NSK

OPERATION MANUAL

Rx Only MADE IN JAPAN

OM-SE0921EN 002

Primado2

Slim Motor G

GLOBUS MEDICAL VERZA™

This motor 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", "periodical maintenance check" and "reprocessing" so that you can continue using the motor 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 Surgical Attachment	OM-SH0084E
Surgical Attachment P300 Attachment	OM-SH0911EN
Primado2 Standard Handpiece 200 G	OM-SH0939EN
NSK Sterile Cutting Accessories for P300 Attachment	OM-SZ0959MA
CUTTING ACCESSORIES - P300 ATTACHMENT CORRESPONDENCE TABLE	OM-SZ0958MA
Globus VERZA™ User Manual	GMUML21

*** Refer to "11 Symbols" section on page 28 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 Primado2 is an AC-electrically powered total surgical system that is intended for cutting, drilling, sawing, and otherwise manipulating soft tissue, hard tissue, bone, bone cement, prosthesis, implant, and other bone related tissue in a variety of surgical procedures, including but not limited to Cranial (Craniofacial/Maxillofacial), ENT, Endoscopic/Arthroscopic, Neuro, Orthopedic, Spinal, and General surgical procedures.
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
⚠ DANGER	Hazard that could result in personal death or serious injury if the safety instructions are not correctly followed.
⚠ WARNING	Hazard that could result in serious injury or damage to the device if the safety instructions are not correctly followed.
⚠ CAUTION	Hazard that could result in light or moderate injury or damage to the device if the safety instructions are not correctly followed.
NOTICE	General product specification information highlighted to avoid product malfunction and performance reduction.

⚠ DANGER

- Do not use this system in a room where there is danger of explosion or in the vicinity of flammable substances. It is especially important not to use this system on a patient to whom a flammable anesthetic agent (dinitrogen monoxide) has been administered.
- Never disassemble or modify the product. Personal injury, electric shock or fire may result.

⚠ WARNING

- When operating the product always consider the safety of the patient.
- 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 intended use and proper method of use.
- This product may be affected when used in rooms with electromagnetic interference and portable or mobile RF communication equipment. Do not use this product around any equipment that generates electromagnetic waves such as an ultrasonic generator and/or electric scalpel. In case equipment generating electromagnetic waves are used around this product, turn off the control unit.

⚠ CAUTION

- U.S. Federal law restricts this device to sale by or on the order of a licensed physician.
- Be sure to read this operation manual prior to use to become completely familiar with the function of each part.
- This product is not sterilized before delivery. Therefore, be sure to sterilize it prior to use.

⚠ CAUTION

- Be sure to operate the attachment/handpiece connected to motor and control unit prior to use. Even if only a slightly abnormal condition such as vibration, abnormal sound, and/or heat generation is detected, stop use and contact your distributor.
- It is recommended that a spare product be kept on hand in case of a breakdown during surgery.
- Do not subject this product to strong impacts such as dropping it on the floor. Personal injury, abnormal heating and fire may result caused by the internal damage.
- The product lifetime and product's ability to operate correctly are mainly determined by mechanical stresses during use and the chemical influences due to processing. If you detect any abnormality such as center run-out of Cutting Accessory, heat generation, vibration or noise, or if the exterior markings (serial number or model number) have become unreadable before or during use, stop using the product immediately and request your distributor for a periodic inspection.
- Do not disconnect the motor cord from the motor. It may cause failure.
- Do not clean the product with solvents such as thinner or benzine solution. Discoloration or deformation may result.
- 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.
- Regarding the operation time of the motor, follow the specification table in "4 Part Names and Specifications". Prolonged, continuous use of the motor may lead to overheating, potentially resulting in an accident.
- If the product is not used for a long period of time, check if it functions correctly and safely before use.
- The temperature of the motor and control unit mounting parts may reach up to 60˚C (140˚F) depending on the environment.

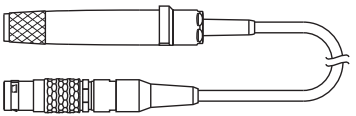
⚠ CAUTION

- Disconnect the motor cord plug from the control unit when the product is not used. If excessive impact is applied, such as hitting the connections without disconnecting them, failure of the motor cord plug may occur.
- 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.

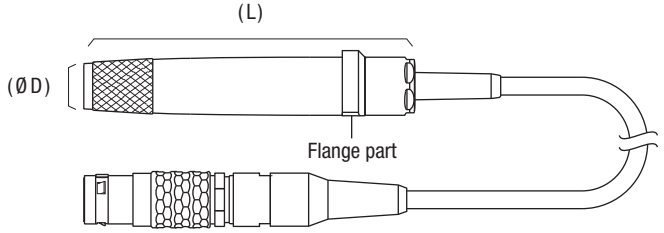
NOTICE

- The user shall be responsible for maintenance and operation.

3 Package Contents

Product name	Order code of NSK	Order code of Globus	Quantity	Fig.
Primado2 Slim Motor G	P200-SMH-G	6261.1301	1	

4 Part Names and Specifications



Order code of NSK	P200-SMH-G
Order code of Globus	6261.1301
Maximum rotation speed	80,000 min^{-1}
Rated input	DC 23.7V
Dimension (ØD x L)	Ø18 × L102.7 mm (Flange part: Ø22)
Weight	331 g
Operation time	3 min. ON / 10 min. OFF
Length of the motor cord	3.5 m

This motor 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

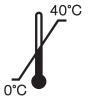
<Foot control>

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

<Attachment/handpiece>

Product name	Standard Handpiece 200		
Order code (NSK/Globus)	P200-2AS / 6261.3001	P200-2AM / 6261.3002	P200-2AL / 6261.3003
	P200-2A110-G / 6261.3004	P200-2SS / 6261.2001	P200-2SM / 6261.2002
	P200-2SL / 6261.2003	P200-2S110-G / 6261.2004	P200-2S225-G / 6261.2007

Product name	Slim Attachment 300 (Slim Attachment Hub)	Slim Attachment 300
Order code (NSK/Globus)	P300-1AHA / 6261.3100	P300-1T130-PB / 6261.3106

Use environment			-
Storage and transportation environment			

5 How to Connect Each Component

⚠ CAUTION

- Refer to the operation manuals of the related products listed in "Table 1" on page 1.

5-1 Connection to the control unit

By matching the mark ● on the motor cord plug and the mark ● on the motor connector (A or B) at the front of the control unit, plug the motor into the connector all the way (Fig. 1).

⚠ CAUTION

- There are two motor connectors. By connecting two motors to the two connectors, you can select the one you want to use by the motor select button of the control unit. (However, both motors cannot be operated simultaneously.) The selected motor can be confirmed in the main panel of the control unit. Refer to the operation manual of the control unit for detail.

* To disconnect the motor, hold the motor cord plug and pull it out with a straight movement.

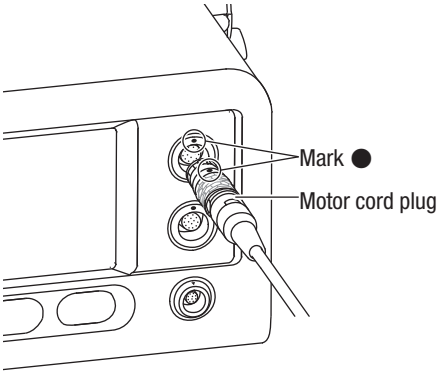


Fig.1

⚠ CAUTION

- If the motor cord cannot be connected to the control unit easily, do not insist. Deformation or cracks might occur. A foreign substance might be obstructing the connection or the connection portion might be deformed. Contact your distributor.
- Whenever you use two motor connectors alternately, be sure to confirm which motor is under operation.
- Connect or disconnect the motor cord only after turning OFF the control unit.
- Do not connect the motor to control units other than Primado2. Otherwise, it could deform the motor connector and cause failure.
- When connecting/disconnecting the motor, do not rotate the motor cord plug. Otherwise, the inside pins might become damaged, leading to failure.
- Do not connect/disconnect the motor cord with wet hands; otherwise, an electric shock might occur.
- Be sure to hold the motor cord plug when disconnecting the motor from the control unit to prevent failure caused by breaking wires.

5-2 Mounting of the attachment/handpiece

⚠ CAUTION

- Prior to mounting/removing the attachment/handpiece, remove the Cutting Accessory. Otherwise, injury might occur.
- If the attachment/handpiece cannot be connected to the motor easily, do not insist. Deformation or cracks might occur. A foreign substance might be obstructing the connection or the connection portion might be deformed. Contact your distributor.
- After mounting the attachment/handpiece, confirm that the attachment/handpiece and motor are connected properly.

<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. 2). Then push the attachment/handpiece firmly into the motor until it clicks.

<Removing>

Pull the attachment/handpiece straight out from the motor.

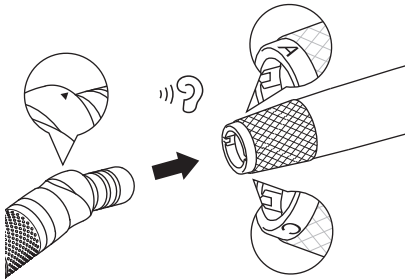


Fig.2

6 Check before Operation

Follow the check list below before use. If any abnormalities are found, stop using the product immediately and contact your distributor.

1. Check for any abnormalities or damage on the outer surface and for any damage or deformation on the pins in the motor cord plug.
2. Check that the motor can be securely connected to the control unit.
3. Depress the pedal of the foot control to check for any abnormal vibration, noise or heating in the motor. Check in the main panel of the control unit that the rotational speed can reach the maximum speed you have set.
4. Check that forward and reverse modes operate normally.
5. Mount the attachment/handpiece to the motor to check their secure connection.

* If any abnormalities are found, stop using the product immediately and contact your distributor.
* Operate the product if none of the above abnormalities are present.
* When checking attachment/handpiece before treatment, refer to the operation manual of attachment/handpiece.

7 Operation

⚠ CAUTION
- Refer to the operation manuals of the related products listed in "Table 1" on page 1.
- The pedal of the foot control is variable. The rotational speed increases/decreases within the preset rotation range, depending on the extent/duration of depressing.

7-1 When using the foot control (FC-73, FC-74)

1 When depressing the pedal of the foot control, the motor starts to operate. When depressing the pedal or releasing it, a short alarm sounds (Fig. 3).

2 In the reverse mode, the Cutting Accessory starts rotating in reverse. During this reverse rotation, the alarm continues to sound.

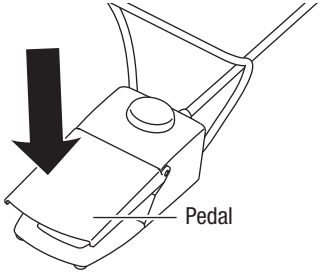


Fig.3

3 Push the foot control button to set the control unit to the pre-determined function (Fig. 4). For the setting of the Foot Control, refer to "6-4 Setting Up the Foot Control" in OM-SE0028E Total Surgical System Primado2 OPERATION MANUAL.

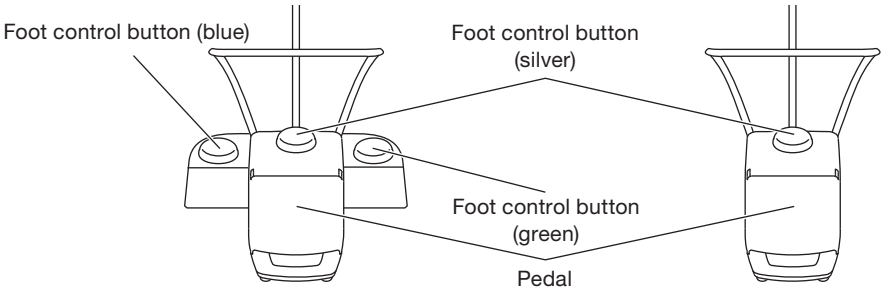


Fig.4

⚠ CAUTION

- Before using the foot control button, be sure to confirm what function is assigned to that button in the sub panel.

8 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.
Motor/attachment/handpiece	Connect the motor and attachment, 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.

9 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 motor before autoclave sterilization. Autoclaving the motor with blood remaining on it may lead to sterilization failure, resulting in infection to the patient and/or user or malfunction of the motor due to blood coagulation.
- Immediately after use, the motor should be cleaned and sterilized. Remaining blood in the motor may cause rust due to blood coagulation. Failure to properly maintain the motor 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.
- NSK has verified the effectiveness of reprocessing.
- 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.

9-1 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, attachment/handpiece, other connections from the motor (for removing the Cutting Accessories from the attachment/handpiece, refer to the attachment/handpiece operation manual listed in "Table 1" on page 1.

3 Remove the motor cord form the control unit.

4 Check for any damage or deterioration on the outer surface of each motor or motor cord, and for any deformation or loss of each connecter pin.

9-2 Cleaning

9-2-1 Manual cleaning

_Pre-cleaning

Remove contaminants on the surface with a cloth or soft bristle brush under running tap water (Fig. 5).

≥ 38˚C (101˚F), ≥ 3.5 L/min, ≥ 60 sec.

Water quality: Drinking water

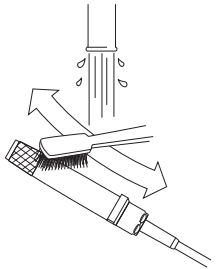


Fig.5

_Cleaning

1 Remove the dirt on the surface of the product using a soft bristle brush moistened with neutral enzymatic detergent.
≥ 1 min
Water quality: Distilled, deionized or demineralized water.
* Detergent used for validation:
Neutral enzymatic detergent: Renuzyme Plus (Getinge)

2 Rinse the product under running tap water.
≥ 38˚C (101˚F), ≥ 3.5 L/min, ≥ 20 sec.
Water quality: Drinking water

3 Rinse the product surface with distilled, deionized or demineralized water.

_Purging

1 Remove moisture on the surface of the product using a dry cloth, air gun, etc.

2 Visually check that all contamination is removed. In case there is residual contamination, repeat the procedures of pre-cleaning through drying until all contamination is removed. Proceed to checking (refer to "9-3 Checking").

9–2–2 Automated cleaning

_Pre-cleaning

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

≥ 38˚C (101˚F), ≥ 3.5 L/min, ≥ 60 sec.

Water quality: Drinking water

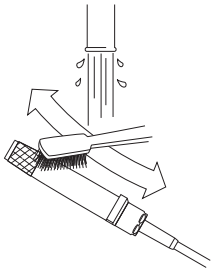


Fig.6

_Cleaning and Disinfection

Perform cleaning and thermal disinfection using a 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 (194-199.4˚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.

2 Visually check that all contamination is removed. In case there is residual contamination, repeat the procedures of pre-cleaning through drying until all contamination is removed.
Proceed to checking (refer to "9–3 Checking").

⚠ CAUTION

- Do not soak the motor into water, or failure might occur.
- 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.
- Refer to the operation manual of the washer-disinfector before operating it.
- Do not clean the motor by a washer sterilizer.
- Be sure to use a disinfector compliant with ISO15883-1, ISO15883-2.
- After cleaning and prior to sterilization, check the motor in the same procedure of "6. Check before Operation".

9-3 Checking

1. Check for any abnormalities or damage on the outer surface and for any damage or deformation on the pins in the plug.
2. Check that the motor can be securely connected to the control unit.
3. Depress the pedal of the foot control to check for any abnormal vibration, noise or heating in the motor. Check on the main panel of the control unit that the rotational speed can reach the maximum speed you have set.
4. Mount the attachment to the motor to check its secure connection. Proceed to packaging / sterilization (refer to "9-4 Packaging / Sterilization").

9-4 Packaging / Sterilization

1. Store the product in a metal sterilization cassette (Fig. 7).

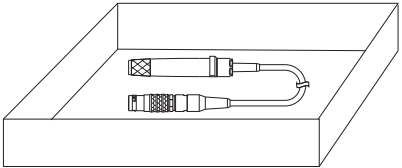


Fig.7

2. Wrap the sterilization cassette with sterilization wrap (Fig. 8).

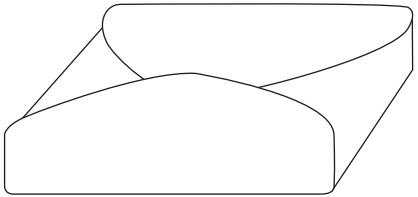


Fig.8

9-5 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	≥ 30 min

⚠ CAUTION

- The motor does not require lubrication. Never lubricate the motor.
- 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.

9-6 Storage

Store the sterilized motor 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 in the atmosphere.

9-7 Carrying to the operating site

Keep the motor sterile when it is carried to the operating site.

10 Troubleshooting

If you are suspecting any faults, check the following once again 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 distributor to fix the problem.

Symptoms	Causes/Points of checking	Countermeasures
No rotation occurs after attaching a cutting accessory and attachment/handpiece.	The twist collet on the attachment/handpiece is OPEN.	After inserting the Cutting Accessory, fasten the twist collet. (Turn it in the direction of ' 🔒 ')
	· The bearing has seized. · Foreign substance inside the bearing. · The bearing is worn out.	Contact your distributor.
Abnormal heating during rotation.	Continuous use over a long period.	Stop operating the attachment/handpiece and motor immediately. Wait until the attachment/ handpiece and motor cool down before continuing to operate.
Abnormal heating during rotation.	· The bearing has seized. · Foreign substance inside the bearing. · The bearing is worn out.	Contact your distributor.
Abnormal vibration and noise. Cutting Accessory run-out.		

11 Symbols

	State of being fixed
	Consult operation instructions
	Caution
	Type BF applied part
	Marking on the outside of equipment or equipment parts that include RF transmitters or that apply RF electromagnetic energy for diagnosis or treatment.
	Dispose of this device and its accessories via methods approved for electronic device and in compliance with the Directive 2012/19/EU
	Manufacturer
	Caution: U.S. Federal law restricts this device to sale by or on the order of a licensed physician.

	Catalog number (Order code)
	Serial No.
	Date of manufacture
	Unique Device Identifier
	GS1 DataMatrix for Unique Device Identifier.
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation

12 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 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 the product after it was purchased.
  - Fault and damage attributable to fire, earthquake, flooding, power surge, environmental pollution or other act 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.

13 Optional Accessories

Product Name	Order code of NSK	Order code of Globus	Quantity	Remarks
Spray Adaptor for Slim	P200-EZ-SM	6261.1703	1	For Standard Handpiece 200 For Slim Attachment 300

14 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.

15 EMC Information

Guidance and manufacturer's declaration - electromagnetic emissions		
The Primado2 is intended for use in the electromagnetic environment specified below. The customer or the user of the Primado2 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR11/ EN55011	Group 1	The Primado2 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/ EN55011	Class B	The Primado2 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions EN/IEC61000-3-2	Not Applicable	
Voltage fluctuations/flicker emissions EN/IEC61000-3-3	Not Applicable	

Guidance and manufacturer's declaration - electromagnetic immunity			
The Primado2 is intended for use in the electromagnetic environment specified below. The customer or the user of the Primado2 should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) EN/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 EN/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 EN/IEC61000-4-5	±1kV line (s) to line (s) ±2kV line (s) to earth	±1kV line (s) to line (s) ±2kV line (s) 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 EN/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 secs	<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 secs	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Primado2 requires continued operation during power mains interruptions, it is recommended that the Primado2 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field EN/IEC61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE 'Ut' is the AC mains voltage prior to application of the test level			

Guidance and manufacturer's declaration - electromagnetic immunity			
The Primado2 is intended for use in the electromagnetic environment specified below. The customer or the user of the Primado2 should assure that it is used in such an environment.			
Immunity test	EN/IEC60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Primado2, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF EN/IEC61000-4-6	3Vrms 150 kHz to 80MHz	3Vrms	$d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz to 800MHz
Radiated RF EN/IEC61000-4-3	3V/m 80MHz to 2.5 GHz	3V/m	$d = 2.3\sqrt{P}$ 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[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80MHz and 800MHz, the higher frequency range applies.			
NOTE 2 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 Primado2 is used exceeds the applicable RF compliance level above, the Primado2 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Primado2.			
b Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.			

Cables and accessories	Maximum length	Complies with	
Motor Cord	3.5m（Unshielded）	RF emissions, CISPR11:	Class B/Group 1
		Electrostatic discharge (ESD):	EN/IEC61000-4-2
Foot Control Cord	3.5m（Unshielded）	Electric fast transient / burst:	EN/IEC61000-4-4
		Surge:	EN/IEC61000-4-5
Power Cord	3.5m（Unshielded）	Voltage dips, short interruptions and voltage variations on power supply input lines:	EN/IEC61000-4-11
		Power frequency (50 / 60Hz) magnetic field:	EN/IEC61000-4-8
		Conducted RF:	EN/IEC61000-4-6
		Radiated RF:	EN/IEC61000-4-3

Recommended separation distances between portable and mobile RF communications equipment and the Primado2.			
The Primado2 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Primado2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Primado2 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 0.1	0.12 0.38	0.12 0.38	0.23 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.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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