Information and Consent for Intracel

Important Background to the Consent Process

Your clinician wishes to help you make an informed decision about your treatment options and any relevant alternative options. You may at any time decline treatment even after giving your consent.

Whilst your clinician will make every effort to understand what significance you would attach to any particular risk it is important to us that you feel comfortable enough to question the clinician on any point of concern during this process. Please feel you have as much time as you wish to reflect on the information given before agreeing to proceed with the treatment.

Purpose of Treatment

You have presented with concerns which have formed the basis of a clinical discussion and examination. The purpose of the proposed treatment is to address your concerns either individually or in combination with other modalities of treatment.

Outcomes

Your clinician will endeavour in good faith to employ the principles of best practice in delivering your treatment. Each patient is individual and response to treatment will vary from patient to patient and treatment to treatment. As such it is difficult to guarantee outcomes will always meet your expectations.

Background Information

Intracel utilises fractional radiofrequency ("RF") microneedling technology; an innovative design that uniquely treats the target area through rapid penetration of specially designed insulated micro-needles without causing extensive damage to the epidermis. Through the action of the microneedles, a tiny column is created in the skin that stimulates natural growth factors facilitating healing. Fractional RF thermolysis selectively damages specific collagen thus promoting the construction of new collagen as well.

Clinical studies suggest that an effective treatment regimen is three to four sessions with acne scarring requiring significantly more treatments. These treatments will be spaced approximately 4-6 weeks apart. Each treatment session targets 15 to 20 % of the skins surface, outlining the need for successive treatments. Your consultant will tailor a specific programme to treat your individual needs.

Commonly Experienced Adverse Events

Moderate level of discomfort, sharp, and/or burning sensations
Skin redness
Skin induration
Superficial crusting / blanching
Pinpoint bleeding

Onset of Herpes Simplex Virus infection in susceptible individuals
Swelling
Folliculitis

Less Common Risks

Hyperpigmentation
Hypopigmentation
Scarring
Infection
Itching/Tingling/numbness
Acne or Milia formation/dermal atrophy or depression are rare risks that cannot be prevented or predicted and may require additional treatment

Important Considerations

Every care is taken to deliver the treatment in a manner which will minimise risk, however you should be aware of the risks, as one may exist upon which you place particular significance.
Patients are advised to take in to account all these potential risks before consenting to treatment. Please make your clinician fully aware of your expectations prior to giving consent.

Safety Profile

Intracel treatment can be performed in your doctor's office. It is a powerful device and treatment must be carried out by a trained and experienced practitioner to ensure that the correct area is treated at the correct levels.

Contraindications and Relative Contraindications to Treatment

Recent sunburn, sun tan, or sun exposure prior to treatment
If you are pregnant, or breastfeeding
Hypopigmentation
History of keloid scarring
Severe dermatitis, active inflammatory acne, or eczema (in treated area)
Active infections
Accutane use within the last 6 months without physician approval
Uncontrolled diabetes
Use of topical Vitamin A derivative medications within the last 3 days
Presence of a pacemaker or defibrillator
History of Herpes Simplex Virus infection (cold sores)

Limited or no clinical data exists regarding the efficacy and tolerance of this treatment in patients having a history of, or currently suffering from, auto-immune disease, auto-immune deficiency, or being under immunosuppressive therapy. The clinician shall therefore decide on the indication on a case by case basis according to the nature of the disease and its treatment and the need for monitoring post-treatment. Your clinician will discuss the need for a preliminary skin testing for hypersensitivity if necessary, or in the case of patients with severe or multiple allergies.

Your clinician will also discuss the suitability of treatment having considered your medical history and any medications you currently take, as appropriate. As such, it is imperative you disclose such medications at the time of your treatment.

Additional Information

Due to the nature of the procedure, a topical anaesthetic may be applied for at least an hour before treatment. You will be monitored during this time to ensure the anaesthetic cream does not adversely affect your blood pressure. During the treatment you will experience a mild prickling sensation across the skin as the treatment head is passed over the area. This increases with the number of passes, the skin can be cooled during treatment to make the experience tolerable. The levels of treatment can be adjusted to suit patient comfort. Occasionally a regional block will be performed to improve your comfort.

Post Treatment

There may be some tenderness, redness and swelling to the site, this is very normal and usually subsides within a few days. Bruising is an occasional outcome and generally resolves It is advisable to avoid extreme temperatures until tenderness and redness subsides. Similarly, strenuous exercise and alcohol would best be avoided for 24 hours. Retinol products (Retin A) are strongly suggested to use for optimal results. These can commence 48-72 hours post treatment, or when redness and inflammation have settled. You should avoid direct/excessive sun exposure for 10 days. A sunscreen of SPF 30 or higher should be used daily and applied every 3-2 hours to assure the skin is protected.

It is important to let your clinician know prior to treatment if you have important work or social engagements which may cause you embarrassment should you bruise excessively. Please ask your clinician for an after care sheet which will give important contact details and a summary of our advice. Please do not hesitate to contact us should you have any concerns post treatment.

Should you feel unwell following your procedure it is important to seek specialist medical advice immediately. In the first, instance call our Clinical Team on one of the following numbers. Occasionally, the phone will be directed to our emergency out of hours service who will contact Dr Curran or another member of the clinical team. Dr. John Curran can also be contacted directly in the event of an emergency or difficulty getting in contact with the clinic.

Jersey 01534 625090 Guernsey 01481 736699 Belfast 02890 319060 (Mon-Fri 08.00 to 17.30)
Dr Curran's Mobile 07781 165797

Consent Statement for Intracel

Consent Confirmation

To help us assess that we have listened to, and responded to, your concerns and preferences and have given you sufficient information in the way that you want and can understand it would be helpful to confirm the following statements:

1. I can confirm that I understand the treatment proposed and any relevant alternatives and I am willing to proceed.

2. I have had sufficient time to appreciate the risks involved and in particular I can confirm the clinical team/clinician has worked with me to understand and discuss those risks to which I would attach particular significance.

3. I am of the opinion that my request for treatment is for medical reasons and/or the personal psychological features that are associated with my request. I have expressed my thoughts and feelings to the treating doctor and consent to the treatment for the purpose of restoring and maintaining the health and my psychological wellbeing.

4. I have read this in conjunction with the information provided and I have had the potential risks and side effects associated with my treatment fully explained to me.

5. I acknowledge and understand that no guarantee or assurance can be made on the results I will get from the treatment.

6. I consent to the taking of photographs in the course of this procedure for the purpose of assessing my progress.

7. I am satisfied that I have sufficient knowledge of the treatment to give informed consent.

Patient has confirmed via E-Signature:

I confirm that I have discussed the treatment plan with the above patient and undertake treatment with the purpose of restoring or maintaining health, including the psychological wellbeing of my patient. I also confirm that I accept duty of care for my patient and the standard of care as set out by the GMC in Good Medical Practice/NMC Guidelines. In doing so, I recognise my primary purpose and undertaking is to place the health and wellness of my patient as my first concern.

Clinician has confirmed via E-Signature: