Instructions For Use

Remote Valve Tissue Expanders (RVTE)

EUROSILICONE™

GC Aesthetics®

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Remote Valve Tissue Expanders **3**

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EN - *Remote Valve Tissue Expanders*

DESCRIPTION

These instructions apply to all REMOTE VALVE TISSUE EXPANDERS Products:
Round Remote Valve Tissue Expanders, Rectangular Remote Valve Tissue Expanders, Cylindrical Straight Remote Valve Tissue Expanders, Cylindrical Curved Remote Valve Tissue Expanders and Croissant Remote Valve Tissue Expanders.
We offer a full range of sterilized Tissue Expanders (sterilized by ethylene oxide), single use medical devices, designed to be filled after implantation with sterile physiological saline solution (also called 'isotonic sodium chloride solution'), which is not provided with the device.
The devices are intended to gradually stretch the tissue adjacent to the implantation area.
The shell is smooth and composed of medical grade silicone elastomer with excellent mechanical performances.
Each device is supplied in a single unit, with its own filling system, and is packaged in a sealed double micro-biological protective packaging, inside a mechanical protective cardboard box.
The labelling provides the necessary information to identify the product. The packaging contains removable labels indicating the characteristics of the implant (lot number, reference number…), implant card, patient, and user leaflets.
The REMOTE VALVE TISSUE EXPANDERS are available in a wide variety of models, with each model available in a variety of sizes. Please refer to the promotional literature for dimensions indications; this documentation is also available on our website at: **www.gcaesthetics.com**
The filling system provided with each expander is the following:

- A sub-cutaneous injection port (Ø 28 mm), to be used with a 25-Gauge needle.

The injection port and connecting tube are radiopaque (barium sulphate) to enable easy detection during clinical examination of the patient.
Important information: We recommend using 25G type needles with these tissue expanders. Use of another type of needle could cause a leak at the injection port. The manufacturer accepts no responsibility for consequences resulting from the use of another needle type.

INTENDED PURPOSE/USE

Tissue Expanders are intended to gradually stretch the tissue adjacent to the implantation area (normally the skin). Once the tissue has expanded sufficiently, the device is removed and the extra tissue can then be used traditionally in the following anatomical areas: scalp, head, face, and neck area, as well as trunk, pennis and extremities. Tissue expansion can also be used in preparation for permanent prosthesis implantation.

INDICATIONS

Remote Valve Tissue Expanders is designed to gradually stretch the tissue adjacent to the implantation area (normally the skin) for the following indications:

- Scar/defect revision
- Pocket creation for final prosthesis

Tissue Expanders are temporary devices and are not intended for permanent implantation. The tissue expander should be removed once adequate tissue has been developed. Their implantation duration should not exceed 6 months.
The possibility of explant surgery taking place at any time during the implantation period should also be discussed with the patient. It is the surgeons' responsibility to advise the patient of all potential complications and risks before surgery.

As tissue expanders can be implanted in various areas, surgeon has sole responsibility and should use the device as per intended use, indication and contra-indication.
Before implantation, the patient should be provided with all information relating to possible complications and side-effects that may arise during and/or after surgery, and to ensure that the patient has given their informed consent.

CONTRA-INDICATIONS

The use of these implants is contraindicated in patients who have one or more of the following conditions:

- Any existing pathology in the implantation area; treatments by irradiation, microwave or steroid diathermy
- History of implants rejection
- Immunological condition presenting disruptions or hypersensitivity
- Infectious condition of any part of the body; poor state of general health
- Psychological instability of the patient
- Patient signs of radiodermatitis: sclero-atrophic skin, dermatitis, ulceration
- Known allergy to silicone
- Any other serious medical condition

INTENDED USER

Remote Valve Tissue Expanders are intended to be used by suitably qualified surgeons who have received appropriate training on how to use the device safely.

IMPORTANT: The surgeon is responsible for conducting the medical assessments regarding the patient's eligibility for implantation and for deciding on the most suitable surgical technique for both the patient and the type of implant chosen.

TARGET POPULATION

The devices are intended to be used in adult populations (excluding pregnant and nursing women), with no known contraindications.

INTENDED CLINICAL BENEFITS

The main direct clinical benefit of Remote Valve Tissue Expanders (RVTE) when indicated for medical indication are the following:

- The Tissue Expander appropriately stretch the tissue adjacent to the implantation area in order to use the skin flap to treat cutaneous defects such as burns or scars, or to implant a permanent implant for medical indication

PERFORMANCE CHARACTERISTICS

The devices are designed and manufactured according to the current EN ISO 14630 and EN ISO 14607 applicable standards concerning non-active surgical implants.

The performance characteristics of the devices in terms of:

- Elongation of the inflatable shell.
- Shell overexpansion.
- Tensile resistance test of the inflatable shell.
- Leakage test of the injection site.
- Visual control of the surface contamination.
- Biocompatibility.
- Sterilization.

Had been validated and comply with the requirements of EN ISO 14630 and EN ISO 14607.

MATERIALS

Our range of Remote Valve Tissue Expanders is manufactured from medical implant grade silicone materials. The composition is as follows:

- Inflatable Shell – Silicone dispersion, Silicone elastomer, Silicone oil, Silicone Rubber + Barium Sulphate, Stainless Steel, Silicone adhesive.
- Injection Port – 304 L Stainless Steel, Silicone rubber + Barium Sulphate, Silicone elastomer, Silicone elastomer+ Barium Sulphate.

LINK TO THE SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

The summary of Safety and effectiveness will be available on the EUDAMED Website when it is live https://ec.europa.eu/tools/eudamed/#/screen/home and the company website (https://www.qcaesthetics.com/).

PATIENT INFORMATION

Any surgical procedure can have complications and risks. Implant surgery is known to provide psychological satisfaction to patients, but like any surgical procedure it can have potential complications and risks. Implantation is an elective procedure, and the patient should be well counselled on the risk/benefit relationship, by the surgeon. Each of the possible complications and warnings should be discussed with the patient prior to the decision to proceed with surgery.

The recommendation for the patient has to consider any previous procedures, accidents, conditions, medications, or other simultaneous treatments of the consumer that may affect the procedure (for example skin, diseases, traumas, and auto-immune diseases).
Each patient should receive the patient information leaflet (provided together with the products) and the patient information booklet during their initial consultation, to allow time for the patient to read and understand the information on risks, follow-up recommendations and benefits associated with the device in order to make an informed decision about proceeding with the surgery.

LIFETIME

Tissue expanders are temporary devices that are not intended for permanent implantation. They should be removed once adequate tissue has been developed.
Their implantation duration should not exceed 6 months. We recommend that no more than 5 injections should be carried out at the injection port.
Health professionals must ensure that the appropriate volume is injected on a case-by-case basis.
Our products must be stored under normal conditions, must be protected from humidity, kept out of direct sunlight, and must be stored with the arrows symbols pointing upwards. Where these conditions are respected, the products have a five-year shelf-life.

MRI COMPATIBILITY

Although Remote Valve Tissue Expanders have not been specifically tested for use in an MRI, please note that these products are all manufactured from medical implant grade silicone materials which are compatible with MRI scan. They also contain stainless steel which is a non-magnetic material. Therefore, there is a minimal risk associated with their use with MRI. We do not take responsibility for any damage caused by using our RVTE in MRI Imaging. No compatibility issues have been reported to date for patients who have undergone MRI scans with such implants.

STEROID USE

The patient should be informed to consult a physician before using steroid drugs in the implant area to avoid extrusion of the implant.

INTERFERENCE

Interference with investigative and treatment techniques (cf. WARNINGS SECTION)

IMPLANT CARD

After surgery, the surgeon should provide to the patient:

- The implant card which should be filled out according to the instructions for Healthcare Professionals filling out the International Implant Card.
- The patient leaflet which is available in the product packaging and on the Information website for patients referenced on the card.

The patient should be informed that the implant card must be always kept on him and it enables:

- The patient to identify the implanted devices and to get access to other information related to the implanted device (e.g., via EUDAMED, and other websites).
- The patients to identify themselves as persons requiring special care in relevant situations (e.g., security checks).
- Emergency clinical staff or first responder to be informed about special care/needs for relevant patients in case of emergency situations.

WARNINGS

ALTERATION/MODIFICATION OF DEVICES

No alteration/modification should be made to the device before implantation. Alteration/Modification of products voids all warranties, express or implied.

DAMAGE OF IMPLANTS – BREAKAGE AT SURGERY

Extreme care should be taken in the use and handling of products to minimize the potential for breakage of shells. All implants have been produced by established manufacturing techniques and under strict quality control standards, but there may be some breakage of devices during handling or in surgery, both in initial and any subsequent surgeries.

Extreme care must be taken to avoid unintentional damage to the implant during the implantation or explantation surgery.

- Do not contact the device with sharp surgical instruments or devices such as scalpels, forceps, hemostats, suture needles and hypodermic needles.
- Do not contact the device with blunt surgical instruments such as clamps, retractors, and dissectors.
- Do not contact the device with cautery devices.
- Do not use excessive manipulation, force, or stress.

Products should be carefully inspected for structural integrity prior to use. Damaged products should not be implanted, do not attempt to repair damaged products. An extra product should be available at the time of surgery in the event of damage to, or contamination of, the device. Recommended procedures for testing, examination and handling of products should be meticulously followed to ensure proper use of products. Patients should be instructed to inform other treating physicians of the presence of implants to minimize the risk of damage.

INTERFERENCE WITH INVESTIGATIVE AND TREATMENT TECHNIQUES

- Radiation Therapy is a relative contraindication for the use of tissue expanders in reconstructive surgery. The decision to use Radiation Therapy in conjunction with Tissue Expanders should be made by the surgeon and the radiation oncologist.
- During radiological examinations, or any other type of diagnosis examination (biopsy, etc.), the patient should ensure that the medical practitioner is aware of the presence of an implant.
- The manufacturer does not prescribe or guarantee the safety of intraluminal introduction of medication, in particular antibiotic or vitamin solutions. The manufacturer of the medication concerned must be consulted if such use is planned.

IMPLANTATION IN A PATHOLOGICAL AREA

If an expansion needs to be performed in a pathological area such as a burn, or after radiotherapy, we recommend waiting 18 months before implantation.

OVER-INFLATION OF THE DEVICE

Over inflation of the device may affect the integrity of the device and cause trauma to the surrounding tissue.
Health professionals must ensure that the appropriate volume is injected on a case-by-case basis.

SHARP OR POINTED OBJECTS

As the device is highly sensitive to contact with sharp or pointed objects, utmost care must be taken when handling the product; excessive handling should be avoided to minimize potential damage to the shell of the product.

SINGLE USE AND RESTERILIZATION

These devices are intended for SINGLE USE ONLY. DO NOT REUSE EXPLANTED PRODUCTS. DO NOT RESTERILIZE ANY PRODUCT.

Explanted products should not be reused because recleaning and re-sterilization procedures may not adequately remove biological residues, such as blood, tissue, and other matter, which could retain resistant pathogens and may also affect the performance of the product.

USE OF DRUGS

We can neither predict, nor warrant, the safety of use of any drugs, including, but not limited to, anesthesia, steroid, antibiotic, and vitamin solutions. If such use is contemplated, the appropriate drug manufacturer should be consulted.

COMPLICATIONS

Particular potential complications inherent to the implantation of our device include but are not limited to:

General risks (anesthesia, infection, etc.) related to any surgical operation and associated medication.

Local risks:

CAPSULAR CONTRACTURE

Formation of a fibrous tissue capsule surrounding the device is a normal physiological response to a foreign body. Contracture of the fibrous capsular tissue surrounding the device may result in firmness, discomfort or pain, distortion, palpability, or displacement of the device.

CICATRIZATION

Cicatrization problems of the surgical approach or even necrosis of the adjacent tissue which could cause exposure and/or extrusion of the implant.

DELAYED WOUND HEALING

Some patients experience delayed healing, and for others the incision site may not heal well. It may open from injury or infection. If the implant is exposed, further surgery will be required. Tissue necrosis is the development of dead tissue around the implant. It will delay wound healing, may cause wound infection, and may require surgical correction and/or implant removal. Tissue necrosis has been reported following the use of steroid drugs, chemotherapy, radiation to tissue, and smoking, but in some cases, it may occur without any known cause.

DEFLATION OF TISSUE EXPANDERS

Deflation of the expansion shell is possible at any time and the containment of saline solution cannot be guaranteed. If leakage is suspected the device should be removed. The patient should be informed of the deflation potential of the device prior to the decision to proceed to surgery. Wrinkling and/or creasing of the expansion shell is inherent to the intended use of this device and may result in weakening and deflation of the expansion shell, especially when left under-filled for a period of time. Careful placement would be advised to avoid fold flaws to ensure well-tolerated expansion. Damage of devices during handling or in surgery can cause early or late deflation.

DISSATISFACTION WITH RESULTS

The complications of incorrect size, misplaced scar location, hypertrophic scarring and those listed below are usually related to surgical technique. Careful size selection, creation of an appropriate and adequate size implantation location, and use of current accepted surgical procedures are the surgeon's responsibility.

DISPLACEMENT OF PRODUCT

Products may displace with accompanying discomfort and/or distortion in shape. Difficult placement techniques may increase the risk of displacement by reducing implantation size and placement accuracy. Displacement may require surgical intervention.

EXPANSION

Expansion must occur gradually, by taking into account the physical capacities of the implant, which should never be exceeded. Expansion must be stopped immediately upon observation of any anomaly of the cutaneous tissue, at the risk of causing damage to the skin flap. Neuropraxia, nerve dysfunctions, or motor deficits can occur if expanders are placed next to a major nerve, especially in the extremities or in the head/neck.

EXTERNAL CAPSULOTOMY

Treatment of capsular contracture by external manual compression may cause the shell to weaken or rupture. There have been reports of rupture and we recommend against the external capsulotomy procedure and is not responsible for the integrity of the implant should manual compression or other external stress techniques be used.

EXTRUSION

Inadequate tissue coverage may result in exposure and extrusion of the device. Skin breakdown can occur with the use of steroid drugs. Tissue sloughing may result from poor vascularization. Signs of skin inflammation, such as tenderness and erythema, may indicate thinning or erosion and must be promptly investigated.

GRANULOMA

Granuloma formation is a common tissue response to the presence of foreign materials. It is possible for a tissue reaction to be caused by the presence of the implant leading to formation of silicone granuloma.

HAEMATOMA/SEROMA

Haematoma, oedema, and accumulation of serous fluid in the implant area.
Haematoma and serous fluid accumulation are complications associated with any type of invasive surgery. Postoperative haematoma and seroma may contribute to infection and/or capsular contracture, they may be minimized by meticulous attention to haemostasis during surgery, and possibly by postoperative use of a closed drainage system. Persistent, excessive bleeding must be controlled before the device is implanted. Any postoperative evacuation of haematoma or seroma must be conducted with care to avoid contamination or damage to the device.

- Temporary or definitive dysaesthesia, immediate or delayed post-operative pain.
- Cicatrization problems of the surgical approach or even necrosis of the adjacent tissue which could cause exposure and/or extrusion of the implant.
- Insufficient tissue expansion or unusable tissue fragment.
- Displacement.
- Allergic reaction.

The possibility of a link between this type of implant and the apparition of systemic illnesses (particularly auto immune) is unlikely but cannot be completely ruled out.
Leak and/or rupture of the device may be caused by poor positioning, post-operative displacement (folded shell), over-filling, impact, etc.
Expansion must occur gradually, by taking into account the physical capacities of the implant, which should never be exceeded. Expansion must be stopped. immediately upon observation of any anomaly of the cutaneous tissue, at the risk of causing damage to the skin flap.
One or more of the complications listed above may result in the necessity for re-operative surgery to remove or replace the device; this is why we recommend that the surgeon considers post-operative follow-up with the patient.
These complications may lead to premature explantation, thus affecting the expected expansion area of the skin flap. Any complication should be reported to a practionner as soon as possible.

INFECTION

Pre-existing infection not resolved before implant placement increases the risk of periprosthetic infection (if applies). Do not expose the implant or filling accessories to contaminants, which increases the risk of infection. There have been reports of fistula around the implantation area following surgery.

Infection is an inherent risk following any type of invasive surgery. Infection around an implant may occur within days, weeks, or even years, after surgery. Signs of acute infection reported in association with implants include erythema, tenderness, fluid accumulation, pain, fever, and cellulitis. Signs of subclinical infection may be difficult to detect.

Postoperative infections should be treated aggressively according to standard medical practices to avoid more serious complications. Infection that is unresponsive to treatment or necrotizing infection may require implant removal. Capsular contracture may be related to infection in the area surrounding the implant.

PAIN

Any unexplainable pain, not associated with any of the complications listed herein, must be promptly investigated.

RUPTURE OF IMPLANTS

Leak and/or rupture of the device may be caused by poor positioning, post-operative displacement (folded shell), over-filling, impact, etc...

Rupture can occur post-operatively from damage to the implant during handling or surgery. Rupture of the shell can also occur from contracture, trauma, or excessive manipulation. Ruptures of unknown etiology have also been reported. If shell rupture is suspected, the implant should be removed.

SENSATION

The risk of temporary or permanent dysesthesia exists following any invasive surgical procedure. Careful surgical technique can minimize, but not preclude this risk. Dysesthesia has been reported following implantation and may be temporary or permanent. The risk of neurological impairment increases with more extensive surgery. Neuropraxia, nerve dysfunctions, or motor deficits can occur if the expander balloons are placed next to a major nerve, especially in the extremities or in the head/neck.

SILICONE ALLERGY

Although silicone allergy is extremely rare, this risk cannot be completely ruled out.

SYSTEMIC ILLNESSES

The possibility of a link between this type of implant and the apparition of systemic illnesses (particularly auto immune) is unlikely but still possible.

TISSUE EXPANSION

Insufficient tissue expansion or inusable tissue fragment.

It is strongly advised to avoid strenuous physical activity while the tissue expander is implanted, and after explantation for a period of time as determined by the surgeon.

OTHER

One or more of the complications listed above may result in the necessity for re-operative surgery to remove or replace the device; this is why we recommend that the surgeon considers post-operative follow-up with the patient.

These complications may lead to premature explantation, thus affecting the expected expansion area of the skin flap. Any complication should be reported to a practitioner as soon as possible.

INSTRUCTIONS FOR USE

STORAGE CONDITIONS

These products must be stored in normal conditions, must be protected from humidity and direct sunlight, and must be stored with the arrows pointing up. In these conditions, they have a shelf life of five years.

SUPPLIED STERILE

Remote Valve Tissue Expanders are supplied in a sterile form (Ethylene Oxide Sterilization), processed by a strictly controlled and validated sterilization cycles with ethylene oxide. Sterility is verified in accordance with standards. The sterility of the implant is maintained only if the package is intact and undamaged. If the sterile packaging has been damaged or unintentionally opened before use do not use.

SINGLE USE

Implants are intended for SINGLE USE ONLY. DO NOT REUSE EXPLANTED PRODUCTS. DO NOT RESTERILIZE ANY PRODUCT. Expanded products should not be reused because recleaning and re-sterilization procedures may not adequately remove biological residues, such as blood, tissue, and other matters, which could retain resistant pathogens and may also affect the performance of the implant.

PACKAGING

Sterile product is supplied in a sealed, double primary package. Sterility is not guaranteed if the package has been damaged or opened. Tear-Off patient record labels are attached to the primary packaging. These labels could be attached to the patients' records. The implant card label intended to be placed on the implant card is also provided on the primary packaging.

TO OPEN PACKAGED STERILE PRODUCT

- Peel open outer package under clean, aseptic conditions, over sterile field, allowing sealed inner package to fall gently into the field.
- Attach patient record portion of the inner label to patient's chart.
- Using aseptic precautions, peel open the inner package.

PRODUCT EXAMINATION AND HANDLING

- The double protective packaging ensuring sterility of the implant shall be checked for any signs of tearing, perforation, or any other signs of contamination. The sterilization indicator must be checked (green after sterilization with ethylene oxide) along with the use-by date indicated on the product labels.
- The device should be removed from its packaging and handled according to the strictest methods of asepsis. It must be examined visually to detect any particular contamination or damage before its implantation.
- Check the device is watertight by first injecting a small quantity of saline solution.
- Never attempt to repair a damaged product.
- Immerse the device in a saline solution bath brought to body temperature before implantation to prevent any contact with airborne and surgical field particulates contaminants.
- Do not immerse the implant in Betadine or Iodine containing solutions. If Betadine or Iodine containing solutions are used in the surgical pocket, ensure that it is rinsed thoroughly so no residual solution remains in the pocket.
- Implant the tissue expander at the desired location and the injection port in sub-cutaneous position. The shell must not be folded when in its final position.
- If necessary, cut the tubes between the tissue expander and the injection port to the desired length and join together by pushing them in around the metallic connector provided. Make sure the tubes are not twisted during connection as this could cause post-operative rotation of the injection port.
- 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.
- Injection ports are made with perforations in the flange. These perforations may be used to stabilize the injection device in position, minimizing movement and preventing it from rotation. Ensure the stitches are not too tight to avoid damaging the injection port.
- Do not insert more than one device per pocket.
- Vigorous massage in the implant area is definitively to be avoided. The medical personnel and the patient must avoid any excessive pressure as well as piercing the implant area (injections, acupuncture, tattoos, or by accident); this could damage the implant.
- The presence of a silicone Oil is likely to be detected in the shells of our products. It prevents the tissue expanders' shel ls from sticking to each other. Please note that it is normal, and it is not a sign of a product defect.
- It is very important to always use the same type of needle to fill the device (25-gauge needles). Connect the needle to a syringe or a suitable filling device and insert the needle at the center of the injection port. Push the needle in as deeply as possible (it will be stopped by a metallic disc at the base of the injection port), while making sure not to pierce the walls of the injection port.
- Transfer the required volume of saline solution, then remove the needle.
- Never fill the expander with anything other than sterile physiological saline solution.

Tissue expansion takes place gradually with injections of saline solution every two weeks until achievement of the required volume. The final volume should always be equal to or less than the volume indicated on the product labels.

Warning: Over-rapid expansion may compromise the vascularization of the cutaneous tissue.

We recommend that no more than 5 injections should be carried out at the injection port.

CONTAMINATION OF IMPLANTS

Care must be taken to prevent surface contaminants such as talc, dust, and skin oils from coming into contact with the device. Products should be inspected for contamination prior to insertion. Contamination at the time of surgery increases the risk of periprosthetic infection, and possibly capsular contracture. The manufacturer accepts no liability for products contaminated by other substances after the product leaves our possession.

Surface contaminants (talc, dust, lint, oils) on surface of implants can cause foreign body reaction, handle with care with surgical gloves (rinsed free of talc) with strict aseptic technique. Do not implant contaminated product.

Back-up products must be readily available at the time of surgery for use in the event of contamination..

SURGICAL PROCEDURE

Correct 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 judgement, and experience. Proper size and shape of implants must be determined for the individual patient by the surgeon. An incision should be of appropriate length to accommodate the style, size, and profile of the Remote Valve Tissue Expander.

INFORMATION ON MATERIALS EXPOSURE

These medical devices are manufactured from medical grade silicone materials which are suitable for long term implantation. Master Files have been filed with the U.S FDA. The materials have undergone biological testing to demonstrate their safety.

In accordance with the ISO14630 and ISO 14607 standards the silicone materials contain specified heavy metals (As, Pb, Cd, Hg, V, Mo, Se, Co, Sb, Ba, Cr, Cu, Sn and NI) at levels below 10 milligrams per kilogram (mg/kg). Anything above the limit is justified in a biological safety assessment.

Based on certification from suppliers the devices are manufactured from materials which:

- Do not contain Carcinogens, Mutagens and Reproductive Toxic Substances (CMR) or Endocrine-Disruptive (ED) substances above regulated threshold levels requiring specific labelling
- Do not intentionally contain Phthalates
- Do not incorporate materials of biological origin

REMOVAL AND DISPOSAL OF DEVICE

Before explantation, empty the tissue expander by cutting the tube and applying pressure.

Our devices must be eliminated and destroyed according to requirements relating to the disposal of infectious waste.

It is strongly advised to avoid strenuous physical activity while the tissue expander is implanted, and after explantation for a period of time as determined by the surgeon.

MATERIALS DEVICE DESCRIPTION

These medical devices are manufactured from medical grade silicone materials which are suitable for long term implantation. Master Files have been filed with the U.S FDA.The following three tables provide quantitative and qualitative information on the materials and substances which patients can be exposed based on chemical characterization of representative devices. The materials and device have been subjected to biocompatibility testing and evaluation, and risk assessments to demonstrate their biological safety. However, individual responses to chemicals may vary, and all reactions cannot be predicted.

Table 1. RVTE Device Materials Quantities

Component	Device materials	RVTE Range (%)
Shell with reinforcing sole	Silicone dispersion	66 - 93
Silicone connector	Silicone elastomer	0.5 - 1.5
Silicone oil	Silicone oil	0.5 - 3.5
Radiopaque filling tube	Silicone rubber + Barium sulphate	1.5 - 7
Metallic connector	Stainless steel*	0.5 - 2
Injection site	Silicone elastomer + Barium sulphate + Stainless steel*	4 - 20

*** Stainless steel is a biologically inert material and therefore no further reporting of data is deemed appropriate.**

Table 2. Chemicals Released from the RVTE

Compounds	Whole device for ref product 16/400* (µg/g or ppm)	Compounds	Whole device for ref product 16/400* (µg/g or ppm)
Volatiles[1] - Chemicals that can be released by breast implants as a gas			
Octacosamethyl cyclotetradecasiloxane	25,74	Hexacosamethyl cyclotridecasiloxane	21,19
Eicosamethyl cyclodecasiloxane	42,39	Docosamethyl cycloundecasiloxane	23,46
Dotriacontamethyl cyclohexadecasiloxane	26,49	Tetracosamethyl cyclododecasiloxane	22,71
Octatriacontamethyl cyclononadecasiloxane	26,49	Hexadecamethyl cyclooctasiloxane	16,65
Tetratriacontamethyl cycloheptadecasiloxane	21,19	Dodecamethyl cyclohexasiloxane	15,14
Triacontamethyl cyclopentadecasiloxane	30,28	Dodecamethyl cyclohexasiloxane	0,55
Hexatriacontamethyl cyclooctadecasiloxane	34,82	Decamethyl cyclopentasiloxane	6,66
Tetracontamethyl cycloeicosasiloxane	34,06	Decamethyl cyclopentasiloxane	1,97
Octadecamethyl cyclononasiloxane	31,03	Trimethylsilanol	0,76
Total volatiles	**582,06 ppm**		
Extractables[2] **-** Chemicals that can be released by breast implants following soaking in water			
Cyclic siloxanes	73,61	Bis (2-ethylhexyl) phthalate	18,17
Diethylene glycol n-butyl ether	5,68	Triethylene glycol mono	0,98
BADGE Bisphenol A	0,06		
Total extractables	**381,59 ppm**		
***The data shown represents samples of the RVTE as ''worst case scenario'' i.e with largest dimensions**			

Table 3. Heavy Metals Found in the RVTE

Heavy metals	Concentration for 16/400 (ppm)	Heavy metals	Concentration for 16/400 (ppm)
Aluminum (Al)	ND*	Molybdenum (Mo)	ND*
Antimony (Sb)	ND*	Nickel (Ni)	ND*
Arsenic (As)	ND*	Palladium (Pd)	ND*
Barium (Ba)	**0,98**	Platinum (Pt)	ND*
Beryllium (Be)	ND*	Potassium (K)	ND*
Boron (B)	**0,01**	Selenium (Se)	ND*
Cadmium (Cd)	ND*	**Silicon (Si)**	**155,93**
Calcium (Ca)	**0,58**	Silver (Ag)	ND*
Chromium (Cr)	ND*	Sodium (Na)	**0,04**
Cobalt (Co)	ND*	Strontium (Sr)	ND*
Copper (Cu)	ND*	**Sulfur (S)**	**0.28**
Indium (In)	ND*	Thallium (Tl)	ND*
Iron (Fe)	ND*	Tin (Sn)	ND*

Lead (Pb)	ND*	Titanium (Ti)	ND*
Lithium (Li)	ND*	Tungsten (W)	ND*
Magnesium (Mg)	ND*	Vanadium (V)	ND*
Manganese (Mn)	ND*	**Zinc (Zn)**	**0,02**
Not Detected means that the level of the individual element was below 0.25 ppm, the quantitation limit of the test method.			

REPORTING OF SERIOUS INCIDENT:

Any serious incident (incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat) should be reported to us via the e-mail address:productsupport@gcaesthetics.com and to the competent authority of the Member State in which the user and/or patient is established.

RETURN OF GOODS POLICY

Prior to the return of any product:

- The "Customer Claim form" must be completed.
- Certification of sterilization or decontamination must be provided with any product returned without its original packaging.
- If the shell of the implant needs to be pierced to facilitate the procedures of decontamination or sterilization, the pierced area must be indicated with an indelible marker on the surface of the product and this must be mentioned on the decontamination certificate.
- Products with a 'Product information' form must be sent to the manufacturer by your distributor only.

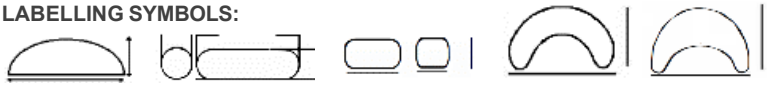
CAUTION:

Federal (USA) law restricts this device to sale by or on the order of a physician.

BIBLIOGRAPHIC REFERENCES

Literature references are available upon request from Eurosilicone.

LABELLING SYMBOLS:



Indicates the products dimensions

Eurosilicone SAS
ZI de la Peyrolière BP 68
84402 APT Cedex France
http://www.gcaesthetics.com

CE 2797