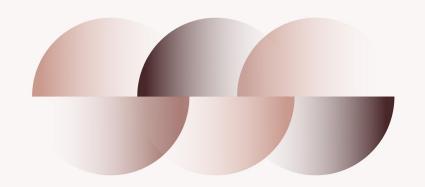


# START & Rising Star: Supporting you in your aesthetic training and early practice



### START



# Meet <u>Samples</u> for <u>Teaching in Aesthetic</u> <u>Residency Training</u> (START)

START is a product sampling program for US-based residents and fellows that provides samples for aesthetic injectable, surgical, and skincare training and education using Allergan Aesthetics products.

# What you get with START

START supports aesthetic residency or fellowship training and includes the following benefits:

#### Nonsurgical Program Specifics

Facial and injectable training samples for on-label use.



1 50 mL vial per quarter per resident

# JUVÉDERM®

1 box per quarter per resident per product



1 box per quarter per resident

#### SKINMEDICA\*

1 sample of each product every 6 months per resident

HA5 0.3 oz, AHA/BHA 1 oz, Even & Correct Serum 0.3 oz, + Scar Recovery Gel 0.5 oz

#### Surgical Program Specifics

For plastic surgery augmentation procedures only. Surgical program benefits apply to plastic surgery residents and fellows only.

Natrelle

8 gel breast implants per year per program Natrelle

16 single-use gel sizers per year per program REVOLVE

Advanced Adipose System

4 boxes (case of 1) per year per program



2 boxes (case of 5 in each box) per year per program

The START program calendar begins on July 1 of each year and ends on June 30 the following year.

All orders are on a first-come, first-served basis while supplies last. Samples and/or no-charge evaluation product are for trial and/or patient use in accordance with product labeling. HCP shall not seek reimbursement or payment from a patient or third-party payer for this product and agrees that this product will not be traded, sold, bartered for, or returned for credit.

Please see Indications and Important Safety Information, including Boxed Warning, for BOTOX® Cosmetic on page 12 and *Natrelle*® Breast Implants on page 13 and Indications and Important Safety Information for JUVÉDERM® Collection of Fillers on page 12, REVOLVE™ Advanced Adipose System on page 13, and SKINVIVE by JUVÉDERM® on page 14.

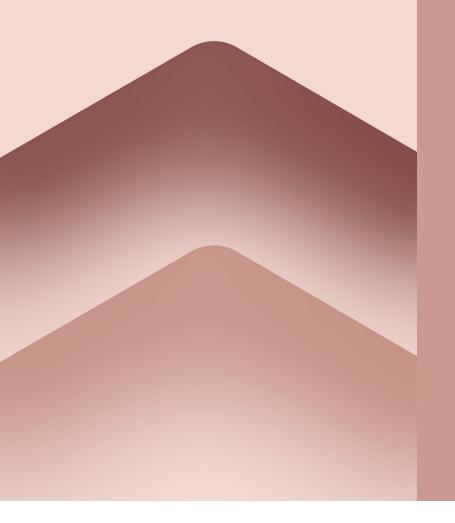
# Program Directors eligibility criteria:

- Licensed medical doctor (MD) or doctor of osteopathic medicine (DO)
- Work at an ACGME-accredited dermatology, plastic surgery, facial plastics, ophthalmology, or otolaryngology teaching program or a society-approved fellowship
- Have an office physically located at an academic institution
- Have a valid and current state license number
- Must be a plastic surgery program director to be eligible to receive surgical program benefits

Samples must be shipped to academic institutions or society-endorsed fellowships.

Program Directors are eligible to receive product samples for on-label training of US residents and fellows.







## How do you enroll in START?

For facial sample orders, please have the program director or coordinator call 1.866.866.2827.

For surgical samples, please contact your Hospital Surgical Sales Representative to ensure you receive the right products for your case.

Questions about START? Email STARTInfo@allergan.com.

Please see Indications and Important Safety Information, including Boxed Warning, for BOTOX® Cosmetic on page 12.



START participants have access to educational programs through:

#### Allergan Medical Institute

IN-PERSON

Knowledge and Education for Young Specialists (KEYS) A one-day program that offers injectable and surgical training in various cities.

Click here for KEYS

ONLINE

#### **AMI** Online

Full access to Allergan Aesthetics online educational content.\*

#### AMIOnline.com

Available aesthetic content includes:

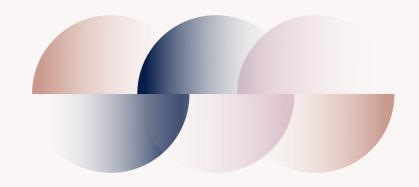
- Facial Injectables: Anatomy and injection techniques
- Skincare: Science and considerations
- Body Contouring: Provider training and best practices

AllerganSurgicalEducation.com In-depth surgical training and access to in-person, virtual, and on-demand programs.

AllerganSurgicalEducation.com

<sup>\*</sup> A customized link to access AMI Online is included in your START shipment confirmation. Please contact your Program Director for this information.





# Meet Rising Star, pricing benefits for aesthetic practices

Rising Star is a program that offers pricing benefits for US-based, board-eligible aesthetic physicians 0–24 months postresidency or postfellowship. This program is intended to support the growth of new aesthetic physicians by reducing up-front product costs to help you focus on establishing your aesthetics practice.



## Rising Star program details

#### Nonsurgical Program Specifics

Facial and injectable training samples for on-label use.



Contact Allergan Aesthetics Sales Representative for sample vials

# JUVÉDERM®

5 free boxes of each product with the purchase of 5 boxes (10 syringes) in any combination



5 free boxes with the purchase of 5 boxes (10 syringes)

#### SKINMEDICA®

20% off first order

#### Surgical Program Specifics

For plastic surgery augmentation procedures only.



\$250 per unit discount for the first 80 implants

Discounted price cannot fall below the minimum price for the product



\$50 per unit discount for the first 80 gel single-use sizers

Discounted price cannot fall below the minimum price for the product



1 free unit with the purchase of 1 unit, for the first 8 units purchased



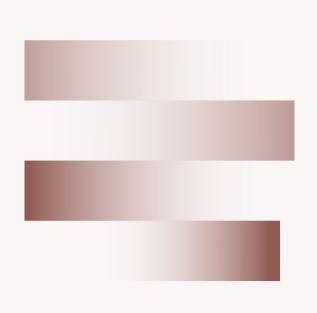
1 free box (case of 5) with the purchase of 1 box, for the first 4 boxes purchased

- Only licensed and eligible practitioners may receive samples at no charge. Sample use must be in accordance with product labeling. These samples are not to be traded, sold, bartered for, or returned for credit, payment, and/or reimbursement.
- Physician must purchase all product before receiving any free goods with the exception of REVOLVE™.
- Offers apply to JUVÉDERM®, SKINVIVE by JUVÉDERM®, and SkinMedica® and can only be used once and are not available for repeat orders. Discounts do not need to be applied to the first order.

Please see Indications and Important Safety Information, including Boxed Warning, for BOTOX® Cosmetic on page 12 and *Natrelle®* Breast Implants on page 13 and Indications and Important Safety Information for JUVÉDERM® Collection of Fillers on page 12, REVOLVE™ Advanced Adipose System on page 13, and SKINVIVE by JUVÉDERM® on page 14.



As a Rising Star plastic surgeon participant, you are eligible to receive one (1) *Natrelle®* Consultation Kit containing a set of breast forms designed to help prospective patients assess their volume options so they can picture their new look.



# How do you enroll in Rising Star?



#### Step 1:

Register at <u>AllerganRisingStar.com</u>. Discounts begin the day you register.

#### Step 2:

Create an account—call the ONE TEAM at (844) NEW-2AGN 844.639.2246

Discounts expire 12 months after registration, with the exception of the *Natrelle*<sup>®</sup> discount, KELLER FUNNEL<sup>®</sup> 2, and REVOLVE<sup>™</sup> System offers, which expire 3 years after initial registration.

Practitioners can join this program up to 24 months after they have graduated and joined or started their own practice.

Questions about Rising Star? Email RisingStar@allergan.com

Please see Indications and Important Safety Information, including Boxed Warning, for *Natrelle®* Breast Implants and Indications and Important Safety Information for REVOLVE™ Advanced Adipose System on page 13.

# Allergan Aesthetics: Supporting Your Aesthetic Practice

We will continue to support your aesthetic practices throughout your career.

Loyalty Programs

Patient Practice

#### Training

#### Allē

Allē allows patients to earn points on a variety of in-office products and treatments from over 50 brands. Patients are able to redeem points for savings on the Allergan Aesthetics portfolio of brands.

alle.com



Natrelle PERKS® is an offer exclusively for Allē Members who receive a breast augmentation with Natrelle® gel breast implants. Natrelle® breast augmentation patients are eligible to redeem a complimentary treatment from the Allergan Aesthetics portfolio.

natrellesurgeon.com/programs

#### ALLERGAN PARTNER APP

Allergan Partner Privileges® is our provider loyalty program that takes your practice to the next level. Earn rewards on Allergan Aesthetics portfolio purchases.

allerganadvantage.com

#### Allergan Medical Institute

Allergan Medical Institute® is committed to providing educational opportunities through a robust portfolio of medical education initiatives designed to advance techniques and achieve desired patient outcomes. Visit our website for on-demand peer-to-peer technique education.

Surgical – <u>AllerganSurgicalEducation.com</u>

Allergan Aesthetics Portfolio and product certifications – AMIOnline.com

#### **Business Efficiency Tools**

#### Advantage |

Allergan Aesthetics

Advantage is the online destination for Allergan Aesthetics! It's never been easier to gain insights into your practice, view personalized content curated just for you, and access your favorite Allergan Aesthetics products and programs.

allerganadvantage.com

#### **BrandBox**

BrandBox is a self-service portal to access ready-to-go Allergan Aesthetics marketing assets for your practice.

 $\underline{allerganbrandbox.com}$ 

#### Sind a Provider

Find a Provider is a practice locator tool that shares your practice's contact information with prospective patients.

allerganadvantage.com



Product Warranty Programs are available on select products to help protect your business.



Brilliant Connections™ is a proprietary platform that allows your practice to create a customized online e-commerce store for SkinMedica® products. Allergan Aesthetics manages all of the ordering, shipping, and overall management while you still earn Allergan Partner Privileges® credit.

Each loyalty program has applicable terms and conditions that are subject to change.

Please see Indications and Important Safety Information, including Boxed Warning, for Natrelle® Breast Implants on page 13.

#### **Practice Support**



Allergan Aesthetics Representatives are some of the most well-respected support personnel in the industry. They provide exceptional practice support through education, tools, and marketing materials customized to meet the needs of your practice.

Allergan Practice Consultants Allergan Digital Consultants

Industry-Leading Fee-for-Service Consulting Group offers practice management resources and guidance such as financial discipline, leadership development, and business planning. Digital experts assist practices with their online presence and digital marketing initiatives.



Allergan Data Labs™ drives patient awareness in our brands and grows the larger aesthetic market through the strategic deployment of digital campaigns. This in-house team also provides a variety of insights and tools for providers.

allergandatalabs.com



Customer Experience Team/ Web Services Support. Highly trained teams are available to support your practice by answering any questions or troubleshooting on all Allergan Aesthetics products, programs, and websites.

877.277.7764

#### BOTOX® Cosmetic (onabotulinumtoxinA) Important Information

#### INDICATIONS

BOTOX® Cosmetic (onabotulinumtoxinA) is indicated in adult patients for the temporary improvement in the appearance of:

- Moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity
- Moderate to severe lateral canthal lines associated with orbicularis oculi activity
- Moderate to severe forehead lines associated with frontalis activity

#### IMPORTANT SAFETY INFORMATION. INCLUDING BOXED WARNING

#### WARNING: DISTANT SPREAD OF TOXIN EFFECT

Postmarketing reports indicate that the effects of BOTOX® Cosmetic and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity, but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have an underlying condition that would predispose them to these symptoms. In unapproved uses and approved indications, cases of spread of effect have been reported at doses comparable to those used to treat cervical dystonia and spasticity and at lower doses

#### CONTRAINDICATIONS

BOTOX® Cosmetic is contraindicated in the presence of infection at the proposed injection site(s) and in individuals with known hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation.

#### WARNINGS AND PRECAUTIONS Lack of Interchangeability Between Botulinum Toxin Products

The potency units of BOTOX® Cosmetic are specific to the preparation and assay method utilized They are not interchangeable with other preparations of botulinum toxin products and, therefore, units of biological activity of BOTOX® Cosmetic cannot be compared to nor converted into units of any other botulinum toxin products assessed with any other specific assay method.

#### Spread of Toxin Effect

Please refer to Boxed Warning for Distant Spread of Toxin Effect.

No definitive serious adverse event reports of distant spread of toxin effect associated with dermatologic use of BOTOX® Cosmetic at the labeled dose of 20 Units (for glabellar lines), 24 Units (for lateral canthal lines), 40 Units (for forehead lines with glabellar lines), 44 Units (for simultaneous treatment of lateral canthal lines and glabellar lines), and 64 Units (for simultaneous treatment of lateral canthal lines, glabellar lines, and forehead lines) have been reported. Patients or caregivers should be advised to seek immediate medical care if swallowing, speech, or respiratory

Serious Adverse Reactions With Unapproved Use
Serious adverse reactions, including excessive weakness, dysphagia, and aspiration pneumonia, with some adverse reactions associated with fatal outcomes, have been reported in patients who received BOTOX® injections for unapproved uses. In these cases, the adverse reactions were not necessarily related to distant spread of toxin, but may have resulted from the administration of BOTOX® to the site of injection and/or adjacent structures. In several of the cases, patients had pre-existing dysphagia or other significant disabilities. There is insufficient information to identify factors associated with an increased risk for adverse reactions associated with the unapproved uses of BOTOX®. The safety and effectiveness of BOTOX® for unapproved uses have not been established.

#### Hypersensitivity Reactions

Serious and/or immediate hypersensitivity reactions have been reported. These reactions include anaphylaxis, serum sickness, urticaria, soft-tissue edema, and dyspnea. If such reactions occur, further injection of BOTOX® Cosmetic should be discontinued and appropriate medical therapy immediately instituted. One fatal case of anaphylaxis has been reported in which lidocaine was used as the diluent and, consequently, the causal agent cannot be reliably determined.

#### Cardiovascular System

There have been reports following administration of BOTOX® of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes Some of these patients had risk factors including pre-existing cardiovascular disease. Use caution when administering to patients with pre-existing cardiovascular disease

#### Increased Risk of Clinically Significant Effects With Pre-existing Neuromuscular Disorders

Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junction disorders (eg, myasthenia gravis or Lambert-Eaton syndrome) should be monitored when given botulinum toxin. Patients with neuromuscular disorders may be at increased risk of clinically significant effects including generalized muscle weakness, diplopia, ptosis dysphonia, dysarthria, severe dysphagia, and respiratory compromise from onabotulinumtoxinA (see Warnings and Precautions).

#### Dysphagia and Breathing Difficulties

Treatment with BOTOX® and other botulinum toxin products can result in swallowing or breathing difficulties. Patients with pre-existing swallowing or breathing difficulties may be more susceptible to these complications. In most cases, this is a consequence of weakening of muscles in the area of injection that are involved in breathing or oropharyngeal muscles that control swallowing or breathing (see Boxed Warning).

#### Pre-existing Conditions at the Injection Site

Caution should be used when BOTOX® Cosmetic treatment is used in the presence of inflammation at the proposed injection site(s) or when excessive weakness or atrophy is present in the target muscle(s).

#### Dry Eye in Patients Treated With BOTOX® Cosmetic

There have been reports of dry eye associated with BOTOX® Cosmetic injection in or near the orbicularis oculi muscle. If symptoms of dry eye (eg, eye irritation, photophobia, or visual changes) persist, consider referring patients to an ophthalmologist.

#### Human Albumin and Transmission of Viral Diseases

This product contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases and variant Creutzfeldt-Jakob disease (vCJD). There is a theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD), but if that risk actually exists, the risk of transmission would also be considered extremely remote. No cases of transmission of viral diseases, CJD or vCJD have ever been identified for licensed albumin or albumin contained in other licensed products

The most frequently reported adverse reactions following injection of BOTOX® Cosmetic for glabellar lines were eyelid ptosis (3%), facial pain (1%), facial paresis (1%), and muscular weakness (1%).

The most frequently reported adverse reaction following injection of BOTOX $^{\circ}$  Cosmetic for lateral canthal lines was evelid edema (1%)

The most frequently reported adverse reactions following injection of BOTOX® Cosmetic for forehead lines with glabellar lines were headache (9%), brow ptosis (2%), and eyelid ptosis (2%).

#### DRUG INTERACTIONS

Co-administration of BOTOX® Cosmetic and aminoglycosides or other agents interfering with neuromuscular transmission (eg, curare-like compounds) should only be performed with caution as the effect of the toxin may be potentiated. Use of anticholinergic drugs after administration of BOTOX® Cosmetic may potentiate systemic anticholinergic effects.

The effect of administering different botulinum neurotoxin products at the same time or within several months of each other is unknown. Excessive neuromuscular weakness may be exacerbated by administration of another botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin

Excessive weakness may also be exaggerated by administration of a muscle relaxant before or after administration of BOTOX $^{\circ}$  Cosmetic.

#### USE IN SPECIFIC POPULATIONS

There are no studies or adequate data from postmarketing surveillance on the developmental risk associated with use of BOTOX® Cosmetic in pregnant women. There are no data on the presence of BOTOX® Cosmetic in human or animal milk, the effects on the breastfed child, or the effects on milk production.

Please see BOTOX® Cosmetic full Prescribing Information including Boxed Warning and Medication Guide.

#### JUVÉDERM® Collection of Fillers Important Information

#### INDICATIONS

JUVÉDERM® VOLUMA® XC injectable gel is indicated for deep (subcutaneous and/or supraperiosteal) injection for cheek augmentation to correct age-related volume deficit in the mid-face and for augmentation of the chin region to improve the chin profile in adults over the age of 21

JUVÉDERM® VOLUX® XC injectable gel is indicated for subcutaneous and/or supraperiosteal injection for improvement of jawline definition in adults over the age of 21 with moderate to severe loss of jawline definition.

JUVÉDERM® VOLLURE® XC injectable gel is indicated for injection into the mid-to-deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds) in adults over the age of 21

JUVÉDERM® VOLBELLA® XC injectable gel is indicated for injection into the lips for lip augmentation and correction of perioral rhytids, and for the improvement of infraorbital hollowing in adults over the

JUVÉDERM® Ultra Plus XC and JUVÉDERM® Ultra XC injectable gels are indicated for injection into the mid-to-deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds)

JUVÉDERM® Ultra XC injectable gel is also indicated for injection into the lips and perioral area for lip augmentation in adults over the age of 21.

#### IMPORTANT SAFETY INFORMATION

#### CONTRAINDICATIONS

These products should not be used in patients who have severe allergies, marked by a history of anaphylaxis or history or presence of multiple severe allergies, and should not be used in patients with a history of allergies to Gram-positive bacterial proteins or lidocaine contained in these products.

- Do not inject into blood vessels. Introduction of these products into the vasculature may lead to embolization, occlusion of the vessels, ischemia, or infarction. Take extra care when injecting soft tissue fillers; for example, after insertion of the needle and just before injection, the plunger rod can be withdrawn slightly to aspirate and verify the needle is not intravascular, inject the product slowly, and apply the least amount of pressure necessary. Rare, but serious, adverse events associated with the intravascular injection of soft tissue fillers in the face have been reported and include temporary or permanent vision impairment, blindness, cerebral ischemia or cerebral hemorrhage leading to stroke, skin necrosis, and damage to underlying facial structures. Immediately stop the injection if a patient exhibits any of the following symptoms: changes in vision, signs of a stroke, blanching of the skin, unusual pain during or shortly after the procedure. Patients should receive prompt medical attention and, possibly, evaluation by an appropriate healthcare professional specialist should an intravascular injection occur
- Product use at specific sites in which an active inflammatory process (skin eruptions such as cysts, pimples, rashes, or hives) or infection is present should be deferred until the underlying process has been controlled

#### **PRECAUTIONS**

To minimize the risk of potential complications, these products should only be used by healthcare professionals who are knowledgeable about the anatomy and the product(s) for use in indicated area(s), and who have appropriate training in facial anatomy, vasculature, safe injection techniques, and identification and management of potential adverse events, including

- The potential risks of soft tissue injections should be discussed with patients prior to treatment to ensure they are aware of signs and symptoms of complications
- The safety and effectiveness for the treatment of anatomic regions other than indicated areas for each product have not been established in controlled clinical studies
- The safety for use of these products in patients with known susceptibility to keloid formation. hypertrophic scarring, and pigmentation disorders has not been studied
- The safety for use during pregnancy and in breastfeeding females has not been established
- The safety for use of JUVÉDERM® VOLUMA® XC has been established in patients between 35 and 65 years of age for cheek augmentation, 22 and 80 years of age for chin augmentation, and 32 and 82 years of age for improvement of temple hollowing
- The safety for use of JUVÉDERM® Ultra Plus XC and JUVÉDERM® Ultra XC in patients under 18 years, and the safety for use of JUVÉDERM® VOLLUX® XC, JUVÉDERM® VOLLURE® XC, and JUVÉDERM® VOLBELLA® XC in patients under 22 years, has not been established
- Dermal filler implantation carries a risk of infection. Follow standard precautions
- Dermal fillers should be used with caution in patients on immunosuppressive therapy
- Patients taking medications that can prolong bleeding (such as aspirin, nonsteroidal anti-inflammatory drugs, and warfarin) may experience increased bruising or bleeding at treatment sites
- Patients who experience skin injury near the site of implantation may be at a higher risk for adverse events
- If laser treatment, chemical peel, or any other procedure based on active dermal response is considered after treatment, or before skin has healed from a procedure prior to treatment, there is a possible risk of eliciting an inflammatory reaction at the injection site
- The safety for use of JUVÉDERM® VOLUMA® XC injectable gel in patients with very thin skin in the mid-face has not been established
- The safety of using a cannula with JUVÉDERM® VOLUMA® XC for cheek augmentation in patients with Fitzpatrick Skin Types V and VI or to improve temple hollowing has not been established
- JUVÉDERM® VOLUMA® XC was not evaluated in subjects with significant skin laxity of the chin, neck, or jaw in the chin augmentation study
- The effect of JUVÉDERM® VOLUMA® XC injection into the chin on facial hair growth has not been studied
- Patients may experience late-onset adverse events with injectable gel implants, and late-onset nodules with use of JUVÉDERM® VOLUMA® XC
- Based on preclinical studies, patients should be limited to 20 mL of any JUVÉDERM $^\circ$  injectable gel per 60 kg (132 lb) body mass per year. The safety of injecting greater amounts has not been established
- Injection of more than 9 mL of JUVÉDERM® VOLUX® XC for improvement of jawline definition has not been studied

The most common reported side effects for JUVÉDERM® injectable gels were redness, swelling, pain, tenderness, firmness, lumps/bumps, bruising, discoloration, and itching. For JUVÉDERM<sup>®</sup> VOLBELLA<sup>®</sup> XC, dryness was also reported. The majority were mild or moderate in severity.

To report an adverse reaction with any product in the JUVÉDERM® Collection, please call Allergan® Product Support at 1-877-345-5372. Please visit rxabbvie.com for more information.

Products in the JUVÉDERM® Collection are available only by a licensed physician or properly licensed practitioner

#### Natrelle® Breast Implants Important Safety Information

- Breast implants are not lifetime devices. The longer patients have them, the greater the chance they will develop complications, which may require more surgery.
- Breast implants have been associated with a cancer of the immune system called breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). Some patients have died from BIA-AI CI
- Patients have also reported a variety of systemic symptoms, such as joint pain, muscle aches, confusion, chronic fatigue, autoimmune diseases, and others. Some patients report complete resolution of symptoms when the implants are removed without replacement.

#### INDICATIONS

Natrelle® Breast Implants are indicated for women for the following:

• Breast augmentation for women at least 22 years old for silicone-filled implants and breast

- augmentation for women at least 18 years old for saline-filled implants. This includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of a primary breast augmentation surgery
- Breast reconstruction. This includes primary reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. Breast reconstruction also includes revision surgery to correct or improve the result of a primary breast reconstruction surgery

#### CONTRAINDICATIONS

- Breast implant surgery should not be performed in:

  Women with active infection anywhere in their body
- Women with existing cancer or precancer of their breast who have not received adequate treatment for those conditions
- Women who are currently pregnant or nursing

#### ADDITIONAL WARNINGS

- See Boxed Warning
- Avoid damage during surgery: Care should be taken to avoid the use of excessive force and to minimize handling of the implant. Forcing of implants through too small an opening or applying concentrated localized pressure on the implants may result in localized weakening of the breast implant shell, potentially leading to shell damage and possible implant rupture. An incision should

- be of appropriate length to accommodate the style, size, and profile of the implants. Use care when using surgical instruments in proximity with the breast implant
- Follow recommended fill volumes for saline implants to decrease possibility of shell wrinkling

#### PRECAUTIONS

Safety and effectiveness have not been established in patients with the following:

- Autoimmune diseases (eg, lupus and scleroderma)
- A compromised immune system (eg, currently receiving immunosuppressive therapy)
- Planned chemotherapy or radiation following breast implant placement
- Conditions or medications that interfere with wound healing and blood clotting
- Reduced blood supply to breast tissue
- Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder and eating disorders. Please discuss any history of mental health disorders prior to surgery. Patients with a diagnosis of depression, or other mental health disorders, should wait until resolution or stabilization of these conditions prior to undergoing breast implantation surgery

#### ADVERSE EVENTS

Possible adverse events with breast implant surgery include implant rupture with silicone implants, implant deflation with saline-filled implants, capsular contracture, reoperation, implant removal, pain, changes in nipple and breast sensation, infection, scarring, asymmetry, wrinkling, implant displacement/migration, implant palpability/visibility, breastfeeding complications, hematoma/ seroma, implant extrusion, necrosis, delayed wound healing, infection, breast tissue atrophy/chest wall deformity, calcium deposits, and lymphadenopathy. Other systemic conditions have been reported with breast implants.

For more information, please see the full Directions for Use at www.allergan.com/products.

To report a problem with Natrelle® Breast Implants, please call Allergan® at 1-800-624-4261.

The sale and distribution of this device is restricted to users and/or user facilities that provide information to patients about the risks and benefits of this device in the form and manner specified in the approved labeling provided by Allergan®.

#### REVOLVE™ Advanced Adipose System Indications and Important Safety Information

#### INDICATIONS

The REVOLVE™ Advanced Adipose System (REVOLVE™ System) is used for aspiration, harvesting, filtering, and transferring of autologous adipose tissue for aesthetic body contouring. This system should be used with a legally marketed vacuum or aspirator apparatus as a source of suction. If harvested fat is to be re-implanted, the harvested fat is only to be used without any additional manipulation. REVOLVE™ System is intended for use in the following surgical specialties when the aspiration of soft tissue is desired: plastic and reconstructive surgery, gastrointestinal and affiliated organ surgery, urological surgery, general surgery, orthopedic surgery, gynecological surgery, thoracic surgery, and laparoscopic surgery.

#### IMPORTANT SAFETY INFORMATION

#### CONTRAINDICATIONS

Contraindications to autologous fat transfer include the presence of any disease processes that adversely affect wound healing, and poor overall health status of the individual.

#### WARNINGS

REVOLVE<sup>TM</sup> System must be used within the same surgical procedure. Reuse of this device in the same patient in a subsequent surgical procedure, or for more than one patient, may result in infection and/or transmission of communicable diseases. Do not use the product if sterile packaging is damaged.

This device will not, in and of itself, produce significant weight reduction. This device should be used with extreme caution in patients with chronic medical conditions such as diabetes, heart, lung, or circulatory system disease or obesity. The volume of blood loss and endogenous body fluid loss may adversely affect intra and/or postoperative hemodynamic stability and patient safety. The capability of providing adequate, timely replacement is essential for patient safety.

#### **PRECAUTIONS**

REVOLVE<sup>TM</sup> System is designed to remove localized deposits of excess fat through small incision and subsequently transfer the tissue back to the patient. Use of this device is limited to those physicians who, by means of formal professional training or sanctioned continuing medical education (including supervised operative experience), have attained proficiency in suction lipoplasty and tissue transfer. Results of this procedure will vary depending upon patient age, surgical site, and experience of the physician. Results of this procedure may or may not be permanent. The amount of fat removed should be limited to that necessary to achieve a desired cosmetic effect. Filling the device with adipose tissue over the maximum fill volume line can lead to occlusion of the mesh resulting in mesh tear.

#### ADVERSE EFFECTS

Some common adverse effects associated with autologous fat transfer are asymmetry, over-and/or under-correction of the treatment site, tissue lumps, bleeding, and scarring. Potential adverse effects associated with REVOLVE™ System include fat necrosis, cyst formation, infection, chronic foreign body response, allergic reaction, and inflammation.

REVOLVE™ System is available by prescription only

For more information, please see the <u>Instructions for Use (IFU)</u> and <u>User Manual</u> for REVOLVE™ System available at www.allergan.com/REVOLVEIFU or call 1.800.678.1605.

To report an adverse reaction, please call Allergan at 1.800.367.5737.

#### SKINVIVE by JUVÉDERM® Injectable Gel Important Information

#### INDICATIONS

SKINVIVE by JUVÉDERM® injectable gel is indicated for intradermal injection to improve skin smoothness of the cheeks in adults over the age of 21.

#### IMPORTANT SAFETY INFORMATION

#### CONTRAINDICATIONS

This product should not be used in patients who have severe allergies, marked by a history of anaphylaxis or history or presence of multiple severe allergies, and should not be used in patients with a history of allergies to Gram-positive bacterial proteins or lidocaine contained in this product.

#### WARNINGS

- Do not inject into blood vessels. Introduction of this product into the vasculature may lead to embolization, occlusion of the vessels, ischemia, or infarction. Take extra care when injecting soft-tissue fillers; for example, after insertion of the needle and just before injection, the plunger rod can be withdrawn slightly to aspirate and verify the needle is not intravascular, inject the product slowly, and apply the least amount of pressure necessary. Rare, but serious, adverse events associated with the intravascular injection of soft-tissue fillers in the face have been reported and include temporary or permanent vision impairment, blindness, cerebral ischemia or cerebral hemorrhage leading to stroke, skin necrosis, and damage to underlying facial structures. Immediately stop the injection if a patient exhibits any of the following symptoms: changes in vision, signs of a stroke, blanching of the skin, unusual pain during or shortly after the procedure. Patients should receive prompt medical attention and, possibly, evaluation by an appropriate healthcare professional specialist should an intravascular injection occur
- Product use at specific sites in which an active inflammatory process (skin eruptions such as cysts, pimples, rashes, or hives) or infection is present should be deferred until the underlying process has been controlled
- Injection site responses consist mainly of short-term inflammatory symptoms and generally resolve within 1 week. Refer to the ADVERSE EVENTS

#### PRECAUTIONS

- To minimize the risk of potential complications, this product should only be used by healthcare
  professionals who have appropriate training, experience, and who are knowledgeable about the
  anatomy at and around the site of injection
- Discuss all potential risks of soft tissue injections with patients prior to treatment and ensure
  patients are aware of signs and symptoms of potential complications
- Limit patients to 20 mL of any JUVÉDERM® injectable gel per 60 kg (130 lbs.) body mass per year. The safety of injecting greater amounts has not been established
- This product is intended for improving skin smoothness and fine lines of the cheeks. The safety
  and effectiveness of use in other areas of the body have not been established
- Injection of more than 6.0 mL of this product (initial and touch-up treatment combined) for improvement of skin smoothness and fine lines of the cheeks has not been studied
- · As with all transcutaneous procedures, injections of the product carry a risk of infection
- The safety for use during pregnancy, in breastfeeding females, and in patients under 22 years has not been established
- The safety in patients with known susceptibility to keloid formation, hypertrophic scarring, or pigmentation disorders has not been studied
- This product should be used with caution in patients on immunosuppressive therapy
- Patients taking medications that can prolong bleeding (such as aspirin, nonsteroidal anti-inflammatory drugs, and warfarin) may experience increased bruising or bleeding at treatment sites
- Patients may experience late onset AEs with use of injectable gel implants, including this product
- This product should only be used by healthcare professionals who have appropriate experience and who are knowledgeable about the anatomy and the product for use in the face
- If laser treatment, chemical peel, or any other procedure based on active dermal response is
  considered after treatment, or before skin has healed from a procedure prior to treatment, there
  is a possible risk of eliciting an inflammatory reaction at the injection site

#### ADVERSE EVENTS

In clinical studies, injection site responses (ISRs) observed in >5% of treated subjects included redness, lumps/bumps, swelling, bruising, pain, tenderness, firmness, discoloration, and itching. Most ISRs were mild. Adverse events reported through postmarketing surveillance outside of the United States included inflammatory reaction, inflammatory nodule, unsatisfactory result, loss/lack of correction, allergic reaction, anxiety, vascular occlusion, infection, dry skin, increase/decrease in sensation, and abscess.

To report an adverse reaction with SKINVIVE by JUVÉDERM®, please call the Allergan® Product Support Department at 1-877-345-5372. Please see Directions for Use or visit <u>SKINVIVEDFU.com</u> for more information.

 ${\sf SKINVIVE}\ by\ {\sf JUV\'EDERM}^{\scriptsize @}\ is\ available\ only\ by\ a\ licensed\ physician\ or\ properly\ licensed\ practitioner.$ 

#### SkinMedica®

Most SkinMedica® products are intended to meet the FDA's definition of a cosmetic product, an article applied to the human body to cleanse, beautify, promote attractiveness, and alter appearances. These SkinMedica® products are not intended to be drug products that diagnose, treat, cure, or prevent any disease or condition. These products have not been approved by the FDA and the statements have not been evaluated by the FDA.

