

TISSUE EXPANDER W/REMOTE INJECTION PORT INSTRUCTIONS FOR USE

DESCRIPTION

Specialty Surgical Products (SSP) Tissue Expanders are intended for temporary subcutaneous and submuscular implantation to develop surgical flaps and additional tissue coverage and are not intended for use beyond 6 months. All Tissue Expanders require periodic, incremental inflation with sterile saline for injection until the desired amount of tissue is developed.

The SSP Tissue Expanders are constructed from silicone elastomer and consist of an expansion envelope with either a smooth, "matte" or textured surface with a remote injection port. SSP tissue expanders are manufactured in a wide range of designs and sizes to meet diverse patient needs and to achieve individualized aesthetic results.

Each expander is supplied sterile. Each expander is supplied with extra silicone tubing and titanium or stainless steel tubing connectors to vary the length of the remote connector tube, and a Luer adapter for rapid intraoperative filling.

Specialty Surgical Products warrants that reasonable care was used in the selection of materials and manufacture of the device. Specialty Surgical Products disclaims any additional warranties concerning the safety or efficacy of the device in any medical procedure, including, but not limited to suitability for the intended use. Specialty Surgical Products makes no representation concerning the useful life of the device. Final approval of the device and its use in any medical procedure are solely the responsibilities of the surgeon.

CAUTION: Federal (USA) law restricts this device to sale or on the order of a physician or properly licensed practitioner.

For more information, please contact the SSP Customer Service Department at 888.878.0811, 406.961.0102, or email customerservice@ssp-inc.com.



SPECIALTY SURGICAL PRODUCTS, INC.

406.961.0102 · Fax: 406.961.0103
1123 North U.S. Hwy 93 · Victor, MT 59875
email: info@ssp-inc.com

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TISSUE EXPANDER W/REMOTE INJECTION PORT

GENERAL INDICATIONS

- Breast reconstruction following mastectomy.
- Correction of underdeveloped breasts.
- Treatment of soft tissue deformities.

GENERAL CONTRAINDICATIONS

- It is the responsibility of the surgeon to advise the prospective patient(s) or their representative, prior to surgery, of the contraindications with the use of this product.
- Tissue covering determined unsuitable by the surgeon. To varying degrees, radiation damage, ulceration, compromised vascularity, or history of compromised wound healing may affect tissue covering suitability.
- Active infection in the body.
- Existing carcinoma at the intended expansion site.
- Adjuvant radiotherapy without filling delay or myocutaneous flap as necessary to avoid unsuitable donor tissue.
- Physiological condition determined by the surgeon to pose unduly high surgical risk of surgical and/or postoperative complications. To varying degrees, sensitive over or underlying anatomy, obesity, smoking, diabetes, autoimmune disease, hypertension, chronic lung or severe cardiovascular disease or osteogenesis imperfecta may affect patient suitability for tissue expander surgery.
- Use of drugs that might result in high surgical risk and/or significant postoperative complications, including any drug that would interfere with blood clotting or effect tissue viability.
- Physiologically unsuitable patient.

INFORMATION THAT SHOULD BE PROVIDED TO THE PATIENT

Tissue expansion can be a beneficial surgical alternative for many pediatric and adult patients. At the surgeon's discretion, the use of a tissue expander may contribute to the benefit of the treatment. Nevertheless, tissue expansion is not appropriate for every patient, because it is a time and labor intensive process that may cause temporary discomfort and distortion. The surgeon is responsible for selecting appropriate candidates and counseling those patients on the risk/benefit relationship. Before expander placement, patients should fully understand the elective nature of the procedure and the nature of the device being used. Patients should be willing to comply with expansion process requirements to minimize the risk of complications.











Enclosed with each Specialty Surgical Products Tissue Expander is an Information and Informed Patient Consent Form that may be used to facilitate awareness and acceptance of the risks associated with silicone tissue expander surgery. It is recommended that the patient read and sign this form. It is also recommended that the patient and the surgeon each keep a copy of this signed form.




WARNINGS, PRECAUTIONS, ADVERSE REACTIONS

Before the decision to proceed with the surgery, the surgeon should inform the patient of the general warnings, precautions, and adverse reactions listed in this package insert, as well as any complications specific to the tissue expander and its intended use. The surgeon should advise the patient that adverse reactions may interfere with the original surgical plan and that medical management may include premature explantation.

SYMBOLLOGY

The following symbology may be used on the product label.

CV	=	Cumulative Volume
DATE	=	Date
DR	=	Surgeon Name
	=	Dimensions
	=	Manufacturing Lot Number
PID	=	Instructions for Use
PN	=	Patient Name / ID
	=	Catalogue Number
RIP-L	=	Remote Port-Large for Use with SSP Tissue Expanders with Remote Ports
RIP-S	=	Remote Port-Standard for Use with SSP Tissue Expanders with Remote Ports
RPA	=	Remote Port Accessory Set for Use with SSP Tissue Expanders with Remote Ports
RV	=	Recommended Volume
SS	=	Smooth Surface
	=	Tissue Expander Incremental Fill Record
TS	=	Textured Surface
TSL	=	Textured Surface with Lateral Extensions
	=	Fill Volume
	=	Winged Needle Infusion Set
	=	Attention: See Instructions for Use
	=	Do Not Reuse, Do Not Resterilize
	=	Use By:
	=	Not Returnable if Opened

	=	Sterilized by Ethylene Oxide
	=	Sterilized by Irradiation
	=	Sterilized by Dry Heat or Steam

RETURNED GOODS POLICY

Tissue expander return value is based on time limits and the condition of the returned product packaging. For more information, please contact your Specialty Surgical Products Customer Service Department at 888.878.0811, 406.961.0102, or your local representative.

REPORTING AND RETURN OF EXPLANTED DEVICES

Explanted devices associated with a complaint or serious injury should be reported and returned to Specialty Surgical Products. In the event of such an explantation, please contact the SSP Customer Service Department toll free at 888.878.0811 or 406.961.0102 for instructions on proper return procedures.

LIMITED WARRANTY, LIMITATION OF LIABILITY, AND DISCLAIMER OF OTHER WARRANTIES

Specialty Surgical Products warrants that reasonable care was used in the manufacture and production of this product. Because Specialty Surgical Products 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, Specialty Surgical Products does not warrant either a good effect or against an ill effect following its use. Specialty Surgical Products shall not be responsible for any incidental or consequential loss, damage, or expenses, directly or indirectly arising from use of this 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 of fitness for use.

PRODUCT ORDERING

To order directly in the US or for product information, please contact Specialty Surgical Products Customer Service Department toll free at 888.878.0811, 406.961.0102 or email customerservice@ssp-inc.com. International orders may also be placed directly with your local representative.

WARNINGS

Alteration

DO NOT alter the expander. Alteration to the original design and fabrication voids all warranties, express or implied, except as provided for alteration of the connector tube in Techniques For Using Tissue Expanders with Remote Injection Ports.

Adulterated Fill

DO NOT use adulterated fill. Expanders are to be filled only with sterile saline for injection, and only as described in the Instructions for Use. Specialty Surgical Products can neither predict nor warrant the safety of intraluminal introduction of any adulterated fill, including but not limited to, anesthetic, steroid, and antibiotic solutions.

Reuse

Expanders are intended for single use only. Do not reuse or resterilize.

Tissue Damage

DO NOT expand if the pressure will compromise wound healing. **DO NOT** expand beyond patient or tissue tolerance. Excessively rapid tissue expansion may compromise the vasculature of the overlying tissue. Stop filling immediately if any signs of tissue damage, wound dehiscence, abnormal skin pallor, erythema, edema, pain, or tenderness are observed. In the absence of other signs, some temporary erythema may occur as a recognized normal tissue response to expansion.

Tissue viability may be adversely affected by radiotherapy steroid use in the surgical pocket, excessive heat or cold therapy, and smoking.

Infection

Infection anywhere in the body must be treated and resolved before surgical placement of any expander. Untreated preexisting infection increases the risk of periprosthetic infections. **DO NOT** expose the expander or injection needles to contaminants, which increase the risk of infection. Patients who present with wound dehiscence, tissue erosion, ichemia, or necrosis run an increased risk of periprosthetic infection. Measures to protect such areas from infection should be taken.

Signs of acute infection reported in association with tissue expanders include erythema, tenderness, fluid accumulation, pain and fever. Infection may compromise the expansion process.³¹ 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 premature expander removal.

See also Infection under ADVERSE REACTIONS.

PRECAUTIONS

Infection

Infection anywhere in the body must be treated and resolved before surgical placement of any expander. Untreated pre-existing infection increases the risk of periprosthetic infections.

Surgical Planning

SSP tissue expanders have many useful applications in diverse clinical situations. SSP relies on the surgeon to know and follow proper surgical procedures specific to the type of expansion and desired physical outcome, expander dimensions, incision placement, pocket dissection, expander filling, and final flap dimensions, using current accepted techniques and individual experience.

Avoiding Contamination at Surgery

To avoid contamination, aseptic technique is essential. **DO NOT** expose the expander to lint, talc, sponge, towels, skin oils, and other surface contaminants. Contamination at the time of surgery increases the risk of periprosthetic infection, which could require premature explantation of the expander.

To minimize the risk of contamination, follow recommended procedures in Instructions for Use.

Avoiding Damage During Surgery

Extreme care should be taken to avoid damage to the expander during surgery. Possible sources of damage include sharp surgical instruments such as scalpels and needles used during the initial surgery, subsequent filling, or hematoma/fluid evacuation.

Products must be carefully inspected for leaks or nicks prior to use. DO NOT attempt to repair damaged products.

To minimize the risk of damage, follow recommended procedures in Instructions for Use for expander handling, examination, placement, and filling.

Maintaining Hemostasis/Avoiding Fluid Accumulation

Postoperative hematoma and seroma may be minimized by meticulous attention to hemostasis during surgery, and possibly by postoperative use of closed drains. Persistent, excessive bleeding must be controlled before the expander is placed. If the incision is remote from the site of expansion, the expander may be filled to tissue tolerance at the time of surgery to help minimize serous fluid accumulation in the surrounding pocket. If wound stability is a concern, inflate only slightly to fill the pocket space without applying tension to the tissue.

Any postoperative evacuation of hematoma or other fluid accumulation must be conducted with care to avoid introduction of contaminants and/or damage to the expander from needles or other sharp instruments.

Avoiding Tissue Damage during Expansion

If the incision site is not remote from and radial to the site of expansion, the wound should be stable before tissue expansion begins. However, a slight amount of inflation to fill the pocket space without tension to the tissue may be initially possible.

Expansion should proceed in moderate increments, never beyond patient or tissue tolerance.

The patient should be carefully monitored during each session. If any signs of tissue damage, abnormal skin pallor, erythema, edema, pain, or tenderness are observed, filling should immediately stop until the problem is resolved.

See also Tissue Damage under WARNINGS and ADVERSE REACTIONS.

Avoiding Expander Damage during Expansion

Extreme care should be taken to avoid needle puncture or other damage to the expander tubing or the injection port during the expansion process.

To minimize the risk of expander damage during expansion, fill the expander only with sterile saline for injection and use the appropriate location methods and instruments, as described in the Remote Injection Port Expander Location and Filling instructions.

ADVERSE REACTIONS

Any patient undergoing a surgical procedure is subject to possible unforeseen operative and postoperative complications. Potential reactions and complications associated with the use of Tissue Expanders should be discussed with and understood by the patient prior to surgery. It is the responsibility of the surgeon, and SSP relies on the surgeon, to provide the patient with this information and to weigh the risk/benefit potential for each patient.

Deflation

Patients should be advised that the expanders may deflate, and require replacement surgery. Deflation occurs when saline leaks through a damaged injection site, disconnected or damaged remote injection site connection tube, or a damaged expander envelope.

If the incision site is not remote from and radial to the site of expansion, the wound should be stable before tissue expansion begins. However, a slight amount of inflation to fill the pocket space without tension to the tissue may be initially possible.

DO NOT unnecessarily delay expansion after placement. The longer the delay, the more likely the formation of a resistant capsule making expansion difficult.

NOTE: Due to the compact design of the remote injection port, clearance for the needle in the port is minimal. The port is designed for use with a 21 gauge or smaller needle. Use of larger needles may damage port sealing capability or result in marginal port entry and subsequent difficulty in filling the device.

- a) Insert a new, sterile 21 gauge (or smaller) standard 12 degree bevel hypodermic needle into injection port. Ideally, the needle should enter perpendicular to the top of the injection port. (See Diagram 2)

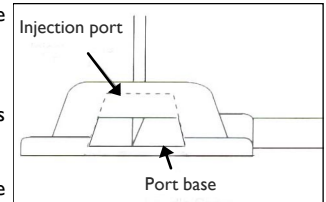


Diagram 2

- b) Penetrate the injection port until the needle is stopped by the port base. (See Diagram 2)

NOTE: The surgeon should feel the needle making gentle contact with port base. Contact must be made with the base to ensure flow into the expansion envelope.

DO NOT force the needle against the port base which may bend or burr the needle, and result in injection port damage.

- c) Fill the expander only with sterile saline for injection, and only through the injection port after precise location of the injection port via palpation. Fill carefully and only to patient and tissue tolerance.

- d) **Optional Intraoperative Filling Only:** A sterile Luer adapter for rapid intraoperative filling convenience is supplied with each Remote Injection Site style expander. Using aseptic technique, cut the tubing near the injection site end. Attach the Luer adapter directly to the connector tube, as shown in Diagram 3. The tubing clamp may be used to occlude tube as desired during the filling process.

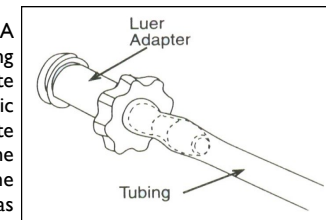


Diagram 3

After initial use, remove the Luer adapter and reconnect the remote injection site tubing using the connectors provided as described in section 1 of *Placement of Tissue Expanders with Remote Injection Ports*.

NEVER proceed with filling beyond patient or tissue tolerance.

Fill volumes during each session, intervals between filling sessions, and total expansion time may vary because they are highly patient and procedure dependent. Filling is typically performed at weekly intervals. A Patient Fill Volume Record card is provided with each expander for recording fill volumes and monitoring the expansion process.

NOTE: The suggested fill volume is located on the product labeling. The patient should be carefully monitored during each session for any signs of adverse reactions. If any signs of tissue damage, abnormal skin pallor, erythema, edema, pain or tenderness are observed, filling should immediately stop until the etiology is determined and the problem resolved.

several times and repeat the inspection. If satisfactory, aspirate all sterile saline and air from the inspected expander, return the expander to the inner/primary peel pouch and keep it covered until implanted to prevent contact with airborne contaminants.

DO NOT implant any device that appears to have particulate contamination, nicks, or leaks.

DO NOT attempt to repair damaged products.

TECHNIQUES FOR USING TISSUE EXPANDERS WITH REMOTE INJECTION PORTS.

DO NOT use force during any of the steps in the following procedures.

DO NOT damage the expander with sharp surgical instruments such as needles and scalpels, or by excessive handling and manipulation during introduction into the surgical pocket.

Placement of Tissue Expanders with Remote Injection Ports

Plan and dissect the surgical pocket for placement of both the expander and the remote injection port using current and accepted surgical techniques. If the pocket is too small, the expander may not have adequate room to unfold, increasing the risk of tissue erosion. If the pocket is too large, the expander may not remain in proper position for filling and expansion.

Place the expander flat and correctly-oriented in the pocket. Place the remote injection port flat and correctly-oriented in a separate subcutaneous pocket ensuring its palpability.

Ensure that the injection port connector tube lies flat and securely connects the injection site to the expander through a subcutaneous tunnel.

OPTIONAL: A sterile accessory set including silicone tubing and titanium or stainless steel tubing connectors is packaged with the device for varying the length of the remote connector tube. Using aseptic technique, cut the tubing, and attach the pieces to opposite ends of the connector so that the tubing meets tightly in the middle, suture tubing ends together as shown in Diagram I (a & b).

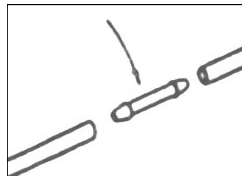


Diagram I (a)

DO NOT use lubricants, which create the risk of pocket contamination. Lubricants may also affect tissue adherence.

Expanders with Lateral Extensions (i.e. suture tabs)

Reinforced lateral extensions located on some expander designs may be sutured once the device is placed in the desired location. Extreme care should be taken to move the expander shell away from the tabs to avoid accidental shell puncture during suturing operations. Tabs may be trimmed if desired. Extreme care should be taken during trimming operations to avoid shell damage with sharp instrument.

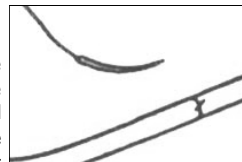


Diagram I (b)

Remote Injection Port Location

Always verify the location and orientation of the injection port by palpation prior to filling.

- Ensure that the base of the injection port is properly oriented for needle entry.
- Prepare the injection site for filling using antiseptic swabs.

Remote Injection Port Expander Filling

If the incision site is remote from and radial to the site of expansion, the expander may be filled to tissue tolerance at the time of surgery. Not only will this help to maintain proper expander placement, but it will also help to minimize fluid accumulation, expander folds, and the formation of a thick, resistant, capsule.

See also Avoiding Damage during Surgery and Avoiding Expander Damage during Expansion, under PRECAUTIONS.

Tissue Damage

Improper patient selection, tissue expander selection, placement and inflation may result in tissue damage and require premature explantation of the expander. Signs of tissue damage include abnormal skin pallor, erythema, edema, pain, or tenderness, and should be promptly investigated. In the absence of other signs, some temporary erythema may occur and is recognized as a normal tissue response to expansion.

The stresses of the expanding device may induce pressure ischemia and necrosis, especially in tight or thin-skinned areas. Folds in a partially filled expander may also result in thinning and erosion of adjacent tissue. Excessively rapid tissue expansion may compromise the vascularity of the overlying tissue.

Radiotherapy, steroid use or other drug therapy in the surgical pocket, excessive heat or cold therapy, and smoking may adversely affect tissue viability.

See also Avoiding Tissue Damage during Expansion, under PRECAUTIONS.

Infection

Preexisting infections not resolved before tissue expander placement increase the risk of periprosthetic infection.

Infection is an inherent risk following any type of invasive surgery and may occur during the tissue expansion process. Remote injection site expanders are associated with greater risk of infection around the injection site and potentially around the expander. Patients who present with wound dehiscence, tissue erosion, ischemia or necrosis, and patients undergoing immediate breast reconstruction run an increased risk of periprosthetic infection. Signs of acute infection reported in association with tissue expanders include erythema, tenderness, fluid accumulation, pain and fever.

Erythema may also occur as a normal response to expansion. Aspiration to differentiate between this type of erythema and erythema as a sign of early infection is a recognized precaution.

Research identifies *Staphylococcus* and *Pseudomonas* organisms in association with infection around tissue expanders. *Edcherichia* and *Streptococcus* organisms have also been noted in association with tissue expanders in the lower extremities. Infection may occur at any time after surgery, and may compromise the expansion process. 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 premature expander removal.

Extrusion

Tissue damage may compromise tissue covering and/or wound healing, result in extrusion, and require premature expander removal. See also Tissue Damage, above.

Hematoma/Seroma

Postoperative hematoma and seroma may contribute to infection. Postoperative hematoma and seroma may be minimized by meticulous attention to hemostasis during surgery and possibly by postoperative use of closed drains. Persistent, excessive bleeding must be controlled before the device is implanted. Acute hemorrhage following scalp expansion has also been reported, possibly due to pressure erosion of a vessel.

Capsular Contracture

Formation of a fibrous tissue capsule around an implanted device is a normal physiological response, although not all capsules contract. Contracture of the fibrous capsular tissue surrounding the expander may cause a range of symptoms including firmness, discomfort, pain, distortion, palpability, and/or displacement. Contracture may make expansion difficult and painful. Lower rates of contracture are associated with expansion begun soon after placement and continued regularly.

Premature Explantation

Adverse reactions may require premature explantation, which may affect desired flap size.

Displacement

The expander may become displaced, especially if the surgical pocket is too large. Remote port displacement may occur, causing kinking of tubing and/or injection port location difficulty necessitating device removal or correction.

Effects on Bone

Chest wall compression has been reported in association with the use of tissue expanders for breast reconstruction. Bone resorption following forehead and scalp tissue expansion has also been reported. The presence of a thick capsule, causing greater resistance to expansion may be a contributing factor. Bone resorption rarely occurs, but is most often reported in pediatric patients who should be monitored closely. The medical literature indicates that following expander removal, effects on bone caused by the pressure of expansion are often completely reversed.

Pain

As expected following any invasive surgical procedure, pain of varying intensity and duration may occur following expander placement. In addition, the expansion process may cause some discomfort but should not cause excessive pain. Pain may indicate expansion beyond tissue tolerance, which could result in ischemia and necrosis. Pain may also accompany other adverse reactions. Unexplained pain must be promptly investigated. Further expansion should be discontinued until the pain is resolved.

Sensation

The possibility of temporary or permanent dysesthesia exists following any invasive surgical procedure. Surgical technique and expansion must be performed carefully to avoid neurological impairment. Nerve traction and compression have been reported in rare cases in association with tissue expansion. Immediate partial deflation should be standard precaution if nerve impingement is suspected and filling should not resume until the problem is resolved.

Cancer

Published studies indicate that breast cancer is no more common in women with implants than those without implants. To the extent that such research applies to the safety of silicone for implantation, it is relevant to tissue expanders in general.

Distortion

Tissue expansion is a time and labor intensive process that may cause temporary discomfort and distortion. Patients should be psychologically suitable, well-informed, and motivated to complete the expansion process. Patient response to the distortion of body image may vary. Negative reactions may include depression and withdrawal.

Hair Thinning

Decreased hair density on the expanded tissue will occur, although the change is usually not noticeable. Temporary inhibition of hair growth during expansion has also been reported.

Inadequate Tissue Flap

Inadequate tissue flap following expansion may occur and may require additional surgery and expansion. In cases with limited viable donor site tissue, such sequential expansion may be included as part of the original surgical plan. See also Surgical Planning, under PRECAUTIONS.

Inflammatory Reaction

Studies evaluating the capsules around textured expanders have reported what were possibly silicone particles within giant cells, indicative of a local foreign body reaction and silicone granuloma formation. Another study suggests that certain types of capsule cells, including some perceived as giant cells, may actually be secretory cells that form in response to the frictional forces of the expander, providing lubrication at the capsule-expander interface.

Connective Tissue Disease

Concern over the association of breast implants to the development of autoimmune or connective tissue diseases, such as lupus, scleroderma or rheumatoid arthritis, has been raised because of cases reported in the literature with small numbers of women with implants. A review of several large epidemiological studies of women with and without implants indicates that these diseases are no more common in women with implants than those in women without implants. To the extent that such research applies to the safety of silicone in general for implantation, it is relevant to tissue expanders.

SURGICAL PROCEDURE

Specialty Surgical Products relies on the surgeons to know and follow the appropriate surgical procedures for the type of expansion performed and expander used. The surgeon must carefully evaluate patient suitability for expansion and desired physical outcome, expander dimensions, incision placement, pocket dissection, expander filling and final flap dimensions using current, accepted techniques and individual experience.

PRODUCT IDENTIFICATION

A patient record label accompanies each device within the internal product packaging. The patient record label provides product-specific information. The patient record label may be attached to the patient's chart for identification purposes.

PRODUCT ACCESSORIES

SSP Tissue Expanders with Remote Injection Ports are supplied with extra silicone tubing and titanium or stainless steel tubing connectors to vary the length of the remote connector tube and a Luer adapter for rapid intraoperative filling. These accessories are provided sterile.

SINGLE USE STERILE PRODUCT

Each Softspan™ Tissue Expander is supplied sterile in a sealed, double primary package. Sterile products are processed by a strictly controlled sterilization cycle developed by Specialty Surgical Products. Sterility of the expander is maintained only if the outer pouch is intact.

DO NOT use the product if the packages or seals have been damaged. Do not reuse or resterilize.

HOW TO OPEN STERILE PRODUCT PACKAGE

Remove the expander and product accessories from their sterile packages in an aseptic environment using talc-free gloved hands.

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

1. Peel open the outer peel pouch using the corner peel edge.
2. Invert the outer peel pouch over the sterile field, allowing the sealed inner peel pouch to gently fall into the field.
3. Peel open the inner/primary peel pouch package using the corner peel edge.
4. Gently retrieve the expander.

Prior to use, keep the expander in the inner/primary peel pouch covered to prevent contact with airborne and surgical field particulate contaminants.

PRELIMINARY PRODUCT EXAMINATION

Prior to use, examine the expander for leakage by partially filling with sterile saline for injection and gently compressing. To avoid missing any leaks due to hand position, reposition the expander