

사용 설명서

Implant
X CUBE V2.0



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INSTRUCTION MANUAL



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 **SAESHIN**

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● USER GUIDELINES

- This product is designed for bone surgery (implant surgery). Please use the product in a proper use and method.
- 1. Type of protection against electric shock:
Class I equipment
Degree of protection against electric shock: Not classified

- Type BF applied parts
Classification according to the degree of protection
against ingress of water as detailed in the current edition of IEC 60529:
Equipment: IPX0, ordinary equipment
Foot Switch: IPX1
This equipment is not suitable for use in the presence of flammable anesthetics
or oxygen
Mode of operation: continuous operation
- 2. Please pay attention to the use considering the patient's safety first of all.
- 3. Please read the instruction manual thoroughly for understanding the functions and
then use the product.
- 4. Check the working status before the surgery and use the product if there is no prob-
lem.
- 5. Stop working and check the problem if there is vibration, heating or strange sound
before or during the use.
- 6. Ask to the manufacturer if the problem is abnormal or unsolved easily.
- 7. Please prepare the extra consumable parts before use. Especially, the contra angle
handpiece doesn't work if the blood or a saline solution comes into the head. So
that we recommend to have an extra for safety.
- 8. Make sure to put a plug in an outlet with earth.
- 9. Change or insert the bur after the motor stops completely. Otherwise, the inside of
contra angle handpiece could be damaged by the bur and it will cause an accident.
- 10. Do not drop from on high or give shock on the product. It damages the product.
- 11. In case the irrigation pump doesn't work, do not bend or fold the tube. The tube
will be broken or taken off.
- 12. Do not disassemble or modify the product. When disassembled, the after sale servi-
ce is not available.
- 13. Please sterilize and lubricate the handpiece immediately after use. Otherwise, the
product could be damaged because of coagulation by the blood or remains from surg-
ery.
- 14. Do not insert the oil into the motor. It damages the bearing or causes heating.
- 15. The control unit and foot control pedal are not autoclavable.

- 16. If the control unit is contaminated, clean with wet cloth and then remove the
moisture with dry cloth after turning the power off.
- 17. Do not use the solvent such as sinner or benzene for cleaning.

- 18. The input power is available at AC100~110V / 220~240V.
** (Check input voltage before connecting the AC power.)

- 19. Dispose the irrigation tube after use as medical waste.

● PRODUCT FEATURES & ADVANTAGES

○ **BLDC motor with high performance designed by Saeshin's own high technology and Know-How**

- BLDC motor(Speed Range 600~50,000) and Angle(Standard equipment 20:1)
provides the optimum torque in surgery.

- * RPM :30rpm ~ 2,500rpm(20:1 is recommended for the optimum use)
- * Torque : 20:1 (5.0 ~ 55 Ncm) / 32:1 (5.0 ~ 65 Ncm)
- * Gear ratio : 1:1, 20:1, 27:1, 32:1

○ **Program memory function**

- * 10 programmable memories for setting Speed, Torque, Rotating Direction,
Irrigation Pump

○ **Automatic overload protection function**

- * If the load on the Bur is higher than set Torque, the motor is stopped
automatically after 2 seconds.
- * For releasing the overload function, push foot control pedal.

○ **Actual RPM and Torque is indicated when motor is running, which makes user verify proper working condition during operation.**

○ **Ergonomic foot control pedal**

- * The foot control pedal is designed ergonomically to control all the functions
and it provides high convenience.

PRODUCT COMPONENTS

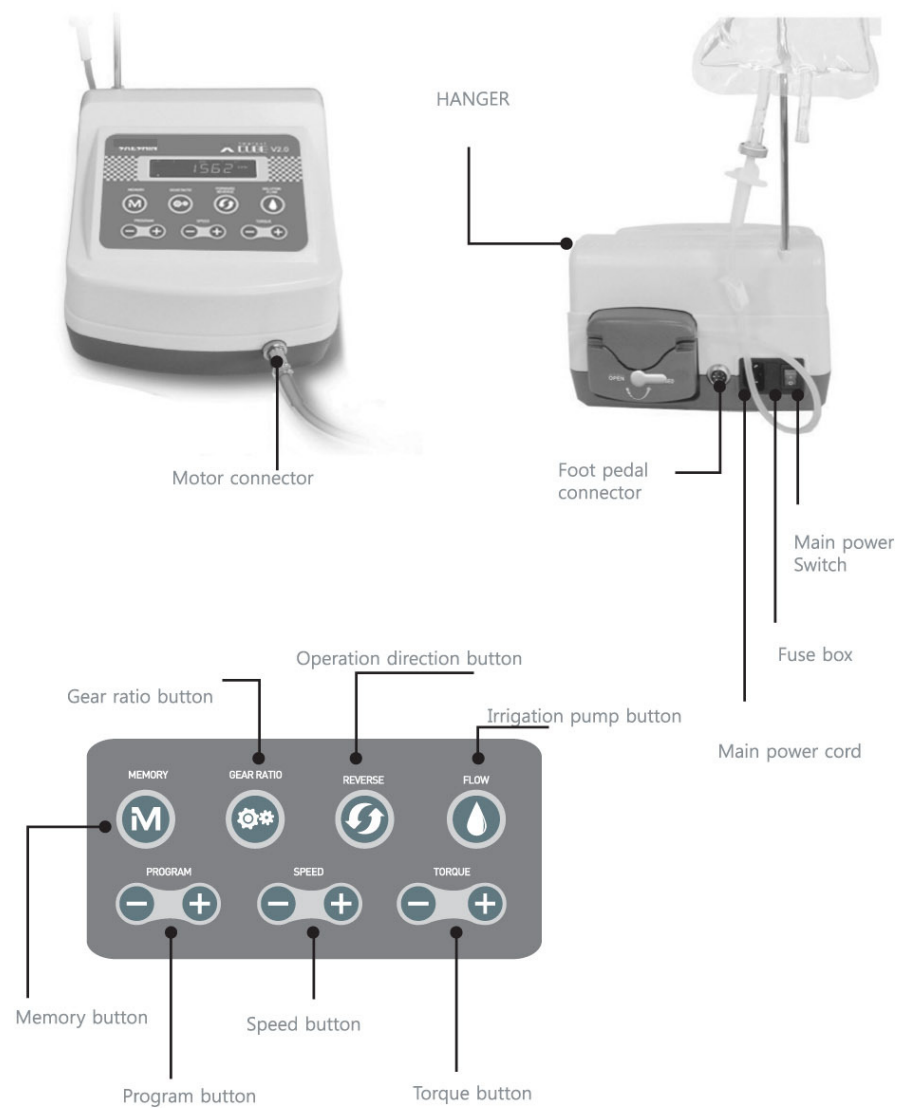
*Please check if all components are included.



| | | | |
|---|-----------------------|----|-------------------------|
| 1 | HANGER | 8 | MOTOR CAP FOR AUTOCLAVE |
| 2 | FOOT CONTROL PEDAL | 9 | WRENCH |
| 3 | CONTROL BOX | 10 | ANGLE HANDPIECE |
| 4 | POWER CORD | 11 | BLDC MOTOR |
| 5 | MOTOR STAND | 12 | TUBE HOLDER |
| 6 | IRRIGATION TUBE | 13 | TUBE CLAMP |
| 7 | INTERNAL SPRAY NOZZLE | 14 | Y-CONNECTOR |

Saline solution is not included in a set and is separate sale by its manufacturers.

PART NAME OF CONTROL UNIT

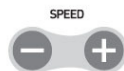


● BUTTONS ON THE OPERATION PANEL



Program button

: Use for selecting the set program number.
(+) button for 1 stage up and (-) button for 1 stage down.



Speed button

: Use for setting the speed (RPM)
(+) button for 1 stage up and (-) button for 1 stage down. keep pressing speed button to change the stage rapidly.
* The setting range of speed is different from the gear ratio.



Torque button

: Use for setting the torque according to the various use such as drilling or tapping.
(+) button for 1 stage up and (-) button for 1 stage down. keep pressing speed button to change the stage rapidly.
* The setting range of torque is different from the gear ratio.

MEMORY



Memory button

: Keep pressing Memory button after completed setting. Then the condition is memorized with beep sound.

GEAR RATIO



Gear ratio button

: Use for setting the gear ratio of the handpiece.

FORWARD REVERSE



Direction button

: Use for selecting the forward or reverse direction.
The beep sound is heard during rotation in reverse direction.

SOLUTION FLOW

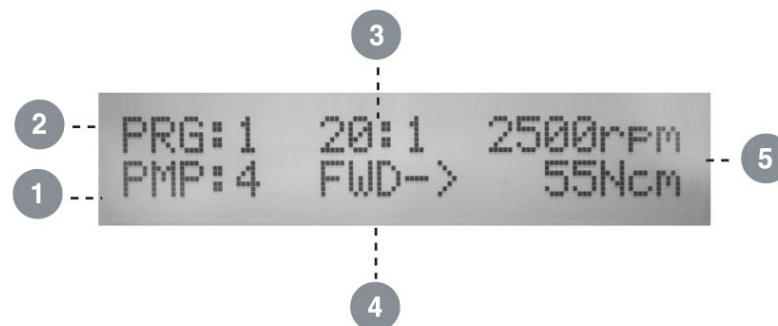


Irrigation pump button

: Use for setting the irrigation volume in 5 stages from 0 to 100ml.

| Irrigation level | Water Pump |
|------------------|---------------|
| 0 | 0 ml/min |
| 1 | abt. 45ml/min |
| 2 | abt. 55ml/min |
| 3 | abt. 65ml/min |
| 4 | abt. 75ml/min |

● LDC WINDOW



1 Irrigation volume display

: It shows the selected irrigation level. Among 4 level, 0 level is no volume and 4th level is maximum 75ml/min.

2 Program number display

: 10 programmable sets from 0 to 9. and it shows program 1 at every power on.

3 Gear ratio display

: It shows the selected gear ratio number.

4 Direction display

: It shows the selected direction.

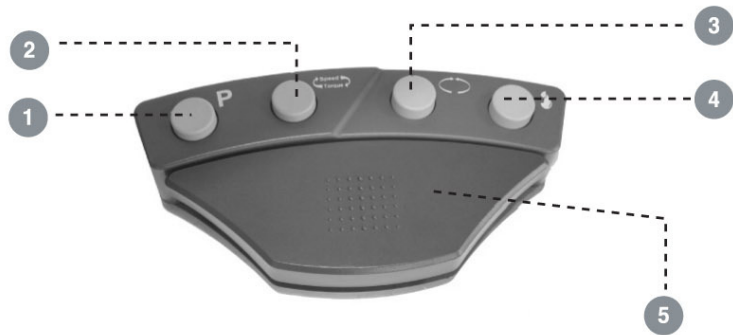
5 Speed / Torque display

: It shows preset RPM and preset Torque when Motor is stopped.
It shows running RPM and running Torque when Motor is running.

⚠ Motor stops running automatically when running Torque reaches preset Torque and keeps it more than 2 seconds.

⚠ Impact and Falling may cause breakage of LCD.

● BUTTONS ON THE FOOT CONTROL PEDAL



- 1 Program button**
: Use for selecting the program. Each press increases 1 stage.
- 2 Not in use currently**
- 3 Operation direction button**
: Use for selecting the operation direction.
- 4 Irrigation pump button**
: Use for setting the irrigation volume. Each press increases 1 stage.
- 5 Speed control pedal**
: The motor speed is controlled by pressing and releasing the pedal.

● CONNECTION OF EACH PART



Warning

Please make sure that power is off !
(Otherwise, it might cause malfunction.)

1 Motor connection

Please insert the motor plug. Check the hole and pins of motor connector in place. Then screw the connector lock for sure.



Connector Lock

2 Foot pedal connection

Please insert the foot pedal plug checking the hole and pins of foot pedal connector in place. Then screw the connector lock for sure.



Connector Lock

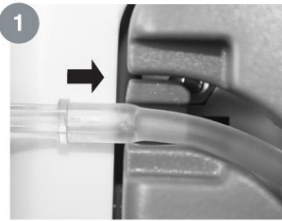
○ CONNECTION OF EACH PART

3 Power cord connection



Insert the power cord into the power socket in the back of control box.

4 Irrigation tube connection

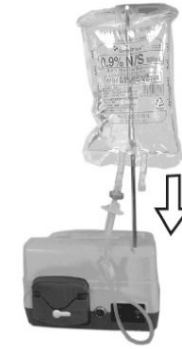


when you turn the open-close knob clockwise at the back of control box, pump cover opens and you see the space between the covers. Then insert the irrigation tube into the space.

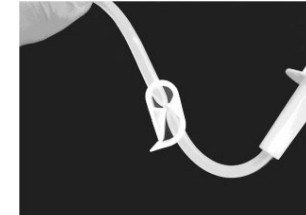
Turn the knob counter-clockwise until closing pump covers. ↻

○ CONNECTION OF EACH PART

5 Bottle setting



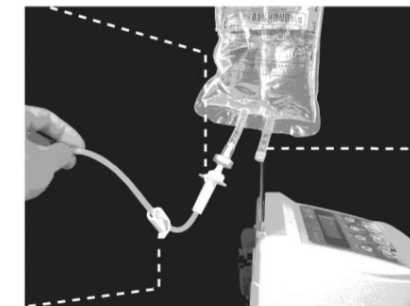
Put the hanger into the hanger hole at the back of control box



6 Irrigation tube insertion

Insert the irrigation tube needle to the bottle in place with the bottle downward. Lock the irrigation stopper placed between the irrigation tube needle and bottle, then insert the breather needle which blows up the air into the bottle. [ATTENTION] If the pump operates while the tube is bent or the water doesn't come out, the tube may be broken or damaged.

Irrigation tube Irrigation tube needle

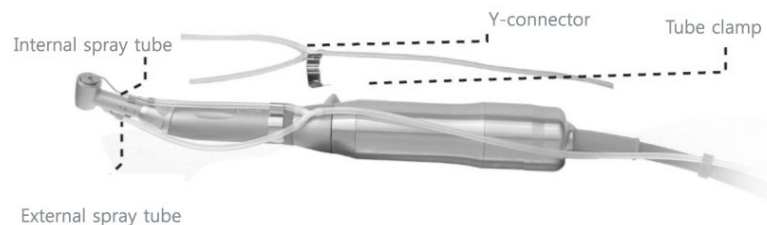


Breather needle

Irrigation Stopper

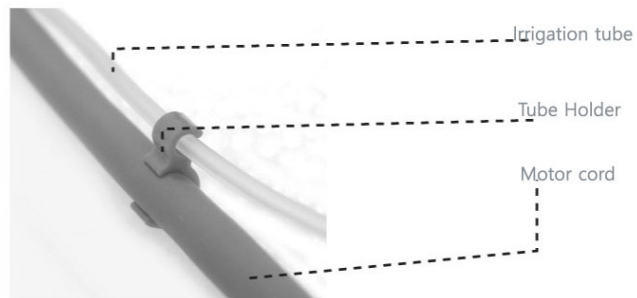
CONNECTION OF EACH PART

7 Irrigation nozzle connection



The internal and external irrigation is available with internal spray nozzle and Y-connector. Connect the accessories as the picture according to the using bur and surgery type. (ATTENTION) If the user presses the button or opens the lever with the internal spray nozzle inserted, the nozzle may be damaged during the bur change.

8 Tube holder connection



Put the motor cord and irrigation tube together with tube holders. Insert the tube holder to the motor cord and then put the irrigation tube for easy work.

OPERATION PROCESS

* OPERATION PROCESS

- (1) Turn on the main switch.
The set program 1 is selected and shown automatically.
- (2) Choose the program.
By pressing the first left button on the pedal, the program changes by 1 stage.
Choose the needed program. **P**
The program returns to number 1 after number 10.
- (3) Check the setting.
Check the display on LCD box to make sure the correct setting.
The number in the middle of LCD shows the speed. If pressing the speed/torque button on the foot pedal, the mode is changed to display the torque.
- (4) Start the operation.
The motor rotates pressing the speed control pedal. It runs at low speed with light press and at high speed with heavy press by the set speed in max .
If the irrigation mode is on, the pump operates also.
- (5) Overload protection function
If the load exceeds the set torque during the use, the overload protection function works not to generate the extra torque.
- (6) Stop the operation.
The working is stopped by stepping out the speed control pedal.
- (7) Change the operation direction.
Press the button on the foot pedal for the reverse direction.
If the reverse direction mode is selected, the beep sound is heard and it continues during the operation.

OPERATION PROCESS/MAINTENANCE

* Program setting

X-Cube has 10 programable memories in conditions below

Setting the gear ratio - speed - torque - operation direction - irrigation pump in order and then press the memory button.

| | | SPEED | TORQUE | | | |
|-----|--------------|---------|---------|-----|---------|----|
| ex) | PRG 1 : 32:1 | 1562rpm | 10 N-cm | FWD | PMP : 4 | 완료 |
| | PRG 2 : 64:1 | 781rpm | 15 N-cm | FWD | PMP : 2 | 완료 |

1 Error and Remedy

If the motor is stopped due to the overload and make the motor operate continuously, circuit safety system cuts the power supply and shows an error code on LCD box.

Indication

Warning!
Torque Limit.

◆ This is indicated when running Torque reaches preset Torque and keep it more than 2 seconds.

* Remedy : Push Foot Control Pedal.

Warning!
Motor Connect Check!

◆ This is indicated when Motor is not connected.

* Remedy : Make sure to connect Motor properly.

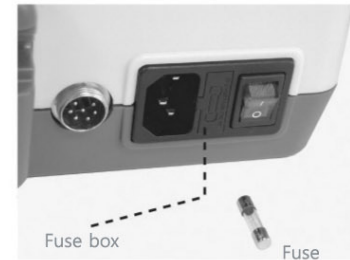
Warning!
Foot Switch Check!!

◆ This is indicated when Foot Control Pedal is not connected

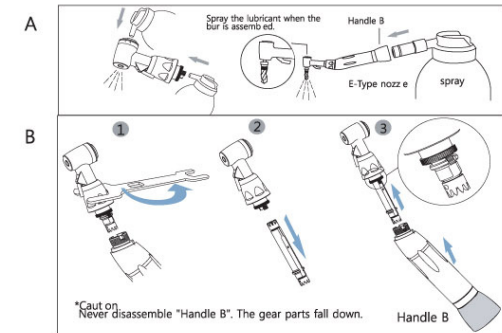
* Remedy : Make sure to connect Foot Control Pedal properly.

CONNECTION OF EACH PART

3 Fuse change



Check the fuse if the control box doesn't work.
The fuse comes out pressing the fuse box at the back of control box.
If it's too tightened, please press the fuse box with the sharp-edge instrument and pull out.



4 Maintenance of contra angle handpiece

[Cleaning & lubrication]

Rotate the head in the water about 10 seconds with high speed to remove the remains (blood, physiologic saline solution, etc.)
Remove the water with the soft cloths or paper towel and then lubricate using the e type nozzle.

[How to insert the lubricant]

As the picture A, insert the e type nozzle to handle B and spray the lubricant about 2~3 seconds.

If the head is polluted badly, spray toward the head after disassembling the joint cap using wrench.

In case of the continuous operation, lubricate every 30 minutes.

lubricate at least once a day.

Make sure to grasp the handpiece firmly during the lubrication to prevent popping out because of the pressure from the spray.

[Disassembling the head]

1. Put the wrench on the joint cap and turn it to the counter clock direction to open.
2. Pull out the gear.
3. Clean and lubricate the parts.
4. Reassembling Fit the gear to the "key" and put into the head.

Check if the gear fits to the head assembly and close smoothly.

Assemble the head part to the body.

Lock the joint cap tightly with the wrench.

Assemble the gear correctly after the lubrication.

The angle may be damaged in case of mis-assembling.

Autoclave

3 Autoclave

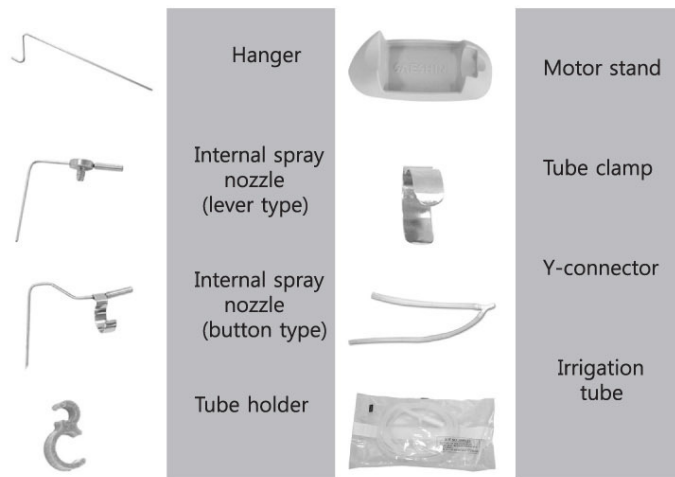
The following accessories are autoclave at 134°C.

Handpiece, BLDC motor,
Internal spray nozzle
Tube Clamp,
Tube Holder,
Motor cap for autoclave

- 1) Clean the remains such as blood or saliva.
- 2) Lubricate the head of handpiece with spray after disassembling.
 - Do not use the spray on the motor. It may cause the breakage.
 - Assemble the motor cap for autoclave on the motor.
- 3) Make sure to use the sterilization bag and seal tightly.
- 4) Put the bag in the sterilization machine and operate at 134°C for 4 minutes or 121°C for 20 minutes.

(ATTENTION) BLDC motor could be damaged in lubrication or sterilization because of the moisture inflow or else, so please take care of handling.
Autoclaving the handpiece with blood or other remains may cause the breakage of the handpiece. Therefore, it is necessary to clean the handpiece before autoclave.
Irrigation tube and Y-connector are disposable. Do not use them again.

3 Accessories



ATTENTION IN X-CUBE USE

1 Keep to the followings BEFORE operating X-CUBE.

- 1) Check the connection of all cords well and correct operation when power-on.
- 2) Check the status of earth for the safety.
- 3) Make sure to check the contact part to patient.
- 4) Check the voltage.

2 Keep to the followings DURING X-CUBE USE.

- 1) Check the status of product and patient constantly during the surgery.
- 2) In case of finding any problem on product or patient, stop the operation in condition of patient's safety or take proper action.
- 3) Keep away the product from the patient.

3 Keep to the followings AFTER OPERATING X-CUBE.

Do not be pressed the power, motor, and foot pedal cords when putting away.

* Product Specification

CONTROL BOX

| | |
|-------------|-----------------------|
| Input | AC100~110V / 220~240V |
| Frequency | 50/60 Hz |
| Output | MAX : 120W |
| pump volume | Max.75mL/min |
| Dimensions | W205 X D210 X H136 |
| Weight | 3.3kg |

IMPLANT MOTOR

| NON LOAD RPM | WEIGHT | D MENSION (mm) | | | | | 134°C |
|--------------|--------|----------------|----|----|----|----|-------|
| | | L | L1 | L2 | D | D1 | |
| 50,000 | 212g | 128 | 32 | 96 | 27 | 10 | |

WARRENTY

* WARRENTY

Handpiece - 1year
Control box & Foot Pedal - 1 year

Warranty does not include misuse or normal wear of bearing, carbon brushes, collet chuck, spindle and armature.

WARRENTY

* SERVICE CHARGE

In case of the fault or malfunction from the misuse of the user

- Using with wrong Input Volage (AC Voltage)
- In case of user's misuse or improper use
- Dropping down during setting or moving
- Using consumable parts or accessories not recommended by manufacturer
- Malfunction after repairing at the places not recommended by manufacturer

Other cases

- Faulty by Act of God (fire, sea wind or water, flood etc.)
- Replacing by the normal wear of the consumable parts (ball bearings, collet chuck, spindle, or armature etc.)

For your safety, Keep to the following.


Do not use with damaged or faulty power cord, plug, and outlet, Contact to the manufacturer. If may cause the danger of fire, electric shock.

When unplug the power cord, hold the plug and do not touch with wet hand. Do not use with loosing power plug causing the danger of electric shock and fire.

Do not bend the power cord excessively and do not press with heavy things. If may cause electric shock and fire.

Do not place near heat equipment and candles or cigarette causing fire.

Close supervision needs if this product is used by or near by the very young, the elderly or invalid. Do not leave children unattended in any room where this product has been installed.

Type of protection against electric shock: 
Class I equipment


◆ Degree of protection against electric shock:
Type BF applied parts

◆ Classification according to the degree of protection against ingress of water as detailed in the current edition of IEC 60529:

◆ Equipment: IPX0, ordinary equipment
Foot Switch: IPX1

◆ This equipment is not suitable for use in the presence of flammable anesthetics or oxygen

◆ Mode of operation: continuous operation with intermittent loading:
Loading time: max. 3 minutes; Rest time: min. 10 minutes.

 Maximum temperature of Applied Parts:
The Head of Handpiece is Applied Parts
The maximum temperature of Applied parts are below:
34°C ambient 25°C or 49°C at ambient 40°C
Therefore use of this parts carefully.

MEMO

"This equipment has been tested and found to comply with the limits for medical devices in IEC 60601-1-2:1994. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected. Consult the manufacturer or field service technician for help."

Use the grounding conductor.
Breakage or electric leak may cause the danger of electric shock.
For grounding, inquiry to electrician or to main office.

Do not drop or damage the handpiece. In case of malfunction, dropping, drowning, do not use and contact to the manufacturer; (If may cause vibration of the bur, overheating, or damage of the bearings.)

*Use the products in proper use as per the instruction and do not use not recommended by the manufacturer.

*If may cause injury or property loss if not following the instructions.

*Saeshin is not responsible for the accident causing by not following the instructions.

Transport and storage conditions:
Temperature : 10 ~ 40°C
Humidity : 30 - 75% RH
Atmospheric Pressure : 700 hPa to 1060 hPa