

2 COMPANIES IN 1 LEGAL ENTITY



WHO ARE WE?



Human Brain Wave (**HBW**) Srl was founded by Dr. Antonio Graziano and Dr. Riccardo D'Aquino in year 2012.

HBW is a science driven company and a medical device manufacturing company, owner of patented Rigenera® Technology, breakthrough innovation in regenerative medicine.

The sale and marketing activity are managed by "Regenera Activa Worldwide SRL", a company founded by Alexandre Andreu (CEO) and Dr. Jose Miguel Casanova (Medical Director), which is the responsible for the worldwide distribution network and evolution of new clinical protocols known as AMT- Autologous Micrografting Technology protocols.

"Innovation & technology to transform patient's experience"





Dr. Antonio Graziano CEO HBW & Inventor of the Rigenera® technology

- Graduated in Dentistry at S.U.N. Dental school in 2004, and PhD in Biotechnology applied to dentistry in 2007
- Associate editor of World Journal of Stem Cell and Journal of Stem Cells Reviews and Reports
- Co-author of several scientific publications in peer reviewed journals in the field of dentistry and > 60 publications related to regenerative medicine since 2003
- Owner of Graziano D'Aquino associate office, a center or regenerative medicine in Turin and co-founder of Rigenera Napoli, a center of regenerative medicine in Naples
- Honored with the S.H.R.O. (Sbarro Health Research Organization) award as "Campanian Excellence in the Medica Field" in 2017 and Forbes CEO Italian Awards 2021 for the healthcare sector
- Executive Director of SHRO Italia ETS Foundation
- Appointed President of the Italian Export Forum (IEF) of Piedmont Region in 2021





INNOVATION IS IN OUR DNA









WE ARE THE FIRST AND TRUE ORIGINALS

THE ONLY PROVEN AUTOLOGOUS MICROGRAFTING PROCEDURE

WE ARE SCIENCE

+80 SCIENTIFIC PUBLICATIONS

WE ARE SAFETY

+450k successful procedures

WE ARE QUALITY

+10 YEARS OF INNOVATION & EXPERTISE

UNLOCKING THE POTENTIAL OF REGENERATIVE MEDICINE





FDA Listed,
FMA approved,
CE certified





MEDICAL CERTIFICATIONS



60

COUNTRIES we commercialize in



PHYSICIANS using the technology



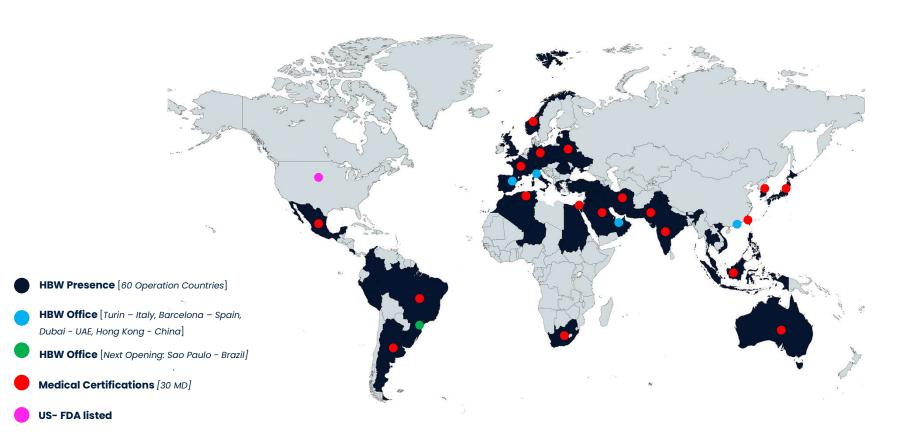
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OFFICES around the world

• Sterile Medical Class IIa Device (according to Regulation (EU) MDD 93/42, rule n. 2)

GLOBAL PRESENCE WITH SIGNIFICANT GROWTH OPPORTUNITIES





ITALY PTP site - Polo Tecnologico Piemontese





- New building Polo Tecnologico Piemontese (PTP) that hosts our production, laboratories and offices;
- Theoretical and practical lessons here in Italy with our selected professors and surgeons;
- Convention and conferences rooms for dedicated events;
- Small clinic for simple surgery trainings;
- Team always available to support partners and in contact with world wide's HBW collaborators;
- Legal site of the SBARRO Health Research Organization ETS Italia*
 (June 2023), Italian Branch of the SHRO US division.

^{*} The Foundation aims to develop scientific research in the field of regenerative medicine, precision and oncology with projects of specialization and scientific training. In addition, it aims to promote knowledge of regenerative medicine in all its forms and potential.

SBARRO Health Research Organization









Sbarro Health Research Organization – SHRO US

SHRO is a nonprofit charity committed to funding excellence in basic genetic research to cure tand diagnose cancer, cardiovascular diseases, diabetes and other chronic illnesses and to foster the raining of young doctors in a spirit of professionalism and humanism.



SHRO includes the Sbarro Institute for Cancer Research and Molecular Medicine, located at Temple University in Philadelphia, (PA)



SHRO affiliated laboratory located at the University of Siena, (IT)



Over 200 SHRO molecular biologists, geneticists, physicists, and chemists work to develop new methods to understand, diagnose and cure disease.

MISSION AND CORPORATE VISION





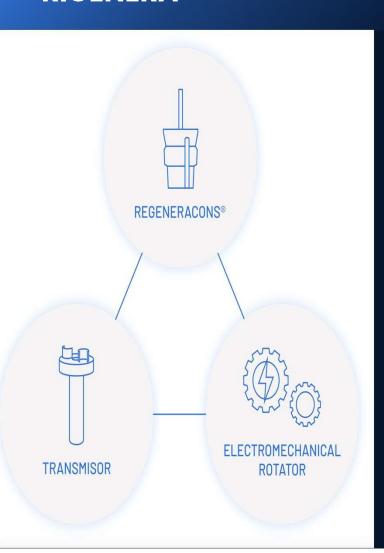
"HBW's mission is to develop and promote innovative regenerative technology easily accessible by patients and healthcare professionals.

The company invests in extensive research & development of innovative medical technology."

- Attentive to future trends in the global market
- Team in constant contact with KOLs, reference Hospitals, Universities and Research Groups Worldwide
- Participation in main international congresses
- · Continuous training and updating to experts
- In vitro and in vivo clinical studies carried on together with referenced institutions
- Positioning guided by continuing medical education
- Safety Treatments, Improved Regenerative Medicine & Personalized Therapy

RIGENERA®

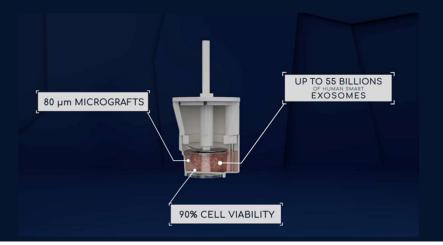




WHAT WE DO?

HBW's core business is based on the production of **RIGENERA®** technology composed by a medical device "Rigeneracons", a specific electromechanical rotor and related accessorizes (Sicurlid, base and Sicurstick, adaptor) to connect the device to the motor.

Thanks to this Technology, we're able to generate through mechanical disaggregation a micrografting suspension (MICROGRAFTS) from autologous and homologous tissue, without enzymes and/or additives using a sterile, disposable medical device.



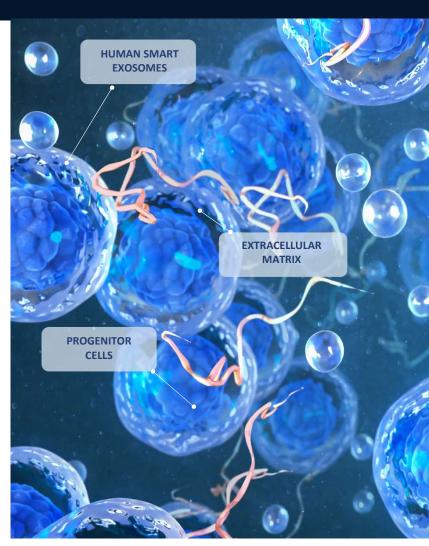
THE SCIENCE BEHIND RIGENERA® TECHNOLOGY



Rigenera® is a **cutting-edge system** based on the controlled mechanical disaggregation of human tissues within the "**Rigeneracons**" disposable and sterile medical device operating at **80 rpm** with **torque of 15 [N*m]**.

This technology allows the **extraction** of **AMT** (Autologous Micrografting Technology) **Triad**, an exclusive tissue-specific micrograft suspension with a unique unaltered composition of **Progenitor Cells (PC)**, **Human Smart Exosomes** vescicles and **Extra-Cellular Matrix (ECM)**.

When AMT Triad is engrafted in the damaged area, it unlocks and boosts the full potential of the body's innate healing capabilities for **personalized** and **advanced regenerative results**.



ADVANTAGES



WHY CHOOSING RIGENERA® TECHNOLOGY















Only one session required

Proven efficacy

No manipulation

No rejection risk, safe

Autologous and Homologous

Minimally invasive











* Patient's own tissue (autologous) without enzymes or additives.

Sample tissue type of the tissue to be treated (homologous)

Quick preparation and easy application method

30 MINUTES

Local anesthesia

No extra equipment/no special preparation

High cell viability

Costeffectiveness

CLINICAL APPLICATIONS





AESTHETIC MEDICINE

- Surgical, traumatological and acneic scars
- Androgenetic
 Alopecia (AGA)
- Preventive treatment for hair thickening
- Skin rejuvenation
- Vitiligo



WOUND HEALING

- Non-healing wounds (acute and chronic)
- Post surgical dehiscences
- Post traumatic wounds
- Vascular or diabetic ulcers
- Burns



ORAL & MAXILLOFACIAL

- Periodontal regeneration
- Sinus lift augmentation
- Socket preservation
- MaxillaryOsteonecrosis
- Soft tissue regenerations



ORTHOPEDIC

- Osteonnecrosis
- Chondropathy
- Cartilage defects
- Sports injuries & pain management

PRODUCT PORTFOLIO











RIGENERACONS

Multiple product codes (different technical features) specific for various application lines

Disposable Class IIa Medical Device specifically designed for the disaggregation of soft or hard tissues to obtain injectable micrografts solution. The use of this Rigeneracons provides **different valumes (mL) of filtered and concentrated micrografts solution.**

Every device:

- owns a grid with 100 hexagonal holes
- any hole is embraced by six micro-blades designed for efficient cutting of hard and soft tissues
- the calibrated holes act as a filter by selecting only the particles and cells smaller than $80~\mu m$







ACCESSORIZES

Sicurlid (Base) – Sicurstick (Adaptor)





Machine N4SA & SICURDRILL

80 rpm rotor machine meant for efficient tissue mechanical disaggregation

MORE PROJECTS



Rigenera® Technology as technique for promoting and monitoring tissue repair and regeneration in micro-gravity (stressed) conditions

WOUND HEALING IN SPACE





"The exploration of space will go ahead, whether we join in it or not, and it is one of the great adventures of all time."

John F. Kennedy

R&D PROJECTS a)



«Our product pipeline is constantly being fortified with specialised applications»

CARDIOGRAFT 1/2

Innovative approach that aims at bringing regenerative medicine into cardiac surgery field.

In detail, it's a novel autologous therapy administered during CABG surgery to treat ischemic cardiac scars and heart failure.

Open heart protocol ready for the market

0,1% of 56 MLN people afflicted - 56.000 treatments with Cardiograft technology a revenue of 560 MLN €

STRONGBONE

It is the first bone grafting technology to replicate the same characteristics of a human bone. Reproducible in vitro, it represents an unlimited supply of multipurpouse, biosecure and cost - effective biomaterial to be employed in a wide array of orthopedic surgeries.

Testing for CE Authorization

NEWRALINK

It is a technology capable of regenerating the peripheral nervous system.

It is able to develop a biocompatible and biodegradable neuroinductive scaffold where FENC cells are placed in culture to obtain a differentiation towards the neuronal line.

In Prototype & testing Phase



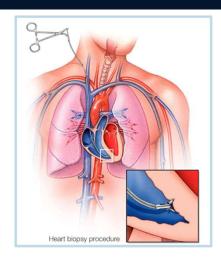
CARDIOGRAFT 2/2

(close protocol – in testing phase)

BIOPSY SAMPLE

TISSUE DISAGGREGATION

MICROGRAFTS DELIVERY SYSTEM



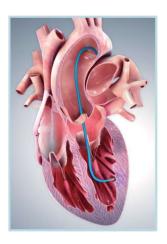








- Add 4 mL of Physiological Solution;
- Disaggregate for 2 minutes.



Micrografts trans endocardial delivery via Helix (Biocardia) to achieve damaged tissue.

Insert a catheter through jugular vein access until it reaches the heart.
Use a bioptome to snip of and retrieve tiny pieces from right ventricle.



STRONGBONE

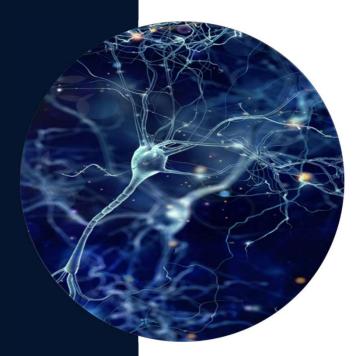
- It's the first bone grafting technology to replicate the same characteristics of a human bone. Reproducible in vitro, it represents an unlimited supply of multipurpouse, biosecure and cost - effective biomaterial to be employed in a wide array of orthopedic surgeries.
- Creation of freeze-dried and sterilized bone substitute of human cellular origin to be used as homologous inert biomaterial for orthopedic reconstruction similar to Class III medical device of heterologous origin.
- Our Biomaterial has all the right attributes to completely reshape the market and create a new standard for substitute bone grafting materials.







NEWRALINK



- It is a technology capable of regenerating the peripheral nervous system.
- Newralink technology is able to develop a biocompatible and biodegradable neuroinductive scaffold where FENC cells are placed in culture to obtain a differentiation towards the neuronal line.
- The biomaterial thus obtained has suitable chemical-physical characteristics to be able to wrap it around a damaged nerve of the peripheral nervous system.

R&D PROJECTS b)



RIGENERA CANCER

Digital Technology for Lung Cancer Treatment, in which Rigenera Device is used to extract high quality RNA to deepen the study of the tumor heterogeneity and its role in medicine precision oncology.

As future perspective, Rigenera® technology will be coupled with magnetic beads to sort CD133+ cells markers to detect the possible presence of cancer stem cells.

Research project in testing phase.

Latest scientific paper (19 Jan 2024):

"Comparison of two mechanical disaggregation methods of fresh lung tissues for extraction of high-quality RNA"

SPORT GENOME



- To understand the Relative Risk (RR) of an athlete being able to suffer a certain cartilage injury.
- To identify and alert those who have a high risk of suffering certain types of injuries of interest to the orthopedic sphere and, help them to identify and optimize workouts, diet, and nutritional plans to prevent or reduce the occurrence of cartilage injury.

In collaboration with SHRO Italia ETS Foundation.

Sponsorship with several sports organizations
(e.g. Napoli and Fiorentina Soccer Teams, Orange Futsal - Asti
Soccer, Reale Società Ginnastica Torino)





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