**DERMOJET® Cleaning and Sterilisation**

**PROCESS**

<table>
<thead>
<tr>
<th>Preparation at the point of use</th>
<th>Deposition</th>
<th>Preparation</th>
<th>Cleaning</th>
<th>Rinsing</th>
<th>Disinfection</th>
<th>Drying</th>
<th>Reassembly</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Wet</strong></td>
<td><strong>-</strong></td>
<td><strong>Selection according to the Cleaning and Disinfection Procedures</strong></td>
<td><strong>Manual</strong></td>
<td><strong>Rinse the apparatus by filling the reservoir with one milliliter of distilled water and eject the water by triggering the apparatus</strong></td>
<td><strong>Chemical</strong></td>
<td><strong>Thermal</strong></td>
<td><strong>-</strong></td>
</tr>
<tr>
<td><strong>Dry</strong></td>
<td><strong>+</strong></td>
<td></td>
<td><strong>Machine</strong></td>
<td><strong>Use ultrasonic, acidic detergent or alkaline detergent without Sodium hypochlorite</strong></td>
<td><strong>Neutral detergent</strong></td>
<td><strong>Do not exceed 140°C</strong></td>
<td><strong>-</strong></td>
</tr>
</tbody>
</table>

**DERMOJET®**

<table>
<thead>
<tr>
<th>PROCESS</th>
<th>DERMÖJET®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparation</td>
<td>The DERMÖJET® can be sterilised indefinitely provided that an overhaul must be performed every 4000 injections, and/or every 18 months.</td>
</tr>
<tr>
<td>Deposition</td>
<td>The DERMÖJET® should be emptied after each treatment and subjected to Sterilising and cleaning.</td>
</tr>
</tbody>
</table>

**STERILISATION**

<table>
<thead>
<tr>
<th>PROCESS</th>
<th>DERMÖJET®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moist heat (preferred method)</td>
<td>134°C during 18 mns unless if other settings are requested by head fay for reusable surgical instruments.</td>
</tr>
<tr>
<td>Low temperature steam and formaldehyde</td>
<td><strong>-</strong></td>
</tr>
<tr>
<td>Dry heat</td>
<td><strong>-</strong></td>
</tr>
<tr>
<td>Gaz plasma</td>
<td><strong>-</strong></td>
</tr>
</tbody>
</table>

**Notes:**

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

**DERMOJET® Cleaning and Sterilisation**

- **Before decontamination DERMÖJET® it is imperative to disassemble.**
- **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.

**DECONTAMINATION**

**Key:**

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

**The various DERMÖJET® models:**

- **The Standard DERMÖJET®** has a polysulfone reservoir and tip.
- **The - HR - DERMÖJET®** has a borosilicate-glass reservoir and a stainless-steel tip.
- **The Polymedical DERMÖJET®** has a borosilicate-glass reservoir and interchangeable tips.

**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.**
2. **Release the ring (the tip snaps into place).**
3. **Ensure that the tip disc and the upper part of the device are tight.**
4. **Fully introduce the lower part of the tip into the cage of the device head while keeping the ring in its lower position.**
5. **The device must not be used if the tip is not seated tightly.**
I-Intended use

The DERMOJET® is exclusively for use:

a) by members of the medical profession,

b) for intradermal injection of 0.1 ml doses, for the purposes of:
   - Local anaesthesia
   - Caricatured injection
   - Treatment of hypertrophic and keloid scars

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

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 a form of a cylinder which can be separated into four parts:

a) The DERMAJET® is supplied non-sterilised; it is your responsibility to sterile it before each use.
   - Read the procedure for sterilisation before handling the device.

b) If the DERMAJET®, fails to function, do not take it apart.
   - If the DERMAJET® fails to function, it must be repaired by AKRA DERMOJET®, or by an approved repairer.
   - Do not use the DERMAJET® when empty.

- Storage after use of the DERMAJET® in its original packaging inside a sterilization bag or self-sealing sterilization pouches, with distilled water inside. Store the DERMAJET® 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.
- 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 fixed in the reservoir, you must immediately stop using the DERMAJET® and have the device completely overhauled. In fact, if the device is poorly maintained, particles from the seals may be ejected from the nozzle.

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 device is not used for long periods. For the DERMAJET® vertically.

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Firing:

Gently 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 squeezing the head onto the piston 2 or 3 times and then firing the device 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.

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

V- Contraindications

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

VI- Cleaning and Sterilisation

The DERMAJET® is supplied non-sterilised; it is your responsibility to sterile it before each use.

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

The device should produce a muted quiet noise and the firing button (No.126) rises by about 1/2 a centimetre.

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

Cleaning and sterilisation procedures

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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.