or indirectly arising from use of this product. Implantech Associates, Inc. SOLE responsibility, in the event Implantech Associates, Inc. determines the product was defective when shipped by Implantech Associates, Inc., shall be replacement of the product. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for use.

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