

## PRODUCT INTRODUCTION

### 1. Product Name

Handpiece for medical use

### 2. Manufacturer

ScienceMedic Co., Ltd.

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Gyeonggi-do, Korea

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### 3. Type Name

SMB-100S, SMB-100M

Basic components : SMB-100C-8, SMB-100BP-8

Optional components :

Common : SMB-T, SMB-100BC-8, SMB-100BS-8

SMB-100BC-4, SMB-100BS-4, SMB-100BP-4

Options for SMB-100M :

SMB-100MS, SMB-100D, SMB-100DM

SMB-100RA, SMB-100R, SMB-100WP

SMB-100DA, SMB-100RC

### 4. Purpose of use

Medical hand piece is an apparatus designed for tapping, drilling, and cutting large and small bones during orthopedic, plastic, and neurological surgeries.

## PRODUCT FEATURES AND SPECIFICATION

### 1. Product Features

#### 1) SMB-100S



No.	Part name	Function
A	Medical saw connection	A part where medical saw is installed
B	Locking robe	A part where medical saw is detachable.
C	Trigger	If trigger is toward 12 o'clock, it operates If trigger is toward 3 o'clock, it is in safe mode.
D	Function button	If clicking to the desired position, it is converted to the speed set by the user. (However, clicking to the end will not work) For cancellation, click once more and the speed returns to the basic.
E	Handle	Handle is used to grip the hand piece.
F	Power inlet	A part where battery housing and battery pack are connected.
G	Battery separation switch	A switch used to connect the battery pack to the main body or separate it from the main body

2) SMB-100M





Forward







Reverse (Standby)

No.	Part name	Function
A	Attachment connection	A part connected to various attachments
B	Trigger	If trigger is toward 12 o'clock, it operates If trigger is toward 3 o'clock, it is in safe mode.
C	Handle	Handle is used to grip the hand piece.
D	Function button	When clicking, at the rer of the main body, Blue: Forward Yellowish green: Reverse (Standgy)
E	Power inlet	A part where battery housing and battery pack are connected.
F	Battery separation switch	A switch used to connect the battery pack to the main body or separate it from the main body

3) Description of components (common)

No.	Type name	Part name	Appearance	Description
1	Battery housing	SMB-100C-8		A case used to install the battery to the hand piece (excluding EO sterilization battery)
2	Battery pack 8 cells	SMB-100BP-8		A battery to deliver power to the hand piece

4) Description of components (options)

No.	Type name	Part name	Appearance	Description
1	SMB-100MS	Micro saw attachment		<p>Micro medical saw is used by being connected to the hand piece (used for SMB-100M)</p>
2	SMB-100D	Drill attachment (combined type chuck)		<p>For a medical drill, it is used by being connected to the hand piece (used for SMB-100M)</p>
3	SMB-100DM	Drill attachment detachable type chuck		<p>It is used when medical device is connected to the hand piece (used for SMB-100M)</p>
4	SMB-100R	Reamer attachment (Stryker, Zimmer, Hodson)		<p>It is used when medical chuck or device is connected to the hand piece (used for SMB-100M)</p>

No.	Type name	Part name	Appearance	Description
5	SMB-100RA	Reamer attachment (AO Synthes)		It is used when medical chuck or device is connected (used for SMB-100M)
6	SMB-100WP	Wire/Pin attachment		It is used when wire/pin is connected to the hand piece (used for SMB-100M)
7	SMB-100DA	AO drill bit attachment		It is used when AO drill bit is connected to the hand piece (used for SMB-100M)
8	SMB-100RC	Reciprocating attachment		It is used when reciprocating medical saw is connected to the hand piece (used for SMB-100M)
9	SMB-100T	Case		All products are stored here.

No.	Type name	Part name	Appearance	Description
10	SMB-100BP-EO	Battery pack for EO sterilization		It is used for EO sterilization of a battery to deliver power to the hand piece. (commonly used)
11	SMB-100BP-4	Battery pack 4 cells		Battery to deliver power to the hand piece (commonly used)
12	SMB-100C-4	Battery housing		A case used to install a battery on the hand piece (commonly used)
13	SMB-100BS-8	Battery shield 8 cells		It is used to prevent contamination when non-sterilization battery is installed on the sterilized battery case. (commonly used)
14	SMB-100BS-4	Battery shield 4 cells		It is used to prevent contamination when non-sterilization battery is installed on the sterilized battery case. (commonly used)
15	SMB-100BC	Battery charger 3 ways		It is used to charging a battery. (commonly used)

## 2. Product specification

### 1) SMB-100S

Blade Oscillation arc 4.5°

CPM 14,000 ±10%

### 2) Specification of optional items for SMB-100M

SMB-100D 1,200RPM ±10% (under load)
SMB-100DM 1,200RPM ±10%
SMB-100R 300RPM ±10%
SMB-100RA 300RPM ±10%
SMB-100WP 1,200RPM ±10% (under load)
SMB-100DA 1,200RPM ±10%
SMB-100RC 20,000CPM ±10%
SMB-100MS 20,000CPM ±10% (under load)

### 3) Specification of common optional items for SMB-100S, SMB-100M

(1) Battery : Li-ion 14.8V d.c. 3000mAh

(2) Battery charger

Input			Output	
Voltage	Frequency	Power	Voltage	Ampere
220V	60Hz	400VA	16.8V	3.0A

(3)Parameters to prevent electric leakage:

-Hand piece: embedded power equipment

-Charger: Class 1 equipment

(4) Classify water penetration: depending on protection against IPX0.

(5) Mode operation:

-Handipiece:Non-continuous operation

-Charger: continuous operation

### 4) Duty cycle

Nol	Type name	Installation part	Starting mode (conditions)
1	SMB-100MS	10 mm toward the direction of a handpiece from the end of a medical cutting device or medical saw	*Duty cycle: non-continuous mode (20 seconds on, 4minutes off, 2 times) *Rest between cycles: 3 hours
2	SMB-100D		*Duty cycle: non-continuous mode (1minute on, 4minutes off, 5 times) *Rest between cycles: 3 hours
3	SMB-100DM		
4	SMB-100R		
5	SMB-100RA		
6	SMB-100WP		
7	SMB-100DA		*Duty cycle: non-continuous mode (20 seconds on, 4minutes off, 2 times) *Rest between cycles: 3 hours
8	SMB-100RC		



Installation part	Start mode (conditions)
10 mm toward the handpiece from the end of the medical saw	*Duty cycle: non-continuous mode (20 seconds on, 4minutes off, 2 times) *Rest between cycles: 3 hours

## How to use

### 1. Preparation before use

- ① Before use, check deformations or cracks on the product appearance.
- ② Check a failure in the operating and connecting parts.
- ③ Install always while the device does not operate.
- ④ Before use, check the state of battery charging.
- ⑤ Before use, understand fully the user manual.
- ⑥ Before use, user should sterilize attachments (saw, drill, reamer)
- ⑦ Unintended or insufficiently knowledged operators prohibited to use.
- ⑧ Intended personnel allowed to use after completing special education (user setting)
- ⑨ Special care required for a battery charger according to potential electronic or other interference information.
- ⑩ Do not place the device at a place where it is difficult to separate the plug of a battery charger.
- ⑪ For using a battery charger, maintain a certain distance from the other device considering electronic effect.

**“Warning: To avoid electric shock, connect this device only to the power source with protective earth.”**

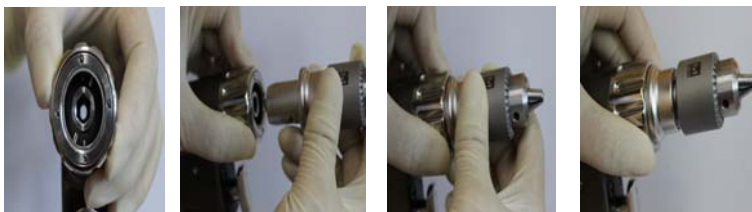
### 2. How to use

#### (SMB-100M)

#### 1) Installing attachments

Caution: Before installing attachments, be sure to set the trigger to the safety mode at all times.

- ① After turning the handpiece attachment connection counterclockwise, release the connection for the attachment to complete its installation.
- ② Install properly the attachment to the purpose.



#### 2) Installing a battery pack

**Warning : Before installing a battery pack, set to the safety mode at all times.**

**Note : Use only a battery pack fully charged.**

- ① Put the battery into the battery housing with a battery shield.
- ② Insert the battery housing into the handpiece power inlet until a click sounds.
- ③ Check if battery housing is firmly fixed to the handpiece.

- ④ After converting the function button to Forward/Reverse mode, press a trigger to check operating state of the handpiece.



### 3) How to operate the handpiece

Warning : – When you do not use a handpiece, store at a safety mode at all times.

- While the handpiece operates, do not use a function button.
- Before operating the handpiece, set it to the safety mode. Then, pull the attachment always to see if it is fixed firmly to the handpiece.
- While the handpiece operates, never touch the rotating components.
- Always respect the recommended cycle to prevent overheat of the device.
- Do not force the attachment excessively. In doing so, attachment may be bent or broken to cause tissue damage, touch control loss, or fragments eruption.



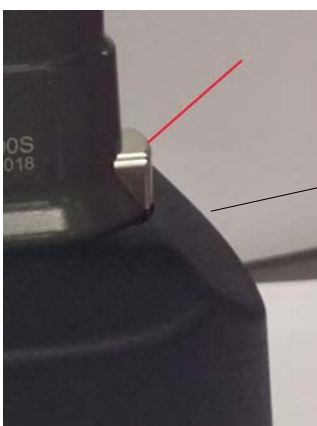
- Caution : – Do not stop the handpiece suddenly. It may cause damage on the electric motor and battery pack. If the handpiece is tripped to a stop, release the trigger instantly. Remove the obstacle and operate the handpiece again.
- In case of power failures during the use of a handpiece, replace with a fully charged battery pack, Otherwise, it may be discharged or damaged, its life reduced.

① Press the trigger slowly for operation.

② For operation, use a function button and Forward/Reverse mode.

### 4) Separating the battery pack.

Warning : Before separating the battery pack, always set to the safety mode.



If you hold the battery housing with one hand and click this button with the other hand, then battery housing is separated.

## 5) Separating the attachment

Warning : Before separating the attachment, always set to the safety mode.

- ① Separate the attachment from the handpiece as necessary.
- ② Turn the attachment connection counterclockwise, and the attachment is separated.



## 6) Operating environment

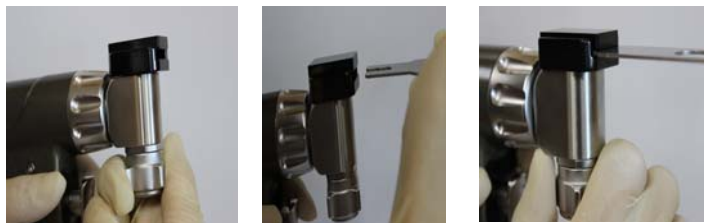
- ① Temperature : 10℃ ~ 40℃
- ② Humidity : 10% ~ 90%
- ③ Atmosphere : 700~1060 hpa

## (SMB-100S)

### 1) Installing the medical saw

Warning : Before installing the medical saw, always set to the safety mode.

- ① Turn the locking switch of the handpiece clockwise.
- ② Medical saw connection goes up. Then push the medical saw to the end.
- ③ If turning the locking switch counterclockwise, medical saw is fixed.
- ④ Pull the medical saw slightly to check if it is firmly fixed to the handpiece.



**Note : Medical saw can be used at any angle position with its 360-degree rotation.**

### 2) Installing the battery pack

Warning : Before installing a battery pack, always set to the safety mode.

Note : Use only a battery pack fully charged.

- ① Put the battery into the battery housing with a battery shield.
- ② Insert the battery housing into the handpiece power inlet until a click sounds.
- ③ Check if battery housing is firmly fixed to the handpiece.
- ④ Turn the trigger to the operation mode, then check the operating state.



### 3) Operating the handpiece

#### Warning

- When you do not use the handpiece, store at a safety mode at all times.
- Before operating the handpiece, pull the medical saw slightly to check if it is firmly fixed to the hand piece.
- Always respect the recommended cycle to prevent overheat of the device.
- Do not force the medical saw excessively like bending or twisting.

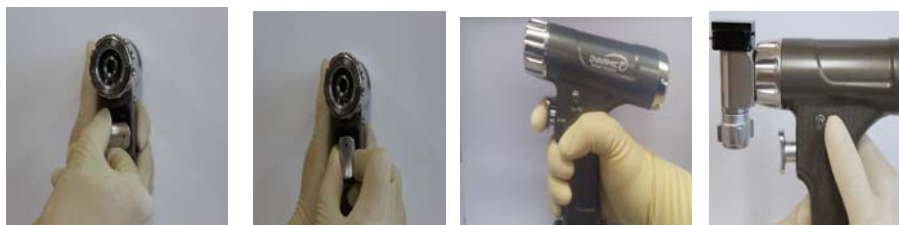
#### Caution

- In case of power failures during the use of a handpiece, replace with a fully charged battery pack, Otherwise, it may be discharged or damaged, its life reduced.

- ① Turn the trigger to the operating position.
- ② If pressing the trigger to the speed as desired by the user and clicking the function button once, that speed is maintained at all times.

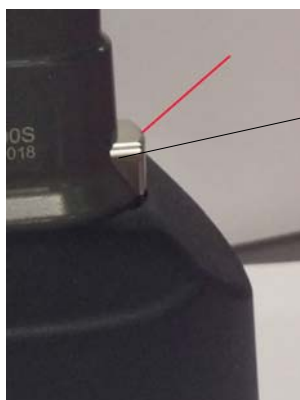
When you want to change the speed, press the function button only in no operation state, it returns to the initial state.

Note : If pressing the trigger to the end, setting does not work.



### 4) Separating the battery pack

Warning : Before separating the battery pack, set to the safety mode at all times.



If you hold the battery housing with one hand and click this button with the other hand, then battery housing is separated.

#### 5) Separating a medical saw

Warning : Before separating the medical saw, set the trigger to the safety mode at all times.

Turn the locking switch counterclockwise, and take out the medical saw.








#### 6) Operating environment

- ① Temperature : 10°C ~ 40°C
- ② Humidity : 10% ~ 90%
- ③ Atmosphere : 700~1060 hpa

### 3. Charging the battery

※ Use care so that the charging terminal is not contacted by the user.

 <p>The image shows the initial screen of the Sciencemedic BATTERY CHARGER. The display is orange and shows the text "Sciencemedic BATTERY CHARGER" and "START" below it.</p>	<p>Initial screen in case of power on</p>
 <p>The image shows the screen displaying "16.3V" and "84%" with the text "STAND BY" below it. The "START" button is visible below the display.</p>	<p>Ready to charge</p>
 <p>The image shows the screen displaying "16.4V" and "85%" with the text "CHARGING" below it. The "START" button is highlighted with a blue glow.</p>	<p>At Ready-to-charge state, if installing the battery and clicking Start button, then charging starts.</p>
 <p>The image shows the screen displaying "16.9V" and "100%" with the text "COMPLETE" below it. The "START" button is highlighted with a blue glow.</p>	<p>Charging completed</p>
 <p>The image shows the screen displaying "ERROR" and "CHECK CONTACT" below it. The "START" button is visible below the display.</p>	<p>Charging error indication The light around START button blinks.</p>

#### 4. Storage after use

##### ① Storage method

- 1) Set the device to the safety mode at all times.
- 2) After use, separate the attachment and battery for storage.
- 3) Store sharp items in a puncture resistant container.
- 4) Storage environment

Temperature : 10°C ~ 40°C

Humidity : 10% ~ 90%

##### ② Moving method

Warning : Pay special attention not to be wounded by the sharp cutting edges while being moved.

Caution : Be cautious of damages by hitting while being moved. Do not mix heavy devices with delicate devices.

##### ③ Cleaning method

Warning : Use alcohol only for cleaning the device.

Separate all detachable components and disposable cutting fittings from the handpiece.

Caution : Do not use lubricants or other chemicals not specified separately.

Do not soak or immerse the device in the liquid.

Do not let the humidity or liquid permeate.

Do not use a tube cleaning device or cotton swab for lumen cleaning..

- 1) Remove all foreign materials from the device using an absorbing paper towel, soft, non-fluffy cloth.
- 2) Clean the device completely with a proper brush.
- 3) Clean the lumen with a soft brush of a proper diameter.

#### 5. Inspection and test

##### Warning

- This device should be inspected and tested only by the user educated and experienced in maintenance and repair of recyclable medical devices
- If damage is found, do not use the device.
- Never disassemble or repair this device. Contact our service center.

##### Note

- Careful, periodic inspection and functional test are the best method to judge shelf life of the device.

##### ① Visual inspection

- A spot where foreign materials may be caught
- A hollow area like a hole or lumen
- An area where foreign materials are compressed by the contact with the device.

##### ② Function inspection

- Check any loose component.
- Check if all moving parts are free to move.
- Check if the device operates as expected.

6. Sterilization

1) Sterilization method : High pressure steam sterilization

Sterilization conditions :

Kind of sterilization	Temperature	Sterilizing time	Dry time
Steam-vacuum	132°C	4 min.	8 min.
Steam Gravity	132°C	10 min.	8 min.
Steam Gravity	121°C	40 min.	8 min.

% In case of non-sterilization product, observe the above matters considering the following matters.

As these products are supplied in non-sterilization state, be sure to sterilize in a high pressure steam furnace before practise.

Sterilize under high pressure steam at more than 132 degrees for over 8 minutes. Besides, be sure to use it with a sterilization indicator so as to check sterilization state.

2) Sterilization method : EO sterilization

Service gas : EO(20%) + CO2(80%)

Sterilization pressure	Sterilization temperature	Sterilization time	cleaning time
1kgf/cm <sup>2</sup>	38°C	5Hour	15Hour
1kgf/cm <sup>2</sup>	56°C	3Hour	10Hour

7. Waste/Recycle

Warning

- If service life of this device is finished, observe regulations about environment protection, recycling of devices, and risk related to the waste.
- Handand dispose of operation wastes safely
- Before sending battery packs exposed to infectious materials to waste treatment facilities , always remove contamination.




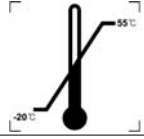




8. Limited warranty

3-month warranty only for batteries

Semi-permanent warranty for the main body and other components



## SIMBOL DEFINITIONS

	<p>Per Directive 2006/66/EC, collect and recycle batteries/battery packs according to EU Member State regulations. This rechargeable battery contains Lithium-ion material.</p>
	<p>Non Sterile</p>
	<p>CONSULT INSTRUCTIONS FOR USE</p>
	<p>TEMPERATURE LIMITATION</p>
	<p>CATALOGUE NUMBER</p>
	<p>BATCH CODE</p>
	<p>CAUTION, CONSULT ACCOMPANYING DOCUMENTS</p>
	<p>Handle with care, and storage</p>