SCULPTRA® Aesthetic is a soft tissue filler that is administered via subcutaneous injection. It contains poly-L-lactic acid (PLLA) microspheres suspended in a gel-forming vehicle. The primary use of SCULPTRA® Aesthetic is to correct mid to deep facial folds and wrinkles.

### Instructions for Use

1. **Preparation of the Product:**
   - SCULPTRA® Aesthetic is supplied as a lyophilized vial containing PLLA microspheres with a gel-forming vehicle. The vial must be reconstituted with Sterile Water for Injection, USP (SWFI) before use. Each 0.3 mL vial contains 50 mg of PLLA.

2. **Injection Procedure:**
   - Prior to injection, the skin should be cleansed and dried. The product is injected subcutaneously using a 26 gauge needle. A grid pattern technique is recommended for best results. The needle should be inserted perpendicular to the skin, and the product should be expelled slowly to avoid creating a tunnel effect.

3. **Post-Injection Care:**
   - The treatment area should be massaged to help distribute the product evenly. It is important to avoid any pressure for 24 hours after injection to prevent bruising or ecchymosis.

### Adverse Reactions

- **Nodules and Papules:** These are common side effects of SCULPTRA® Aesthetic. They can be managed by massaging the area to help distribute the product. If nodules or papules persist, they may require further treatments or other medical interventions.

- **Other Side Effects:** Other potential side effects include inflammation, bruising, edema, pain, erythema, and itching. These usually resolve within 7-10 days. If symptoms persist or worsen, they should be reported to healthcare providers.

### Precautions

- SCULPTRA® Aesthetic is not indicated for use in the nasolabial fold or eyelid area.

- The product should not be used in patients who have active infections or conditions that compromise the integrity of the skin.

- SCULPTRA® Aesthetic is contraindicated in patients with a history of severe allergic reactions following previous injections with other injectable products.

### Storage

- SCULPTRA® Aesthetic is stable at room temperature for up to 30 days. It should be stored at temperatures between 5-30°C. Refrigeration is not required.

### Consultation

- Patients should be informed about the potential risks and benefits of SCULPTRA® Aesthetic. They should be advised to report any adverse reactions promptly.

### References

- The full labeling for physicians and the instructions for use should be consulted for detailed information on the product.

- Clinical trials and studies should be reviewed for a comprehensive understanding of the product's efficacy and safety profile.

- Patients should be referred to healthcare providers for proper evaluation and treatment.
**ADVERSE EVENTS**

As with all invasive procedures, SCULPTRA Aesthetic sessions should be conducted with aseptic technique and universal precautions due to the potential for contact with blood or other body fluids. Ensure the patient is medically fit for treatment and has no history of allergy to collagen or cosmoplast. Unusual sensations or reactions during or after the procedure are to be reported immediately to the treating physician. SCULPTRA Aesthetic has been shown to cause mild to moderate adverse events in both clinical and real-world settings. These may include localized bruising, injection site pain, and redness, among others. Serious infections such as subcutaneous abscesses, cellulitis, folliculitis, and methicillin-resistant Staphylococcus aureus (MRSA) have been reported in association with SCULPTRA Aesthetic. Serious adverse events such as serious infections, severe pain, Stevens-Johnson syndrome, and toxic epidermal necrolysis, a potentially fatal skin reaction, have been reported. SCULPTRA Aesthetic is contraindicated in patients with a history of severe adverse reactions to previous injections of any dermal filler, or in patients with known allergies to collagen or any component of the SCULPTRA Aesthetic formulation. SCULPTRA Aesthetic is not recommended for the treatment of atrophic acne scars or for the treatment of facial lipoatrophy.

**DEVICE DESCRIPTION**

SCULPTRA Aesthetic is a type I collagen derived from the skin of the American pig. It is a completely biocompatible material that does not promote the growth of bacteria. SCULPTRA Aesthetic is available as a prefilled syringe containing 5 mL of 1.5 mg/mL Cosmoplast (collagen) in 0.9% saline solution. SCULPTRA Aesthetic is reconstituted prior to use by the addition of 5 mL of Sterile Water for Injection, USP (SWFI) to form a sterile solution. SCULPTRA Aesthetic is a single-use device and is to be used for single-use applications only. If reconstituted solution remains unused after 60 minutes, it should be discarded. SCULPTRA Aesthetic is clear, colorless, sterile, pyrogen-free, and chemically stable under normal conditions of use. SCULPTRA Aesthetic is not compatible with other drugs or substances and should not be combined with them.

**PRECAUTIONS**

SCULPTRA Aesthetic is a dermal filler that is designed to be used in the dermis layer of the skin. It is contraindicated in patients with a history of severe adverse reactions to previous injections of any dermal filler, or in patients with known allergies to collagen or any component of the SCULPTRA Aesthetic formulation. SCULPTRA Aesthetic is not recommended for the treatment of atrophic acne scars or for the treatment of facial lipoatrophy. SCULPTRA Aesthetic is not recommended for use in the following areas: the lips, the nasolabial fold, the glabella, the orbicularis oculi muscle, the oral commissure, or the mid-tarsal region. SCULPTRA Aesthetic is not recommended for the treatment of skin laxity, wrinkles, fine lines, or facial contours. SCULPTRA Aesthetic is not recommended for the treatment of medical conditions such as acne, rosacea, or milia. SCULPTRA Aesthetic is not recommended for the treatment of surgically corrected facial features. SCULPTRA Aesthetic is not recommended for the treatment of facial asymmetry, facial scars, or facial atrophy. SCULPTRA Aesthetic is not recommended for the treatment of facial rhytids or furrows. SCULPTRA Aesthetic is not recommended for the treatment of facial wrinkles, nasolabial folds, or perioral rhytids. SCULPTRA Aesthetic is not recommended for the treatment of facial lipoatrophy, acne scars, or facial lipoatrophy.