CUI™ BRAND REMOTE INJECTION PORT

ALLERGAN

THE SCIENCE OF REJUVENATION™

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a licensed physician.

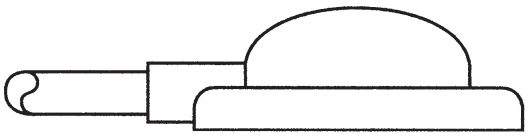
TABLE OF CONTENTS

Section

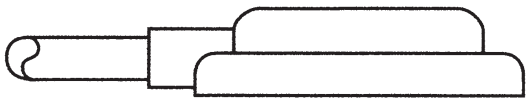
PORT STYLES

Remote Injection Ports

HIGH PROFILE
HPP



LOW PROFILE
LPP



MICRODOME
MDP

DESCRIPTION

CUI™ Remote Injection Ports are designed to be compatible with any standard or VERSAFIL™ CUI™ Tissue Expander. All ports are designed to be self-sealing when punctured with a 12 degree standard bevel needle.

INDICATIONS

The CUI™ Remote Injection Port is designed for use only with a CUI™ Tissue Expander. It cannot be used with any other device. No fluid other than sterile normal saline may be injected through the port.

CONTRAINDICATIONS

- Open cuts or sores at the implant site.
- Poor general patient health.
- Systemic disorders such as diabetes.
- Cardiovascular disease.
- Physiological and anatomical anomalies.
- Previous repeated contour correction failures.
- Inadequate tissue coverage.
- Tissue covering determined unsuitable by the surgeon. To varying degree, radiation damage, ulceration, compromised vascularity, or history of compromised wound healing may affect tissue covering suitability.
- Physiological condition determined by the surgeon to pose unduly high risk of surgical and/or postoperative complications. To varying degree, obesity, smoking, diabetes, autoimmune disease, coagulopathy, chronic lung or severe cardiovascular disease may affect patient suitability for surgical implantation.
- Use of drugs that may result in high surgical risk and/or significant postoperative complication, including any drug that would interfere with blood clotting.
- Psychologically unsuitable patient, including negativism or lack of understanding motivation, or cooperation. Sensitive over or underlying anatomy.

NOTE: The above indications and contraindications are generalized. Each patient must be individually evaluated for surgery based on the medical judgment of the physician.

See the Package Insert provided with each CUI™ Tissue Expander for additional Contraindications.

INFORMATION THAT SHOULD BE PROVIDED TO THE PATIENT

Tissue expansion surgery is known to provide psychological satisfaction to patients. Nevertheless, it is not without potential risks. Tissue Expansion surgery is an elective procedure and the patient should be well counseled on the risk-benefit relationship.

Before the decision to proceed with surgery, Allergan relies upon the surgeon to inform the patient of the general warnings, precautions, and adverse reactions listed in this package insert, as well as any complications specific to the implant device and intended use. The surgeon should advise the patient that medical management of serious adverse reactions may include explantation.

POSSIBLE COMPLICATIONS AND WARNINGS

Possible complications associated with tissue expansion surgery are listed below. Possible complications, risks, and alternative procedures should be discussed with the patient prior to the decision to proceed with surgery. Other potential complications such as infection, poor reaction to medication/surgical procedure, hematoma, nerve damage or irritation, thrombosis of blood vessels, hypertrophic scarring, inappropriate scar location, and those other risks associated with all surgical procedures, including temporary or permanent anesthesia or hyperesthesia are not addressed here but should be discussed with the patient.

In addition to the list of Possible Complications and Warnings listed in the package insert supplied with each CUI™ Tissue Expander, the following information should be reviewed.

1. Temporary Device
The CUI™ Remote Injection Port, like the CUI™ Tissue Expander, is a temporary device and is not intended for long term or permanent implantation. The Remote Injection Port and Tissue Expander should be removed once adequate tissue has been developed, as extended periods of implantation increase the likelihood of spontaneous deflation.

2. Port Leakage
The port may leak due to an excessive number of punctures or to an inadequate tubing connection.

3. Port Rotation
The port may rotate after implantation, thus making penetration through the anterior surface difficult or impossible.

4. Port Migration/Encapsulation
The port may migrate or become encapsulated, making palpable location difficult.

5. Reuse
DO NOT reuse explanted products. Biological residues such as blood, tissue and other matter which could retain resistant pathogens may not be removed by cleaning and sterilization.

6. Explantation
Patients should be advised that medical management of adverse reactions may include explantation. Explantation and replacement may also be indicated to achieve patient satisfaction.

7. Smoking
Patient should be informed that smoking may interfere with the healing process by increasing the risk of ischemia and necrosis.

8. Contamination at Surgery
Adherence to meticulous aseptic techniques is essential to minimize the potential for contamination of the port. DO NOT expose the port to lint, talc, sponge, towel, skin oils, and other surface contaminants. Contamination at the time of surgery increases the risk of periprosthetic infection.

9. Fluid Use
The CUI™ Remote Injection Port is designed for passage of sterile normal saline. No fluid other than sterile normal saline may be injected through the Remote Access Port.

10. Use with CUI™ Tissue Expanders
The CUI™ Remote Injection Port is designed for use only with a CUI™ Tissue Expander.

DO NOT attempt to use with any other device.

11. Dissatisfaction with Cosmetic Results

Patient should be informed that dissatisfying cosmetic results such as scar deformity, hypertrophic scarring, asymmetry, and unanticipated contour may occur. Careful surgical planning and technique can minimize, but not preclude the risk of such results. Preexisting asymmetry may not be entirely correctable.

Physiological and behavioral differences among patients and variations in surgical techniques and medical treatments account for a wide variety of responses to Tissue Expansion surgery. Revision surgery may be indicated to maintain patient satisfaction, but carries additional considerations and risks, and should be kept to a minimum. Revision surgery may be complicated by scarring, tissue deficit, and decreased vascularity from previous surgery.

HOW SUPPLIED

SINGLE USE
This product is for single use only

DO NOT reuse explanted products

STERILE DEVICES
Each sterile device is supplied in a sealed double primary package. Sterility of the device is maintained only if the package seal is intact. **DO NOT** use product if the package seal has been damaged. **DO NOT** attempt to resterilize using ethylene oxide which is known to cause adverse tissue reaction if not completely removed from the implant.

PRODUCT IDENTIFICATION/PATIENT RECORD LABEL
Patient record labels accompany each device within the internal product packaging. The patient record label provides product specific information and is pressure sensitive so that the backing may be removed and the label attached directly to the chart.

INSTRUCTIONS FOR USE

SURGICAL PROCEDURE
Proper surgical procedures and techniques are the responsibility of the medical profession. Each surgeon must evalute the suitability of the patient based upon current accepted techniques, individual judgment, and experience. Only those who intimately understand the physiology and mechanics of tissue expansion should inflate the device.

The surgeon must carefully evaluate the expander size and contour, incision placement, pocket dissection, and implant placement criteria with respect to the patient's anatomy and desired physical outcome. The surgeon should observe current and accepted techniques to minimize the risk of adverse, and potentially disfiguring, reactions.

HOW TO OPEN STERILE PRODUCT PACKAGE
Remove the port from its package in an aseptic environment and using talc-free gloved hands.

DO NOT expose the port to lint, talc, sponge, towel, skin oils, and other surface contaminants.

1. Peel open the outer pouch.
2. Invert the outer pouch over the sterile field, allowing the sealed inner pouch to fall gently into the sterile field.
3. Peel open the inner pouch.
4. Invert the inner pouch over the sterile field, allowing the port to fall gently into the sterile field.

Prior to use, keep the port in the inner pouch to prevent contact with airborne and surgical field particulate contaminants.

PORT ATTACHMENT

1. Choose the desired location for the tubing connector.
   Note: If possible, the connector should be placed no closer than 1 centimeter from the expander envelope or from the injection port.
2. Clamp the tubing on either side of the proposed break, if necessary, to prevent fluids from entering either the expander envelope or the injection port.
3. Sever the tubing and dispose of the unwanted port.
4. Trim the tubing to the desired length.
5. Insert the tubing connector into the tubing attached to the port. Sterile isotonic saline may be used as a lubricant. Do the same with the tube attached to the envelope, making sure that the two ends of the tubing meet in the center of the tubing connector (Figure 1).
6. As a safeguard, the connection should be secured by tying non-absorbable sutures over the tubing.

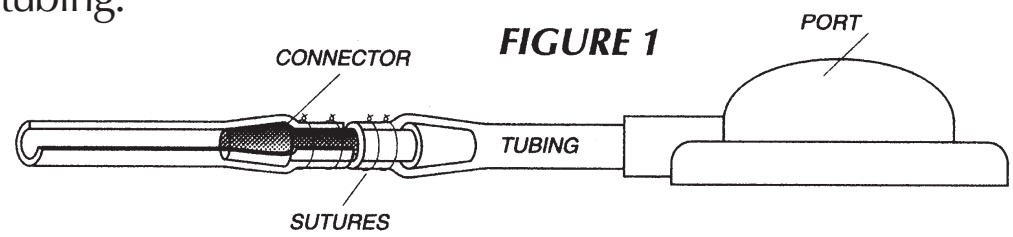


FIGURE 1

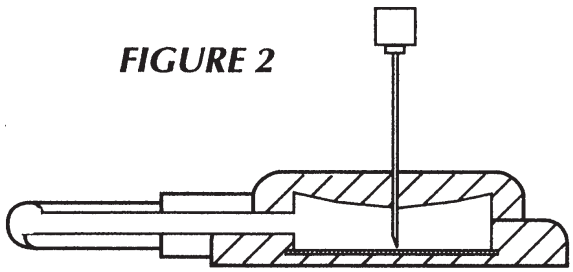
7. Verify the patency of the connection.
   - Place an appropriate size needle into the injection port.
   - Through the needle introduce a small amount of sterile saline through the port and tubing and verify free flow.
8. Locate the port in the desired pocket.

DO NOT implant damaged or contaminated devices.

The following information should be read carefully prior to use of port.

1. Use only a new 23 gauge or smaller needle on all sizes of domed ports.
2. Always try to penetrate the central area of the port (Figure 2).
3. With the needle perpendicular to the top surface of the port, drive the needle through the self-sealing dome until the needle stop is encountered (Figure 2).
4. It is recommended that no more than ten injections be made into the dome port; additional punctures may reduce the sealing ability of the port.

FIGURE 2



Dome ports are supplied with holes around the flange of the dome for suture fixation.

No other part of the port should be penetrated by suture for purpose of fixation.

REPORTING AND RETURN OF EXPLANTED DEVICES

Explanted devices associated with a complaint or serious injury should be reported and returned to Allergan. In the event of such an explantation, please contact the Allergan Customer Care Department at 800.766.0171 for a Return Kit and explant return information.

RETURN GOODS POLICY

Product returns should be handled through an Allergan Breast Aesthetics Business Development Manager or through the Allergan Customer Care Department at 800.766.0171. Return value is based on time limitations. All package seals must be intact to be eligible for return. Returned product may be subject to a restocking charge. Certain products are non-returnable, including custom products.

LIMITED WARRANTY, LIMITATION OF LIABILITY AND DISCLAIMER OF OTHER WARRANTIES

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

CAUTION: U.S. Federal Law restricts these devices to sale by or on the order of a licensed physician.

PRODUCT ORDERING

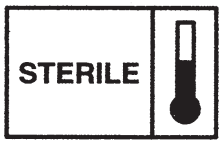
To order directly in the U.S. A. or for product information, please contact your Allergan Breast Aesthetics Business Development manager or the Allergan Custormer Care Department at 800.766.0171.

SYMBOLOGY

The following symbology may be used on the product label:

Attention! See Instruction for Use

Do Not Reuse



Method of Sterilization: Dry Heat
Date of Sterilization: Year and Month

LOT

Batch Code (Manufacturing lot)

SN

Serial Number

REF

Product Catalog Number

QTY

Content of Product Box

STYLE

Device Style

Allergan
2525 Dupont Drive
Irvine, CA 92612

THE SCIENCE OF REJUVENATION™

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