

SLM-1101





# Contents

1. Safety Warning and Caution	-----	4
2. Product Introduction	-----	9
2-1 Principle of Operation	-----	9
2-2 Composition	-----	10
2-3 Structure	-----	11
2-4 Cart	-----	13
2-5 Power Cable	-----	13
2-6 How to Install	-----	14
3. How to Use	-----	15
3-1 Booting	-----	15
3-2 Power Off	-----	15
3-3 Main Screen	-----	15
3-5 Mode and Setting	-----	16
3-6 Motor Control	-----	17
3-7 Count and Perforation	-----	18
3-8 Needle Selection	-----	19
3-9 Information and Save	-----	20
4. Maintenance and Storage	-----	21
4-1. Maintenance	-----	21
4-2. Storage	-----	21
5. Troubleshooting	-----	22
6. Product Specification	-----	23
6-1 Generals	-----	23
7. Label	-----	24
7-1 STALUKE Label	-----	24

## 1. Safety Warning and Cautions

**This device is a medical device (electric medical perforator),  
so users should always pay attention to safety and use it safely by  
following the usage procedures described in the user manual**

Be sure to read "Safety Warnings and Precautions" before use and use it correctly. Be sure to follow the precautions shown here because they contain important information regarding safety. After reading, please keep it in a place where the user can always see it. If you rent or transfer this product to someone else, be sure to give it the user manual along with it. This manual classifies the degree of risk in case of incorrect handling into the following three levels.



### Hazrd

This symbol indicates a potential hazard that could result in death or serious injury if handled incorrectly.



### Warning

This mark indicates a situation where serious personal injury or property damage may occur if handled incorrectly.



### Caution

This mark indicates situations where personal injury or material damage may occur if handled incorrectly.



### Hazard : Hazardous Factor

- Modifications to this device are not permitted.
- Do not modify this device without the manufacturer's permission.
- If changes to this device are unavoidable, appropriate inspections and tests must be performed to ensure continued safe use of the device.



### Hazard: Prohibition of Use

Never use it together with the following medical electronic devices  
(There is a risk of malfunction.)

- Implantable medical electronic devices such as pace makers
- Life-supporting medical electronic devices such as artificial hearts
- Mountable medical electronic medical devices such as electrocardiographs

## 1. Safety Warning and Cautions



**Waring : Inhibition of Use**

**① If any of the following applies, be sure to consult a doctor before using or do not use..**

• Person with pacemaker	• Person with malignant tumors
• High fever	• Pregnant women
• Person with perception impairment	• Acute illness
• Skin problems in the area of use	• Patients using artificial organs or artificial bone
• Person who have had a heart attack or currently have a serious heart condition (especially with pacemaker)	

**② Do not use on the following body parts.**

• Gonads	• Heart
• Brain	• Belly with pregnancy
• Metal or plastic in body	• Surroundings where silicone, etc. are inserted
• blood vessels	• Bacterial infection areas on the skin

**③ If you are receiving hospital treatment or outpatient treatment, please consult with your doctor before using.**

**④ People suffering from severe kidney disease, undergoing kidney dialysis treatment, or allergic skin diseases**

**⑤ If any abnormality occurs on the skin or body, stop use immediately and consult a doctor.**



**Hazard : Do not use the device other than the person in charge or a person with professional training according to a specialist's prescription.**



**Warning : Power**

- To avoid risk of electric shock, this device must only be connected to a power supply with protective earthing.
- Rated power is 100-240V~, 50/60Hz. Be sure to use a dedicated power outlet for the power plug.
- Do not use damaged power cords or loose outlets.
- Insert the power plug securely to avoid poor contact.
- Do not use multiple power plugs plugged into one outlet.
- Do not pull on the power cord. (If the cord part is damaged, it may cause fire or electric shock.)
- Do not scratch, damage, or forcibly bend, pull, twist, or tie the power cord.
- The cord or cable may be damaged, causing fire or electric shock.
- Always keep the power plug clean to prevent it from being contaminated with foreign substances.
- Use when damaged or covered with foreign substances Doing so may cause fire or electric shock.
- Do not plug in or unplug the power plug with wet hands. There is a risk of electric shock.

## 1. Safety Warning and Cautions

---



### Caution : Power

- Do not place the power cord in a path where people pass by.
- In case of lightning, it is best to unplug the power plug.
- When not in use or when stopping use in an emergency, there is a Turn off the power switch.



### Caution : Install and Stock

- When transporting the product, do not drop it or subject it to severe shock.
- Avoid exposing this product to direct sunlight.
- Do not place flammable solvents such as alcohol or thinner near the product. Also, do not place the product near electric heaters or stoves. Do not install. (It may cause product deformation, ignition or fire.)
- Do not install the product on an inclined surface or in a place prone to shaking or severe vibration.
- Do not store or use in places with high temperature and humidity.
- Keep out of reach of children.



### Caution : Usage

- This equipment is suitable for use in industrial fields and hospitals, but wireless communication is recommended when used in residential environments. They may not provide adequate protection for the Services.
- If not used for a long time, turn off the power switch on the back of the device.
- Do not disassemble, repair, or modify the product arbitrarily. It may be dangerous as it may cause electric shock or abnormal operation.
- If a problem occurs with the product, stop using it immediately and contact the place of purchase or our customer service center.
- If any abnormality is discovered during use, stop using immediately and consult a doctor.
- Do not subject the product to strong impact or throw it.
- If there is anything not recorded in the user manual, be sure to check the contents with the place where you purchased the product or our head office before using it.
- Be sure to understand the usage and operation instructions before use.



### Caution : Stock

- When wiping the main body to keep the product clean, wipe it with a wet soft cloth and dry it before use.
- Do not clean the product with thinner, benzene, etc. (this may cause discoloration or deformation).

---

## 1. Safety Warning and Cautions

---

### **FCC Part 15.19**

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

### **FCC Part 15.21**

Any changes or modifications (including the antennas) to this device that are not expressly approved by the manufacturer may void the user's authority to operate the equipment.

### **RF Exposure Statement (2.1091)**

- FCC RF Radiation Exposure Statement: This equipment complies with FCC RF Radiation exposure limits set forth for an uncontrolled environment.
- This device and its antenna must not be co-located or operating in conjunction with any other antenna or transmitter.
- This equipment should be installed and operated with a minimum of distance of 20cm between the radiator and your body.

## 1. Safety Warning and Cautions

### Labeling Information

Symbol	Explanation	Symbol	Explanation
	Manufacturer		Caution
	Model name		Warning
	Manufactured date		Fragile
	BF mount part		Open direction
	Temperature limit		Stock in dried condition
	Humidity limit		No use of hooks
	Atmospheric pressure Limit		Handle with care
	Serial number		Emergency stop
	Follow the instruction		Emergency Stop label
	Non-reusable		output   Channel   markLabel (right side)
			output   Channel   markLabel (left side)
	Good Manufacturing Procedure		Protective ground label
<b>T2L, 250V</b>	Fuse Label	<b>220 V, 60Hz</b>	Power label

---

## 2. Product Introduction

---

### 2-1. Principle of Operation

- This product is an electric medical perforator that is used to perforate the skin by rotating the tip.

## 2. Product Introduction

### 2-2. Composition



No	부속품	수량	기타
1		1	Basic Composition
2		1	Basic Composition

## 2. Product Introduction

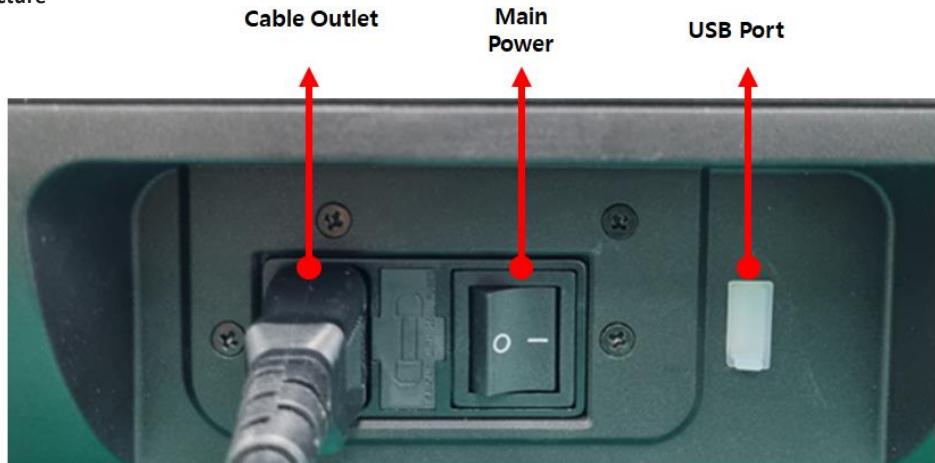
### 2-3. Structure



No.	Item	Function
1	10.1 " TFT LCD	Displays the status of the product and sets product operation using touch-based icons.
2	Power Button	AC power ON/OFF

## 2. Product Introduction

### 2-3. Structure



No.	Item	Function
1	USB Port	Connect USB memory when upgrading programs and storing captured screens
2	Main Power	AC Power On/Off
3	Cable Outlet	AC power cable connection

## 2. Product Introduction

### 2-4. Cart



No.	Name	Function
1	Holder	Holding the main body
2	Wheel	Wheels for cart movement (fixable)

### 2-5. Power Cable



Name	Function
Power cable (1,800mm)	Cable that supplies power to the product

## 2. Product Introduction

### 2-6. How to Install

#### (1) Power cable connection assembly



Connect the AC power cable to the power cable connection assembly on the back of the product.

After connecting, press the main power switch to turn on the main unit so that it can be approved

### 3. How to Use

#### 3-1 Booting

- 1) If you press the power button of the body for more than 1 second, the power light is turned on blue



Booting Button

#### 3-2 Power Off

Press and hold the power button on the main unit for more than 1 second to turn off the main unit.

#### 3-3 Main Screen

You can turn the power on or off by pressing and holding the power button



### 3. How to Use

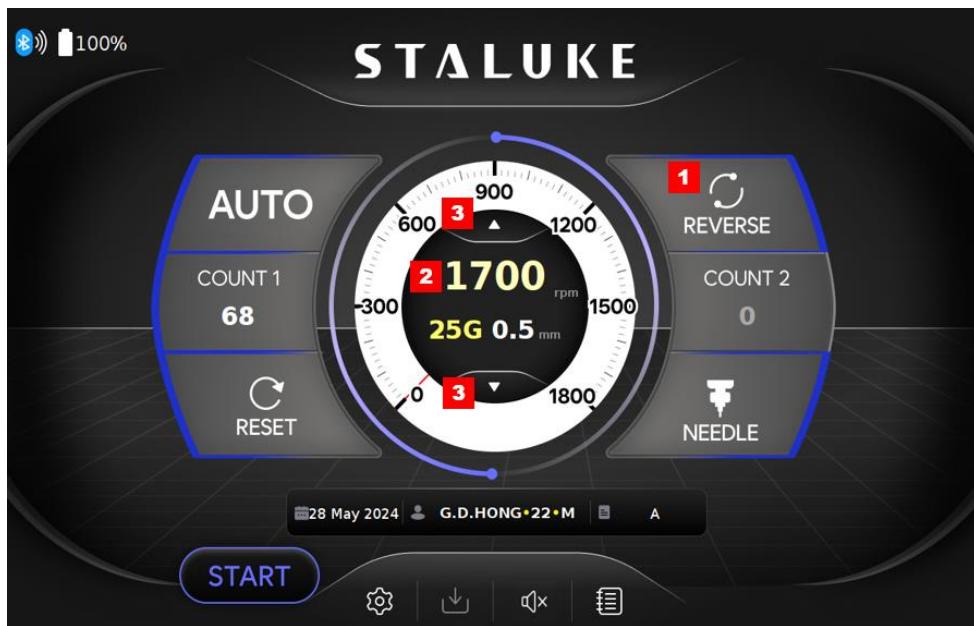
#### 3-5 Mode and Setting



No.	Icon	Name	Explanation
1	<b>AUTO</b>	Modes	The motor rotates continuously, and tip contact is automatically detected when piercing the skin, increasing the number of punctures.
			The motor rotates only when the operation button is pressed, and the number of drilling increases each time the operation button is pressed.
2		Setting	Use when firmware upgrade is needed, prohibited the user to be access
3		Mute	Mute selection
4		Use instruction Video	Play use instruction video

### 3. How to Use

#### 3-6 Motor Control



No.	Icon	Name	Explanation
1	REVERSE	Rotation Direction	Select motor rotation direction (forward/reverse)
2	<b>1700</b> rpm	RPM	Motor speed (RPM) display
3		RPM control	Increase/decrease motor speed (± 10)

### 3. How to Use

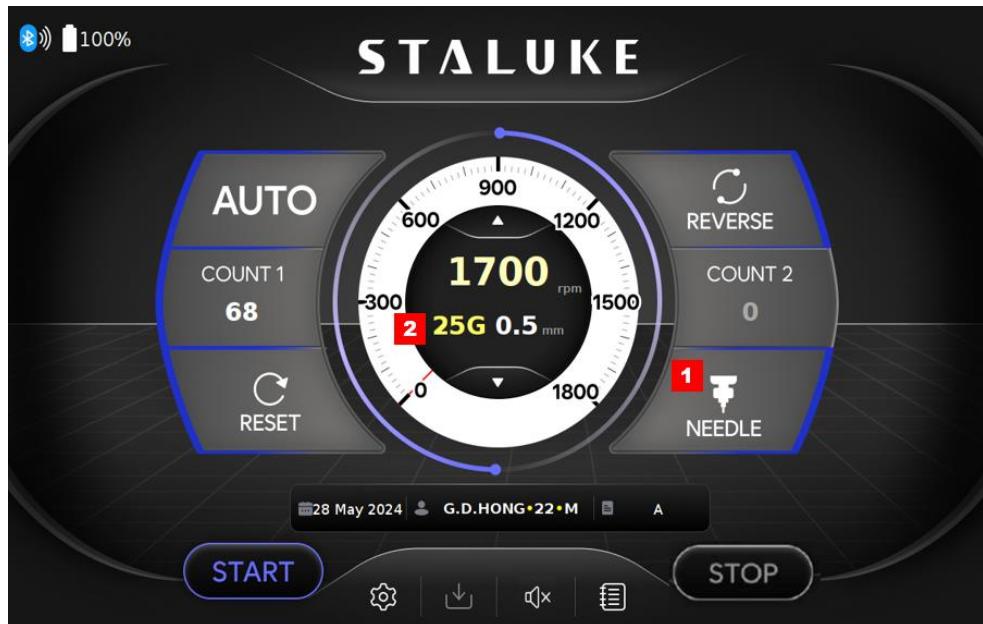
#### 3-7 Count and Perforation



No.	Icon	Name	Explanation
1	COUNT 1 <b>68</b>	Count 1	Select Count 1 and display the number of perforations (maximum 9999)
2	COUNT 2 <b>0</b>	Count 2	Select Count 2 and display the number of perforations (maximum 9999)
3	 RESET	Reset	Reset the number of punctures for the selected Count
4		Start	Start button (active during operation)
5		Stop	Stop the operation

### 3. How to Use

#### 3-8 Needle Selection



No.	Icon	Name	Explanation
1	 NEEDLE	Needle selection	Needle selection (0.5 → 0.6 → 0.7 → 0.8 → 1.1 → 1.3 → 1.6 → 2.1 sequence)
2	<b>25G 0.5 mm</b>	Needle information	Selected Needle information (25G 0.5mm → ... → 14G 2.1mm sequence)

### 3. How to Use

#### 3-9 Information and Save



No.	Icon	Name	Explanation
1		Bluetooth Status	Displays communication status (disabled when communication is disconnected)
2		Battery Status	Displays the remaining battery level
3		Operation Date	Display the current operation date
4		Patients Information	Display name, age and gender
5		Type of Operation	Display type of operation
6		Screenshot	When pressed while the USB is inserted into the USB port on the back of the main body, the current screen is captured and saved as a photo file on USB.

---

## 4. Maintenance and Storage

---

### 4-1. Maintenance

- 1) Store indoors safe from tilt, shock, vibration, etc.
- 3) Store in a place away from direct sunlight.
- 4) Do not store in places with rapid temperature changes or high temperatures and humidity.
- 5) After use, store the connection cables, etc. in their proper place.
- 6) Do not store the cable with a sharp bend or twist.
- 7) After use, wipe the product surface clean with a dry cloth and then store it.
- 8) Keep out of reach of children.
- 9) When reusing a product that has not been used for a long time, check its safety and operation before use.
- 10) When updating software, the manufacturer will visit to perform and confirm it, so please do not perform it yourself.

### 4-2. Storage

- 1) Before cleaning, be sure to turn off the main switch and disconnect the power plug before cleaning.
- 2) When storing or cleaning, be careful not to subject the product to strong impact or cause accessories to fall on the floor.
- 3) Clean carefully to prevent moisture from penetrating into the main body
- 4) After handling the product, allow it to dry sufficiently.

## 5. Troubleshooting

### ※ Checkpoint before reporting a malfunction

If a trouble occurs with this device, please check the following before contacting our head office or sales office.

Trouble	Solution
The device does not power on (Booting malfunction)	<ol style="list-style-type: none"><li>1) Check whether the power cord is properly connected to the power socket.</li><li>2) Turn the main switch OFF and then ON again.</li><li>3) If the power does not work properly, open the fuse box in the power socket and check the fuse. If there is a problem, replace it with a new identical fuse.</li></ol>

## 6. Product Specification

### 6-1. Generals

Product Name	Electric Medical Perforator
Model Name	SLM-1101
Manufacturer	Seoulinmedicare Co., Ltd.
Address	4 <sup>th</sup> floor Seoulin Global Center 593-16, Dongtangiheung-ro, Hwaseong-si, Gyeonggi-do, Republic of Korea
Registration No.	4488
Product Approval No.	Approval in process
Intended Use	An electric device used to perforate into tissue or bone
Package Unit	1set
How to Use	Listed in attached document
Cautions for Use	Listed in attached document
Storage Condition	Temperature(-10°C~40°C), Humidity(20%~80%), Atmospheric pressure(700~1060hPa)
Operation Condition	Temperature(10~40°C), Humidity(30~70%), Atmospheric pressure(800~1060hPa)
AC Power / Hz	AC 100~240V , 50/60Hz
Power Consumption	100VA
Electrical Protection	Class 1, BF type
Dimension / Weight	492mm(W) X 320mm(D) X 340mm(H) / 4.5kg
Water Proof Level	Product: IPX0



If you wish to replace the device or need to dispose of it because its expected shelf life has expired, please dispose of it according to your hospital's standard disposal procedures.

## 7. Label

### 7-1. STALUKE Label

      			
Electric Medical Perfoator	 REF	SLM-1101	 UDI
S T A L U K E	 SN		
100-240V, 50/60Hz, 100VA	 W		
     			
FCC ID	2BG22SLM-1101		
 	SeoulMedicare	4th Floor, Seoul Global Center, 593-16, Dongtangiheung-ro, Hwaseong-Si, Gyeonggi-Do, Korea T : +82-31-742-5319 F : +82-050-4981-5319	

# WARRANTY

Company	Product	Electric Medical Perforator
	Warranty	12 months free warranty from date of purchase
	Date of purchase	
	Serial No	
	Distributor	
	Contact	
Customer	Name	
	Contact	
	Address	

For performance and functional defects that occur within the warranty period of this product, we will repair it free of charge, and if repair is not possible, we will exchange the product.

※ Repairs will be made in accordance with warranty standards only if a breakdown occurs during normal use by the customer.

※ If there is no product warranty or no information is provided, you will receive paid or free A/S according to the quality warranty period specified in the Consumer Protection Act.

1. In the following cases, the provisions of the warranty do not apply.

- ① In case of performance defects or breakdowns that occur after the warranty period has expired
- ② In case of damage caused by the consumer's intention or the consumer's negligence, such as flooding or shock.
- ③ In case of failure caused by improving or modifying the structure, performance, or function of the product by a third party other than our A/S service
- ④ Malfunction or damage caused by using an unapproved charger
- ⑤ Malfunction or damage caused by natural disaster or external causes
- ⑥ Replacement consumables and parts

2. A/S costs for products beyond the warranty period are charged.



4<sup>th</sup> floor Seoulin Global Center 593-16, Dongtangiheung-ro, Hwaseong-si,  
Gyeonggi-do, Republic of Korea

Tel 031-742-5319 Fax 050-4981-5319 [Homepage](http://www.seoulinmedicare.com) [www.seoulinmedicare.com](http://www.seoulinmedicare.com)

© SeoulinMediCare Co., Ltd. All rights reserved.

Issued date 2024.05.14(Rev.0)