

The biotechnology RIGENERA® for tissue micro-grafts in regenerative medicine.



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The genesis of Rigenera® : The first studies that led to the development of Rigenera® technology date back to 2006 and were conducted by two Italian researchers, Dr. Antonio Graziano and Dr. Riccardo D'Aquino during their PhD program in Biotechnology applied to stem cells. Rigenera® is a Class I medical device manufactured in Italy by [HBW](#), worldwide patented and marketed all over the world. [TiRigenera](#) is in charge of the distribution of the device and it is supported by a local medical Faculty which is responsible for the methodology.

The Rigenera® system has been marketed since 2013 and in recent years it is becoming increasingly successful in the European and International market. Although Rigenera® technology was born from dental surgeries, today it is applied in many areas of regenerative medicine such as in the treatment of wound healing in reconstructive plastic surgery. Moreover it is widely used in aesthetic medicine for the treatment of androgenetic alopecia and in the skin rejuvenation.



What is Rigenera® : Rigenera® is a mechanical disaggregator of biological tissues (i.e. dermis, connective tissue, bone tissue, dental pulp and cartilaginous tissue) able to autologously, homologously and minimally invasively obtain micrografts. The device is made up of a 100-hole steel grid on which six micro-scalpel are inserted and of a filter that allows the selection of cells

with a diameter of about 50 microns. In vitro studies have shown that the cell population obtained after the mechanical disgregation of different tissues is made up of cell progenitors with a vitality of over 90%. Both of these properties are at the basis of the regenerative potential of micro-grafts.

A great advantage in using Rigenera® is that the collection, processing and implantation of micro-grafts take place at the same surgical time, where donor and recipient are in fact the same person.

The Rigenera® method does not involve any risk for the patient as it is mini-invasive and it involves taking small pieces of skin, even in case of large lesions ([see the tutorial for hair restoration application](#))

Methodic is simple and with low risk : The invasiveness of medical treatment is minimal as Rigenera® technology is a single application without additional dressings (no pharmaceutical products, no chemical products) except for physiological solution. Similarly, there is no risk to the staff, as the use is simple and intuitive and it is applicable also in the outpatient clinic. Training and learning is a short process and basically involves a training session of the procedure by the product specialist.

Micro-graft drives the tissue regeneration : Rigenera® offers the advantage of obtaining calibrated 50-70 microns micro-grafts, immediately ready for use by bypassing the step of culturing and expanding in vitro. The cells' sizes are important in the regenerative medicine because numerous scientific evidence show that cell progenitors are localized in the "side population". This subgroup is characterized by 'steminality', that is the ability to replicate and differentiate in different cell types.

Cell death in grafts vs micro-grafts : A problem associated with traditional tissue grafts is the high death rate of progenitors cells due to the breakdown of blood vessels during the recovery process of the grafts themselves. Rigenera® technology overcome this issue because the fast mechanical fragmentation of the tissues, in order to obtain cells, does not influence cell viability as shown in several articles published in recent years (*Finding et al., JCP 2015, Monti et al., JCP 2017*).

Legal aspects : From a legal point of view, the characteristics of the product lead to the following remarks:

- ≡ it is a micro fractured / micro disrupted human tissue containing, among other substances, autologous adult cells
- ≡ tissue removal from the patient and minimal manipulation occurring during surgery
- ≡ donor and recipient are the same person

Based on the above aspects, it is clear that:

- ≡ the tissue is not subject to significant manipulation;
- ≡ the tissue fraction is used in a single surgical time, so that banking is avoided
- ≡ the doctor obtains an autologous product that can be used without constraints as a self-sealing graft

Conclusions : Micro-grafts is a key technique in tissue regeneration because it is the **fastest and most effective way for clinical use of stem cells**. Micro-graft can be obtained easily and safely using the Rigenera® tissue breaker, which is based on an exclusively mechanical action, at a single surgical time, without the addition of any chemical or pharmaceutical element, and which does not apply significant manipulation that legally limits its use. Rigenera® is today the only class 1 medical device with CE and FDA certification that allows the preparation of microinstructions through a mechanical process for tissue regeneration treatments.

Rigenera® is protected by a worldwide patent: it is a unique medical device in the world. It is one of the great novelties in regenerative medicine that has already demonstrated its effectiveness in dealing with wound healing in reconstructive plastic surgery and in the care of androgenetic alopecia in aesthetic medicine. Moreover it begins to demonstrate extraordinary results in parallel fields such as regeneration of cartilage in orthopedics.

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