Implantech®

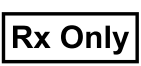
Superior Patient Aesthetics

INSTRUCTIONS FOR USE – CANADIAN PHYSICIANS ONLY

ContourFlex™

Silicone Contoured Carving Block 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

PHYSICIAN'S INFORMATION DATA SHEET

DESCRIPTION

Implantech's Contoured Carving Block (including Gluteal and Calf ContourFlex™ Implants) are 100% medical grade solid silicone elastomers that have been molded into various convex and oval shapes and durometers. These long term implants are designed as space occupying devices for augmentation and reconstructive surgery.

INDICATIONS FOR USE

Contoured Carving Block Implants (including Gluteal and Calf ContourFlex™ Implants) are indicated for augmentation and reconstructive surgery. Augmentation surgery with these devices is restricted to patients at least 22 years old.
The devices are carvable to allow the surgeon to shape the device should additional shaping be desired.

CONTRAINDICATIONS

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

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

Augmentation surgery can provide satisfaction to patients. Nevertheless, it is not without potential complications and risks. Implantation surgery is an ELECTIVE PROCEDURE and the patients 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 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

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

Resorption of bone underlying the implant or atrophy of underlying muscle can occur. Tissue necrosis and extrusion of the implant may occur. Inadequate tissue covering, inadequate size surgical pocket or too large an implant are potential causes.

Displacement or shifting of the implant has been reported. The size of the surgical pocket may be a factor.

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.

Compartment syndrome has been reported after the implantation of body implants, and occurs most frequently in the lower leg. It may occur due to any trauma, including surgical trauma associated with implant surgery. Removal of the implant may be indicated.

There is a body of reports in the medical literature regarding the possible association of Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) to certain textured Breast Implants. There are also individual case reports in the medical literature proposing the possibility of Gluteal Implant Associated-ALCL associated with textured gluteal implants, however there is no documented link between the devices in these case reports and Implantech's devices.

Utmost care should be taken to avoid damage to the implant during handling or in surgery. Care should be used when trimming to avoid creating cuts or tears into the device which may propagate (trimmings should be continuous and clean cut). Avoid contact with sharp objects such as surgical instruments or suture needles that may produce cuts or tears into the device. Avoid undue handling with blunt instruments or manipulation which can tear the device. (Note: Cuts/Tears/ Breakage of devices have been reported before, during and after implantation.)

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 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.

SURGICAL TECHNIQUES/DIRECTIONS/PRECAUTIONS

- **DEVICE INSPECTION** - The device should be inspected for any nicks, tears, or other defects immediately prior to use. Implantech implants are carvable, but care should be taken during carving to avoid making any cuts or tears which may propagate (trimmings should be continuous and clean cut).
- **SURGICAL TECHNIQUE** - The implantation of solid silicone gluteal and calf implants involves a variety of surgical techniques. Therefore, the surgeon is advised to use the method which her/his own practice and discretion dictate to be best for the patient, consistent with the device IFU.
- **IMPLANT SELECTION** - Some of the important surgical and implant sizing variables that have been identified include the following:
    - The implant should be consistent in size with the patient's surgical site dimensions, bearing in mind the laxity of the tissue and the projection of the implant.
    - A thorough discussion should be conducted with the patient, employing appropriate visual aids such as imaging, sizing implants, or other options to clarify surgical objectives and reduce the incidence of reoperation for implant size or design change.
    - The following may cause implants to be more palpable: larger implants, subcutaneous or subfascial placement, and an insufficient amount of skin/tissue available to cover the implant.

- Available tissue must provide adequate coverage of the implant.

- **INCISION AND SITE SELECTION**
  - The incision site should be chosen to allow appropriate access to the implant location, keeping in mind the need for adequate tissue covering of the implant.
  - The implant can be folded or curled during implantation, to allow for a smaller incision. However, the surgeon should use direct visualization and implant palpation to assure that the implant has unfolded and is properly placed in the pocket.

- **IMPLANT PLACEMENT SELECTION**
  - A well-defined, dry pocket of adequate size and symmetry must be created to allow the implant to be placed flat on a smooth surface.
  - Submuscular or intramuscular placement may make surgery last longer, may make recovery longer, may be more painful, and may make it more difficult to perform some reoperation procedures than subcutaneous or subfascial placement. The possible benefits of this placement are that it may result in less palpable implants. Also, submuscular or intramuscular placement, when feasible, may be preferable if the patient has thin or weakened surrounding tissue.
  - Subcutaneous or subfascial placement may make surgery and recovery shorter, may be less painful, and may be easier to access for reoperation than the submuscular placement. However, this placement may result in more palpable implants.

- **MAINTAINING HEMOSTASIS/AVOIDING FLUID ACCUMULATION**
  - Careful hemostasis is important to prevent postoperative hematoma

formation. Should excessive bleeding persist, implantation of the device should be delayed until bleeding is controlled. Postoperative evacuation of hematoma or seroma must be conducted with care to avoid implant contamination, or damage from sharp instruments, retraction, or needles.

- **RECORDING PROCEDURE**
  - Each implant is supplied with multiple Patient Record Labels showing the catalogue and lot numbers for that device. Patient Record Labels are located on the internal product packaging attached to the label. The Patient Record Label should be affixed to the patient's chart and other records so the device can be easily identified in the future. If a Patient Record Label is unavailable, the lot number, catalogue number, and description of the device may be copied by hand from the device label.

- **POSTOPERATIVE CARE**
  - You should advise your patient that they will likely feel tired and sore for several days following the operation, and that the augmented and surrounding areas may remain swollen and sensitive to physical contact for a month or longer. You should also advise your patient that they may experience a feeling of tightness in the surgical area as their skin adjusts to the augmented size. For at least a couple of weeks, the patient should avoid any strenuous activities that could raise their pulse and blood pressure. The patient should be able to return to work within a few days. Massage exercises of the augmented area may also be recommended, as appropriate. Your postoperative care instructions may vary from these based upon your own practical experience, these are only being offered as general guidelines.

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. Sizers are available from Implantech for the convenience of the surgeon.

SUPPLIED STERILE OR NON-STERILE

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.
This device is sterilized by a Dry Heat process which results in a natural variation in translucency from product to product.

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 double-packaged in polyethylene bags. A tear-off

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

TO OPEN STERILE PRODUCT:

- Peel open outer package under clean aseptic conditions.
- Invert outer package over sterile field, allowing sealed inner package to fall on field.
- 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 SIZERS

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:

- Minimum of 30 minutes at 270°F, 30 psi.

Do not use an autoclave cycle that includes a vacuum phase (such as pre-conditioning phase or in post-conditioning as a drying phase.

When steam autoclaving, 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.

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 warrants that reasonable care was used in the manufacture and production of the product. Because Implantech 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 does not warrant either a good effect or against an ill effect following its use. Implantech shall not be responsible for any incidental or consequential loss, damage, or expenses directly or indirectly arising from use of this product. Implantech's SOLE responsibility, in the event Implantech determines the product was defective when shipped by Implantech 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.

ISO 13485 CERTIFIED QUALITY SYSTEM

MANUFACTURER

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