



# OPERATION MANUAL

Rx Only

MADE IN JAPAN

OM-SH0939EN 001

# Primado2

Standard Handpiece 200 G



VERZA™

This attachment/handpiece is to be used exclusively with our total surgical system Primado2. We recommend that prior to use, you carefully read this document regarding "precaution for handling and operation", "connection method", "operation method", "check before operation", "periodic maintenance check" and "reprocessing" so that you can continue using the attachment/handpiece in the future.

In addition, keep this operation manual in a place where a user can reference it at any given time.

\* In this operation manual, bur and drill are collectively called Cutting Accessory(ies).

\* The reference number of the Operation Manual of the related products is as follows:

Table 1

Operation manual title	Operation manual No.
Total Surgical System Primado2	OM-SE0028E
Primado2 Slim Motor G	OM-SE0921EN
Globus VERZA™ User Manual	GMUML21




**\* Refer to "12 Symbols" section on page 45 for reference.**

# 1 User and Indications for Use

- User : Qualified Professionals (Surgeon with knowledge and skills required for operating this product).
- Indications for Use : The Attachment is intended to be used with electric surgical instruments and cutting accessories for cutting, drilling, removal, and shaping of bone in the procedures of: Neuro, Spine, Orthopedic, ENT, Maxillofacial, and General Surgery.
- Intended patient population : The user shall determine the patient.

## 2 Precautions for Handling and Operation

- Read these precautions carefully and use only as intended or instructed.
- Safety instructions are intended to avoid potential hazards that could result in personal injury or damage to the device. Safety instructions are classified as follows in accordance with the seriousness of the risk.

Class	Degree of risk
 <b>DANGER</b>	Hazard that could result in personal death or serious injury if the safety instructions are not correctly followed.
 <b>WARNING</b>	Hazard that could result in serious injury or damage to the device if the safety instructions are not correctly followed.
 <b>CAUTION</b>	Hazard that could result in light or moderate injury or damage to the device if the safety instructions are not correctly followed.
<b>NOTICE</b>	General product specification information highlighted to avoid product malfunction and performance reduction.



## DANGER

- DO NOT use this product in a room where there is a danger of explosion or in the vicinity of flammable substances. It is especially important not to use this product on a patient to whom a flammable anesthetic agent (dinitrogen monoxide) has been administered.
- Never disassemble or modify the product. Disassembly and/or modification may cause personal injury and/or damage to the motor (Including motor cord) and/or attachment/handpiece.



## WARNING

- This is a medical system; do not allow anybody to use it other than surgeons who are familiar with the procedures. Use this system in accordance with its indications for use and proper method of use.
- When operating the product, always consider the safety of the patient.
- The Cutting Accessory is for single use only. DO NOT reuse or reprocess it. If you reuse or reprocess it, the following risks may occur:
  - Infection.
  - Personal injury due to damaged Cutting Accessory.
  - System defect due to damaged/deformed Cutting Accessory.
- Irrigate appropriately while cutting in order to prevent necrosis of bones and tissues.
- The attachment/handpiece should be cleaned, lubricated and sterilized after use.



## WARNING

- Clean the attachment/handpiece immediately after use. If blood remains on the product, product failure or overheating may occur due to blood coagulation and product corrosion. This may cause thermal injuries. Also, if the attachment/handpiece is autoclaved with blood remaining, sterilization failure may occur, resulting in infection to the patient and/or user. (Refer to "10 Reprocessing").
- Be sure to check for rust on the appearance of the attachment/handpiece and irrigation nozzle before use. If there is any rust, stop using them and contact your distributor. Then, dispose of them according to "15 Disposing Product". Concerning the Cutting Accessories, refer to the operation manuals of the related products listed in "Table 1" on page 1. Using an attachment/handpiece and irrigation nozzle with rust may lead to adverse sequelae due to potential toxic effects from chemicals present in the particulates, trigger immunogenic responses leading to adverse reactions or interfere with the wound healing response, or interfere with the reabsorption of cerebrospinal fluid (CSF).
- Perform an inspection before use according to "8 Check before Operation". If abnormal vibration or noise is found, the following issues are suspected:
  - The internal consumables (ball bearings, etc.) are worn and/or damaged.
  - The chuck is open and/or there is a bad connection of each part.
  - System defect due to damaged/deformed Cutting Accessory.Using the attachment/handpiece in these conditions may lead to heat generation causing thermal injury. Perform "11 Troubleshooting" in this case. If the issue does not improve after troubleshooting, contact your distributor.
- DO NOT place the attachment/motor (including motor cord) on the patient or the drape covering the patient. Doing so may cause an accident, injury or thermal injury to the patient and/or surgical staff.



## WARNING

- Prevent any debris or other foreign materials from entering into the attachment/handpiece. Failure to do so may lead to heat generation, causing thermal injury.
- DO NOT allow strong impact on the product (e.g., dropping the attachment/motor on a hard surface). Doing so may cause personal injury, abnormal heating, fire and/or thermal injury due to product damage.
- This attachment/handpiece is a non-sterile product. After purchase or repair of the attachment/handpiece, be sure to clean, lubricate and sterilize the attachment/handpiece according to this operation manual before use (Refer to "10 Reprocessing").
- DO NOT use bent, damaged or deformed Cutting Accessories. If they are used, the attachment/handpiece may not clamp the Cutting Accessory securely and it may break and/or cause accidents.
- DO NOT put excessive pressure on the Cutting Accessory. Doing so may bend or damage the Cutting Accessory, or cause excessive heat generation on the Cutting Accessory, attachment/handpiece and motor, which could lead to thermal injury.
- Avoid continuous use of the product and use it intermittently to prevent excessive heat generation. In case of heat generation, immediately stop use until the product cools down. Be careful not to touch the heated area. Doing so may cause thermal injury.
- When replacing the Cutting Accessory, be sure to completely take your foot off the foot control pedal to stop the attachment/handpiece completely. Otherwise, a patient or surgical staff may be injured by unintentional movement of the motor and the Cutting Accessory.
- DO NOT operate the attachment/handpiece if the markings of the twist collet are not aligned (i.e., chuck is open) after the Cutting Accessory is mounted. Doing so may cause thermal injury due to heat generation and potentially damage to the attachment/handpiece.



## WARNING

- DO NOT use the Primado2 control unit and motor in a room with electromagnetic interference or adjacent to portable/mobile RF communication equipment. Use in such environments may affect the control unit and the motor. When using an ultrasonic generator or electrosurgical cutting and coagulation device that produces electromagnetic waves around them, turn off the power of the control unit.



## CAUTION

- U.S. Federal law restricts these attachments/handpieces to sale by or on the order of a licensed physician.
- Users shall be responsible for any judgement that relates to the application of this product to a patient.
- Users are responsible for the operational control, maintenance and continual inspection of this system.
- Be sure to read this operation manual and the operation manuals for "Total Surgical System Primado2" and "Primado2 Slim Motor G (P200-SMH-G)" in order to become completely familiar with the function of each part before use.
- Be sure to perform "8 Check before Operation" by operating the product with the motor, attachments/handpieces and Cutting Accessory mounted before use. If any abnormal condition is detected, stop using the product and perform "11 Troubleshooting".
- Wear Personal Protective Equipment (PPE) for safety and health when using the Cutting Accessories.
- Use the Cutting Accessories specified by Globus only. Using other manufacturer's Cutting Accessories may cause a fault or an accident.





## CAUTION

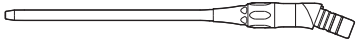
- It is recommended that spare product be kept on hand in case of a breakdown during surgery.
- Never turn the twist collet during operation of the attachment/handpiece.
- DO NOT touch the rotating part of any attachments/handpieces during operation.
- If the rotating Cutting Accessory catches hold of operating table drapes, injury and/or damage to the Cutting Accessory and the system may occur. DO NOT allow the rotating Cutting Accessory to come in contact with drapes.
- Make sure that the shank part of the Cutting Accessories attached to the attachment/handpiece is clean. An unclean shank may cause center deviation and/or prevent proper clamping.
- After mounting the Cutting Accessory and locking the chuck, pull it lightly to confirm that it is securely connected to the attachment/handpiece.
- DO NOT operate the attachment/handpiece when the Cutting Accessory is not mounted.
- Before removing the Cutting Accessory from the attachment/handpiece, stop the rotation of the attachment/handpiece completely.
- When mounting or removing the motor and attachment/handpiece while using the Primado2 control unit and motor, be sure to turn off the main power switch of the control unit. If the main power switch is ON, an unintentional movement may occur, which could result in injury to users.
- Use new Cutting Accessories for every surgical operation for safety.
- This device is for indoor use only.



## CAUTION

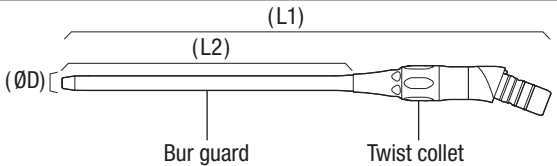
- Perform regular function and maintenance checks for the devices and parts (Refer to "9 Periodical Maintenance Checks").
- If the product is not used for a long period of time, check if it functions correctly and safely before use.
- If chemicals, solutions or disinfectants are left on the surface of the attachment/handpiece, wipe it away immediately. If it is left, it may lead to discoloration, deformation, rust and/or corrosion.
- DO NOT use the following fluids to wipe, immerse or clean the product: strong/super acidic water, strong acid/alkaline chemicals, chlorine-containing solutions, and solvents such as benzine or thinner.
- The temperature at the tip of the attachment/handpiece may reach up to 60°C (140°F) depending on the environment.
- Check the correct connection of the followings before using Primado2 control unit.
  - Connection of the attachment/handpiece and motor.
  - Connection of the motor cord plug and foot control cord plug to the control unit.
  - Connection of the power cord connector to the control unit.
  - Connection of the power cord plug to the outlet.
- Please report any serious incident that may occur in connection with this product and its accessories to the distributor as well as to your national authority.

### 3 Package Contents

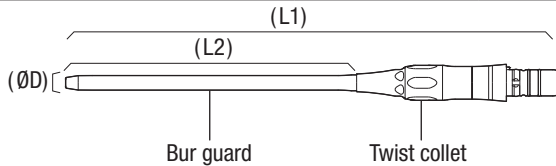
Product name	Order code of NSK	Order code of Globus	Quantity	Fig.
Standard Handpiece 200 (Angled)	P200-2A110-G	6261.3004	1	
Standard Handpiece 200 (Straight)	P200-2S110-G	6261.2004	1	
	P200-2S225-G	6261.2007	1	

\*One of the products is included in the package.

## 4 Part Names and Specifications



Order code of NSK	P200-2A110-G
Order code of Globus	6261.3004
Maximum rotation speed	80,000 min <sup>-1</sup>
Dimension of attachment/ handpiece (L1)	184.6 mm
Dimension of bur guard (ØD x L2)	Ø5.5 x 110 mm
Applicable irrigation nozzle	PD-IN-2L
Applicable Cutting Accessories	Refer to Table 2 in "6 Mounting the Cutting Accessories".



Order code of NSK	P200-2S110-G	P200-2S225-G
Order code of Globus	6261.2004	6261.2007
Maximum rotation speed	80,000 min <sup>-1</sup>	
Dimension of attachment/ handpiece (L1)	186.1 mm	301.1 mm
Dimension of bur guard (ØD x L2)	Ø5.5 x 110 mm	Ø7.0 x 225 mm
Applicable irrigation nozzle	PD-IN-2L	-
Applicable Cutting Accessories	Refer to Table 2 in "6 Mounting the Cutting Accessories".	

This attachment/handpiece is compatible with the following Primado2 products:

<Control unit>






Product name	Primado2 Control Unit for 120V
Order code (NSK/Globus)	P200-CU-120 / 6261.1101

<Foot control>

Product name	Primado2 Single Foot Control	Primado2 Multi Foot Control
Order code (NSK/Globus)	FC-73 / 6261.1201	FC-74 / 6261.1202

<Motor>

Product name	Primado2 Slim Motor G
Order code (NSK/Globus)	P200-SMH-G / 6261.1301

Use environment			-
Store and transportation environment			

## 5 Mounting the Attachment/Handpiece



- WARNING**
- Refer to the operation manual of Primado2 Motor G.
  - Remove the Cutting Accessory before mounting or removing the attachment/handpiece to prevent personal injury.
  - After mounting the attachment/handpiece, make sure that it is correctly connected to the motor.

### <Mounting>

- 1 Insert the attachment/handpiece straight into the motor.
- 2 Align the '▲' symbol of the attachment/handpiece with the 'A' or 'C' symbol (either one) of the motor (Fig. 1). Then push the attachment/handpiece firmly into the motor until it clicks.

### <Removing>

Pull the attachment/handpiece straight out from the motor.

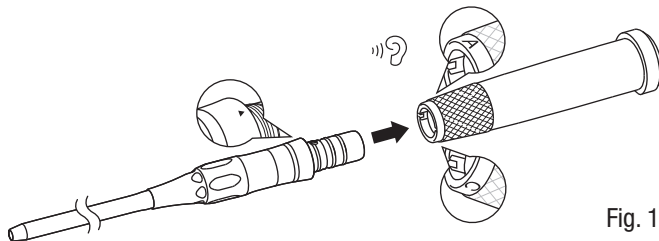


Fig. 1

## 6 Mounting the Cutting Accessories



### WARNING

- Be sure to use the Globus specified Cutting Accessory for this attachment/handpiece. Refer to Table 2 in "6 Mounting the Cutting Accessories". When using an unrecommended Cutting Accessory, it cannot be firmly fixed. This may lead to the Cutting Accessory coming off during surgical operation.
- DO NOT rotate the attachment/handpiece if the chuck of the attachment/handpiece is open. Doing so may cause thermal injury and/or damage to the product due to heat generation of the attachment/handpiece.



### CAUTION

- After mounting the Cutting Accessory and locking the chuck, pull it lightly to confirm that it is securely connected to the attachment/handpiece.
- Before use, confirm that the Cutting Accessory does not come off by operating the attachment/handpiece.
- DO NOT operate the attachment/handpiece when the Cutting Accessory is not mounted.
- Before mounting or removing the Cutting Accessory, be sure to stop the attachment/handpiece completely.

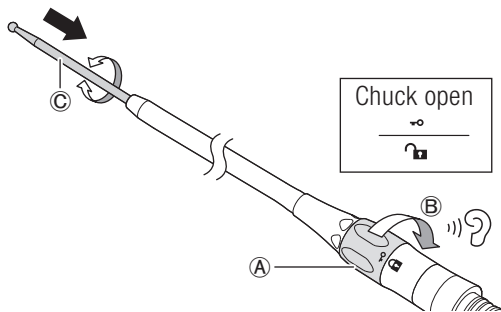
To confirm the compatible Cutting Accessory, refer to Table 2.

Table 2

Compatible Cutting Accessory				Attachment/handpiece
6261.5204S	6261.5304S	6261.5404S	6261.5504S	P200-2S110-G / 6261.2004
6261.7204S	6261.7304S	6261.7404S	6261.7504S	P200-2A110-G / 6261.3004
6261.6184S	6261.6224S	6261.6304S	-	
6261.5257S	6261.5357S	6261.5457S	6261.5557S	P200-2S225-G / 6261.2007

<Mounting>

- 1 Rotate the twist collet (A) in the direction of (B) until it clicks. Insert the Cutting Accessory (C) all the way while twisting it (Fig. 2).





- 2** Rotate the twist collet in the direction of **D** until it clicks (Fig. 3).

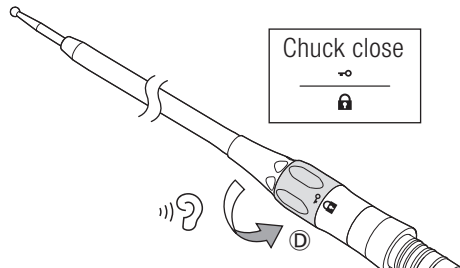


Fig. 3

- 3** Pull the Cutting Accessory **C** lightly to confirm that it is securely connected to the attachment/handpiece (Fig. 4).

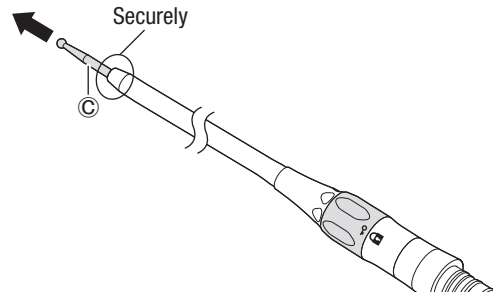


Fig. 4

<Removing>

Perform steps 1 through 2 of the mounting procedure in the reverse order.

## 7 Mounting the Irrigation Nozzle (Optional)



### CAUTION

- Mount the Cutting Accessory to the attachment/handpiece after mounting the irrigation nozzle.
- Be sure to use the NSK-specified irrigation nozzle (Refer to "4 Part Names and Specifications").
- Refer to the operation manual of Total Surgical System Primado2.

- 1 Insert the irrigation nozzle onto the bur guard of the attachment/handpiece, making sure that the correct end of the irrigation nozzle goes in (Fig. 5).
- 2 Insert the irrigation tube into the irrigation nozzle (Fig. 5).
- 3 For the related connection and the setting on the control unit, refer to the operation manual of Total Surgical System Primado2.

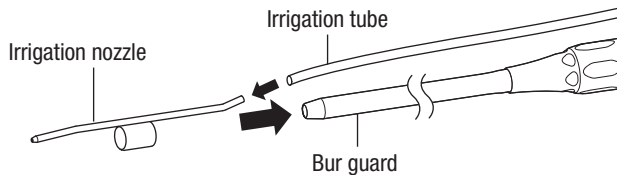


Fig. 5

## **8** Check before Operation

Conduct a check before operation according to the following procedure to confirm that there are no abnormalities. If any abnormality is observed, perform "11 Troubleshooting".

- 1** Attach the attachment/handpiece to the motor, then attach the Cutting Accessory to the attachment/handpiece.  
(Refer to "5 Mounting the Attachment/Handpiece", and "6 Mounting the Cutting Accessories".)
- 2** Check for abnormalities at the connection part of the attachment/handpiece and Cutting Accessory.
- 3** Operate the attachment/handpiece at the rotational speed permissible for the Cutting Accessory mounted. Confirm that nothing is loose and that no abnormal vibration, heating or noise occurs.

If any abnormality is observed, stop use and perform "11 Troubleshooting".

- 4** Ensure that there are no abnormalities before use.

## 9 Periodical Maintenance Checks

Every three months, perform periodical maintenance checks on this product according to the following list. If any abnormalities are found, contact your authorized distributor.

Checking item	Description
Outer surface	Check for any scratches, damage or abnormalities on the outer surface.
Each connection part	Check for any scratches, damage or deformity of each connection part.
Attachment/handpiece/ motor	Connect the attachment/handpiece and motor, and check for abnormalities at the connection part.
Rotation	After connecting each part, fasten the twist collet of the attachment/handpiece and rotate the motor for approximately 1 minute by pressing the foot control pedal. Check for any abnormal vibration, noise or heat generation. Check that the motor stops normally after releasing the foot control pedal.

## 10 Reprocessing

The reprocessing instructions are created based on the requirements of ISO 17664-1.

The effectiveness of the following reprocessing procedures have been verified.



### WARNING

- Since no reprocessing methods have been validated for removal of transmissible spongiform encephalopathy (TSE) agents from medical devices, the reusable devices should not be used for patients with known or suspected Creutzfeldt-Jakob Disease (CJD). In case of using this device on a patient infected by Creutzfeldt-Jakob disease or when contamination with high risk tissues/organs is suspected, the devices shall be disposed immediately.
- Follow the regulations or guidelines of each country.
- Reprocess this product after every surgical operation.
- The Cutting Accessory is for single use only. DO NOT reuse or reprocess it. If you reuse or reprocess it, the following risks may occur:
  - Infection.
  - Personal injury due to damaged Cutting Accessory.
  - System defect due to damaged/deformed Cutting Accessory.



## WARNING

- Thoroughly clean the attachment/handpiece before autoclave sterilization. Autoclaving the attachment/handpiece with blood remaining on it may lead to sterilization failure, resulting in infection to the patient and/or user or malfunction of the attachment/handpiece due to blood coagulation.
- Immediately after use, the attachment/handpiece should be cleaned, lubricated and sterilized. Remaining blood in the attachment/handpiece may cause rust due to blood coagulation. Failure to properly maintain the attachment/handpiece may lead to overheating, causing thermal injuries and/or product failure.



## CAUTION

- For detailed information on reprocessing of the related products, refer to the operation manual listed in "Table 1" on page 1.
- Wear Personal Protective Equipment (PPE) to prevent infection.

## 10-1 Preparation

Treatment at the operating site

- 1 Remove visible contaminants such as blood using a lint-free cloth moistened with distilled water, deionized water or mineral-free water at the operating site.
- 2 Remove the Cutting Accessory, motor, irrigation nozzle and other connections from the attachment/handpiece (for removing the attachment/handpiece from the motor, refer to the motor operation manual listed in "Table 1" on page 1.

## 10-2 Cleaning



### CAUTION

- DO NOT use a lint cloth or metal brush for cleaning.
- DO NOT use a chlorinated cleaner, benzene or thinner for cleaning to prevent damage to the product.
- DO NOT clean the product with an ultrasonic cleaning apparatus to prevent damage to the product.
- When using detergents other than the ones we used for validation, it is necessary to verify the effectiveness based on the information provided by the manufacturer of the detergent and the information obtained from testing.
- Prepare the detergent according to the instructions of the detergent manufacturer when using the detergent.
- Refer to the operation manual of the washer disinfectant before operating it.
- Be sure to use a disinfectant compliant with ISO15883.

## 10-2-1 Manual Cleaning

### ◇ Attachment/Handpiece

#### \_Pre-cleaning

Remove contaminants on the surface with a cloth or soft bristle brush under running tap water (Fig. 6).

For products with moving parts, perform cleaning while moving all parts (Fig. 7).

≤ 38°C (104°F), ≥ 3.5 L/min, ≥ 30 sec.

Water quality: Drinking water

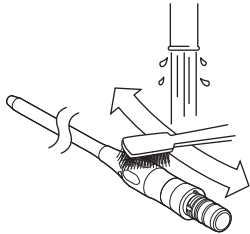


Fig. 6

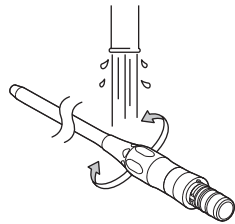


Fig. 7



## \_Cleaning

- 1 Prepare cleaning solution in the cleaning tank under the following conditions (prepare the cleaning solution according to the instructions of the detergent manufacturer).

Temperature	Water quality	Detergent
45° C (113° F)	Distilled water Deionized water Demineralized water	Neutral enzymatic detergent for medical purposes (pH 7.0 - 8.0)

\* Detergent used for validation:

Neutral enzymatic detergent: Renuzyme Plus (Getinge)

- 2 Immerse the product in the cleaning tank for 20 - 30 min (Fig. 8).

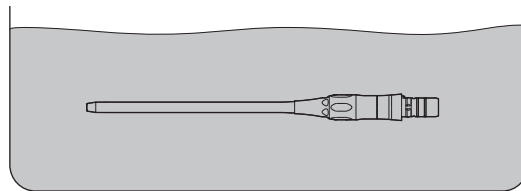


Fig. 8

- 3** Thoroughly rinse the dirt released in immersion as well as the detergent under running tap water.  
For products with moving parts, perform cleaning while moving all parts (Fig. 9).

≤ 38°C (104°F), ≥ 3.5 L/min, ≥ 10 sec.

Water quality: Drinking water

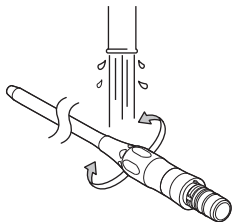


Fig. 9

- 4** Rinse the product surface with distilled, deionized or demineralized water (Fig. 10).

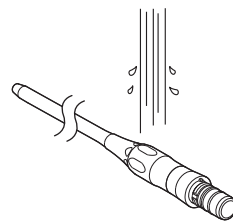


Fig. 10

## \_Purging

- 1 Remove moisture on the surface of the product using a dry cloth, air gun, etc (Fig. 11).

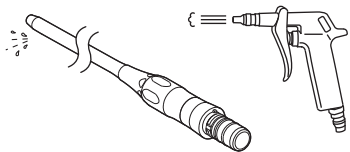


Fig. 11

- 2 Visually check that all contamination is removed (Fig. 12). In case there is residual contamination, repeat the procedures of Pre-cleaning through Purging until all contamination is removed. Proceed to Lubrication (Refer to "10-3 Lubrication").

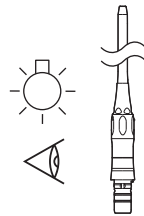


Fig. 12

## ◇ Irrigation Nozzle (Optional)

### \_Pre-cleaning

Remove contaminants on the surface with a cloth or soft bristle brush under running tap water (Fig. 13).

$\leq 38^{\circ}\text{C}$  ( $104^{\circ}\text{F}$ ),  $\geq 3.5$  L/min,  $\geq 15$  sec.

Water quality: Drinking water

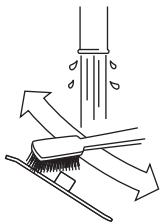


Fig. 13

## \_Cleaning

- 1 Prepare cleaning solution in the cleaning tank under the following conditions (prepare the cleaning solution according to the instructions of the detergent manufacturer).

Temperature	Water quality	Detergent
45° C (113° F)	Distilled water Deionized water Demineralized water	Neutral enzymatic detergent for medical purposes (pH 7.0 - 8.0)

\* Detergent used for validation:

Neutral enzymatic detergent: Renuzyme Plus (Getinge)

- 2 Immerse the product in the cleaning tank for 20 - 30 min (Fig. 14).

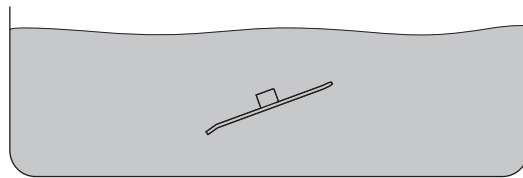


Fig. 14

- 3** Thoroughly rinse the dirt released in immersion as well as the detergent under running tap water (Fig. 15).  
≤ 38°C (104°F), ≥ 3.5 L/min, ≥ 10 sec.  
Water quality: Drinking water

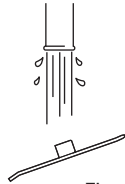


Fig. 15

- 4** Rinse the product surface with distilled, deionized or demineralized water (Fig. 16).

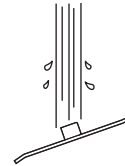


Fig. 16

## \_Purging

- 1 Remove moisture inside and on the surface of the product using a dry cloth, air gun, etc (Fig. 17).

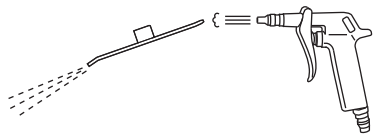


Fig. 17

- 2 Visually check that all contamination is removed (Fig. 18). In case there is residual contamination, repeat the procedures of Pre-cleaning through Purging until all contamination is removed. Proceed to Checking (Refer to "10-4 Checking").

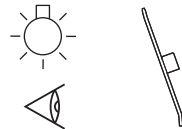


Fig. 18

## 10-2-2 Automated Cleaning

### ◇ Attachment/Handpiece

#### \_Pre-cleaning

- 1 Remove contaminants on the surface with a cloth or soft bristle brush under running tap water (Fig. 19).

For products with moving parts, perform cleaning while moving all parts (Fig. 20).

≤ 38°C (104°F), ≥ 3.5 L/min, ≥ 30 sec.

Water quality: Drinking water

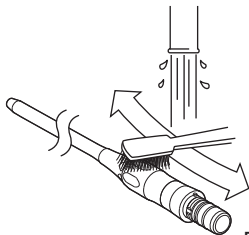


Fig. 19

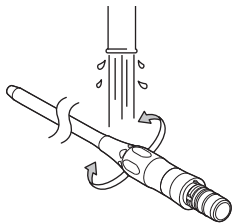


Fig. 20

- 2 Turn the twist collet to the closed position (if applicable) (Fig. 21).

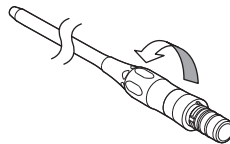


Fig. 21

- 3 Place the product in the cleaning basket and set the cleaning basket in the washer-disinfector (Fig. 22).

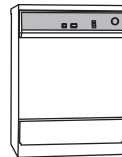
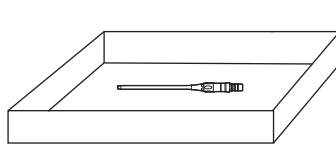


Fig. 22



## Cleaning and Disinfection

Perform cleaning and thermal disinfection using the washer-disinfector under the following conditions:

	Temperature	Time	Water quality	Detergent
Pre-cleaning	< 25°C (77°F)	3 min	Tap water	-
Cleaning	40 - 60°C (104 - 140°F)	≥ 5 min	Distilled water Deionized water Demineralized water	Neutral enzymatic detergent for medical purposes (pH 7.0 - 8.0)
Rinsing	> 10°C (50°F)	≥ 1 min		-
Thermal disinfection	90 - 93°C (194 - 199°F)	5 min		-
Drying	Set the washer-disinfector according to the instruction of the manufacturer.			

\* Detergent used for validation:

Neutral enzymatic detergent: Renuzyme Plus (Getinge)

## \_Purging

- 1 Remove moisture on the surface of the product using a dry cloth, air gun, etc (Fig. 23).

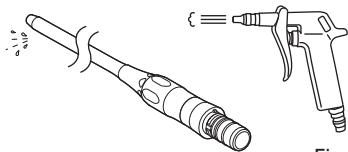


Fig. 23

- 2 Visually check that all contamination is removed (Fig. 24).  
In case there is residual contamination, repeat the procedures of Pre-cleaning through Purging until all contamination is removed.  
Proceed to Lubrication (Refer to "10-3 Lubrication").

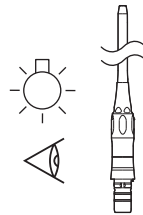


Fig. 24

## ◇ Irrigation Nozzle

### \_Pre-cleaning

- 1 Remove contaminants on the surface with a cloth or soft bristle brush under running tap water (Fig. 25).  
 $\leq 38^{\circ}\text{C}$  ( $104^{\circ}\text{F}$ ),  $\geq 3.5$  L/min,  $\geq 15$  sec.  
Water quality: Drinking water

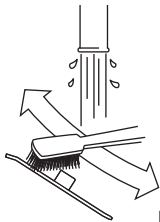


Fig. 25

- 2 Place the Irrigation Nozzle in the cleaning basket and set the cleaning basket in the washer-disinfector (Fig. 26).

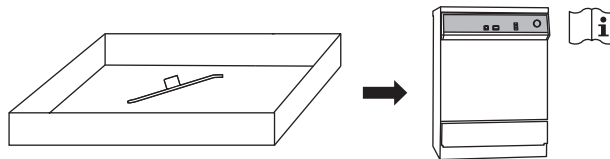


Fig. 26

## Cleaning and Disinfection

Perform cleaning and thermal disinfection using the washer-disinfector under the following conditions:

	Temperature	Time	Water quality	Detergent
Pre-cleaning	< 25°C (77°F)	3 min	Tap water	-
Cleaning	40 - 60°C (104 - 140°F)	≥ 5 min	Distilled water Deionized water Demineralized water	Neutral enzymatic detergent for medical purposes (pH 7.0 - 8.0)
Rinsing	> 10°C (50°F)	≥ 1 min		-
Thermal disinfection	90 - 93°C (194 - 199°F)	5 min		-
Drying	Set the washer-disinfector according to the instruction of the manufacturer.			

\* Detergent used for validation:

Neutral enzymatic detergent: Renuzyme Plus (Getinge)

## \_Purging

- 1 Remove moisture inside and on the surface of the product using a dry cloth, air gun, etc (Fig. 27).

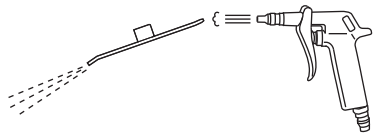


Fig. 27

- 2 Visually check that all contamination is removed (Fig. 28). In case there is residual contamination, repeat the procedures of Pre-cleaning through Purging until all contamination is removed. Proceed to Checking (Refer to "10-4 Checking").

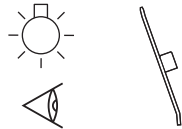


Fig. 28

## 10-3 Lubrication

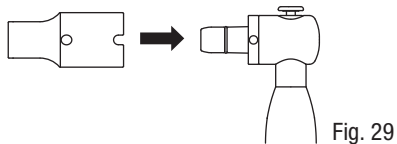


### CAUTION

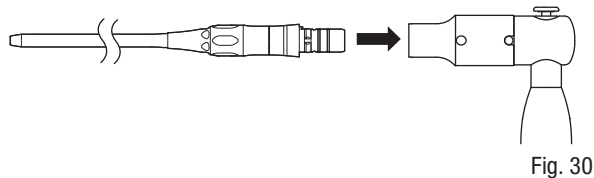
- DO NOT use anything other than PANA SPRAY Plus for lubrication.
- Shake PANA SPRAY Plus well before use.
- Due to its structure, the lubrication oil of PANA SPRAY Plus comes out from the tip of the attachment/handpiece and the twist collet part. To prevent dispersal of the lubrication oil in the surrounding area, it is recommended to cover the attachment/handpiece with a paper towel, tissue, or use the Spray Mist Absorber.
- After lubrication and prior to sterilization, check the attachment/handpiece in the same procedure of "8 Check before Operation".
- After lubrication, there might be high pressure inside the Spray Adaptor for Slim. Exercise caution when removing the Spray Adaptor for Slim, as it may pop out with significant force.

Lubricate the product using separately sold Spray Adaptor for Slim, EZ Spray Adaptor and PANA SPRAY Plus. Refer to "14 Optional Accessories".

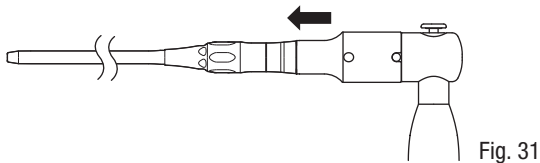
- 1** Connect each part of PANA SPRAY Plus, EZ Spray Grip, and Spray Adaptor for Slim (Fig. 29).



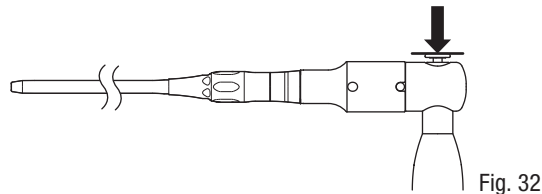
- 2** Mount the attachment/handpiece to the Spray Adaptor for Slim (Fig. 30).



- 3** Pull the product to make sure that it is securely connected (Fig. 31).



- 4** Hold the attachment/handpiece firmly to prevent it from moving by the pressure of PANA SPRAY Plus. Spray PANA SPRAY Plus for 3 - 5 sec (Fig. 32).



- 5** Remove the attachment/handpiece from the Spray Adaptor for Slim by depressing the release button **(A)** on the Spray Adaptor for Slim (Fig. 33).

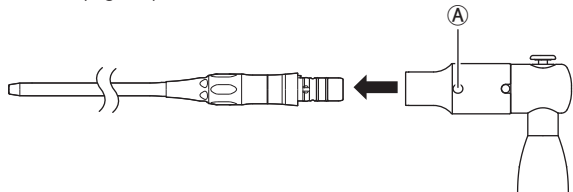


Fig. 33

- 6** Remove the Spray Adaptor for Slim from the EZ Spray Grip by depressing the release button **(B)** on the EZ Spray Grip (Fig. 34).

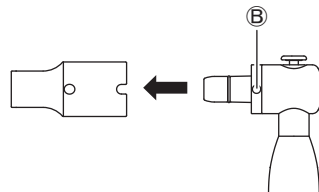


Fig. 34

#### 10-4 Checking

- 1** Confirm that there is no damage on the outer surface and connection parts of the product or missing parts.
- 2** Check with the same procedure described in "8 Check before Operation". Proceed to Packaging / Sterilization (Refer to "10-5 Packaging / Sterilization").



## 10-5 Packaging / Sterilization

We confirmed that the following sterilization procedure is in accordance with ISO 17665.

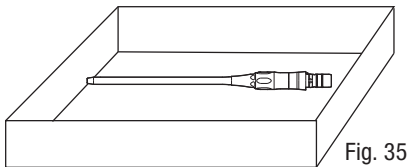


### CAUTION

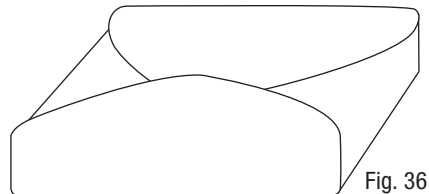
- The sterilization parameters are indicated for sterilization and immediate use only.
- Use a sterilization cassette approved as a medical device (use an FDA-approved sterilization cassette to perform sterilization).
- Use a wrap compliant with ISO 11607-1 (use an FDA-approved wrap to perform sterilization).
- Follow the wrap manufacturer's instruction for how to use the wrap.
- DO NOT heat or cool the product too quickly when autoclaving. Rapid change in temperature could cause damage to the product.
- The validity of sterilization methods other than autoclaving is not confirmed.
- DO NOT touch the product immediately after autoclaving as the product is very hot.
- Use an FDA-approved steam sterilizer to perform sterilization.

## Packaging

**1** Store the product in a metal sterilization cassette (Fig. 35).



**2** Wrap the sterilization cassette with sterilization wrap (Fig. 36).



## Sterilization

Perform autoclave sterilization under the following conditions:

Sterilization method	Sterilization temperature	Sterilization time	Drying time
Pre-vacuum autoclave	132°C (269.6°F)	≥ 4 min	≥ 20 min

<Non Autoclavable Product>

Spray Adaptor for Slim

## 10-5 Storage

Store the sterilized attachment/handpiece in a place where it can be kept sterile until the next use.



### CAUTION

- Store the products in a place avoiding adverse effects from atmospheric pressure, temperature, humidity, ventilation, direct sun, dust and salinity/sulfur content atmosphere.

## 10-6 Carrying to the operating site

Keep the attachment/handpiece sterile when it is carried to the operating site.

## 11 Troubleshooting

If you are suspect any faults, check the following troubleshooting guide prior to asking for repair work. If none of these cases is applicable or if the situation does not improve despite your efforts or measures, the damage could be serious; call your authorized distributor to fix the problem.

Symptoms	Causes/Points of checking	Countermeasures
The attachment/handpiece cannot be connected to the motor.	The ' ▲ ' symbol of the attachment/handpiece and 'A' or 'C' symbol (either one) of the motor are not aligned.	Align the ' ▲ ' symbol of the attachment/handpiece and 'A' or 'C' symbol (either one) of the motor, then push the attachment/handpiece in until it clicks to connect firmly.
	Connection part has been deformed.	Contact your distributor.
The Cutting Accessory cannot be firmly mounted.	The Cutting Accessory has not been inserted deep enough.	Insert the Cutting Accessory all the way through.
	The twist collet is in ' OPEN ' (chuck open position).	After inserting the Cutting Accessory, fasten the twist collet (chuck close position).
	The twist collet has been damaged or deformed.	Contact your distributor.

Symptoms	Causes/Points of checking	Countermeasures
No rotation when the Cutting Accessory is securely mounted.	<ul style="list-style-type: none"> <li>• The bearing has overheated.</li> <li>• Foreign materials inside.</li> <li>• The bearing has worn out.</li> </ul>	Contact your distributor.
Overheating (during operation).	The twist collet is in ' OPEN ' (chuck open position).	After inserting the Cutting Accessory, fasten the twist collet.
	The ' ▲ ' symbol of the attachment/handpiece and 'A' or 'C' symbol (either one) of the motor are not aligned.	Align the ' ▲ ' symbol of the attachment/handpiece and 'A' or 'C' symbol (either one) of the motor, then push the attachment/handpiece in until it clicks to connect firmly.
	Continuous use over a long period.	Stop using the attachment/handpiece and the motor immediately. Wait until the attachment/handpiece and the motor cool down before using the attachment/handpiece and the motor again.
	<ul style="list-style-type: none"> <li>• The bearing has overheated.</li> <li>• Foreign materials inside.</li> <li>• The bearing has worn out.</li> </ul>	Contact your distributor.

Symptoms	Causes/Points of checking	Countermeasures
Abnormal vibration and noise. Cutting Accessory run-out.	<ul style="list-style-type: none"> <li>• The bearing has overheated.</li> <li>• Foreign materials inside.</li> <li>• The bearing has worn out.</li> </ul>	Contact your distributor.

## 12 Symbols



Listen (Clicking sound)



Caution



Date of manufacture



State of being fixed



Manufacturer



Unique Device Identifier



State of being unfixed



Caution: U.S. Federal law restricts this device to sale by or on the order of a licensed physician.



GS1 DataMatrix for Unique Device Identifier.



Lighting



Catalog number (Order code)



Temperature limitation



Visual check



Delivered in a non-sterile condition



Humidity limitation



Consult operation instructions



Serial No.



Atmospheric pressure limitation

## 13 Warranty

Our products are subjected to rigorous quality control and inspections. In the unlikely event of a product proving to be faulty within the guarantee period when it has been used normally, it will be repaired free of charge subject to the terms and conditions below. For such repair requests, please contact your distributor.

Guarantee period.....One year

- In the following cases, the repair has to be paid for even if the product is within the guarantee period:
  - Fault and damage caused by misuse, or inappropriate repair or modification.
  - Fault and damage caused during transit or dropping after the product was purchased.
  - Fault and damage attributable to fire, earthquake, flooding, power surge, environmental pollution or other acts of providence.
  - Fault and damage caused by the use of consumables or methods other than those specified by NSK.
  - When the product has been repaired using components other than genuine components supplied by NSK.
- For repairs after the guarantee period, please contact your distributor from whom the product was purchased.

## 14 Optional Accessories

Product Name	Order code of NSK	Order code of Globus	Quantity	Remarks
PANA SPRAY Plus	Z182600	6261.1701	1	-
PANA SPRAY Plus (6pcs)	Y900630	6261.1702	1	6 pcs per set.
Spray Adaptor for Slim	P200-EZ-SM	6261.1703	1	For Standard Attachment 200 G.
EZ Spray Adaptor	PD-EZ-M	6261.1704	1	For Spray Adaptor for Slim.
Irrigation Nozzle	PD-IN-2L	6261.1503	1	For Standard Attachment 200 G.



## **15** Disposing Product

In order to avoid the health risks of operators handling the disposal of medical equipment, as well as the risks of environmental contamination caused thereof, a surgeon is required to confirm the equipment is sterile. Ask specialist firms who are licensed to dispose of specially controlled industrial wastes, to dispose the product for you.

Manufacturer

**NAKANISHI INC.**  [www.nsk-surgery.com](http://www.nsk-surgery.com)

700 Shimohinata, Kanuma, Tochigi 322-8666, Japan

Importer

**NSK America Corp.**

1800 Global Parkway, Hoffman Estates, IL 60192, USA

Distributed by

**Globus Medical, Inc.**

2560 General Armistead Avenue, Audubon, PA 19403, USA

Specifications are subject to change without notice.

2023-12-08 CACD1213 005E