

REGENERA ACTIVA AMT® PROTOCOL:
STEP BY STEP GUIDE

REGENERA ACTIVA AMT® PROTOCOL IN ANDROGENETIC ALOPECIA MANAGEMENT

The **Regenera Activa AMT®** protocol is a minimally invasive procedure proven to effectively delay the biological progression of androgenetic alopecia (AGA). This protocol is supported by multiple studies using the patented **Rigenera®** technology to obtain the AMT® Triad for treating AGA patients.

HANDY INFORMATION FOR USERS

WARNING & RECOMMENDATIONS

- The user physician must be familiar with the operating manual of the medical devices prior to use.
- Only qualified physicians who can judge if the treatment fits the patient's condition should use the product.
- Rigeneracons® is a single-use disposable medical device and must be disposed of as per local guidelines.
- Check the seal, possible damage, or term of validity of the product before use.
- The Rigeneracons® must not be resterilized, because the integrity of each microblade cannot be assured after one single use of the device.

ADVERSE EVENTS

Being an autologous, homologous, and minimally invasive procedure, this treatment presents no severe adverse events and, once it is done, offers fast recovery and return to everyday life within 48 hours.

STORAGE

Store the product in a well-ventilated and dry place at room temperature.

PREVIOUS CONSIDERATIONS

1

Signed consent is required, like in any other aesthetic medicine procedure. Its characteristics will be subjected to local laws. Thus, the physician must be acquainted with them.

2

Pictures must follow a previously established guideline. Light, distance to focus, zoom, and camera from the pre-treatment photo must be the same for all the follow-up photos, so they can be compared.

3

Clinical record is mandatory in accordance with local laws and requirements, despite this being a minimally invasive medical procedure.

4

Patients must be diagnosed with an ongoing process of Androgenetic Alopecia, discarding other possible concomitant causes for alopecia.

5

To achieve visible macroscopic results, trichoscopic analysis must report:

- $\geq 20\%$ of thin hairs ($\leq 30\mu\text{m}$) in the frontal area.
- Lower cumulative hair thickness (measured in mm/cm^2 in the frontal area than in temporal and occipital areas, independently).

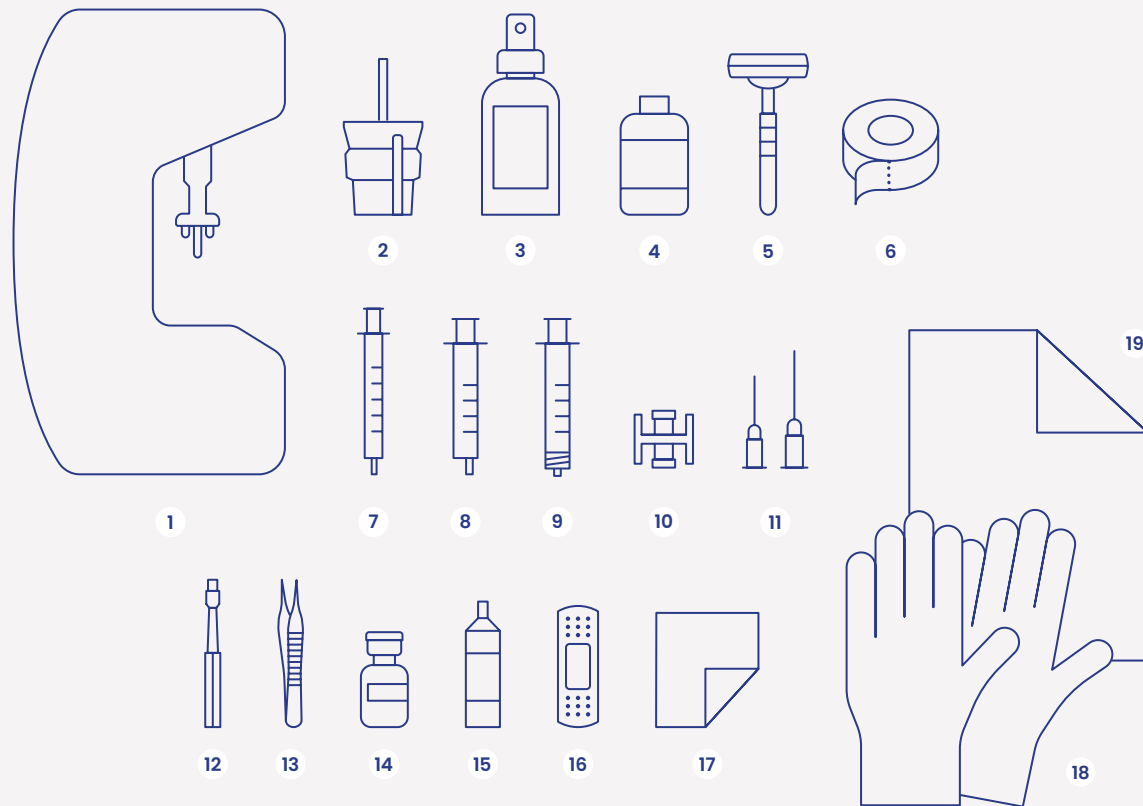
6

Absence of local inflammatory pathologies must be assured.

7

Grafts must be procured from a healthy hair follicle area.

REQUIRED MATERIALS



- 1 Regenera® N4SA EVO Machine
- 2 EVO Rigeneracons®
- 3 2% aqueous chlorhexidine
- 4 2% lidocaine without vasoconstrictors
- 5 Hair razor
- 6 Paper tape (micropore)
- 7 Syringe 1 ml (anaesthesia)
- 8 Two 3 ml Luer Slip syringes (micrografting solution collection)
- 9 Two 3 ml Luer Lock syringes (AMT® Solution infiltration)
- 10 Syringe connectors
- 11 Needles 30G x ½, 0.3 x 12 mm
- 12 Needles 21G x 1½, 0.8 x 40 mm
- 13 Dermal punch 2.5 mm
- 14 Sterile Adson Tweezers (toothless)
- 15 Injectable saline solution
- 16 Adrenalin 1mg/ml
- 17 Band-aids
- 18 Sterile gauze pads
- 19 Sterile gloves
- 20 Sterile sizes

INNOVATIVE SOLUTIONS FOR HAIR FOLLICLE REGENERATION

Regenera Activa AMT® protocol, a safe and minimally invasive procedure designed to treat androgenetic alopecia, restoring hair density and thickness. By transferring the body's regenerative potential precisely where it's needed, the protocol promotes healthy hair growth with unparalleled precision.



STEP 1
Diagnose



STEP 2
Preparation &
Anaesthesia



STEP 3
Extraction



STEP 4
Disaggregation &
Collection with Patented
Regenera Technology



STEP 5
AMT® Triad Injection
in the scalp



STEP 1 Diagnose

Ensure that the patient is diagnosed with AGA, exclude any other types of alopecia.

EXAMINATION IN 2 STEPS:

- Clinical history – family genetic history of hair loss
- Physical examination using Trichoscopy or any other imaging tool for high quality microscopic and macroscopic images. Images of NON-SHAVED scalp area taken from frontal, temporal, occipital area, optionally vertex. Usually, it is required in each area 1 clinical image, 1 – 20x magnification and 4 – 50x magnification.
- Follow international trichoscopy guidelines for AGA differential diagnostic



STEP 3 Extraction

- **Inject 1 ml of Lidocaine 2% anaesthetic without vasoconstrictor** in the periphery of the donor area, blocking and avoiding flooding the donor tissue.
- Extract **3 biopsy punches** with a 2.5 mm dermal punch. While extracting place them in a sterile gauze moistened with antiseptic.*
- Place the 3 biopsies in the **EVO Rigeneracons®**, on the grid under the helix.



STEP 2 Preparation & Anaesthesia

- **Prepare** the sterile field with all necessary materials.
 - Sterile conditions and surgical behaviour must always be guaranteed.
 - Leave the disposable material on an accessory table. The whole set must be ready-to-use and kept sterile.
 - Connect the Rigenera® N4SA EVO machine to the power supply. A green and red lights will start flashing.
 - Turn on the machine by pressing the central button. Then, only a green light will flash every few seconds until activation.
 - Withdraw the protective shield from the EVO Rigeneracons® and discard it. A second cover with the activator chip keeps the EVO Rigeneracons® in a sterile environment.
 - Activate the system by approaching the activator chip of the EVO Rigeneracons® to the lector on the Rigenera® N4SA EVO machine. A steady green light will indicate that the system is activated for an entire hour.
 - Ensure optimal light.
 - Use goggles (optional).
 - Use sterile gloves.
- **Disinfect** the extraction area with an antiseptic solution (alcohol 70%, chlorhexidine...). Micrografts will be extracted from the **thick-hair-follicles mastoid area**, containing entire hair follicle complexes.
- **Mark** the extraction area with a dermal marker.
- **Shave** gently to remove the stratum corneum.



STEP 4 Disaggregation & Collection

- Add approximately **1.8 ml of saline solution** through the extraction hole with a Luer Slip syringe, until the solution slightly floods the biopsies.**
- Close the cap, attach the EVO Rigeneracons® Derma to the Sicurlid and Sicurstick and place it in the **Rigenera® N4SA EVO machine**.
- **Press the central button** in the machine front to start disaggregation. 2 consecutive minutes of mechanical disaggregation are required.
- **Cure** the patient's donor area by second intention and apply a band-aid.
- **Extract the solution obtained** with a 3 ml Luer Slip syringe (syringe 1) and save it. This is a high concentration micrografts solution.
- Add again approximately 1.8 ml of saline solution in the EVO Rigeneracons® Derma to wash and retrieve remaining micrografts.
- Manually rotate the helix through the stick of the EVO Rigeneracons® Derma to perform a final 1-minute cycle to collect any remaining material.
- **Extract the solution obtained** with a 3 ml Luer Slip syringe (syringe 2) and save it. This is a low concentration micrografts solution.
- **Mix** syringe 1 and syringe 2 using a connector.
- **Split** the volume between the two syringes.
- **Increase** the volume up to 3 ml with saline solution in each syringe. The result is **6 ml of AMT® Solution** divided into two syringes.
- Optionally, transfer the AMT® Solution to Luer Lock syringes for a safer infiltration.
(See dilution diagram in Figure 1).



STEP 5 Infiltration

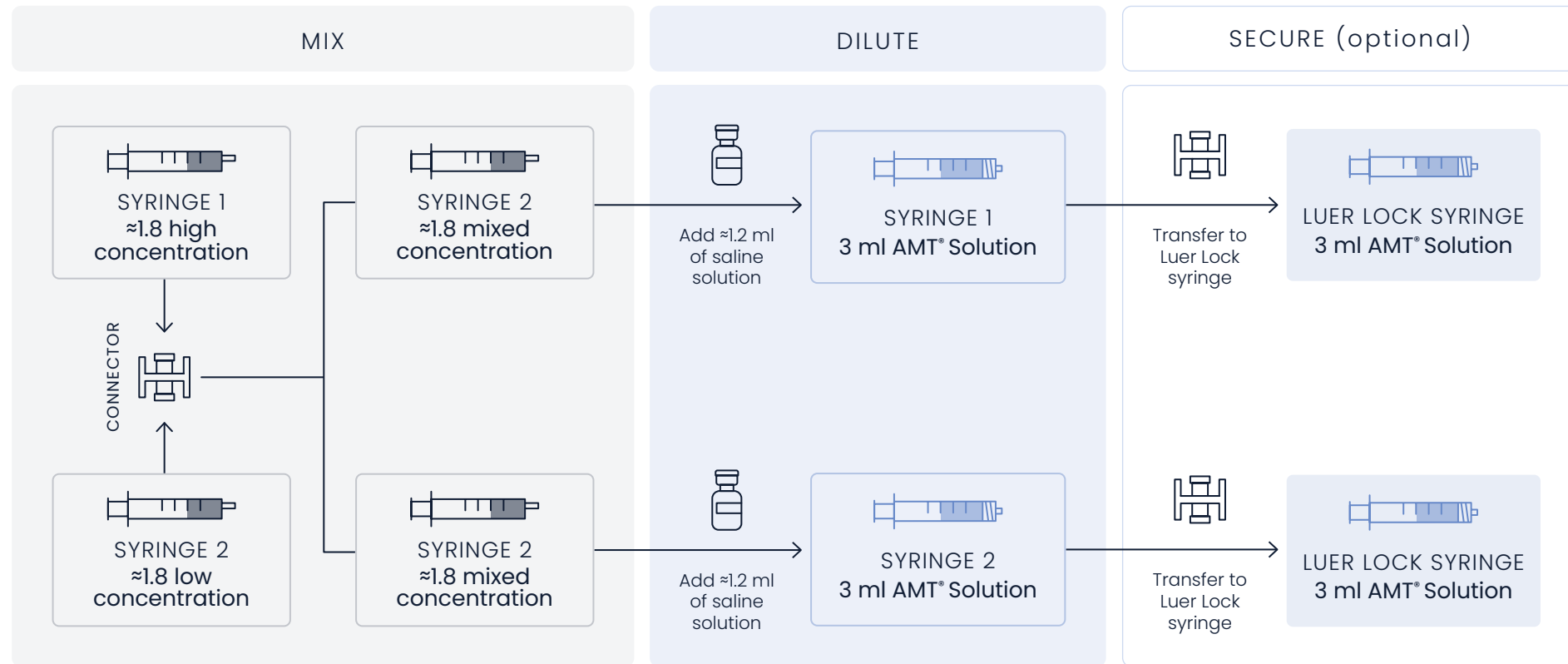
- **Disinfect** the infiltration area with antiseptic solution.
- Injections shall be approximately **0.1 ml per cm²**.
- **Inject** the AMT® Solution with a 30G x ½, 0.3 x 12 mm needle with a 45 degrees inclination to the scalp, into the deep dermis or superficial subcutaneous at most.
- **Gently massage** the scalp for one minute after the injections to distribute the solution.

* The procedure is standard and simple, but some complication may arise related to the small size of the sample.

- The tissue might stay inside the dermal punch. Use a needle to help extraction.
- The tissue might get washed away by blood.
- Second intention is enough to cure the donor area. Exceptionally, a stitch together with Vicryl Rapid 4/0 might be required for each incision.

** The grid must be wet, and the sample must be slightly flooded, but not submerged in the saline solution. If too much saline solution has been used, causing biopsies to float on it, aspirate and discard the excess solution.

FIGURE 1
DILUTION DIAGRAM FOR THE OBTENTION
OF THE AMT® TRIAD SOLUTION



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POST-PROCEDURE

1

Pictures must be taken in the exact same conditions as in the pre-procedure.

2

Patient must avoid activities that increase hydrostatic blood pressure in the first 48 hours: sports, yoga, sauna, etc.

3

Avoid showering during the first 24 hours.

4

Wound hygiene must be controlled.

5

Sun protection is mandatory.

Before & After Cases

Dr. Joshua Chong
Dr. Tina Fang
Dr. Malkova



BEFORE



AFTER

3 months after AMT® Procedure



BEFORE



AFTER

3 months after AMT® Procedure



BEFORE



AFTER

1 month after AMT® Procedure



BEFORE



AFTER

3 months after AMT® Procedure



BEFORE



AFTER

3 months after AMT® Procedure