

## INTRODUCTION

The use of PRP in aesthetic procedures is widely accepted and practiced throughout the US aesthetic market. More recently, some practitioners have used a heated form of PRP to convert the PRP into a gel-like, autologous substance before re-injecting it, to obtain immediately visible volumizing effect that can last for up to three months before gradually being reabsorbed by the body.

## ABOUT THE PROCEDURE

The technique comprises the typical withdrawal of the patient's own blood and processing it by centrifuge to isolate the platelet rich plasma for use. The target plasma itself separates into platelet rich and platelet poor plasma. Ordinarily the poor plasma is discarded once the platelet rich plasma is drawn off for use. In the present procedure, the poor plasma is gently water-heated to 100° Centigrade, transforming it from a liquid to a gel. The plasma gel is allowed to cool and is then re-mixed with the platelet rich plasma to form an injectable gel PRP, one that both volumizes and retains the rejuvenating benefits of PRP. The procedure typically takes about an hour and may involve an aesthetic topical cream, injections, or sedation according to the treatment parameters and the licensed practitioner's discretion.

## INFORMED CONSENT

I was told about the possible side effects of the procedure, including: skin redness, mild bruising, bleeding, pain, itching at the injection site, visible papules, transitory skin discoloration, hypopigmentation, temporal or permanent hyperpigmentation, local heat, swelling, allergic reactions, infection at the injection site, septicemia, damage to a nerve or muscle, headache, nausea, vomiting, dizziness, fainting, lack of efficacy or worsening of the original condition, vascular occlusion and its consequences, necrosis, permanent scars, blindness, thromboembolism and its consequences, product migration to different areas than the injected area, and facial asymmetry. Any adverse reaction should be reported immediately.

I understand that a full course of treatment may involve multiple sessions, according to treatment parameters and individual response and that I must comply with the agreed upon treatment schedule, otherwise results may be compromised.

I recognize that during the course of the procedure unforeseen conditions may necessitate different procedures than this above and I authorize the licensed practitioner or assistants to perform such other procedures if they find them professionally desired.

I understand that not everyone is a candidate for this treatment and results may vary. Therefore, there is no guarantee as to the results that may be obtained.

## ALTERNATIVE TREATMENT

Alternative treatments to Cellenis Derma™ may include the use of dermal fillers, blocking injections such as Botox, routine skin care, oral and/or topical prescription and/or non-prescription medications, microneedling, laser treatments, and even cosmetic/plastic surgery. Each of these alternatives carry their own inherent risks and benefits. However, since this treatment is elective and is done for cosmetic purpose only, no treatment at all should also be considered a viable alternative.

## ALLERGIC REACTION

An allergic reaction from Cellenis Derma™ is not likely given the autologous nature of the procedure, i.e., the use of your own blood. If an allergic reaction were to occur, you must contact our office immediately, as it may require further treatment.

## LACK OF PERMANENT RESULT

The Cellenis Derma™ will not completely or permanently volumize your skin. It is important that your expectations should be realistic and that you understand the procedure has its limitations and duration. Additional, complementary, or combination therapies or procedures may be necessary to achieve or maintain a desired effect.

## UNSATISFACTORY RESULT

Like any cosmetic procedure, there is the possibility of a poor or disappointing result from the Cellenis Derma™. There is no absolute guaranty of outcome or product efficacy. That said, our the Cellenis Derma™ is designed to deliver results and changes to your appearance consistent with what we typically describe or discuss with our patients.

## CELLENIS DERMA ACKNOWLEDGEMENT AND RELEASE

By signature below, I acknowledge that I have read and understand the content of this informed consent. I have been given a reasonable opportunity to ask questions, all of which have been answered in a satisfactory manner to me. I understand that results can vary and that no guarantee, neither expressed nor implied, has been or will be given to me regarding my results. I am aware of the risks and benefits associated with the Cellenis Derma procedure, as well as available alternative treatments. I understand that Cellenis Derma is an elective procedure, performed solely for cosmetic purposes, and is not critical to my health. On my own free will, I am requesting and providing my informed consent, to undergo Cellenis Derma treatment(s) by \_\_\_\_\_ [AND/OR] at the office located at \_\_\_\_\_

I assume all risks as my own and hereby release and agree to hold harmless, Aesthetic Management Partners, LLC, their providers, estheticians, and any other staff member, affiliate, or independent contractor from any liability, both seen and unforeseen, now and forever arising from my treatment.

\_\_\_\_\_  
PATIENT SIGNATURE

\_\_\_\_\_  
PRINT NAME

\_\_\_\_\_  
DATE

**FDA CLEARANCE:** CELLENIS PRP IS DESIGNED TO BE USED FOR THE SAFE AND RAPID PREPARATION OF AUTOLOGOUS PLATELET-RICH-PLASMA (PRP) FROM A SMALL SAMPLE OF PERIPHERAL BLOOD AT THE PATIENT POINT OF CARE. THE PRP IS MIXED WITH AUTOGRAFT AND/OR ALLOGRAFT BONE PRIOR TO APPLICATION TO A BONY DEFECT FOR IMPROVING HANDLING CHARACTERISTICS.