# CLEANE

PERSONAL MEDICAL DEVICE

THERMAL ACNE CARE

# Spot-heat acne treatment, **a 2 min 30 sec routine**

CLEANE, a medical device for acne treatment




Korea MFDS License No. 08-766

FDA 510(k)

MEDICON

01 · TECHNOLOGY

# Delivered to the acne spot: **thermal technology**

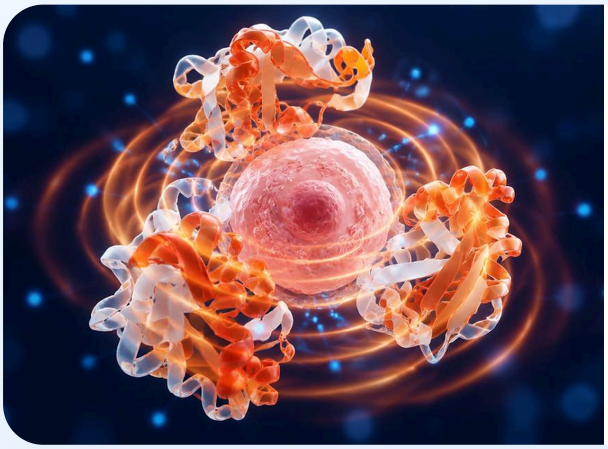
The moment the heating tip touches the skin, **heat at a steady temperature** is delivered to the acne spot.




**48.3 °C**
Average tip output temperature (47.2–49.4°C)

**150 sec**
Time to reach the set temperature (max.)

**2:30**
Time per use · auto stop



THERMAL SHOCK

## Heat → heat shock protein (HSP) synthesis

Heat delivered to the skin increases HSP60 and HSP70 synthesis, supporting the immune response against acne bacteria.

02 · EVIDENCE

# Backed by **a paper and a human-use test**

SCI paper · treatment efficacy

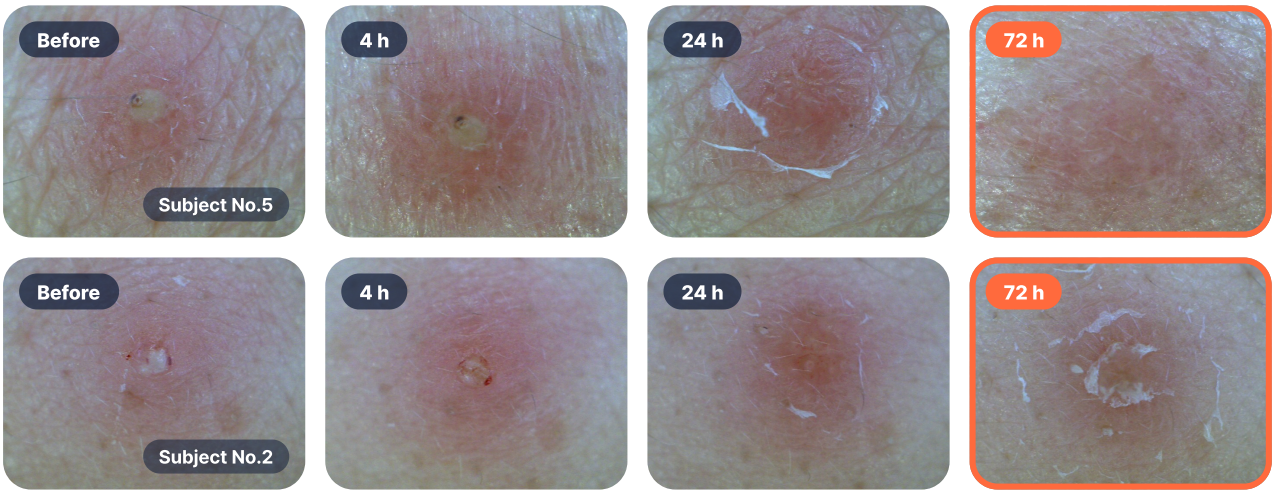
## 84.6%

### 11 of 13 subjects, positive results after a single use

Assessed by cross-polarized imaging and erythema index before and after use and at 6, 24 and 48 hours · judged by dermatologists

### Human-use test · changes over 72 hours

Dermapro Co., Ltd. · magnified skin imaging (×50)




Brief redness at 4 hours, then erythema and papules subside by 72 hours. All subjects reported "acne improved and reduced in size."

APPROVALS · CERTIFICATIONS

**MFDS (Korea)**
Product license No. 08-766

**FDA**
United States 510(k)

**GMP**
Manufacturing & quality control compliant

**ISO 13485**
Medical device quality management system

※ Results may vary depending on individual skin condition.

03 · PRODUCT

# Thermal care in **a compact device**




Heat

## Heating tip that touches the skin

The metal tip delivers heat at a steady temperature.

Auto

## Auto temperature and timing

Holds the set temperature and stops by itself when time is up.

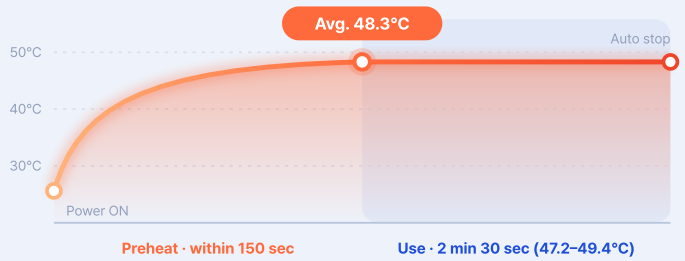
Portable

## 30 g, the size of a lipstick

Cap it and slip it into your pouch. USB rechargeable.

## Temperature is the key

Tip output temperature




IN THE BOX

| | |
|---|---|
| Main unit | 1 |
| Protective cap | 1 |
| Charging cable | USB |
| User manual | 1 |

04 · HOW TO USE

# One button, **simple acne care**

Just follow the lamp color and the beeps.




## 01

### Power on

Press the button briefly and the heating tip warms up.

## 02

### Ready

The lamp blinks with a beep.

## 03

### Use for 2:30

Press the button once more and hold the tip on the acne spot. A beep sounds every 3 seconds.

## 04

### Auto stop

Press again within 60 seconds to continue on another spot. Hold for 2 seconds to turn off.

**Up to 3 times a day**
Wait at least 4 hours between uses

**Max. 3 times per spot**
Do not repeat beyond that

**Charge 1 hour before first use**
Does not operate while charging

**Wipe and store after use**
Clean with an alcohol swab and put the cap on

BEFORE USE

## Do not use **in these cases**

This is a medical device. Please read the precautions in the user manual.

- Blackheads and whiteheads; severe nodular or cystic acne
- Sensitive areas such as around the eyes and lips; heat-sensitive skin
- Other skin diseases, infected skin, boils, wounds, insect bites
- Use by children alone (adult supervision required)

※ If you are using medication that causes skin peeling or heat sensitivity, consult a doctor before use. If you feel pain or notice any abnormal reaction, stop using the device immediately and consult a professional.

# CLEANE

ACNE THERAPY DEVICE




## SPECIFICATION

| | |
|---|---|
| Product · Model<br>**Medical heating device (A16150) · CLEANE** | Intended use<br>**Personal medical device for acne treatment (thermotherapy device)** |
| Product license no. (Korea MFDS)<br>**No. 08-766** | Output temperature<br>**47.2 – 49.4 °C · heat-up within 150 sec** |
| Operating time<br>**2 min 30 sec (auto stop)** | Battery<br>**DC 3.7V · 250mAh · power consumption 3VA** |
| Charging<br>**USB charging (cable included)** | Weight · Manufacturer<br>**30 g · MEDICON Co., Ltd., Republic of Korea** |

This product is a medical device. Be sure to read the precautions and instructions before use.

MEDICON

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