



Ultrasonic Bone Surgery System

*Variosurg*

**OPERATION MANUAL**

Please read this Operation Manual carefully before use, and file for future reference.



Powerful Partners®




Thank you for purchasing our VarioSurg.

This device is intended for use in dentistry and oral surgery.

Implant site preparation, Bone harvesting, Sinus surgery, Osteoplasty, Osteotomy, General oral surgery, Tooth extraction, Syndesmotomy, Tooth avulsion, Periodontal surgery, Cyst surgery


We recommend that prior to use, you carefully read this document regarding instructions for use, handling method, or maintenance check so that you can carry on using the unit in the future. In addition, please keep this operation manual in a place where a user can refer to it at any given time.

■ Classification of Devices

- Classification by type of protection against electric shock:
  - Class I devices
- Classification by degree of protection against electric shock:
  - Applied part type BF 
- Classification by sterilization or disinfection method allowed by the manufacturer:
  - Refer to Sterilization.
- Classification by degree of protection against harmful intrusion of liquid based on IEC60529:
  - Foot pedal ... IPX8 (protected against immersion)
- Classification by safety level of use in air, flammable anesthetic gas or dinitrogen monoxide (laughing gas), flammable anesthetic gas
  - Not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous dioxide
- Classification by mode of operation:
  - Continuously operating device

Guidance and manufacturer's declaration - electromagnetic emissions		
The VarioSurg is intended for use in the electromagnetic environment specified below. The customer or the user of the VarioSurg should assure that is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR11	Group 1	The VarioSurg uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	class B	The VarioSurg is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:
Harmonic emissions IEC61000-3-2	class A	
Voltage fluctuations/ flicker emissions IEC61000-3-3	Complies	Warning: This equipment / system is intended for use by healthcare professionals only. This equipment / system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures such as re-orienting or relocating the VarioSurg or shielding the location.

Guidance and manufacturer's declaration - electromagnetic immunity			
The VarioSurg is intended for use in the electromagnetic environment specified below. The customer or the user of the VarioSurg should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge(ESD) IEC61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC61000-4-4	±2kV for power supply lines ±1kV for input/output	±2kV for power supply lines ±1kV for input/output	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1kV line to line ±2kV lines to earth	±1kV line to line ±2kV lines to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 sec	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the VarioSurg requires continued operation during power mains interruptions, it is recommended that the VarioSurg be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
<b>NOTE:</b> Ut is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The VarioSurg is intended for use in the electromagnetic environment specified below. The customer or the user of the VarioSurg should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RFIEC61000-4-6	3Vrms150 kHz to 80MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the VarioSurg, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <b>Recommended separation distance</b>  $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80MHz to 800MHz $d = 2.3 \sqrt{P}$ 800MHz to 2.5GHz  Where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RFIEC61000-4-3	3V/m80MHz to 2.5 GHz	3 V/m	
NOTE 1 At 80MHz and 800MHz, the higher frequency range applies.			
NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobiles radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the VarioSurg is used exceeds the applicable RF compliance level above, the VarioSurg should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the VarioSurg.			
b Over the frequency range 150kHz to 80MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the VarioSurg			
The VarioSurg is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the VarioSurg can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the VarioSurg as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150kHz to 80MHz $d = 1.2 \sqrt{P}$	80MHz to 800MHz $d = 1.2 \sqrt{P}$	800MHz to 2.5GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Cables and accessories	Maximum length	Complies with
Handpiece cord	2m	RF emissions, CISPR11, Class B/ Group 1
Foot Controller	2m	Harmonic emissions, IEC61000-3-2
		Voltage fluctuations/ flicker emission, IEC61000-3-3
		Electrostatic discharge(ESD), IEC61000-4-2
		Surge IEC61000-4-5
		Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11
		Power frequency(50/60Hz) magnetic field IEC61000-4-8
		Conducted RF IEC61000-4-6
Radiated RF IEC61000-4-3		

## Symbols



TUV Rhineland of North America is a Nationally Recognized Testing Laboratory (NRTL) in the United States and is accredited by the Standards Council of Canada to certify electro-medical products to Canadian Notional Standards



This product is designed not to become the ignition source in air and flammable anesthetic gas.



The EU directive 93/42/EEC was applied in the design and production of this medical device.



Protected against the effects of continuous immersion in dust and water.



Dispose of this device and its accessories via methods approved for electronic device and in compliance with the Directive 2002/96/CE



Type BF applied part



See Operation Manual

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## ⚠ Safety Precautions and Indications of Dangerous Items

- We recommend that prior to using the device; you read carefully the safety precautions in order to operate it correctly.
- Indications of Dangerous Items is designed so that you can use the product safely, thus obviating any safety hazard or damage to you or others. They are classified according to their magnitude and emergency degree of safety hazard or damages. As each and every item concerns safety, observe them.

Classification	Degree of Danger or Danger and Seriousness
⚠ <b>WARNING</b>	Explains an instruction where personal injury or physical damage may occur.
⚠ <b>CAUTION</b>	Explains an instruction where minor to medium injury or physical damage may occur.
⚠ <b>NOTICE</b>	Explains an instruction that should be observed for safety reasons.

## 1. Safety precautions prior to use



### Warning

- This product is Medical Electrical equipment. EMC (Electromagnetic compatibility) is described in the accompanying documentation.
- Portable and mobile RF communications equipment can affect Medical Electrical equipment. Do not use RF equipment outskirts for the product.
- Do not plug or unplug the power cord with a wet hand. You may get an electric shock.
- Do not use the unit in any room where there is the risk of explosion or in the vicinity of combustible material. In particular, you must not use the unit for a patient who has been anesthetized with flammable anesthetic gas (laughing gas).
- In use, be careful so that no water or antiseptic solution spills onto the control unit, which might cause fire or have you get an electric shock. If any water or antiseptic solution spills, immediately wipe it off with a dry cloth, etc.
- Be careful not to give strong shock (dropping, in particular) to a handpiece. This might break the optics or give you an electric shock.
- You must not touch the connections (electric pins) of the handpiece or of the handpiece cord.
- You must neither disassemble nor make alterations to the unit.
- Do not use the unit on any patient who has a cardiac pacemaker (the unit may affect operation of a cardiac pacemaker).
- Make sure to use the specified fuse.
- Do not turn the power ON/OFF switch without reason, It might blow out a fuse.
- If you feel any abnormality such as vibration, heat generation, abnormal noise, etc., prior or during the use of the unit, immediately stop using it.
- Do not place anything within 10 centimeters around the unit.



### Cautions

- Only qualified personal is allowed to use the device in dentistry or oral surgery : Qualified doctors in medicine and surgeons. Assistants and paramedical personal, under the responsibility of qualified doctors in medicine or surgeons.
- When using the unit in surgery, make sure to take action for contingency, such as preparing 2 sets of the unit in case of failure.
- Give the priority to patient's safety, and pay adequate attention so that there will be no accident.
- Place the unit on a flat and horizontal area. Be careful not to give any strong shock (such as dropping) to the control unit.
- Before using the unit, make sure to operate it outside the oral cavity for checking. Then, if you find any abnormality, immediately stop using it and contact the dealer.
- Turn the power switch OFF prior to disconnecting the power cord or handpiece cord by holding their plugs. Do not unplug by pulling on cords: they may be broken.
- Do not unplug the power cord or handpiece cord while pressing on the foot control.
- When the pump gets wet, wipe well and dry it. If the pump remains wet, it may not work normally as the roller inside the pump may slip.
- If you bend or fold the irrigation tube while the pump is in operation, the irrigation tube may be broken or disconnected.
- If you feel any abnormality in the irrigation flow, there is the possibility that the irrigation tube is worn and saline solution leaks out. Thus, replace the irrigation tube.
- The irrigation tube is disposable. After using it once, dispose of it as medical waste.
- Do not separate the handpiece from its cord, except when you replace the lamp.
- Neither turn the power switch ON with the handpiece cord unconnected, nor turns it ON while pressing on the foot control.
- Always remove the tip prior to disconnecting the handpiece cord, install or remove the irrigation tube. Otherwise, you might get your hand, etc. injured by the tip.
- Never sterilize the handpiece, etc., with ultraviolet radiation, which might cause discoloration.

### Cautions

- If any water drops remain on the handpiece or handpiece cord after autoclaving, wipe them off. If you leave them, they might result in stain.
- Saline solution is used for irrigating and cooling down. If the irrigation flow is not adequate, bone cells might necrotize or tooth surface might be damaged.
- In use, never allow the vibrating tip to touch any prosthesis such as ceramics. Touching might cause break or chipping.
- In use, never allow the vibrating tip to touch a metal crown, porcelain crown, etc., which may cause loosening or breakage, etc.
- You must use the tip within the power range described on the tip case. If you use it out of the power range, the tip might break or damage an operative site.
- Do not use a tip that is scratched, twisted or rusted, etc. In use, the tip may break.
- A diamond-coated tip shall be disposable. Thus, use it only once for treatment. Otherwise, cells that might have adhered to the diamond debris and still remaining even after cleaning or autoclaving might invade the mouth cavity of another patient.
- Never grind the tip or bend it to change the angle, etc. In use, the tip might break or might not vibrate.
- Even if the tip is used at the appropriate output level, overloading it might cause tooth chipping or tooth fracture. Use it together with a suction device and be careful not to leave any tip fragment in an operative site.
- Try to keep saline solution coming out of the tip end off the unit. It might cause peeling of the sheet or discoloration of the casing.
- Make sure to use a tip manufactured by our company.
- Prevent the tip from directly touching the gum, skin, or nerves, which might cause a burn or accident. In addition, do not touch mucosa membranes with any tip other than those dedicated.
- The tip will abrade away as it is used. When it becomes worn, it might vibrate weakly or not vibrate, or its coating might peel off. Whenever you have observed abrasion of the tip or peeling of the coating, or felt a weakening of the vibration, replace it with a new one. For any tip other than those diamond-coated, we recommend that you replace it after using it five times, to achieve optimum cutting performance.
- When replacing the tip, make sure to stop vibrating it and to securely fasten it using the special tip replacing wrench. Poorly fastened, it might vibrate weakly or not vibrate at all.
- If you install the tip with dirt attached to its threading, it might vibrate weakly or not vibrate. When the threading is dirty, clean it.
- If you feel the tip not vibrating, remove it from an operative site, and press the foot control again. If this does not improve the condition, re-fasten the tip or turn the power off once and restart it.
- Store this product at temperatures of -10 to 60° (14 to 140°F), humidity of 10 to 85% RH, and atmospheric pressure of 500 to 1060 hPa, and in any place where there is no water drop inside the control unit. Storage in any other place might lead to a failure.

### Notice

- When the vibrating handpiece or handpiece cord is in the vicinity of any computer or LAN cable, it might affect them. If it is in the vicinity of a radio receiver, the receiver might be affected. If you use any device such as a digital video, digital camera, etc. in its vicinity, electromagnetic interference might affect these devices.
- Turn the power switch off after use. In addition, if you do not use the unit for a long time, disconnect the mains plug.
- Clean/sterilize the unit immediately after using it. Then store it. Leaving it with blood, etc. attached thereto might lead to a failure.
- When you have not used the unit for some time and use it again, you must check before using that the unit can work normally and safely.
- Responsibility for operation and maintenance check of a medical device lies with the user.

## 2. Features of the product

Key feature: High cutting ability can shorten time for treatment.

Visibility: Light embedded within the handpiece provides the surgeon with a clear sight for a safe surgery.

Safety: Even if the unit accidentally touches an operative site, it does not damage the soft tissue.

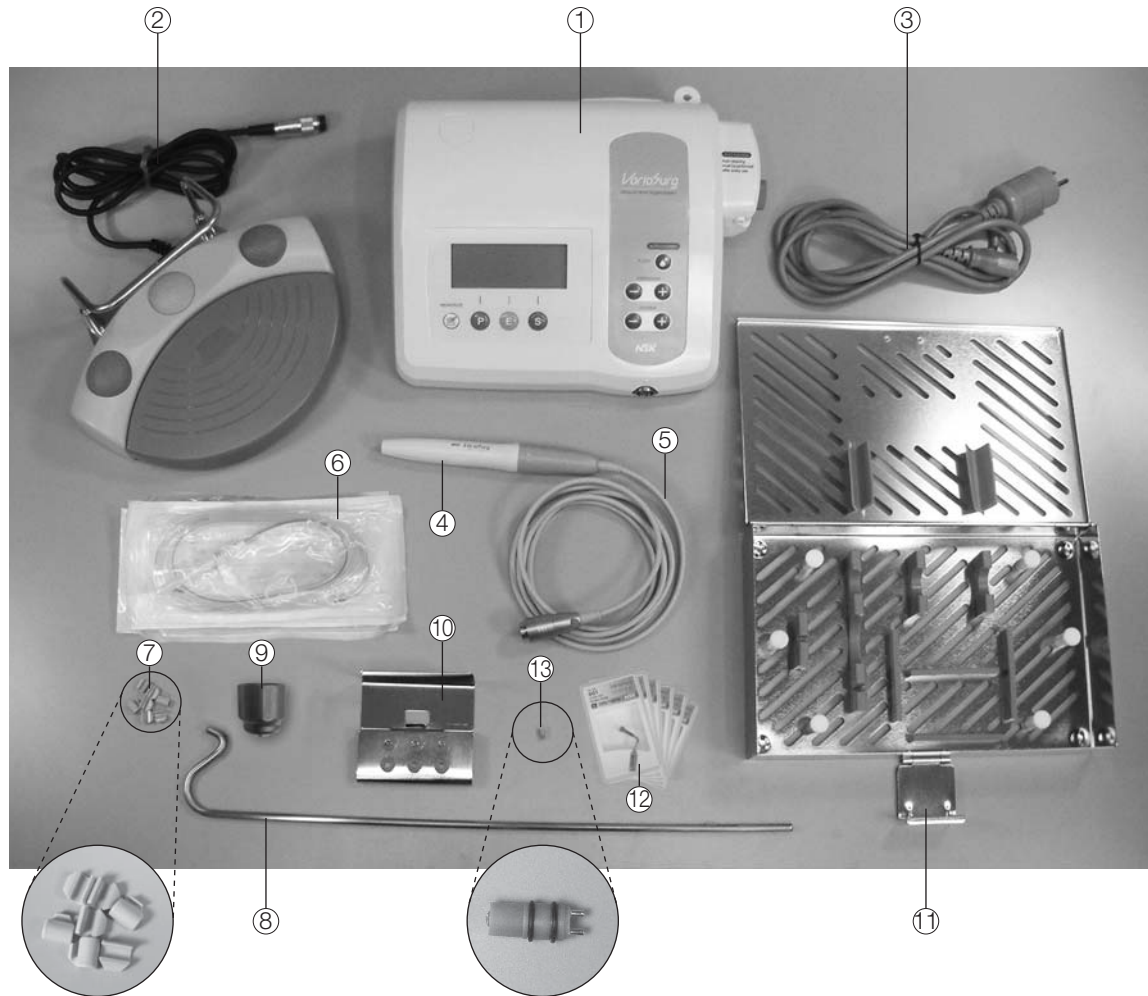
Cavitation Effect: The cavitation effect washes away any blood from an area under treatment, thus ensuring a clear view of the operative field.

Minimally invasive: Irrigation flow suppresses heat generation during bone cutting or peeling.

## 3. Specifications

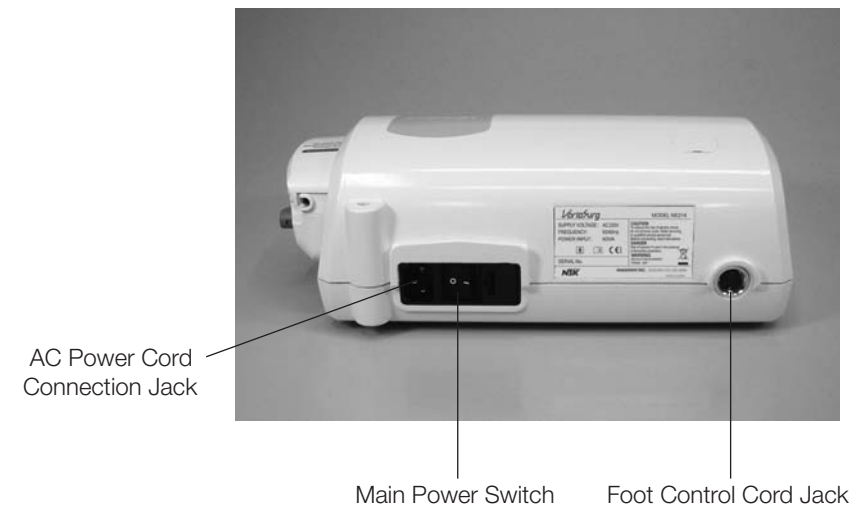
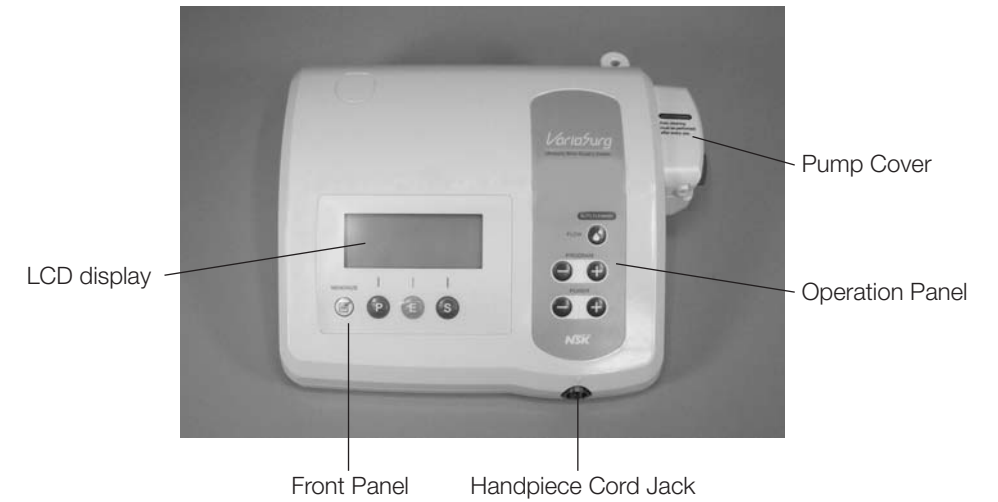
Type	NE214	
Rated power supply	AC100V 50/60Hz, AC120V 50/60Hz, AC230V 50/60Hz	
Resonance frequency	28~32kHz	
Maximum output	17W	
Power supply input	50VA	
Lighting	Halogen lamp	
Dimensions	W268 x D230 x H103(mm)	
Weight	3.1kg	
Fuse	100/120V Specification...T1.25AL 250V 230V Specification...T630mAL 250V	
Use environment	Temperature	0 - 40 °C
	Humidity	30 - 75 %
	Atmospheric pressure	70 - 106 kPa
Store environment	Temperature	-10 - 60 °C
	Humidity	10 - 85 %
	Atmospheric pressure	50 - 106 kPa

## 4. Package Contents



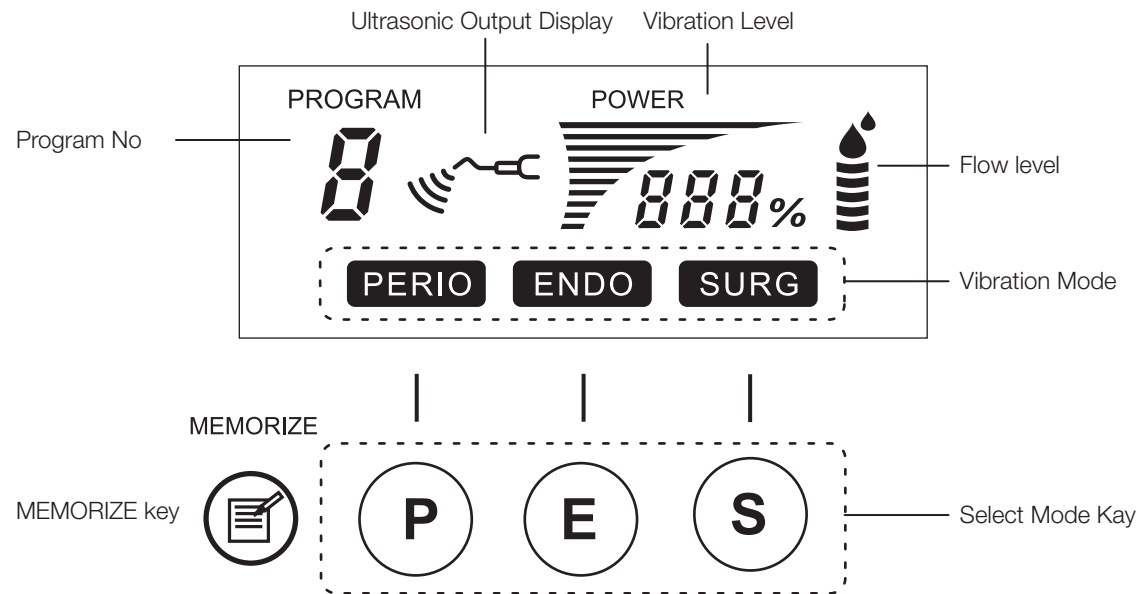
No.	Part Name	Quantity
①	Control Unit with Irrigation Pump	1
②	Foot Control	1
③	AC Power Cord	1
④	Autoclavable Handpiece	1
⑤	Autoclavable Cord	1
⑥	Irrigation Tube	5
⑦	Tube Holder	7
⑧	Saline Solution Hanger Post	1
⑨	Tip Wrench	1
⑩	Tips Holder	1
⑪	Sterilization Cassette	1
⑫	Tips	6 (Basic Kit)
⑬	Spare VA lamp	1

## 5. Control Unit with an Irrigation Pump



## Description of Operation

### ◆ Front panel and LCD display



#### Ultrasonic Output Display

Displaying animation during oscillation of ultrasonic wave.

PROGRAM



#### Program No.

Displaying selected program No.

POWER



#### Vibration Level

Ten bars indicate the level of vibration.



#### Flow level

Displays the selected coolant solution flow volume level.



#### Vibration Mode

Displaying selected mode only.

MEMORIZE



#### MEMORIZE key

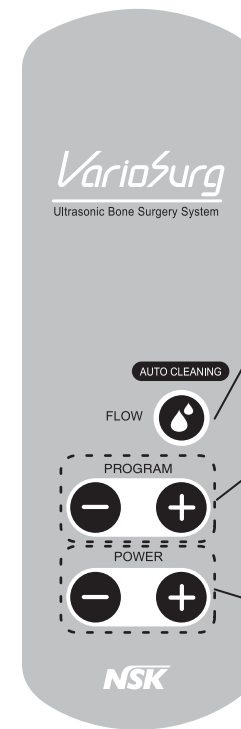
Memorizing operation conditions displayed on the liquid crystal display (LCD) panel.



#### Select Mode Key

Select any mode according to a purpose of treatment. This changes the range of power.

### ◆ Operation panel



#### Flow Key

Adjust the amount of coolant water. This displays the coolant water on the LCD panel. This is adjustable even during oscillation of ultrasonic wave.

#### Automatic Cleaning Mode

After the button is long held down for about 3 seconds, the pump will rotate at the maximum water amount for 30 seconds (to clean the interior of the handpiece).

#### Program Key

Selects a program. This displays the program No. on the LCD panel. + key allows to increase the level while - key allows to decrease it. It cannot be activated during oscillation of ultrasonic wave.

#### Power Key

Adjusts intensity of vibration. Power level is displayed on the LCD panel. + key allows to increase the level while - key allows to decrease it. This is adjustable even during oscillation of ultrasonic wave.

#### Program No.

The program Nos. are assigned as listed below:

SURG mode ... Program No. 1, No.2, No.3, No.4, No.5

ENDO mode ... Program No.6, No.7

PERIO mode ... Program No.8, No.9

\*Program No.1 and No.2 and No.3 have burst function (hammer drill effect).

Program No.1 ... 10 Hz

Program No.2 ... 30 Hz

Program No.3 ... 60 Hz

} Set appropriate Program No. depending on bone density.

\*Program No.4 and No.5 provide continuous vibration without the burst function.

#### Vibration Level

SURG mode ... You can select the mode in increments of 10% from 10% to 100%.

ENDO mode ... You can select the mode in increments of 5% from 5% to 50%, and in increments of 10% thereafter.

#### Amount of Coolant Flow

You can adjust the filled water amount in 5 stages. The range of [FLOW] water is as follows:

SURG mode ... You can select in 5 stages from 15 ml/min to 90 ml/min.

ENDO and PERIO modes ... You can select in 5 stages from 10 ml/min to 38 ml/min.

However, depending on the condition of the irrigation tube, there may be some tolerance in the water amount.

When you set a low value of the [FLOW] water, the pump starts fast and slows down to the set value.

## Memory Function

Pressing [MEMORIZE] key, store the parameters displayed on the LCD into the selected Program No. Check the values of the parameters to be stored and press the key for 1 second or longer. A “beep” is produced when parameters are saved.

In SURG mode you can only save settings of SURG mode setting. You cannot save a setting state of any other mode. This also applies to the other modes.

When you have made a change to setting and pressed [MEMORIZE] key again, the setting saved in that Program No. is erased and the new setting is saved.

## Selecting Mode

Select mode by [Select Mode] key.

## Automatic Cleaning Mode

After holding the Auto Cleaning key down for around 3 seconds, the pump rotates at the maximum coolant flow of 90 ml/min, to clean the interior of the handpiece, irrespective of the mode selected.

## Program Key

The key selects a program. Program No. is displayed on the LCD panel. + is in ascending order, while – is in descending order. Programs cannot be changed during oscillation of ultrasonic emission.

## Power Key

The key adjusts intensity of ultrasonic vibration. The power level is displayed on the LCD panel. + key allows to increase the level while – key allows to decrease it. You can adjust intensity of the vibration even during ultrasonic emission. Use low levels when you start, and adjust the power level according to the operating conditions.

### CAUTION

The LCD display panel is made from liquid crystal and should always be handled with care.

## 6. Foot Control



### ON-OFF Switch for Water Flow

While you are pressing on that switch, irrigation is delivered at the setting of 5.

### PROGRAM (+) Switch

Every time you step on the switch, the program number increases by 1.

### PROGRAM (-) Switch

Every time you step on the switch, the program number decreases by 1.

### Vibration ON-OFF Switch

While you are pressing on the switch, vibration are generated at the setting level displayed on the panel.

### CAUTION

Even when you erroneously turn the power ON with the vibration ON/OFF switch pressed, ON, vibration does not occur (you only hear warning sequences of 3 beeps).



## 7. Installation

### 7-1 Connecting the Handpiece Cord

With ▲ mark of the cord plug facing upward, insert it into the socket of the control unit.(Fig.1). Then, make sure to hold the rear of the connector and press it till it clicks. Then, try to pull it in order to check that it has been locked. To remove the plug, hold the lock joint and pull it out.



Fig. 1

### 7-2 Connecting the Foot Control

Face the screw on the foot pedal control cord plug downward then insert the plug into the foot control cordjack on the control unit.Screw the plug by fastening the lock unit.



Fig. 2

### 7-3 Connecting the AC Power Cord

Make sure that the power switch is turned OFF (○ side). Securely insert the power cord into the inlet located on the rear of the control unit, according to the shape of the power cord. Insert the plug of the power cord into a wall outlet of rated power supply from which earthing can be taken.

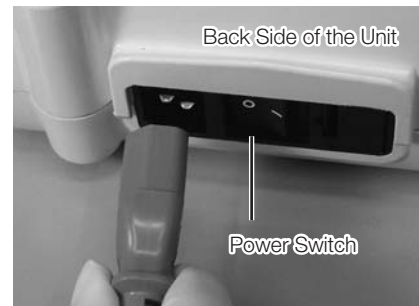


Fig. 3

### 7-4 Mounting the Saline Solution Hanger Post

Insert the saline solution hanger post into the encircled area on the unit. Match the guiding pin of the hanger to the slot of the hole. Then, check for correct placement and stability of the saline solution hanger post.



Fig. 4

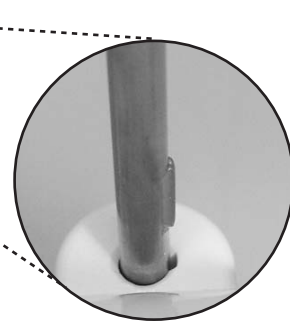


Fig. 5

### 7-5 Installing the Irrigation Tube

- (1) ① Turn the pump knob to OPEN position, and hook the side of the tube equipped with the irrigation tube needle (See Fig. 13) to the right side (A) of the pump. Insert the tube deep in the direction of WATER WAY. Then, be careful that the tube is not twisted.



Fig. 6

- ② Hook the tube to the left side (B) marked with CLOSE.

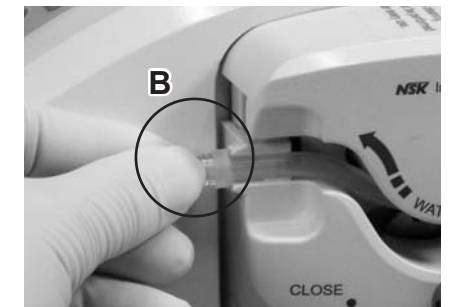


Fig. 7

- ③ Hook the tube to the CLOSE side. Check that it has been pushed deeply to the back.

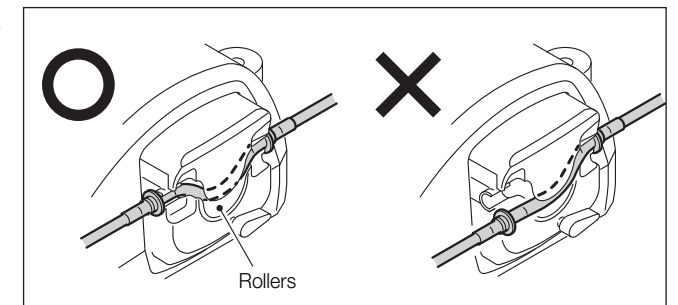


Fig. 8

- ④ Turn the pump knob to the CLOSE side.



Fig. 9

#### ⚠ CAUTION

At any time, insure that there is enough saline solution inside the bag.

- ⑤ Hook the irrigation tube to the pump as illustrated in Fig. 10.



Fig. 10

- (2) Insert the free end of the irrigation tube deep around the water pipe of the handpiece.



Fig. 11

### CAUTION

Shallow insertion might unfasten the tube. In addition, except when you replace the tube, always keep the end of the tube connected to the water pipe.

- (3) ① Close the tube clamp located between the irrigation tube needle and the irrigation pump, as illustrated in Fig. 12.

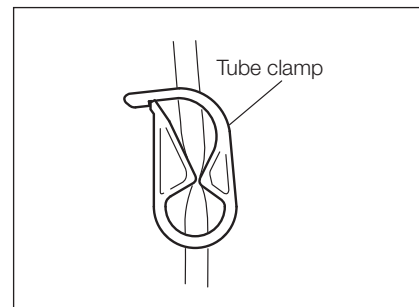


Fig. 12

- ② Hook the bottle to the hanger and insert the irrigation tube needle into the bottle cap.

### CAUTION

Use only 500ml saline solution bags.  
Never hang more than 800 grams to the hanger post.

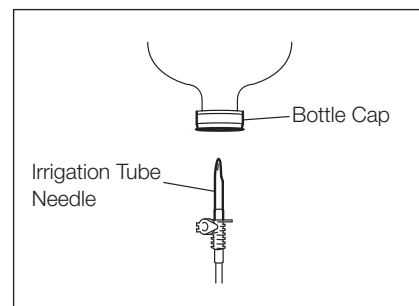


Fig. 13

- ③ Open the tube cap to supply air into the bottle.

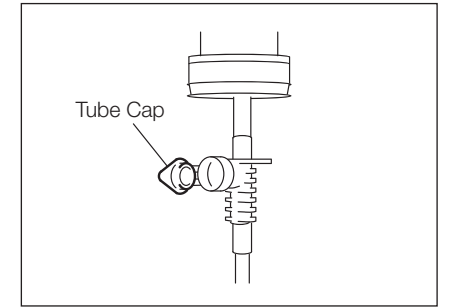


Fig. 14

## 7-6 Attaching the Tube Holder

Use the Tube Holder to assemble together the Handpiece Cord and the Irrigation Tube. It is easier to fasten them onto the Handpiece Cord first and, next, onto the Irrigation Tube.

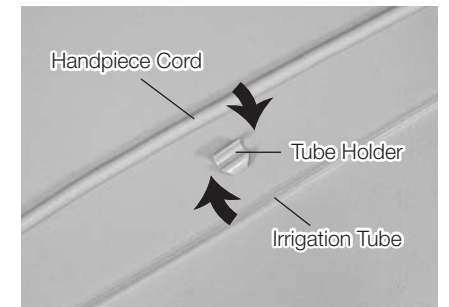


Fig. 15

### CAUTION

- Assemble the handpiece cord and irrigation tube by means of the 7 tube holders. (Fig. 16)
- If you let the irrigation pump operate with the tube bent or with no liquid flowing, the tube might be ruptured or fall off from the bottle.

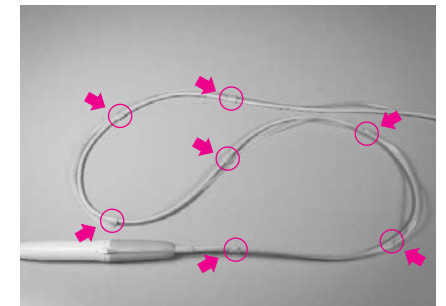


Fig. 16

## 8. Operation

### 8-1 Attaching or detaching the Tip

To **tighten** the tip, screw it first gently by hand (Fig. 17).  
Next, introduce it from the end of the tip to the hole of the wrench (Fig. 18).

#### CAUTION

- To avoid any wound, particularly take care that the end of the tip is not contacted internally of tip wrench inside (Fig 19).
- If the wrench is turned whereas it is excentric, tightening is likely to be insufficient and the ultrasonic vibrations can be strongly weakened.

Firmly hold the wrench and turn tip wrench clockwise as viewed from Fig. 17. So, turn it till you hear a click. To remove the tip, place the wrench in the same way that for tightening, but hold it (Fig. 20) and turn it counter-clockwise.

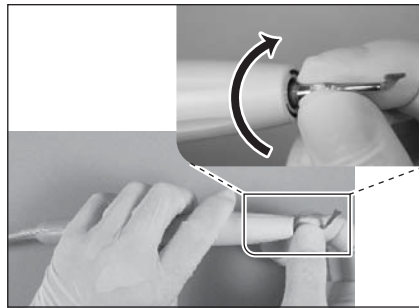


Fig. 17

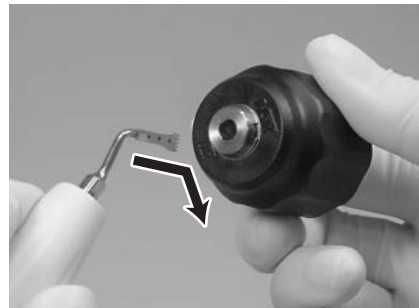


Fig. 18



Fig. 19

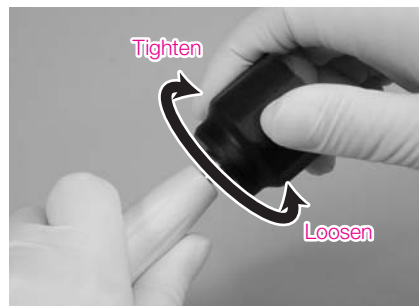


Fig. 20

#### CAUTION

When you install the tip, make sure to use the sterilized one.

### 8-2 Checking and Adjustments

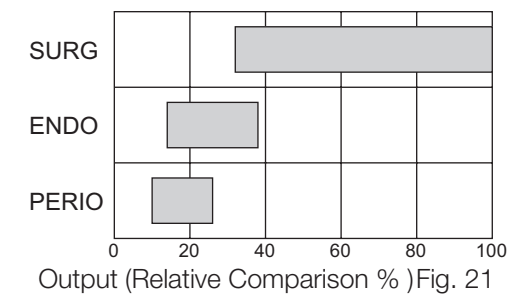
- (1) Checking Irrigation circuit  
Ensure that the irrigation tube is correctly connected to the saline solution pack, pump, and handpiece.
- (2) Switching the mains supply ON  
Turn ON the power switch located at the rear of the unit. (See Fig. 3).
 

○	
power OFF	power ON
- (3) Priming irrigation circuit  
Immediately before using the unit, release the tube clamp from the irrigation tube, step on the ON-OFF switch for water flow of the foot control, and check that the saline solution flows normally out of the tip end. With a new tube, it takes several seconds for the saline solution to reach the tip.
- (4) Setting Output  
Press [ Select Mode ] key on front panel for select suitable application. Adjust the amount of water, select a program, and adjust power on the Operation panel.  
Fig. 21 shows a comparison of outputs of respective modes:

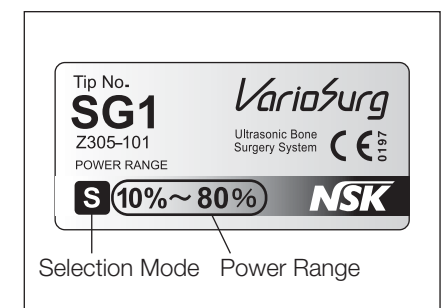
Set to the power mode described on the tip case and use it within the power range (Fig. 22).

The abbreviations for the selection modes mean the following:

- S ... Surg mode
- E ... Endo mode
- P ... Perio mode



Output (Relative Comparison %) Fig. 21



Selection Mode Power Range

Fig. 22

#### CAUTION

- If you set out of the power out of the range described on the tip case, the tip might break, damage a tooth surface, gum or mucous membrane.
- When you first purchase a tip, it has not been sterilized. Thus, you must sterilize it prior to use. Also note that you cannot sterilize the tip case.

(5) Activation

When you step on the foot control, the tip is activated. Then the light of the handpiece also turns on. When you use it for the first time and thus the irrigation tube is not filled with saline solution, check the following:

- Let it ultrasonic vibrate outside the oral cavity of a patient, rotate the pump, and check that the saline solution flows out of the tip end.
- Check that the light turns on.
- Check that there is no unpleasant feeling with the handpiece and tip.

**CAUTION**

- Similarly after replacing the bottle, turn the ultrasonic vibration ON outside the oral cavity of a patient, and check that the saline solution flows out of the tip end.
- Press Adjust Power key within the power range and use while checking appropriate vibration.
- Do not turn ON the ultrasonic vibration with no saline solution. No water filling would lead to heat generation at the handpiece. It might also damage an operative site or tooth surface.
- In use, do not apply too much pressure to the tip end.
- The unit is designed to display an error (E-P) and to stop vibrations if the pump does not work due to some failure.

**NOTICE**

When the power is turned OFF, settings are stored with the current display. The next time the power is turned ON, the unit returns to the previous state (last memory function). However, as it does not have influence on the program memory, save the setting by pressing MEMORIZE key if you wish to save the current setting as a program.

## 9. Care and Sterilization

### 9-1 Auto Cleaning

- (1) After using with saline solution, clean the interior of the handpiece with distilled water. Pull out the needle from the saline solution bag, plunge the needle in the container (such as a cup, etc.) in which the distilled water is contained **open the tube clamp for irrigation tube**, and press the [FLOW] key for about 3 seconds till the pumps starts (Auto Cleaning). During automatic cleaning, Water mark flashes. The bar of the power display indicates the remaining time, and decreases by one scale for every 3 seconds.

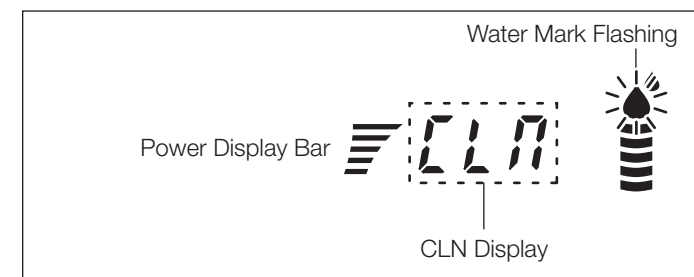


Fig. 23

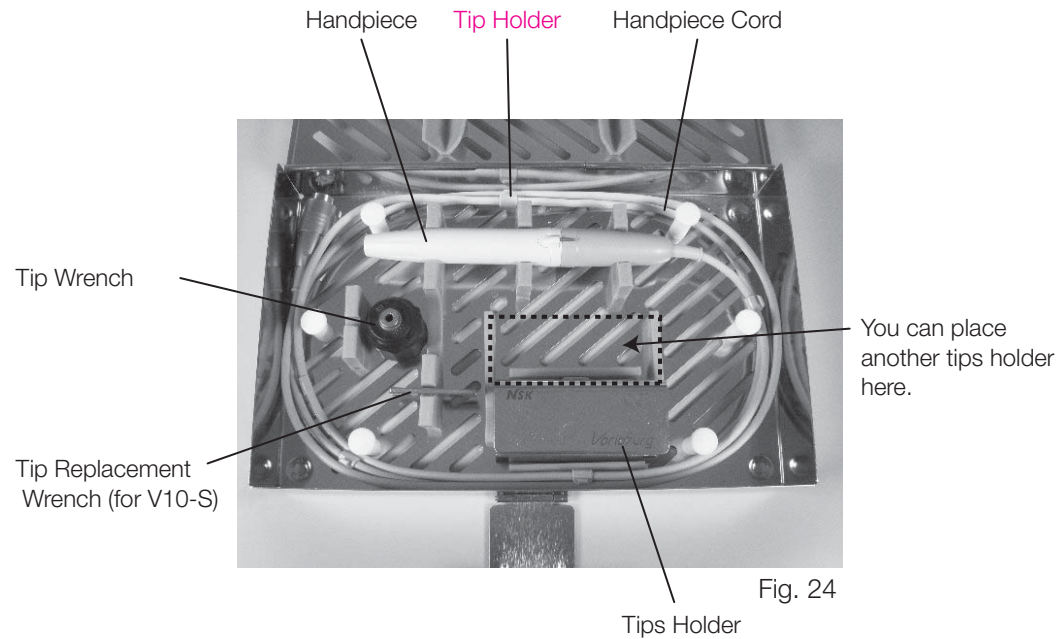
**CAUTION**

Enter the auto cleaning mode, and the pump rotates at the maximum water filling amount for 30 seconds. Be careful as water flows out of the end of the handpiece. If you leave the handpiece without performing this rinsing operation, sodium chloride will crystallize inside the handpiece, which might clog the irrigation hole and thus prevent saline solution from outflowing.

- (2) Remove the handpiece cord and the irrigation tube from the unit. After separating the irrigation tube from the handpiece cord, place the cord inside the sterilization cassette with the handpiece still attached. We recommend to leave the tube holders fastened to the cable. After using the irrigation tube, dispose of it as medical waste.

(3) Tips, Tip Wrenches and Tips Holders

- ① Wash and brush down any stain on the surfaces with a resin brush, etc. (you should not use a metal brush), and wipe them off with cotton impregnated with rubbing alcohol.
- ② Put the tips in the tips holder, and then place the tips holder in the sterilization cassette.
- ③ The sterilization cassette can accommodate up to 2 tips holders.
- ④ Put the tip wrenches in the sterilization cassette.
- ⑤ As shown in Fig. 22, put what is to be sterilized in the sterilization cassette, then close and lock it with the swivelling lever.
- ⑥ Do not put a maintenance tip (V10-S and V-P10) in the tip holder. Instead, put them in an autoclaving bag and seal the bag.



(4) Sterilization

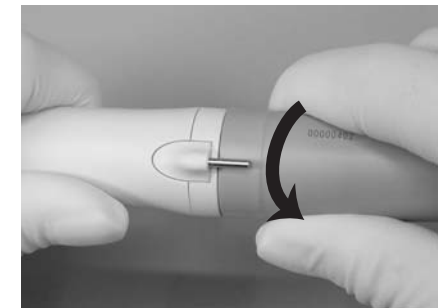
Steam autoclave is recommended.  
 Perform autoclave sterilization at temperatures up to 135°C.  
 Example: 20 minutes at 121°C or 15 minutes at 132°C  
 Note that you cannot autoclave the control unit and the foot control.

**CAUTION**

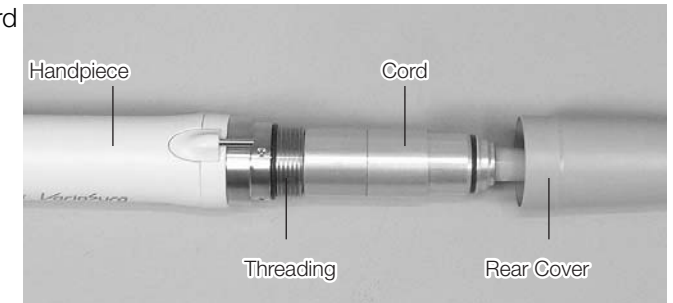
- Never sterilize the handpiece, etc., with ultraviolet radiation, which might cause discoloration.
- If you autoclave sterilize the handpiece together with any instrument to which antiseptic solution adheres, discoloration might occur.
- If the temperature jumps beyond 135°C during the drying process, skip this drying process.
- The lower part of the autoclave is close to the heating element. The temperature in this area can exceed the settings. To avoid this, place the sterilization cassette on the upper or middle stage.
- Do not wash the product in a thermodisinfectant.
- When you finish treatment of one patient, turn the power of the control unit OFF.
- If any saline solution or stain adheres to the control unit, well wipe it off with a cloth impregnated with clean water and squeezed out. Then, wipe the unit well with a dry cloth.
- Do not clean the unit with any solvent such as thinner, benzene, etc.

9-2 Exchanging the Halogen Lamp

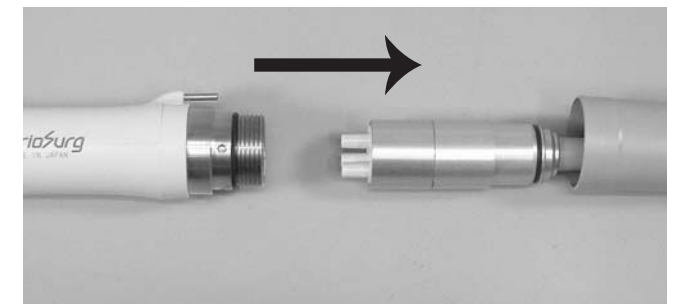
Remove the rear cover from the handpiece only when replacing the lamp. Turn the rear cover in the arrow direction and remove it (See Fig. 25). Prior to lamp replacement, disconnect the handpiece out from the control unit.



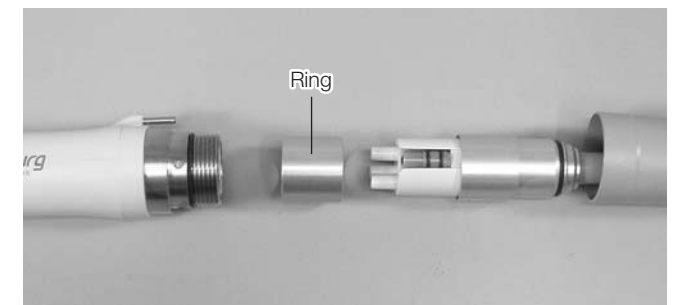
Turn the rear cover, and slide the cord backward (Fig. 26).



Slowly pull the handpiece out (Fig. 27).



Slowly pull the ring out (Fig. 28).



Insert a thin slotted screwdriver, etc. into the highlighted area, and remove the lamp (Fig. 27). Securely insert a connecting terminals of a new lamp, mating with the socket holes. Then, apply the ring, mate the projection of the cord end with the hole of the handpiece, and insert the former into the latter. Place the rear cover, and secure it to the handpiece by screwing CW.

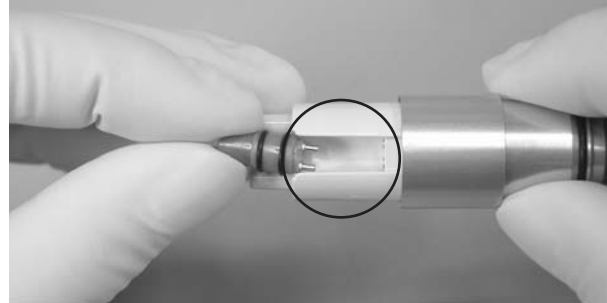


Fig. 29

### **⚠ WARNING**


Never touch the electrical connections of the handpiece and of the lamp. Touching the connections might damage them.

### **⚠ CAUTION**

- Remove the tip before disassembling the handpiece. Otherwise, the tip might cause injury.
- Then, drain any liquid from the handpiece by using a syringe and injecting air at the water pipe. Remove the rear cover only when all the liquids are drained. Any remaining saline solution in the handpiece might spill onto the lamp and cause corrosion.
- Do not directly touch a glass area of a new lamp with your finger and protect it against any shock.

## 10. Troubleshooting guide

If you suspect a failure, check the following before asking for a repair. When an error code is displayed, refer to the table of error codes (Page 26). If no case applies to you, or when the condition does not improve even after taking action, this product is likely to have failed. Thus, please contact the dealer.

Case	Possible Cause	Action to Take
The power does not turn on (the LCD screen does not light up).	The power cord is not connected to the unit.	Check the connection.
	The plug is not inserted into a socket, or no electricity is supplied to the socket.	Check the connection.
	A fuse has blown.	Contact your dealer.
	An internal fuse has blown.	Contact your dealer.
Although the power turns on, the unit displays Vibration icon and beeps.	 Oscillator Mark	If the foot control is stepped when the power is turned on, the unit does not operate in order to prevent possible accident. Release the foot control and try again.
The tip does not vibrate	The foot control is not connected.	Check the connection.
	The handpiece and cord are not connected. Or the cord is not connected to the unit.	Check the connection.
The tip does not vibrate (Oscillator Mark displays).	Circuit failure.	Contact your dealer.

Case	Possible Cause	Action to Take
The tip vibrates, but weakly. It does not cut easily.	Abrasion/break of a tip	Replace the old tip with a new one.
	Bad mode.	Select an appropriate mode.
	The tip has not been tightened correctly.	Tighten the tip once again with the tip wrench, until it clicks.
	Power setting is too low.	Reset to the mode and power range described on the tip case.
	The foot control is not plugged in correctly.	Plug in the foot control correctly.
	Failure inside the handpiece.	Contact your dealer.
	Failure inside the foot control.	Contact your dealer.
The tip breaks easily.	Power setting is too high for that tip.	Reset to the mode and power range described on the tip case.
The tip loosens easily.	The tip has been tightened inadequately.	Tighten the tip once again with the tip wrench, until it clicks.
You hear loud abnormal noise from the handpiece.	Power setting is not appropriate for that tip.	Reset to the mode and power range described on the tip case.
	The tip has been tightened inadequately.	Tighten the tip once again with the tip wrench, until it clicks.
	Failure inside the handpiece or the control unit.	Contact your dealer.

Case	Possible Cause	Action to Take
The handpiece becomes hot.	You have not set appropriate output to the attached tip.	Reset to the mode and power range described on the tip case.
	The tip has been tightened inadequately.	Tighten the tip once again with the tip wrench, until it clicks and it rotates.
	Failure inside the handpiece or inside the control unit.	Contact your dealer.
	Foreign material is clogged in the handpiece, thus preventing saline solution from outflowing.	Inject air to the water pipe with a syringe. If clogging still remains, contact your dealer.
	No saline solution is supplied.	Check the remaining amount in the bottle and whether or not there is any crack in the irrigation tube.
	Saline solution does not turn into spray.	Saline solution can't turn into spray under certain conditions.
The water does not come out. The amount is small.	The foot control is not connected.	Check the connection.
	The tube is not connected to the bottle. The tube is not connected to the handpiece.	Check the connection.
	The tube is not correctly set in the pump.	Check the set part (See 7-5 (1)).
	The pump cover is not closed (the pump is spinning free).	Close the cover.
	The tube is broken (it leaks somewhere).	Replace the tube.









Case	Possible Cause	Action to Take
Water leakage	Water leakage from the connection between the bottle and the irrigation tube.	Securely insert the needle into the bottle (See 7-5 (3)).
	Water leakage from the connection between the handpiece and the irrigation tube	Securely place the tube end around the water pipe of the handpiece (See 7-5 (2)).
	Water leakage from the irrigation tube	Replace the irrigation tube.
The pump does not stop.	It is "auto cleaning" mode.	If you want to stop it, press [FLOW] key.
	You have stepped on the Water Filling Flow of the foot control.	Move your foot away from the foot control.
	Circuit failure.	Contact your dealer.
The lamp does not light up.	Halogen lamp blew.	Replace the bulb (See 9-2).
	The connection terminals of the VA lamp are not inserted correctly into the socket holes.	Mate the connection terminal of the VA lamp with the socket hole, and insert it securely.
	Failure inside the control unit or inside the handpiece cord.	Contact your dealer.
	Failure or disconnection of the circuit.	Contact your dealer.
The display on the LCD screen is abnormal. The display is missing.	Overheating.	Extremely high temperature might disable the LCD display (when the temperature goes down, it recovers).
	An error code is displayed.	Refer to the table of error codes.
	Failure of the LCD display or driving circuit.	After restarting the unit, if icons are missing on the display, contact your dealer.
The memory does not work. Even it works, numeric values are wrong.	You have forgotten to press on [MEMORAIZE] key.	Check the parameters to store and press [MEMORAIZE] key.
	You have stepped on the foot control.	While the handpiece is operating, the unit does not memorize.

◆ Table of Error Codes

Error Code	Possible Error	Action to Take
E-0	Circuit failure.	Contact your dealer.
E-2	You pressed the tip end too hard, thus applying heavy load to its end, or the tip end is stunk and fixed.	Press Vibration ON/OFF switch of the foot control and slowly pull out the tip while letting it vibrate. Be careful not to apply overload to the tip end.
	The tip tightening force is inadequate.	Using the tip wrench, securely attach the tip till it "clicks".
	The tip is not mounted.	Mount the tip and tighten it.
E-4	A cable is disconnected inside the handpiece or inside the unit.	Replace with a spare handpiece, or contact your dealer.
	Overload occurred due to long and continuous operation.	Turn the power off, leave the unit until it cools down. Then, use the unit again. If this error occurs frequently while operated in the normal range, contact your dealer.
E-F	A cable is disconnected inside the foot control.	Replace the foot control or contact your dealer.
E-P	The rotor of the pump is locked, etc.	Check whether the tube is mounted correctly. If the rotor does not rotate even when you remove the tube and step on the foot control, it is likely to be a circuit failure. Thus, contact your dealer.



## 11. Optional Accessorie

Product Name	Items pictures	Product No.
Handpiece Handpiece Cord		Y141-420
set of 5 Irrigation Tubings		Y900-113
Set of 3 VA halogen lamps		Y900-107
Set of 7 Tubing holders		Y900-767
Sterilization Cassette		Z313-102
Tips Holder		Z221-086
Tip Wrench		Z221-077
E Tip Replacement Wrench For V10-S		Z217-399

## 12. Disposing Product

Ask the dealer about waste disposal.

## 13. Warranty

- The manufacturer will warrant the quality of the product for one year after you purchased it, provided that you use it in accordance with the method and procedures described in this operation manual.
- Note, however, that if you did not observe what is written in this operation manual or for any single use goods, the warranty will not apply.