GCA® Testicular Implants ES

1. Testicular Implants ES. Instructions for use. 2021. GC Aesthetics®.

DESCRIPTION

GCA® manufactures a full range of testicular implants pre-filled with silicone gel. The shell of these implants is made of a number of layers of medical-quality silicone elastomers, with an excellent mechanical performance. A central layer, called the 'barrier layer', has been specially formulated to minimise the permeability of the shell to the silicone gel. These implants have a tab at the top to attach them to the surrounding tissue.

MAIN FEATURES

- Oval shape[1].
- Smooth surface[1].
- ParaGel™: high cohesive, medical grade gel, provides controlled gel distribution[1].
- Disc-shaped closure patch[1].
- Fixation tab attached to the upper pole of the device which permits the attaching of the implants to surrounding tissues[1].

MRI COMPATIBILITY

Although these implants have not been specifically tested for use in an MRI. They are all manufactured from medical implant grade silicone materials which are compatible with MRI Scan. The implantable silicone grade material is the same as that used in other silicone implants where patients have undergone MRI Scans and no compatibility issues have been reported to date.

STERILIZATION PROCESS

Implants are designed for SINGLE USE ONLY and supplied sterile (Ethylene oxyde sterilization). DO NOT RE-USE EXPLANTED PRODUCTS. NO PRODUCT MAY BE RESTERILISED. Explanted products must not be reused, as there is a risk that re-sterilisation and cleaning procedures would not completely eliminate biological residues such as blood, tissue and other substances. Pathogenic organisms may remain and the implant performances could be affected.

CE certification by BSI with certificate number 645522. Our breast implants are manufactured in accordance with the internationally recognized Quality Management System Standard ISO 13485.

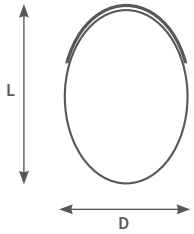
CE 2797 bsi.

INDICATIONS

Testicular implants are indicated for the following:

- Cosmetic Augmentation Surgery
- Reparative surgery
- Gender reassignment surgery
- Cases of congenital malformation, injury and/or testicular disease.

ES 520			Smooth Surface
Product Code	Diameter (cm)	Length (cm)	Volume (cc)
52006	2.2	2.8	6.0
52012	2.8	3.3	12.0
52018	3.0	4.2	18.0
52022	3.3	4.7	22.0
52026	3.3	5.2	26.0



INSTRUCTIONS FOR USE

1) Implantation of the device

Firstly, the double protective packaging ensuring the sterility of the implant should be checked for any signs of tearing, perforation, or any other sign of contamination. The sterilisation indicator must be checked (green after sterilisation with ethylene oxide) along with the use-by date indicated on the product labels.

NEVER use an implant with damaged protective packaging.

The device can then be withdrawn from its packaging and handled according to the strictest methods of asepsis. The product must be examined visually to detect any particular contamination or damage before its implantation.

NEVER implant a product presenting evidence of contamination or damage.

NEVER attempt to repair a damaged product.

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2) Guidelines

It is recommended to submerge the device in a saline solution bath brought to body temperature before implantation to prevent any contact with a contaminant in suspension in the air and in the surgical environment.

3) Warning

NEVER bring the device into contact with any product other than sterile saline solution, in particular iodine or betadine. If iodine-based solutions are used in the receiving area, rinse thoroughly to eliminate any residue.

It is the responsibility of the surgeon to select the site of incision, the method of anatomisation and the location of the implant, according to the anatomy of the patient and the desired aesthetic results. The surgeon must ensure that the incision is sufficiently wide to allow insertion of the device and to avoid any damage. Insufficient dissection may increase the risk of rupture and/or poor positioning of the device.

4) GCA® Recommendations

GCA® recommends that the testicular implant should be attached by the tab to the inside of the scrotum to minimise displacement of the implant as much as possible. Any sutures required for this should not be made too tight to avoid damaging the tab.

It is recommended that a spare device should be close at hand during surgery in order to compensate any defect in the device or mishandling.

DO NOT force the positioning of gel-filled implants. The gel may remain permanently deformed following incorrect handling which has a consequence on the aesthetic result.

DO NOT insert more than one device in each receiving area

In the event of accidental rupture of the implant in the receiving area, the gel may be recovered with the index finger, the hand inside a double glove. The gel may be removed from the cavity with the hand and the outer glove used to wrap and destroy the gel. Fill the surgical cavity with gauze compresses. Instruments can be cleaned with isopropylic alcohol.

Vigorous massage in the implant area is to be definitively avoided.

The medical personnel and the patient must avoid pricking the mi plant area (injections, acupuncture, tattoos, or by accident); this could damage the implant.

The practice of strenuous physical exercise following surgery is strongly discouraged for a period to be determined with the surgeon.

GCA® recommends that the patient use a form of retention for a period that will also be determined with the surgeon.

A Confident Choice for Life™

For more information about our products please visit:
gcaesthetics.com or email: **info@gcaesthetics.com**