

INFORMED CONSENT FOR  
**FILLER INJECTION**

**BELLAFILL**  
**BELOTERO PRODUCTS**  
**JUVEDERM PRODUCTS**  
**RADIESSE**  
**RESTYLANE PRODUCTS**  
**SCULPTRA**  
**VERSA PRODUCTS**

(PLEASE READ THIS DOCUMENT, INITIAL THE BOTTOM OF EACH PAGE  
AND SIGN THE LAST TWO PAGES)

PATIENT NAME \_\_\_\_\_

**KAROL A GUTOWSKI, MD**  
**ANDREA MARTIN, MD**  
**(THE PHYSICIANS)**

## **INSTRUCTIONS**

This is an informed-consent document which has been prepared to help inform you concerning a soft tissue filler injection, its risks, and alternative treatments. It is important that you read this information carefully and completely. Please initial each page, indicating that you have read the page and sign the consent for this procedure.

## **INTRODUCTION**

Dermal and soft tissue fillers are injected to temporarily correct wrinkles. They add volume, thereby filling lines, wrinkles, and folds from the inside out. Treatment results are immediate. After the first treatment, additional treatment(s) with filler may be needed to achieve the desired level of correction. The need for additional treatments varies from patient to patient. Over time, the filler will gradually break down and be absorbed by your body, depending on the type of filler. As a result, injections will need to be repeated to maintain the desired effect. Depending on the filler used, the results can last from 3 months up to 5 years. Some fillers have lasted longer than 5 years and may be permanent.

## **ALTERNATIVE TREATMENTS**

Alternatives include not performing the treatment at all. Other alternative treatments which vary in discomfort, effect and duration include animal derived filler products, fillers derived from the patient's own fat tissues, synthetic plastic or silicone permanent implants or toxins that can paralyze muscles that cause some wrinkles.

**Disclaimer of "Off-Label" use** - Each filler is FDA approved for use in the specific areas of the face. However, once a product is FDA approved, it may be used in other areas of the face and body, as determined by a medical professional. Therefore, any filler injection may include off-label use in an effort to give the best result possible.

## **RISKS OF DERMAL & SOFT TISSUE FILLERS**

Every procedure involves a certain amount of risk, and it is important that you understand the risks involved. An individual's choice to undergo this procedure is based on the comparison of the risk to potential benefit. Although most patients do not experience the following complications, you should discuss each of them to make sure you understand the risks, potential complications, and consequences of dermal fillers.

**Pain** - Fillers are injected into the skin using a fine needle to reduce injection discomfort. You may choose to anesthetize the treatment area either topically, with a local block or both. Please consult your physician about pain management. Tenderness is occasionally experienced and is usually temporary, resolving in 2 to 3 days.

**Skin Disorders** - It is common to have a temporary redness, bruising and swelling following a treatment. This will usually subside in the first few hours after a session but may last for several days to a week. Minimize exposure of treated areas to excessive sunlight, UV lamp exposure, and extreme cold weather until any swelling and redness have disappeared. Avoid use of alcohol for the next 24 hours. While very rare, scarring can occur following treatment. Also, fillers should not be used in patients with a known potential for keloid formation or heavy scarring. Some fillers may produce nodules under the skin which might be seen or felt by the patient. In rare cases, an inflammatory granuloma may develop, which could require surgical removal of the filler. You may also notice a bluish hue of your skin where the filler was injected.

**Bleeding and bruising** - Pinpoint bleeding is rare but can occur following treatments. Bruising is seen on occasion following treatments. Rarely, bruising can last for weeks or months and might even be permanent. Patients using Aspirin, Ibuprofen, Advil, Motrin, Nuprin, Aleve, garlic, Gingko Biloba, Vitamin E, or blood thinners have an increased risk of bleeding or bruising at the injection site.

**Unsatisfactory results** - There is the possibility of a poor or inadequate response from dermal fillers. There might be an uneven appearance of the face with some areas more affected by the filler than others. In most cases, this uneven appearance can be corrected by more injections in the same or nearby areas. In some cases, though, this uneven appearance can persist for several weeks or months. The practice of medicine and surgery is not an exact science. Although, good results are expected, there is no guarantee or warranty expressed or

implied, on the results that may be obtained. The use of laser treatments on top of the injection sites carries the risk of lessening or loss of the filler.

**Allergic reactions** - Fillers should not be used in individuals with a known previous history of reactions. In rare cases, local allergies to tape, preservatives used in cosmetics or topical preparations have been reported. Systemic reactions (which are more serious) may result from prescription medicines.

**Infection** - Although infection following dermal filler injections is unusual, bacterial, fungal, and viral infections can occur. Additional treatments or antibiotics may be needed. Most cases are easily treatable but, in rare cases, permanent scarring in the area can occur. If you have a history of herpes simplex in the area to be treated, we recommend prophylactic antivirals before and after injection around the mouth.

**Swelling** - Some swelling (edema) is common after any injection and tend to resolve in a few hours. In some cases, swelling may last for a few days and rarely, there may be prolonged swelling lasting a few weeks or months.

**Lumps and tissue irregularities** - Some lumps or irregularities are possible but usually resolve with time or gentle massage. In rare cases, long-term lumps (granulomas) may occur requiring treatment.

**Need for reversal of injection** - If you are not satisfied with the result, some fillers can be "undone" with an injection of hyaluronidase, which dissolves the filler. This may require an extra payment. Radiesse, Bellafill, and Sculptra CANNOT be dissolved.

**Damage to deeper structures**- Deeper structures such as nerves, blood vessels, and the eyeball may be damaged during the injection. Injury to deeper structures may be temporary or permanent. This may result in skin loss causing wounds, scar, and deformity. Blindness is possible.

**Migration of filler** - The product may migrate from its original injection site to other areas and produce unintended effects.

**Eye Disorders**- Functional and irritative disorders of eye structures may rarely occur following filler injections.

**Asymmetry** - The human face and eyelid region is normally asymmetrical with respect to structural anatomy and function. There can be a variation from one side to the other in terms of the response to filler injection.

**Pain**- Discomfort associated with filler injections is usually short duration.

**Skin disorders**- Skin rash and swelling may rarely occur following filler injection.

**Unknown risks**-The long-term effect of filler on tissue is unknown. There is the possibility of additional risks and risk factors may be discovered.

**Unsatisfactory result**-There is the possibility of a poor or inadequate response from filler injection. Additional filler injections may be necessary. Surgical procedures or treatments may be needed to improve results after filler injection.

**Long-term effects**- Subsequent alterations in appearance may occur as the result of aging, weight loss or gain, sun exposure, or other circumstances not related to filler injections. Filler injection does not stop the aging process or produce permanent tightening of the skin. Future surgery or other treatments may be necessary.

**Pregnancy and nursing mothers**- Animal reproduction studies have not been performed to determine if filler injections could produce fetal harm. It is not known if filler material can be excreted in human milk.

**Blindness**- Blindness is extremely rare after filler injections. However, it can be caused by internal bleeding around the eyeball or due filler material traveling in a blood vessel to the eye. The occurrence of this is very rare.

### **HEALTH INSURANCE**

Most health insurance companies exclude coverage for cosmetic surgical procedures and treatments or any complications that might occur from the same. Please carefully review your health insurance subscriber information pamphlet.

### **ADDITIONAL TREATMENT NECESSARY**

There are many variable conditions in addition to risk and potential complications that may influence the long-term result of filler injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with filler injections. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or other treatments may be necessary. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained.

### **FINANCIAL RESPONSIBILITIES**

The cost of injection may involve several charges. This includes the professional fee for the injections, follow up visits to monitor the effectiveness of the treatment, and the cost of the material itself. It is unlikely that injections to treat cosmetic problems would be covered by your health insurance. Additional costs of medical treatment would be your responsibility should complications develop from filler injections.

### **DISCLAIMER**

Informed-consent documents are used to communicate information about the proposed treatment of a condition along with disclosure of risks and alternative forms of treatment(s). The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances.

However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined based on all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

### **DURATION OF RESULTS**

While exact duration of filler effects cannot be promised, typical results are as follows:

**BELLAFILL** - 2 to 5 years, may be longer or permanent

**BELOTERO** - 3 to 9 months

**JUVEDERM PRODUCTS** - 6 to 9 months

**RADIESSE** - 9 to 12 months

**RESTITLANE PRODUCTS** - 6 to 9 months

**SCULPTRA** - 1 to 2 years

**VERSA PRODUCTS** - 6 to 9 months

**It is important that you read the above information carefully and have all your questions answered before signing the consent on the next page.**

**CONSENT FOR SURGERY/ PROCEDURE or TREATMENT**

1. I hereby authorize The Physicians and such assistants as may be selected, to perform the following procedure or treatment:

**Dermal & Soft Tissue Filler Injection  
BELLAFILL, BELOTERO PRODUCTS, JUVEDERM PRODUCTS,  
RADIESSE, RESTYLANE PRODUCTS, SCULPTRA, VERSA PRODUCTS**

I have received the following information sheet:  
**INFORMED-CONSENT for FILLER INJECTION**

2. I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risks, and the possibility of complications or injury.
3. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
4. I consent to the photographing or video recording of the procedure to be performed, including appropriate portions of my body, for medical, scientific, or educational purposes, provided my identity is not revealed by the pictures.
5. For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.
6. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:  
a. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN  
b. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT  
c. THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-6). I AM SATISFIED WITH THE EXPLANATION.

\_\_\_\_\_  
Patient or Person Authorized to Sign for Patient

\_\_\_\_\_  
Witness

Date \_\_\_\_\_

## AUTHORIZATION & CONSENT FOR RELEASE OF MEDICAL IMAGES

It is important that you read this information carefully and completely. After reviewing, please sign the consent as proposed by The Physicians or their representatives.

### INTRODUCTION

For your medical records, images (photographs, slides, videos, interviews or any other images of you, or components of your medical record) may be taken before, during, or after a surgical procedure or treatment. These images may be needed to document your medical condition, used as supporting material for authorizing medical coverage and payments, and treatment planning. Consent is required to take, use and release such images. Since The Physicians are also educators of other physicians, researchers, and healthcare professionals, your images may be used for other purposes as described below.

### 1. CONSENT TO TAKE PHOTOGRAPHS, SLIDES, DIGITAL IMAGES, AND VIDEOGRAPHY

I hereby authorize The Physicians and/or their associates to take any images before, during and after my treatments or surgeries.

### 2. CONSENT FOR RELEASE OF PHOTOGRAPHS/SLIDES/VIDEOGRAPHY

I hereby authorize The Physicians and their associates to use any of these images for professional medical purposes deemed appropriate including but not limited to showing these images on public or commercial television, electronic digital networks including the internet, print or visual or broadcast media, for purposes of examination, testing, credentialing and/or certifying purposes for medical education, patient education, lay publication, or during lectures to medical or lay groups, for marketing and advertising, and for use in medical teaching, research or dissemination of medical information to medical and nonmedical audiences, including, but not limited to, journal or book publications, presentations, conferences, and print marketing material (magazine, newspaper, etc) or electronic media (television, internet, etc).

### 3. CONSENT FOR RELEASE TO PROFESSIONAL ORGANIZATIONS

I further authorize The Physicians and their associates to release such images to the American Society of Plastic Surgeons (ASPS), the American Society for Aesthetic Plastic Surgery (ASAPS), the American Board of Plastic Surgery (ABPS), the American Academy of Facial Plastic and Reconstructive Surgery (AAFPRS), and the American Board of Facial Plastic and Reconstructive Surgery (ABFPRS). I provide this authorization as a voluntary contribution in the interests of public education. The images may be used for publication in print, visual or electronic media, specifically including, but not limited to, medical journals (such as *Plastic and Reconstructive Surgery*, *Annals of Plastic Surgery*, *Aesthetic Plastic Surgery*), textbooks, lay publications, patient education or during lectures for the purpose of informing the medical profession or the public about plastic surgery methods, medical education or examination material by ASPS, ASAPS, ABPS, AAFPRS and ABFPRS. I understand that such images shall become the property of ASPS, ASAPS, ABPS, AAFPRS and ABFPRS and may be retained or released by these organizations for the limited purpose mentioned above. I also grant permission for the use of any of my medical records including illustrations, photographs, video, or other imaging records created in my case, for use in examination, certifying and/or re-certifying purposes by ABPS and ABFPRS.

I understand that I will not be identified by name in any release of these materials but in some cases the images may contain features that may make my identity recognizable. I release and discharge The Physicians and all parties acting on their authority from all rights that I may have in these images, and from any claims that I have related their use in the above-mentioned manner.

I also release The Physicians and any employees or agents from all liability, including any claims of libel or invasion of privacy, directly or indirectly connected with, arising out of or resulting from the taking and authorized use of these images or recorded interviews.

I understand that I have the right to request cessation of recording or filming at any time. I understand that I will not be entitled to monetary payment or any other consideration as a result of any use of these images and /or my interview.

Patient Name \_\_\_\_\_

**Patient Signature** \_\_\_\_\_

Witness or Guardian/Parent \_\_\_\_\_

Date \_\_\_\_\_

Date \_\_\_\_\_