

Start the cleaning program (see table below). Remove the parts from the washer-disinfector at the end of the program. Always store the DERMOJET® parts separately in their packaging after removing them from the washer-disinfector.

Example: Automatic cleaning and disinfection in washer-disinfectors:

- **Pre-wash**: >2 minutes cold tap water (< 45°C)
- **Washing**: 55°C 10 min with Neodisher MediClean Forte (Dr. Weigert) (in purified water)
- **Rinsing**: <45°C duration 2 minutes (Purified water)
- **Thermal disinfection at 90°C for 6 minutes, meeting criterion A₀ > 3,000.** (Demineralized water)
- **Drying**: 115°C for 15 minutes

Combined cleaning process using the mild alkaline enzymatic detergent neodisher MediClean forte from Chemische Fabrik Dr. Weigert GmbH & CO. KG.

No.	Stage		Medium
1	Pre-wash	Duration :2 minutes	• Tap water (cold, <45°C)
2	Cleaning	Duration/Temperature: 10 minutes:at 55°C ₂	• Cleaning solution mild alkaline enzymatic 0.5% ₂ (v/v) in demineralized water-realized ₃
3	Intermediate wash	Duration :2 minutes	• Demineralized water (cold) _{3,4}
4	Thermal disinfection ₁	Respecting the value A ₀ national provisions, e.g. A value pf at least 3000 at 90°C for 6 minutes	• Demineralized water ₃
5	Drying ₂	Duration:15 minutes Temperature :115°C	• Hot air
6	Check that all residue has disappeared		

¹Automatic cleaning must be carried out in a washer-disinfector in accordance with the standard series ISO 15883.

²Recommendation of the action time of concentration, temperature and pH according to the manufacturer's product sheet.

³Water quality in accordance with SN EN 285

⁴Limit value for chemical residues in accordance with the cleaning solution manufacturer's instructions

⁵If necessary, the instruments should be thoroughly dried with medical compressed air after drying. in the washer-disinfector.

- Process 2/ Autoclave sterilization

The complete head, body, reservoir (Radel®) and tip (Stainless steel) must be placed separately in their packaging and autoclaved (moist heat) at

134°C for 18 minutes, (holding time) according to a validated method.

Drying time 10 minutes minimum

After sterilization, leave the 4 parts of the DERMOJET separated in its sterile packaging until its next use,

The practitioner is therefore advised to replace the tip and reservoir and screw the head and body as part of the injection technique. Carry out the following manipulations in a closed and clean environment using sterile, powder-free gloves: see Chapter IV - Injection technique of our instructions for use.



Before any use, the device must be sterilized.



The DERMOJET® is delivered non-sterile, it is your responsibility to sterilize it before each use.

VII/ Guarantee

One year against all manufacturing defects (parts and labor, up to a limit of 4000 injections, seals, nozzle and reservoir are "consumable" parts and are therefore not covered by the warranty).

Without servicing/repairs every 18 months or 4000 injections, the DERMOJET will no longer be covered by the warranty.

The DERMOJET® "HR" is equipped with a Radel® reservoir and a stainless steel tip.

Lifespan: 10 years

Each DERMOJET® has its own serial number, which ensures its traceability.

DERMOJET®, registered trademarks and models, made in France.

The CE marking certifies the product's conformity with the essential requirements of the Medical Devices Directive 93/42/EEC and MDR 2017/745. Version 01/25E. 2020



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LEGEND OF THE SYMBOLS USED			
ISO (if applicable)	Symbol and Reference	Symbol Title	Meaning of the Symbol
ISO 15223-1 Medical devices		Manufacturer	Indicates the manufacturer of the medical device
		Use before	Indicates the date after which the medical device should no longer be used.
		Batch code / Batch number	Indicates the manufacturer's batch code so that the batch can be identified.
		Number of catalog	Indicates the manufacturer's catalog number so that the medical device can be identified.
		Serial number	Indicates the serial number of the device
		Non-sterile	Indicates a medical device that has not undergone a sterilization process
		Warning	Indicates the need for the user to consult the operating instructions
Symbols to be used with labels, labeling and information to be provided relating to medical devices		Medical device	Indicates that the item is a medical device

AKRA DERMOJET®

Instructions for use DERMOJET® HR



Important: Read the instructions carefully before use

I/ Destinations

The use of DERMOJET® is reserved exclusively for:

a/ to any person who is a member of the medical profession

- b/ Its use is intended for intradermal injections in doses of 0.1 ml in the context of:
- Local anesthesia (lidocaine hydrochloride)
 - Corticosteroid injection (triamcinolone acetonide)
 - Medical treatment of hypertrophic and choroidal scars (triamcinolone acetonide)
 - Treatment of warts (lidocaine hydrochloride)

⚠ Only use medicines with marketing authorization; other uses are prohibited.

II/ Description of the device

The DERMOJET®, equipped with a single-dose head set at 0.1 ml, delivers approximately +/- 36 doses. The DERMOJET® comes in the form of a cylinder that separates into four elements.

has **A syringe body** made entirely of stainless steel, a central piston, a tension spring and a cocking lever.

b/ An injection head including most of the "consumable" spare parts such as seals, filters, ruby nozzle where the liquid is ejected.

c/ A tank Radel®, which contains the liquid to be injected, with a capacity of 4 ml (i.e. 36 doses of 0.1 ml after arming complete).

d/ A fixed tip in the shape of a stainless steel ring

III/ Handling precautions

a/ The DERMOJET® is delivered non-sterile, it is your responsibility to sterilize it and carry out cleaning and decontamination before each use.

Read the processes relating to sterilization, cleaning and decontamination before any handling. b/ In the event of a breakdown, do not disassemble the DERMOJET®.

In the event of a breakdown, the DERMOJET® must be repaired by AKRA DERMOJET® or by an approved repairer. Do not use the DERMOJET® when empty.

Do not leave liquid in the tank after use. **except distilled water to avoid drying out the seals if the device is not used for long periods.**

Store the DERMOJET® upright with the injection head facing down and at room temperature.

c/ ⚠ Have it serviced every 4000 uses, or every 18 months by AKRA DERMOJET®, or by an approved repairer.

⚠ Consumables:

the device being equipped with viton seals, it is imperative to periodically check the condition of the seals. Note that if black particles float in the tank, you must immediately stop using the DERMOJET® and have the device completely serviced. In fact, if the device is poorly maintained, seal particles can be ejected from the nozzle. Then ask your authorized repairer or AKRA DERMOJET® to change all flat seals 28 and 31 and O-rings 6, 7 and 12 as well as the filters and the Radel® tank..

When the DERMOJET® is declared unrepairable by your authorized repairer or by our company, AKRA DERMOJET® will collect it for disposal; the device has a lifespan of 10 years.

IV/ Injection technique

Perform the following manipulations in a clean, enclosed environment using sterile, powder-free gloves:

- Armament:

Unscrew the injection head and remove it with the reservoir, withdraw your medicinal solution using a sterile syringe from its bottle original, then fill it by inserting it into the tank up to the circular filling indicator. The tank tube can hold a quantity of 4 ml.

Dose variability is +/- 0.01 ml, tighten the head firmly to obtain the maximum dose. Do not leave the injection head exposed to the air for more than 10 seconds with the reservoir

filled. Tighten the head firmly to obtain the maximum dose. Due to friction related to stainless steel, the DERMOJET® cannot be used more than 500 times per day.

⚠ Please note: you cannot put glass cartridges in the tank!



The device is armed by holding it **vertically** by lowering the lever (No. 126).

The device should then produce a noise that is both duller and quieter and the **arming button (No. 120): rises by approximately 1/2 centimeter.**



Once armed, be careful not to accidentally press this button before injecting.

- Injection:

Please note that after unscrewing the injection head, and especially after sterilization, a small amount of air remains in the head's duct. This must be evacuated by pushing the head onto the piston 2 to 3 times, then priming 3 or 4 times in the vacuum. Once you have noticed that the liquid is ejected in a fine jet, you can then start using the device.

To perform the injection, position the tip of the head against the skin, perpendicular to the skin plane, and press the trigger button (no. 120).

Variations in penetration depth depend on the injection site, distance and angle relative to the skin plane. Typically, it ranges from 4 to 6 mm; the appearance of a papule at the top of which a small opening can be seen allows immediate visual inspection.

⚠ If the papule does not appear, immediately have the device completely serviced.

V/ Contraindications

DERMOJET® should not be used outside of the intended indications, and generally in any area likely to suffer damage following injection under pressure, particularly in the **eyeball**, and the **blood vessels**.

Do not use DERMOJET® on the face except for the treatment of keloid scars in the chin and submental region.

VI/ Cleaning and Sterilization

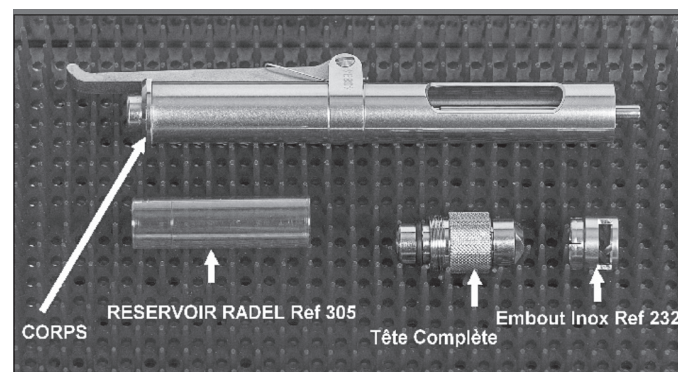
⚠ Read the cleaning and sterilization processes.

DERMOJET® disinfection, cleaning and sterilization process:

Pre-treatment:

Unscrew the injection head from the DERMOJET body, remove the reservoir and the stainless steel distance tip, the device will be broken down into 4 separate parts:

The complete head, body, tank (Radel®) and tip (Stainless steel) (see photo)



- Process 1/ Automatic cleaning and disinfection

The complete head, body, tank (Radel®) and nozzle (Stainless steel) must be placed disassembled.

Place the disassembled parts in the washer-disinfector so that water can drain through the holes. Check that the parts do not touch each other.