Skin repigmentation, e.g. due to non-progressive vitiligo or hypochromic post-traumatic scars.

A NEW APPROACH TO VITILIGO

ViticeLL®

Giving Colors Back To Life

Laboratoires GENÉVRIER

ViticeLL®

a new approach to vitiligo

Vitiligo affects between 0.5 and 2% of the general population [1]. This skin condition is characterised by its visibility when certain parts of the body are affected. Its effects on quality of life and self-esteem are now widely recognised [1]. Patients live with the fear of it worsening, accompanied by a feeling of anger, embarrassment or shame [1]. For more than one in four patients, vitiligo has repercussions on their social life [1]. The prevalence of alexithymia is up to 24% and that of depression may reach 39% [1]. The impact of the condition is such that one study has shown that, in women, it is comparable to that of psoriasis [2].

Moreover, standard treatments are not without problems. The recent European recommendations from the European Dermatology Forum in 2013 reiterate the need to avoid the use of topical corticosteroids on the face, that calcineurin inhibitors still benefit from only a limited number of quality studies, and that phototherapy remains long and demanding [3].

In this context, an autologous graft is a particularly interesting therapeutic option in the case of stable, segmental or focal pattern vitiligo. Various studies show significant repigmentation in more than 70% of patients treated [4], the best results reaching 84% in the case of segmental vitiligo [5].

Strictly limited to a hospital environment for a long time, this technique is now available in independent practice so that the best of the latest technologies can give patients suffering from vitiligo their colours of life back.

1) Sampogna F *et al.* Identification of categories at risk for high quality of Life impairment in patients with vitiligo. Brit. J Dermatol 2008 159, pp351-359.
2) Ongenae K *et al.* Effect of vitiligo on self-reported health-related quality of Life. Brit J Dermatol 2005 152, pp1165-1172.
3) Taieb A *et al.* Guidelines for the management of vitiligo: the European Dermatology Forum consensus. Brit Ass Dermatol 2013 168, pp5-19.
4) Gauthier Y, Benzekri L. Non-cultured epidermal suspension in vitiligo: From laboratory to clinic. Indian J Dermatol Venereol Leprol 2012;78:59-63.
5) Mulekar SV. Long-term Follow-up Study of Segmental and Focal Vitiligo Treated by Autologous, Noncultured Melanocyte-Keratinocyte Cell Transplantation. Arch Dermatol. 2004;140:1211-1215.

ViticeLL®

giving colors back to life

Viticell® is a medical device that makes **autologous grafting possible at the patient's convenience.** It is indicated for skin **repigmentation,** e.g. due to **non-progressive vitiligo** or for **hypochromic post-traumatic scars.**

From a thin skin biopsy (0.2-0.3 mm thick), Viticell® disaggregates the tissue to generate a cell suspension consisting of a mixed population of cells, mainly basal keratinocytes but also Langerhans cells, melanocytes and fibroblasts.

From a biopsy of 4-10 cm^2 of thin skin, Viticell® makes it possible to graft a surface area of 5 to 10 times greater, i.e. **20-100 cm^2** .

Viticell® provides the reagents and equipment needed to prepare an autologous epidermal cell suspension to be applied dropwise to the surface being treated.

Viticell® should be used under medical recommendation. The skin biopsy, the handling and application of the autologous cell suspension for therapeutic purposes must be conducted by a physician in accordance with current legislation.

* The surface to be treated should not exceed this ratio of 10; the recommended ratio being 5 times the size of the biopsy.

Viticell® in practice

Viticell® is a **single-use,** self-contained device for the preparation of an autologous cell suspension to reseed a patch of depigmented skin after dermabraison.

The Viticell® device should be handled on a prepared sterile area.

Once opened, Viticell® must be used immediately and disposed of after use.

In order to maximise cell viability, the biopsy should be processed immediately after removal and used for grafting as soon as possible. Do not use disinfectants containing ammonium salts on the skin to be treated.

The cell suspension is only to be used on the patient the biopsy was taken from.

Contraindications

The cell suspension should not be applied on to an infected or necrotic wound.
Viticell® should not be used in patients who are hypersensitive to hyaluronic acid or trypsin.

Storage

Viticell® should be stored between **2 and 8 C.**
The components of the device should be stored in their packaging until use;. The enzyme is highly sensitive to light and should be kept in its original vial.

Viticell®

the device

Viticell® is a *Class III* medical device consisting of reagents and ancillary equipment: enzyme solutions and application solutions, sterile instruments. The device also includes a portable instant heat pack containing a saturated aqueous sodium acetate solution which generates heat when it crystallises.

Viticell kit components:

4 pre-filled syringes for the cell suspension and for application containing:

- 1 Digesting buffer DB
- 1 Wasing buffer WB
- 1 Collecting buffer CB
- 1 Hyaluronic acid HA

1 vial containing trypsin
1 compartmentalised Petri dish for digestion and washing
1 empty container for the cell suspension
3 x 18G transfer needles
1 instant heat pack

All components of the kit are sterile apart from the heat pack. The components are identified by a coloured patch with the initials (in English) of the contents.

Other equipment required

In addition to a suitable sterile surgical sheet, preparing the graft and applying it require sterile gloves, sterile tweezers, a sterile scalpel, eye protection and protective clothing. Other instruments necessary for the biopsy are a dermatome and associated equipment (a sterile surgical knife and tweezers), antiseptic, sterile saline, instruments for dermabrasion and dressings (both primary and secondary).

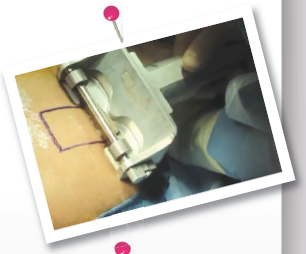
How to use ViticeLL®

1. Preparation of the patient

- The area from which the graft is to be removed should be disinfected and, if necessary, anaesthetised (subcutaneously if possible).

2. Preparation of the digestion solution

- The device should be brought to room temperature 30 minutes before use. The components of the kit are arranged on a sterile surgical area.
- Prepare the digestion solution by injecting the contents of the syringe containing the digesting buffer into the vial containing the digesting cocktail.
- Mix and transfer into one of the compartments of the Petri dish.
- Activate the heat pack by pressing on the metal button in the centre of the heat pack. Place the Petri dish on it.



3. Skin biopsy

- Take a thin skin biopsy (0.2 – 0.3 mm thick) with a surface area of 4-10 cm^2 from the donor site (the pigmentation and texture of which should be similar to those of the treatment site). Use of a dermatome is recommended.
- Clean the donor site with an antiseptic solution then rinse with a sterile saline solution.
- Dress the donor site as usual.

4. Enzymatic digestion of the biopsy

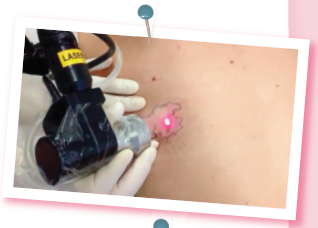
- Transfer the biopsy into the compartment of the Petri dish containing the digestion medium. Close the dish and leave it on the warm heat pack for 15 minutes.

5. Rinsing and disaggregation

- Place the rinsing medium into the second compartment of the Petri dish. Rinse the biopsy in the washing buffer for a few seconds.
- Remove the biopsy and place it inside the lid of the Petri dish with the dermo-epidermal junction upwards.
- Separate the dermis from the epidermis using tweezers and scalpel.

6. Collection of the epidermal cells

- Cover the biopsy fragments with collecting buffer
- Scrape the cells from the junction surface with a scalpel and cut the epidermal part coarsely to obtain a mixture of cells.
- Collect the cell suspension in the provided container.



7. Preparation of the site to be treated

- The site to be treated should be abraded using a laser or another suitable method.
- The area should be disinfected in advance and anaesthetised as required.

8. Performance of the cell suspension

- Resuspend the hyaluronic acid solution into the cell suspension
- Mix and collect the cell suspension in the syringe in two batches (the syringe volume not being sufficient to collect the entire suspension).

9. Application of the cell suspension

- Place the suspension dropwise onto the area to be treated. **Do not inject the cell suspension.**

10. Post-operative care

- Apply a non-adhesive fine-mesh dressing with low absorptive capacity to prevent the wound drying out. The dressing should be kept on for one week.
- A secondary dressing may be applied.
- Phototherapy may be considered one month after the grafting.

For complete information, refer to the instructions for use

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