

DERMOJET® Cleaning and Sterilisation

PROCESSUS		DERMOJET®	
Preparation at the point of use	Deposition	Wet	-
		Dry	+
	Preparation	Selection according to the Cleaning and Disinfection Procedures	
DECONTAMINATION	Cleaning	Manual	Cleaning inside the lumen : rinse the DERMJET by filling the reservoir with one ml of distilled water with neutral detergent and eject the neutral detergent by triggering the apparatus, but after, the same procedure will have to be used with distilled water only to eject the remaining detergent outside the lumen
		Machine	+
		Ultrasonic	+
		Alkaline detergent	+
		Acidic detergent	Do not use detergent with Sodium hypochlorite
		Neutral detergent	+
	Rinsing	Rinse the apparatus by filling the reservoir with one millilitre of distilled water and eject the water by triggering the apparatus	
	Disinfection	Chemical	To clean and dry all the parts unscrew the head from the syringe body and to immerse both parts in the disinfection solution (i.e. chlorine dioxide), usually for 15 minutes.
		Thermal	+
	Drying	Tmax	Do not exceed 120° C
Reassembly	Replace the reservoir and screw back the head to the body .		

DERMOJET® Cleaning and Sterilisation

Before decontamination DERMJET, it is imperative to disassembly :
Unscrew the head of the unit, remove the reservoir and the interchangeable tip for the polymedical model. All elements can be decontaminated.
WARNING: borosilicate glass tanks can break under impact.

PROCESS		DERMOJET®	
Maintenance	The DERMJET® can be sterilized indefinitely provided that an overhaul must be performed every 4000 injections, and/or every 18 months	The DERMJET® should be emptied after each treatment and subjected to Sterilizing and cleaning	
	STERILISATION	Moist heat* (preferred method)	134°C during 18 mns unless if others settings are requested by local laws for reusable surgical instruments
Low temperature steam and fomaldehyde		-	
Dry heat		-	
Gaz plasma		-	

Key :
+ suitable
- no suitable
NA not applicable
*Process established under the norm ISO 17664

The various DERMOJET® models:

The Standard DERMJET® has a polysulfone reservoir and tip.
The « HR » DERMJET® has a borosilicate-glass reservoir and a stainless-steel tip.
The Polymedical DERMJET® has a borosilicate-glass reservoir and interchangeable tips.

⚠ Do not use the DERMJET when empty : the Polymedical DERMJET tip and the reservoir could be damaged and become unusable.

How to use the interchangeable tips of the Polymedical model :



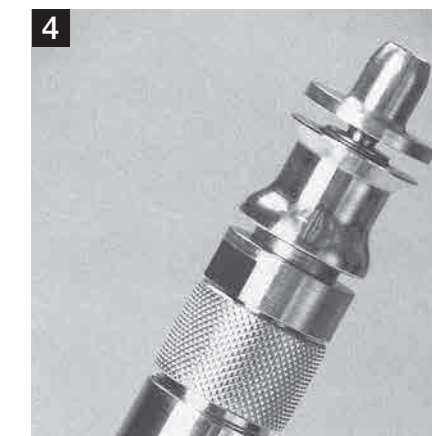
1 The tip must be introduced after lowering the ring to expose the cage of the device head



3 Release the ring (the tip snaps into place). Ensure that the tip disc and the upper part of the device are tight



2 Fully introduce the lower part of the tip into the cage of the device head while keeping the ring in its lower position



4 The device must not be used if the tip is not seated tightly

DERMOJET®
Needle-free injector



Instructions
for use
Read the instructions
carefully before use

DERMOJET® models standard, « HR » or polymédical.
Important : Read the instructions carefully before use.

I-Intended use

The DERMOJET® is exclusively for use :

- by members of the medical profession,
- for intradermal injection of 0.1ml doses, for the purposes of :
 - Local anaesthesia
 - Corticosteroid injection
 - Treatment of hypertrophic and keloid scars
 - Treatment of warts

Only use medicinal products which have marketing authorisation, any other use is strictly prohibited

II-Description of the device

The DERMOJET® is fitted with a single-dose head set at 0.1 ml and delivers about ± 36 doses.

The DERMOJET® comes in the form of a cylinder which can be separated into four parts :

- A syringe body made entirely in stainless steel, comprising a central piston, a main spring, and a loading lever.

- An injector head including most of the replaceable spare parts such as seals, filters and the ruby nozzle from which the liquid is ejected.

- A reservoir made of transparent borosilicate glass (quite fragile for handling) or polysulfone or radel, which contains the liquid to be injected. Its capacity is 4 ml (i.e. 36 doses of 0.1 ml after the device is cocked).

- A fixed tip in the form of a stainless-steel (or polysulfone) ring, or a removable tip for the Polymedical model.

III-Handling precautions

- The DERMOJET® is supplied non-sterilised ; it is your responsibility to sterilise it before each use. Read the procedure for sterilisation before handling the device.
- If the DERMOJET®, fails to function, do not take it apart. If the DERMOJET® fails to function, it must be repaired by AKRA DERMOJET®, or by an approved repairer. Do not use the DERMOJET® when empty.

Storage after use of the DERMOJET: in its original packaging inside a sterilization bag or self-sealing sterilization pouches, with distilled water inside. Store the DERMOJET vertically.

Do not leave liquid in the reservoir after use except for distilled water to prevent the seals drying if the device is not used for long periods.

Store the DERMOJET® vertically.

- An overhaul must be performed after it has been used 4,000 times, or every 18 months.**

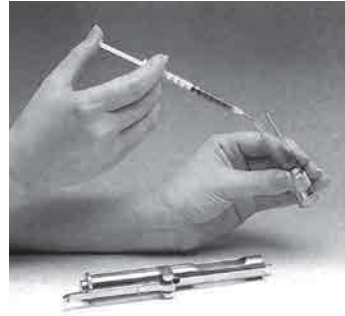
As the device is fitted with Viton seals, it is essential to check the condition of the seals periodically. If black particles float in the reservoir, you must immediately stop using the DERMOJET and have the device completely overhauled. In fact, if the device is poorly maintained, particles from the seals may be ejected from the nozzle. Ask your approved supplier to change all the flat seals 28 and 31, and O-rings 6, 7 and 12, and the filters. When the unit is declared non-repairable by your approved supplier or by our company, AKRA DERMOJET will collect it for scrapping; the lifetime of the device is 15 years.

IV- Injection technique

Perform the following procedures in a clean-room environment:

Loading:

Unscrew the injector head and remove it with the reservoir. Take up the solution of medicinal product into a sterile syringe from its original vial, and introduce the needle into the reservoir to fill it.



The reservoir tube can take 4 ml of liquid. After filling the reservoir, screw the injector head back onto the body of the device.

Do not leave the injector head exposed to the open air for more than 10 seconds with the reservoir filled.

Dose variability is ± 0.01 ml. Screw on the head tightly to obtain the maximum dose.

Due to the friction of the stainless steel, the DERMOJET should not be used more than 800 times a day.

Please note: Glass Carpules cannot be put into the reservoir.

The device is cocked by holding it vertically and folding down the loading lever (No.126).



The device should produce a muted quiet noise **and the firing button (No.120) rises by about 1/2 a centimetre.**



DERMOJET® not cocked



DERMOJET® cocked

Once it is cocked, avoid accidentally pressing on this button before carrying out the injection.

Firing:

Kindly note that after unscrewing the injector head, and particularly after sterilisation, a small volume of air remains in the injector head channel. This must be purged by pushing the head onto the piston 2 or 3 times and then firing 3 or 4 times into the air.

After ensuring that the liquid is ejected in a fine jet, you can start to use the device.

To carry out the injection, place the tip of the head perpendicular to the skin in contact with it, and press on the firing button (No.120).

The variation in the depth of penetration depends on the injection site, the distance from and the angle relative to the skin surface. Generally speaking, this depth varies from 4 to 6 mm. A characteristic papule on the top of which can be seen a small hole provides an immediate visual check.

V Contraindications

The DERMOJET® should not be used other than for the indications stated, nor, generally, in any area likely to suffer lesions following injection under pressure, particularly the eyeball and blood vessels.

VI - Cleaning and Sterilisation

Read the cleaning and sterilisation procedures.

The device must be sterilised before each use.

VII-Guarantee

One year against manufacturing faults - parts and labour, for up to 4,000 injections ; the seals, tips and reservoir are «consumables» and are therefore not covered by the guarantee.

Cleaning and sterilisation procedures

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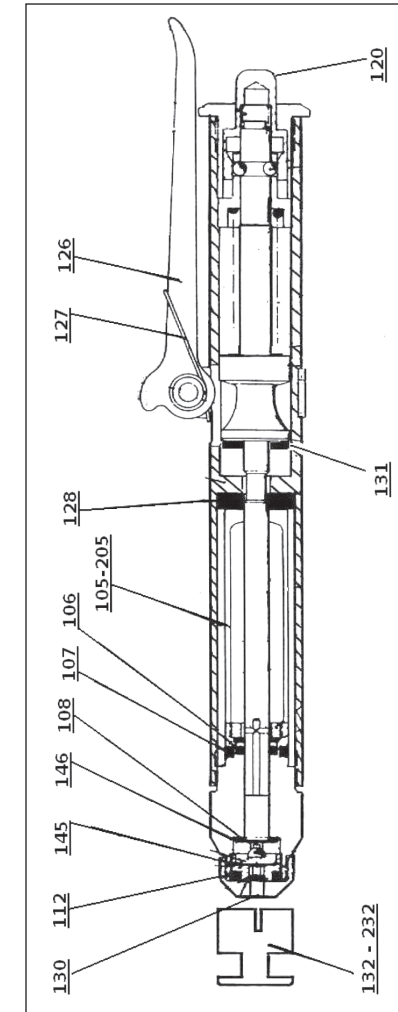
DERMOJET® Parts List

Only the consumable spare parts and also the Inox parts mentioned in the instructions for use are shown :

Each DERMOJET® has its own serial No., aiding traceability.

DERMOJET® Standard, HR, and Polymedical are registered trademarks and models, manufactured in France.

EC labelling indicates that the product complies with the basic requirements of Directive 93/42/EEC on Medical Devices.



- 105 : Reservoir Tube
 - 106 : O-Ring R3
 - 107 : O-Ring R7
 - 108 : Washer
 - 112 : O-Ring R5a
 - 145 : Filter Coarse
 - 146 : Filter Fine
 - 120 : Firing Button
 - 126 : Loading Lever
 - 127 : Lever Spring
 - 128 : Top Seal
 - 130 : Jet Washer
 - 131 : Shaft Collar
 - 132 : Distance Piece
 - 205 : Pyrex® reservoir Tube
- (* HR * and polymédical Model)
 232 :Inox distance Piece
 (* HR * Model)

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