INSTRUCTIONS FOR USE

DERMATIC ® 1

Euromi

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1. Product description

1.1 General information

This user manual concerns the Dermatic® 1 and describes the procedure to follow to use the device safely.

The Dermatic® 1 is a non-sterile reusable device.

1.2 Composition

The Dermatic® 1 is supplied in a case, including:

NUMÉRO	DESCRIPTION	RÉFÉRENCE
1	Dermatic® 1	1103D-1
2	Charger	1203CHARGEUR D1
3	Case	1000DL-001 + 1203D-001
4	Dermatic kit x 10 (single-use catheter and guide) Needle 12 mm	1203HPF3410 1203AM30G12
5	BD single-use 10ml syringe (x10)	1757-305959/1
6	Black spiral hose	5903D13-005
7	Power cord (2 meters)	5903D13-001
8	Instructions for use	
9	USB stick (with the user manual, the marketing folders and a tutorial video for installation)	

A small compressor (1203AC500S) easy to carry and to use is also available (at an additional cost).

1.3 Description

The Dermatic® 1 is a mesotherapy gun powered by compressed air used to inject, with a super thin needle, micro doses of medicinal substances under the skin, close to the problem to be treated. The gun allows a high injection speed for the practitioner and ensures a painless treatment for the patient.

The Dermatic® 1 includes:

- automatic / manual mode;
- adjustment of the quantity injected;
- adjustment of the burst mode (injection rate);
- adjustment of the needle penetration depth;
- clamping system to avoid product loss;
- visual verification.

2. Indications

The Dermatic® 1 is indicated for:

- aesthetic procedures (mesolift, cellulite);
- dermatological procedures (fibrous scars, hair loss);
- rheumatologic, spinal pathologies ;
- sport traumas (tendonitis, pulled muscle);
- blood circulation troubles.

3. Contra-indications

The Dermatic® 1 cannot be used on:

- patients presenting active skin lesions (eczema, infections, psoriasis, etc.);
- skin infection
- patients allergic to the products injected;
- pregnant women;
- breast-feeding women;
- patients receiving an anticoagulant treatment.

Mesotherapy cannot be used on the lower eyelids or on the corners of the mouth.

4. Possible complications

Possible complications are:

- bruises/hematomas where the product is injected;
- allergic reaction;
- redness.

5. Warning

5.1 General information

The results of the procedure vary depending on the age of the patient, on the parts of the body treated and on the physician's experience but also on the type and quality of product injected. The results can be permanent or temporary.

The device can be used **for 4 hours without interruption in a room where the temperature is between 0 and 40° and where the relative humidity is between 40 and 70%**. Do not use the device in a hazardous environment.

5.2 Qualification / Responsibilities

The Dermatic® can only be sold to and used by physicians or qualified health professionals.

Euromi S.A. does not supply the product for injection. The selection and the amount of the product for injection is the responsibility of the user. The user must verify the maximum amount of the product that can be injected in the patient per session.

Using an air source that does not provide medical air is the responsibility of the user.

Using other accessories than those supplied by Euromi S.A. is the responsibility of the user.

These unauthorized accessories do not comply with the quality requirements of the Dermatic® 1 and are therefore **prohibited.**

Any use of the device outside of its intended use described in this manual is not the responsibility of Euromi S.A..

5.3 Maintenance

Maintenance must be done once a year.

Dermatic® 1 repairs or maintenance must only be carried out by the Technical Department of Euromi S.A. or by a technician authorized by Euromi S.A..

The device has a **5-year service life** providing that the maintenance is done annually. This service life has been determined based on the service life of the electrical and electronic components.

Any modification of the Dermatic® 1 device is prohibited.

Never open the gun or the charger.

5.4 Reuse

The syringes and the kits (containing the guide and catheter), as well as the needle are sterile and single-use. Y**ou must therefore change the syringes, the kit and the needle for each new patient.**

Do not use any single-use sterile equipment (syringe, kit and needle) with torn or damaged packaging.

Anything not specified in this user manual is strictly prohibited.

6. Use of the device

6.1 Operating conditions

For the Dermatic® 1 to meet your expectations, it is strongly recommended to follow certain operating conditions:

- **Inlet pressure of 5 bars.**
- **Use a new syringe and kit (catheter, guide) and needle for each new patient.**
- **Connect the catheter just before use to avoid contamination or damage.**
- **We recommend using a BD 10 mL plastic syringe with a Luer Lock.**
- **We recommend using a 30G x 1/2» (0.30 x 12.7 mm) needle.**
- **The annual maintenance of the device should be carried out by Euromi S.A. or by a distributor authorized by Euromi S.A.**

The injectable substance is not supplied by Euromi S.A. and is the user's responsibility.

6.2 Assembly instructions

- **Assembly of the power unit: compressed air**

The Dermatic® 1 is a device that operates with compressed air. The air inlet connection (max 5.0 bars) is at the bottom of the gun grip (blue part).

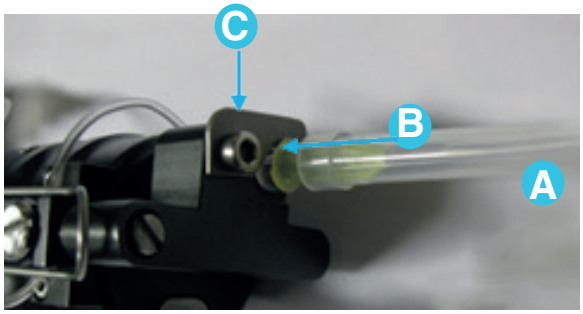
Connect the Dermatic® 1 to a compressor according to the following steps:

1) **Connect the air supply spiral hose to the Dermatic® 1:** insert the end of the air supply spiral hose into the bottom of the Dermatic® gun grip (blue part).
2) **Connect the air supply spiral hose to the compressor:** screw, without forcing, the manometer connector onto the compressor.

- **Connecting the catheter**

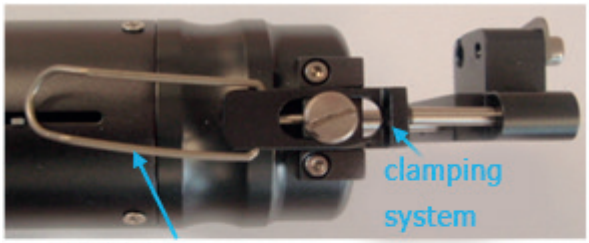
Caution: always connect the catheter **before connecting the syringe**.
Connect the catheter as follows:

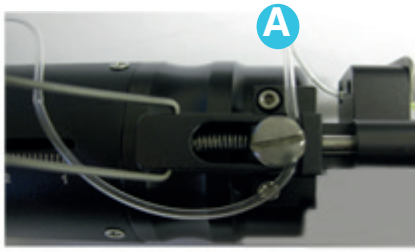
1) **Place the needle on the Dermatic® kit.** A
Then, **place the needle in the holder** B provided for this purpose on the gun nose.
Then **close the safety latch** C to hold the needle in place.

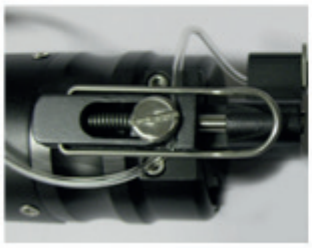


2) Put the catheter into the clamping system:

• Select the « Manual mode ».
• Action and maintain pressure on the trigger to open the clamping system
• Open the retaining system
• Place the catheter tubing into the clamping system
• Ensure that the tube connected to the needle is the shortest possible. A
• Release the trigger.
• Close the retaining system.





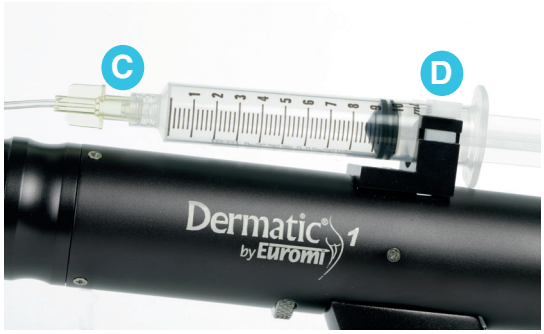


The clamping system will control the injection and will significantly reduce product loss:
• The open position releases the product;
• the closed position stops the product injection.

The user therefore prevents drops from flowing when the needle is not inserted into the patient's skin

• <u>Placing the syringe</u>

• Fill the syringe with the desired product.
• Release the **syringe pump** A by loosening the **pressure regulator** placed at the back of the gun. B
• Connect the tip of the catheter to the **Luer Lock connector of the syringe.** C
• Place the syringe in the **slot provided** for this purpose D on the top of the gun. Several syringe adaptors are available (1ml, 2ml, 5ml ou 10ml).
A 10ml adaptor is supplied with the Dermatic®, the others can be ordered separately.
• Once the syringe is installed and connected to the catheter, adjust the rear stopper and block it according to the desired pressure, by tightening the **regulator** located at the back of the gun. B

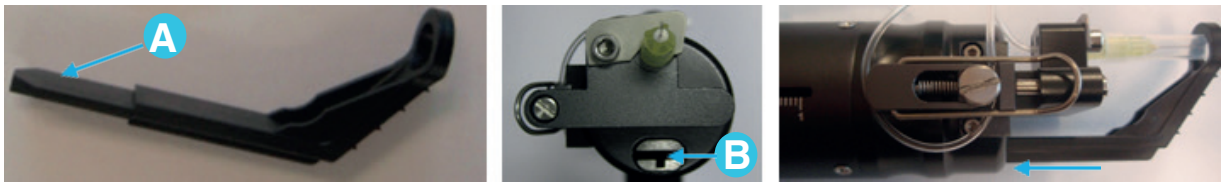


• **Placing the guide**

The gun of the Dermatic® is equipped with a guide that, as the needle and the catheter, **must be changed after each use on a patient**.

• To install the guide, take the gun with one hand and **insert the lower end** A without forcing, **into the opening at the bottom of the gun nose.** B

• Once the guide has been installed, remove the needle cap.



• **To remove the guide**, take the gun in one hand and, using the other hand, **gently pull it out** to remove it from the gun.

6.3 Operating principe

• **Adjustment of the needle penetration depth**

To adjust the needle penetration depth into the epidermis, **use the wheel located above the trigger**. A

When the device is pointed towards the operator, turn the wheel:

• **Clockwise to decrease the needle penetration depth.**
• **Anticlockwise to increase the needle penetration depth.**

The depth is visible on the milimeter ruler situated on the lateral face of the gun and can vary **from 1mm to 12mm**.

- **Mode selection**

Two operating modes are available: MANUAL and AUTO.

- **MANUAL mode**

To select the « MANUAL » mode on the Dermatic® 1, move the switch located on the gun body to the right:

• **The operator controls the speed and the quantity of product injected by pressing and releasing the trigger**. Therefore, these parameters (speed and quantity) should not be configured.

• The product continues to be injected until the operator removes his finger from the trigger.

- **AUTO mode**

To select the « AUTO » mode on the Dermatic® 1, move the switch located on the gun body to the left:

• The « AUTO » mode uses the previously selected parameters for speed and quantity of product injected.

• Each time the operator presses the trigger, the needle penetrates and exits the epidermis with a constant speed until the operator releases the trigger. For automatic repeated injections, the operator must keep pressure on the trigger.

• The burst speed is determined by the position of the trigger (go to " **burst speed setting** ").

• The quantity of liquid that the operator can inject into the patient is determined by the speed at which the operator is working, by the inlet pressure on the gun, by the drop size and by the viscosity of the product injected.

- **Adjusting the pressure on the syringe plunger (quantity of injected product)**

Various liquid quantities can be injected. To adjust the quantity of liquid to be injected into the patient's epidermis, select the " AUTO " mode and use the s**mall wheel of the mechanical regulator located at the rear of the gun**.

The quantity of liquid injected into the patient is determined by the time the needle remains in the patient's skin, but it is also highly dependent on the viscosity of the product injected.

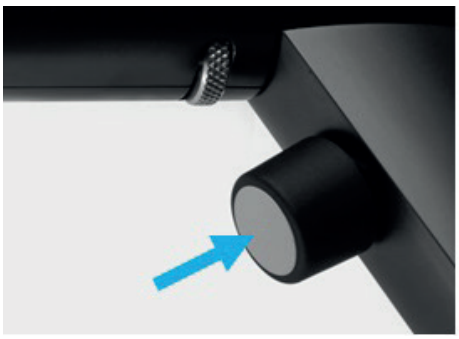
Please note that we recommend using a BD 10 mL plastic syringe.

- **Adjusting the burst speed**

The burst speed can be adjusted **using the trigger on the gun grip**.
The burst speed is determined by the position of the trigger. **This speed can vary from 1 to 350 shots per minute.**

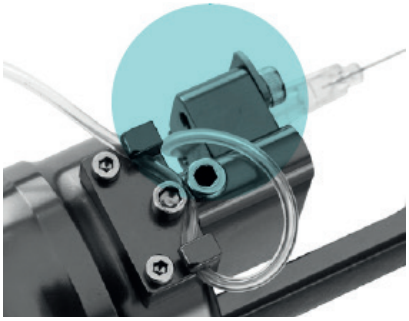
When the device is facing the operator:

- **To increase the burst speed**, select the " AUTO " mode and turn the trigger counterclockwise (**follow the « + » direction of the arrow**).
- **To decrease the burst speed**, turn the trigger clockwise (**follow the « – » direction of the arrow**).



- **Delay clamping system**

The delay clamping system enables the gun to **provide the requested quantity of liquid only when the needle is in the skin**.



Indeed, the tubing supplying the liquid is blocked until the needle enters the epidermis thereby significantly **reducing product loss**. In this manner, the physician prevents drops flowing when the needle is not inserted into the patient's skin.

6.4 Disconnecting the compressed air supply

To disconnect the Dermatic® 1 from the compressor, follow the following steps:

1) Disconnect the air supply hose from the compressor.

2) Disconnect the air supply hose from the Dermatic®, removing the other end of the air supply hose from the Dermatic® gun grip.

6.5 Charging the battery

The gun operates on a nickel–metal hydride 3.6V – 600mAh battery. **A new battery has a battery life of 4 hours.**

When the battery is discharged, it is possible to connect it to the charger while using the device. **Only use the power cord supplied by Euromi**. When the charger is switched on, the blue indicator on the charger lights up.

The Dermatic® 1 is equipped with a smart charger enabling it to charge at a very high speed and to automatically stop when fully charged. **The total charging time for a completely discharged battery is one hour**. The charging begins as soon as the gun is connected to the charger.

Insert the charger plug into the connector located below the gun grip, next to the compressed air inlet. Caution: do not force the charger plug into the gun connector. The electrical connector is fitted with a lug to ensure correct insertion.

To disconnect the charger, gently pull down the connector located at the bottom of the gun grip.
The red indicator on the gun lights up when the gun is connected to the charger and switches off when the battery is fully charged.

The battery can't be replaced by the user. It can only be replaced by Euromi S.A. technicians or by technicians authorized by Euromi S.A.

7. Cleaning - Reuse of the device - Resterilization

After each use, remove and discard the syringe and the kit (**catheter, skin stabilizer and needle, all being sterile and SINGLE-USE accessories**). Clean the Dermatic® 1 gun using a cloth dampened with denatured alcohol or any other disinfectant (Dettol®, etc.).

It is highly important to always use sterile equipment. Using non-sterile equipments might have severe consequences and is under the responsibility of the user.

Do not use any single-use sterile equipment (syringe and kit) with torn or damaged packaging. Once the protection lid of a needle has been removed, never replace it.

The used needles and syringes must be discarded in a container intended for this purpose (sharps container).

After each use, rub the gun with a cloth and water or alcohol.

8. Transport and storage of the device

The Dermatic® 1 and all accessories must be transported and stored in their original packaging (case), in a dry, clean and dust-free place. The device should be stored at a temperature between 10°C and 40°C.

9. Case of materiovigilance

In case of serious risk or of a serious incident with the Dermatic® 1 that might lead to or might have led to the death of a patient/user or to a serious deterioration in the patient's/user's health status, please advise the competent authorities as well as the Euromi S.A. company, using the following email address : **materiovigilance@euromi.com**.

10. Return management

All devices for which a claim is filed or representing a risk of a serious incident must be returned to the local materiovigilance representant of Euromi S.A..

Before returning a device, please decontaminate and disinfect it (following the operative procedures).

11. Warranties – warranties limits

All Euromi S.A. devices have a one-year warranty, from the installation date or the invoice date provided that the customer has sent the warranty certificate duly filled in and signed back to EUROMI S.A. Euromi S.A. guarantees that all delivered devices do not have any defects or malfunction.

Euromi S.A. guarantees that all Dermatic® 1 devices are manufactured with rigour and that all precautions are taken.

However, Euromi S.A. can't control the storage and operating conditions of its products, neither the patients selection nor the surgical technique that the user chooses to use. Furthermore, Euromi S.A. can't guarantee the surgery results or the patient satisfaction and can't forsee the potential adverse effects that could appear after surgery, as described in this manual. Therefore, Euromi S.A. can't be held responsible in case of misuse, loss or damage of one of its devices.

Euromi S.A. agrees to replace a Dermatic® 1 if and only if the device is faulty when it leaves the company premises. This clause serves as a guarantee and excludes any other guarantee that wouldn't be transcribed verbatim in this manual, whether it's explicit or implicit according to the law, and including but not limited to implicit quality guarantee or use aptitude.

Carefully read the user manual before using the device

Serial number

Reference

Device conformity marking

Class II equipment

Device manufacturer

Product must be disposed of at a suitable recovery and recycling facility

Type applied part (classification of protection against electrical shock

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