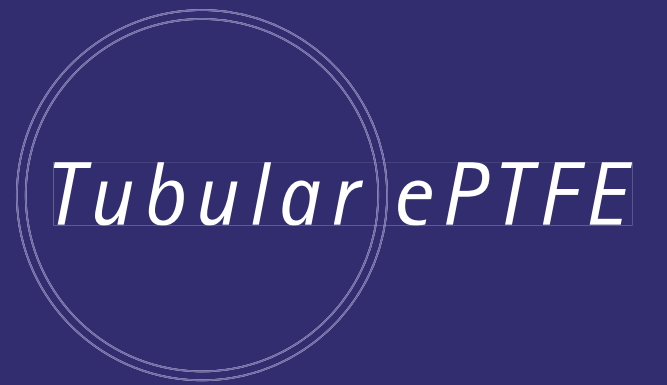


UltraSoft™

Tubular ePTFE Facial Implants

UltraSoft™

Facial Implants



UltraSoft™ and UltraSoft-RC™ Ordering Information

CATALOG NUMBER	PRODUCT	OD (MM)	LENGTH (MM)	WALL THICKNESS (MM)
S321107	UltraSoft™	3.2	110	0.7
S400907	UltraSoft™	4.0	90	0.7
S401107	UltraSoft™	4.0	110	0.7
S401108	UltraSoft™	4.0	110	0.8
S400912-1S	UltraSoft™ Strand	4.0	90	1.2
S481108	UltraSoft™	4.8	110	0.8
C300830	UltraSoft-RC™ Standard	30.0	80	3.0
C301430	UltraSoft-RC™ Long	30.0	140	3.0

INDICATIONS FOR USE

UltraSoft™/UltraSoft-RC™ facial implant is indicated for plastic and reconstructive surgery, including subdermal soft tissue augmentation of the facial area.

CONTRAINDICATIONS

UltraSoft/UltraSoft-RC implant must not be used as a vascular graft material, as a replacement for deteriorated blood vessels or for repair of any other cardiovascular defect. UltraSoft/UltraSoft-RC implant must not be used for reconstruction of the temporomandibular joint (TMJ). UltraSoft/UltraSoft-RC implant must not be implanted in the dermis (see Precautions) or as a dermal replacement.

WARNINGS

If UltraSoft/UltraSoft-RC implant becomes exposed during healing, treat to avoid infection. If infection occurs, remove the material. Exercise care when releasing the trocar (insertion tool) through the exit site as it is a sharp instrument which can injure facial tissue. Do not perform the UltraSoft/UltraSoft-RC facial implant procedure while the patient is following an aspirin regime, or taking other medication which will inhibit the healing process.

PRECAUTIONS

Caution: Inspect sealed sterile packaging prior to opening. If the seal is broken, contents may not be sterile and may cause infection in the patient.

Caution: Use nonabsorbable sutures for applications requiring attachment strength.

Caution: The material should not be implanted in the dermis. This could lead to complications such as fistula formation, infections, extrusion and induration.

Caution: The material should not be implanted in infected or potentially infected tissue beds or over open cavities, because infection or extrusions may result.

Caution: Introduction of the material either through the nose or mouth should be avoided due to increased potential for infection.

Caution: This material is not intended for load bearing applications such as bone, tendon, or ligament replacement.

Caution: The material may become infected or tender after implantation requiring its removal. A significant infection may result in damage or loss to the overlying skin. A hematoma or seroma (collections of blood or serum) could form requiring surgical drainage.

Caution: The body may have a hypersensitivity or allergic reaction to the material which would require its removal. This may result in significant transient inflammation, possibly infection.

Caution: Bruising or swelling can occur, as in any operation, but should disappear as with any bruise or swelling.

Caution: Irregularity of the implant associated with lumping may occur. This may require a surgical procedure to adjust the implant.

Caution: Caution should be exercised when treating patients who are prone to hypertrophic or keloid scars.

ADVERSE EVENTS

Possible adverse reactions with any facial implant material may include, but are not limited to: inflammation, infection, fistula formation, extrusion, hematoma, induration, seroma formation, inadequate healing, skin discoloration and inadequate or excessive augmentation.



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Customer Service:

800-997-4868 (USA and Canada)
800-654-2873 (USA and Canada)

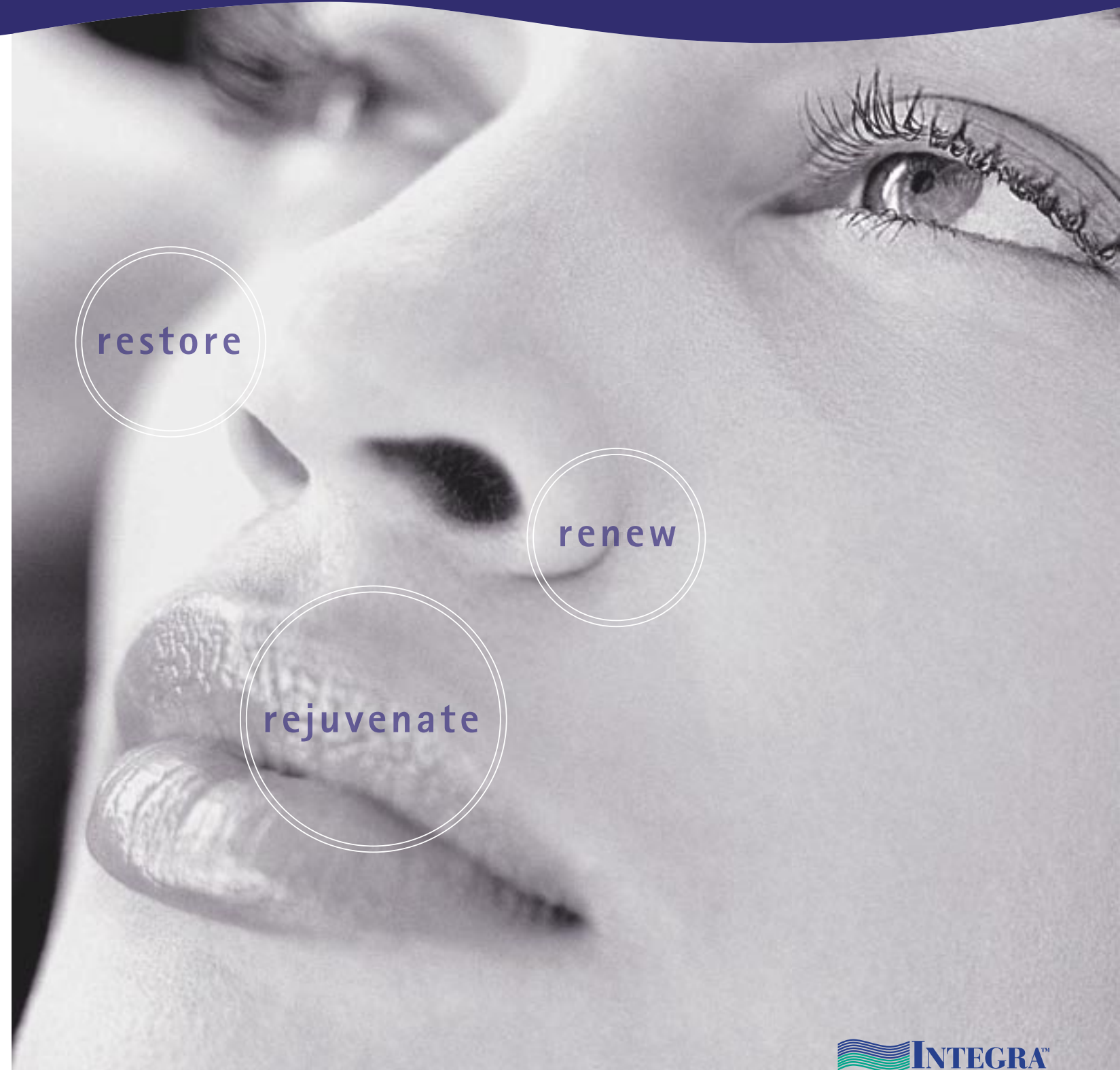
609-275-0500 (Outside USA)
609-275-5363 (Fax)

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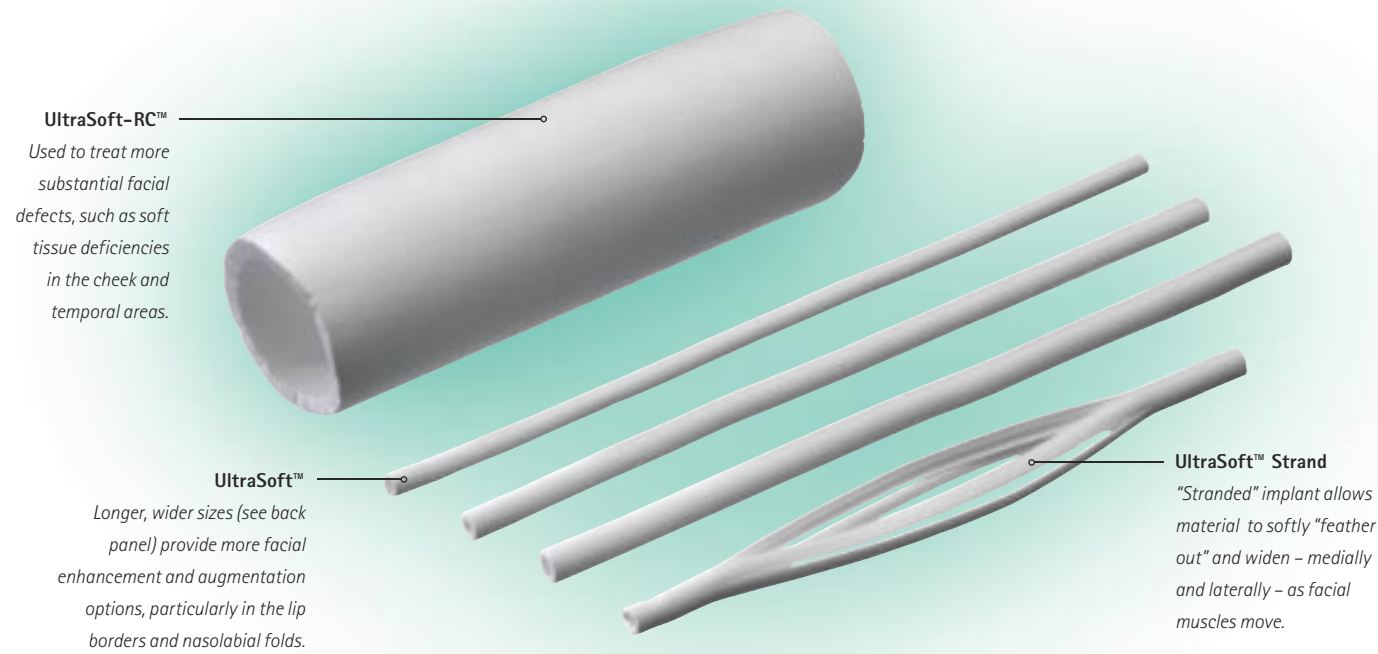
References:

Greene D, Pruitt L, Maas C. Biomechanical Effects of e-PTFE Implant Structure on Soft Tissue Implantation Stability: A Study in the Porcine Model. *The Laryngoscope*. July 1997; 107:957-962.



UltraSoft™ Facial Implants

The only no-touch system with a patented tubular design.



Enhanced patient comfort with superior stability through tissue ingrowth.

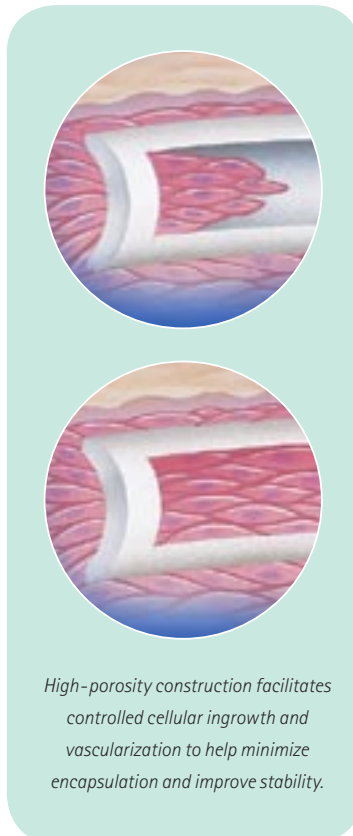
Give your patients the predictable, long lasting results they want with UltraSoft – the next generation soft facial implant.

UltraSoft implants are constructed of pure, supple, ePTFE polymer, a proven bio-compatible material with a soft, natural feel and 25-year history of physician success. UltraSoft's patented, tubular design encourages soft tissue ingrowth, which reduces palpability and promotes long-term stability. Each implant comes pre-loaded on a self-contained, no-touch delivery system that helps reduce infection risk and ensure accurate placement. Now, subdural delivery is almost as simple as administering an injection. Other advantages include:

- Very soft in-tissue profile
- Excellent post-surgical stability
- Various widths and lengths for a choice of augmentation levels
- Low rate of infection
- Permanent, yet reversible treatment option

Education and Support.

Peer observations and a preceptorship program are available. Ask your Integra Plastic and Reconstructive Sales Specialist for complete details.



The safe, soft, comfortable way to get long-term results.

UltraSoft™ and UltraSoft-RC™ (reconstructive) facial implants provide a safe, long-lasting treatment option for facial soft tissue augmentation. They may be indicated for areas with:

- Actual tissue loss
- Relative tissue deficiency
- Deep facial creases, such as nasolabial folds
- Oral commissures or deep glabellar furrows
- Deficiencies caused by trauma or medical conditions



UltraSoft
By providing subdural structure and support, UltraSoft enhances lip fullness and definition, and helps minimize adjacent, fine-vertical creasing.



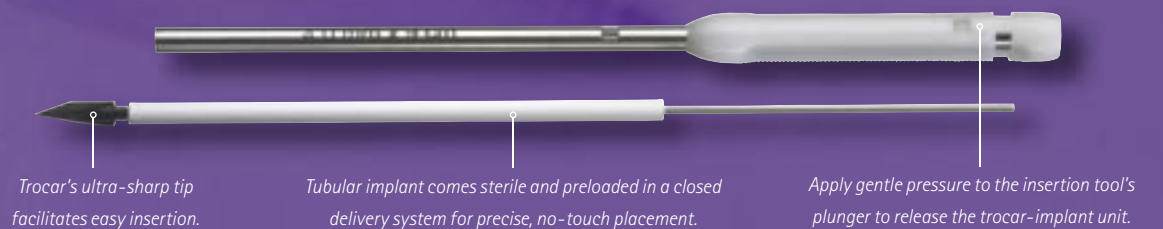
UltraSoft-RC
UltraSoft-RC implants are introduced subcutaneously to plump and correct furrows, nasal labial folds and marionette lines. UltraSoft-RC also helps reduce smile and frown lines, and to enhance the vermilion border.

"With UltraSoft, they've increased the size of the lumen... it's much softer and more pliable... and most importantly, more capable of movement with the face."

—Nicholas Lowe, M.D., F.R.C.P.
(Excerpted from *Cosmetic Surgery Times* Vol.5, 6|02.)

Patented, no-touch delivery system.

Each implant comes pre-loaded on a self-contained delivery system that helps reduce infection risk and ensures accurate placement.



Renew. Rejuvenate. Restore. With UltraSoft tubular implants... the shape of things to come.