



OPERATION MANUAL

Surgical Attachment

Primado2

Standard Handpiece 200

Slim Handpiece 200

Super Slim Handpiece 200

Drill Handpiece 200

Contra Angle Handpiece 200

Metal Cutting Handpiece 200

Rx Only




OM-SH0084E 001

These Attachments/Handpieces are to be used exclusively with Primado2, our surgical operation control unit.

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 Attachments/Handpieces in the future. In addition, keep this operation manual in a place where a user can refer to it at any given time.

Precautions for handling and operation

- Read these safety precautions thoroughly before use and operate the product properly.
- These indicators are to allow you to use the product safely, prevent danger and harm to you and others. These are classified by degree of danger, damage and seriousness. All indicators concern safety, therefore be sure to follow them.

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.
N O T I C E	General product specification information highlighted to avoid product malfunction and performance reduction.

Intended Use

- Only qualified persons are allowed to use these Attachments/Handpieces for bone operations (removal, cutting, perforation and formation), or cutting implants. The applicable Attachment/Handpiece for cutting implants is Metal Cutting Handpiece 200.

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. 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 system may be affected when used in rooms with electromagnetic interference and portable or mobile RF communication equipments. Do not use this system around any equipment that generates electromagnetic waves such as an ultrasonic generator or electrical scalpel. In case equipment generating electromagnetic waves are used around this system, 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 manual prior to use to become completely familiar with the function of each part.

 **CAUTION**

- The Attachments/Handpieces are not sterilized before delivery. Therefore, be sure to sterilize them prior to use.
- 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 heat generation is detected, stop use and contact your dealer.
- Should the product function abnormally, cease operation immediately and return the Attachment/Handpiece to your dealer for repair.
- Do not turn the Twist Collet during operation of the Attachment/Handpiece. It may cause damage to the Motor or Attachment/Handpiece.
- Do not allow any impact on to the product. Do not drop the product. Personal injury, abnormal heating and fire may result caused by the internal damage.
- Do not use bent, damaged or deformed burs that are not suitable for the Attachment/Handpiece. If used, the Attachment/Handpiece will not grip the bur securely and it may break or cause injury/malfunctions.
- DO NOT place the Attachment/Handpiece/motor on the patient or the drape covering the patient.
Failing to do so may cause an accident, injury or thermal injury to the patient and/or surgical staff.
- DO NOT put excessive pressure on the Cutting Accessory, which may cause it to bend and become damaged. Excessive pressure may cause heat generation on the Cutting Accessory, Attachment/Handpiece and Motor which could lead to thermal injury.
Use Cutting Accessories, Attachment/Handpiece and Motors intermittently to prevent heat generation.
In case of heat generation, immediately stop its use until it cools down. DO NOT touch the heated area.
- Make sure that the shank part of the Bur/Drill to be attached is clean. A dirty shank part may cause center deviation or reduction of holding.
- Protect the region of the wound from the metal tips when using the Metal Cutting Handpiece 200.

 **CAUTION**

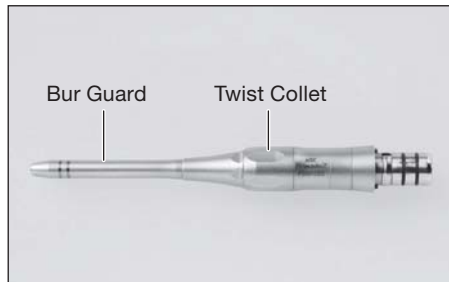
- Hold implant parts firmly to prevent debris from flying while cutting the implant. Also, use large amounts of irrigation during use to cool the cutting surface while cutting.
- Turn off the power of the Control Unit when mounting or removing the Motor and Attachment/Handpiece. Mounting or removing it with the power on may cause personal injury due to an unexpected rotation.
- Use new Burs and Drills for every surgical operation.
- Do not clean the product with solvents such as thinner or benzene solution. Discoloration or deformation may result.
- The temperature at the tip of the Attachment/Handpiece may reach up to 60°C depending on the environment.

NOTICE

- The user shall be responsible for maintenance and operation.

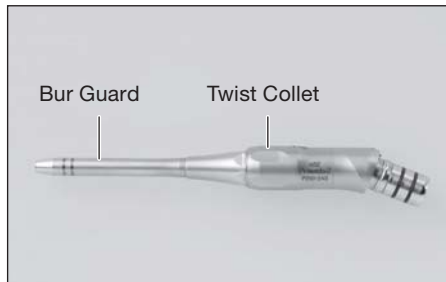
1 Part Names

<Straight type>



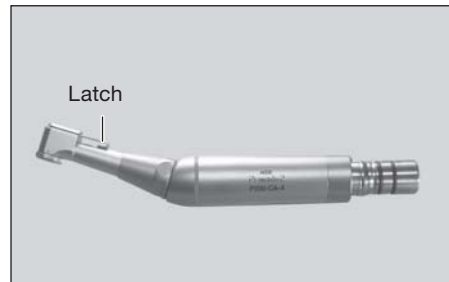
*P200-2SS.

<Angled type>



*P200-2AS.

<Contra Angle Type>



*P200-CA-4.

2 Check before Operation

Conduct pre-use checks by the following procedure to confirm that there are no abnormalities.

- 1) Mount a Bur or Drill.
- 2) Operate the Attachment/Handpiece. Confirm that nothing is loose and that no abnormal vibration, heating or noise occurs. If any abnormality is observed, contact your dealer for repair.
- 3) Ensure there are no abnormalities before use.

3 Connecting / Disconnecting Motor and Attachment / Handpiece



CAUTION

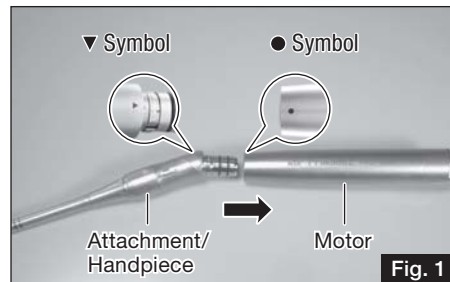
- When mounting or removing the Attachment/Handpiece, set the Safety Lock to " OFF " on the Hand Switch of the Motor (Motor with Hand Control).
- Refer to the Operation Manual of Motor.
- Prior to mounting/removing the Attachment/Handpiece, remove the Bur or Drill. Otherwise, injury might occur.
- After mounting the Attachment/Handpiece, confirm that they are connected properly.

<Mounting>

- 1) Push the Attachment/Handpiece into the Motor straight.
- 2) Align the ' ▼ ' Symbol of the Attachment/Handpiece and ' ● ' Symbol of the Motor, then push the Attachment/Handpiece in until it clicks to connect firmly.

<Removing>

Pull out the Attachment/Handpiece from the Motor straight.



4 Mounting and Removing Burs and Drills



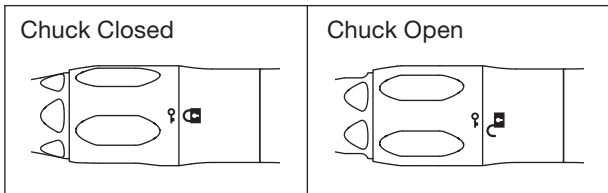
CAUTION

- Use only Burs and Drills specified by NSK. The use of other Burs and Drills may cause a fault or an accident.
- Use Burs and Drills that are suitable for the Attachment/Handpiece. The use of unsuitable Burs and Drills may cause a fault or an accident.
- After mounting a Bur or Drill, pull it lightly to confirm that it is securely connected.
- Before use, confirm that the Bur or Drill does not come off by operating the Attachment/Handpiece.
- Do not operate the Attachment/Handpiece when a Bur or a Drill is not mounted.
- Remove the Bur or Drill from the Attachment/Handpiece after the Attachment/Handpiece has completely stopped.
- Do not operate the Attachment/Handpiece if the '↻' symbol and '🔒' symbol are not aligned (chuck is open). It may cause heat generation and damage to the Attachment/Handpiece.

◆ **Standard Handpiece 200, Slim Handpiece 200, Super Slimn Handpiece 200, Drill Handpiece 200 and Metal Cutting Handpiece 200**

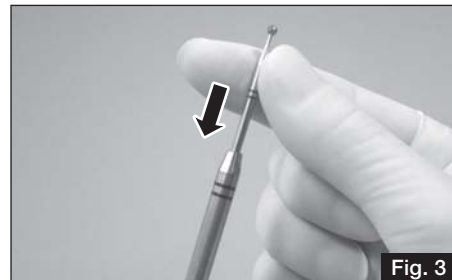
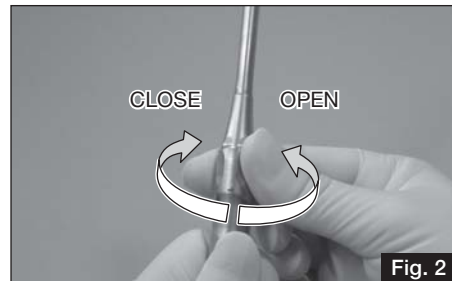
<Mounting>


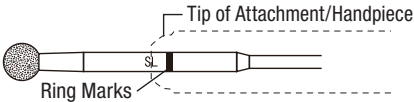



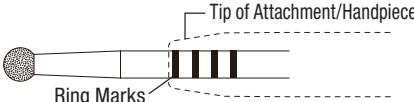

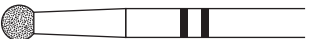


1) Turn the Twist Collet in the direction of '↻' until it clicks (Fig. 2).


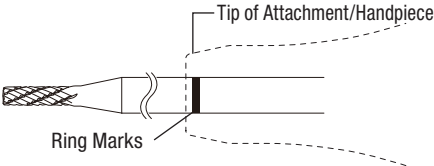
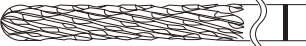
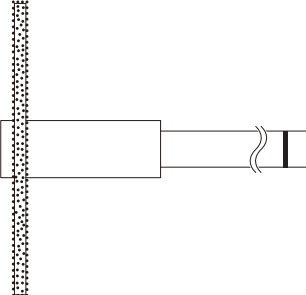


2) Insert the Bur or Drill through the tip of the Attachment/Handpiece all the way, twisting it slightly with your fingers (Fig. 3).

If there are Ring Marks on the Bur, you can check if the Bur or the Drill has gone deep enough, using the table below as a reference.



Bur/Drill		Ring Mark	Attachment/Handpiece
Ø1mm Primado Bur (L)		 <p>Identification letters can be partially seen near the tip of the Attachment/Handpiece, though the Ring Marks are hidden inside the Attachment/Handpiece.</p>	P200-1A135
Ø1mm Primado Bur (EL)			P200-1A155 P200-1A155-C
Ø1mm Primado Bur (SL)			P200-1A175 P200-1A175-C
Ø1mm Primado Bur (SPL)		No Ring Marks	P200-RA330 P200-RA330-L
Ø2.35mm Primado Bur (MS)		 <p>Ring Marks should not be visible when the Bur is inserted correctly, as they are hidden inside the tip of the Attachment/Handpiece.</p>	P200-2SMS P200-2AMS
Ø2.35mm Primado Bur (ES)			P200-2SES P200-2AES
Ø2.35mm Primado Bur (S)			P200-2SS P200-2AS
Ø2.35mm Primado Bur (M)			P200-2SM P200-2AM
Ø2.35mm Primado Bur (L)			P200-2SL P200-2AL

Bur/Drill	Ring Mark		Attachment/Handpiece
Ø2.35mm Primado Twist Drill Ø2.35mm Primado Wirepass Drill	No Ring Marks		P200-2SD
Ø3.17mm Primado Metal Cutting Carbide Bur (1.6)			P200-3MC
3.17mm Primado Metal Cutting Carbide Bur (3.0)			
Ø3.17mm Primado Metal Cutting Diamond Disk (25.4)			
<p>Ring Marks should not be visible when the Bur is inserted correctly, as they are hidden inside the tip of the Attachment/Handpiece.</p>			



CAUTION

- Twist Drill and Wirepass Drill do not have Ring Marks.
- Insert the Bur/Drill all the way through the Attachment/Handpiece for a firm connection. If it is not connected firmly, the Bur/Drill may come off during a surgical procedure and interrupt a surgery.
- When the Bur is firmly mounted, confirm that '↻' symbol and '🔒' symbol are aligned.

3) Turn the Twist Collet in the direction of '🔒' until it clicks (Fig. 2) to connect the Bur/Drill firmly. After mounting the Bur/Drill, confirm that it is firmly connected by pulling it lightly.

<Removing>

- 1) Turn the Twist Collet in the direction of '🔓' until it clicks (Fig. 2).
- 2) Pull the Bur/Drill through the tip of the Attachment/Handpiece straight (Fig.4)



Fig. 4

◆ Contra Angle Handpiece 200

For the Bur, use a commercially available $\varnothing 2.35\text{mm}$ Contra Bur.

<Mounting>

1) Slide the Latch in the direction of " OPEN " (Fig. 5).

2) Match the notch of the Bur to the corresponding part of the shaft and push the Bur all the way through (Fig. 6).

3) Slide the Latch in the direction of " CLOSE " to set the Bur in place (Fig. 5).

<Removing>

Slide the Latch in the direction of " OPEN " to remove the Bur.

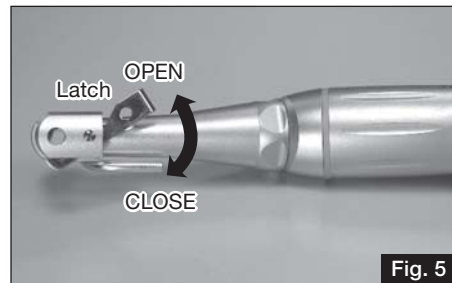


Fig. 5

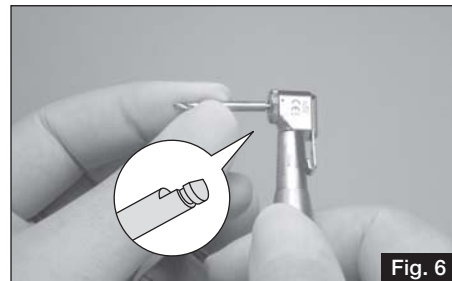


Fig. 6

◆ Removing Bur Guard



CAUTION

- Tighten the Removal Ring of the Bur Guard securely prior to use in order to avoid an accident caused by the Bur Guard coming off during use.

Attachment/Handpiece are: P200-1A135, P200-1A155, P200-1A155-C, P200-1A175, P200-1A175-C, P200-RA330, P200-RA330-L

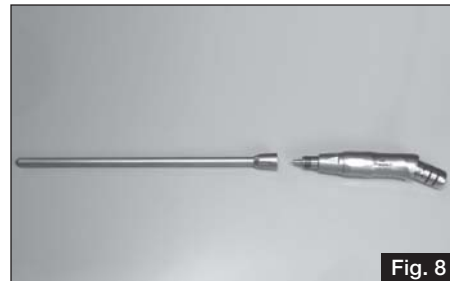
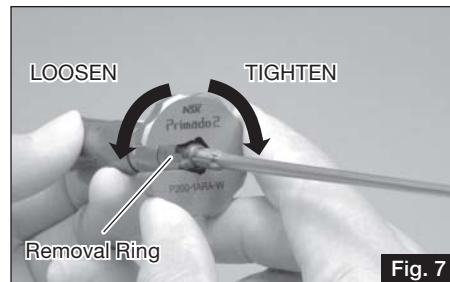
The Bur Guard can be removed using a Wrench (Order Code: P200-1ARA-W), an accessory for the Attachment/Handpiece.

<Removing>

Place the Wrench onto the Removal Ring of the Bur Guard, turn it in the direction of " LOOSEN " as shown in Fig. 7 and pull out straight.

<Mounting>

Align the Bur Guard with the Attachment/Handpiece, tighten the Removal Ring several times with your fingers before tightening it securely with the Wrench.



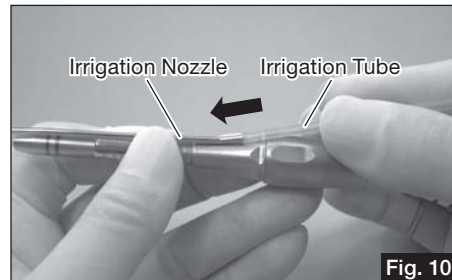
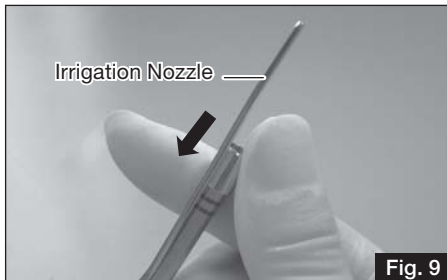
5 Mounting Irrigation Nozzle



CAUTION

- Mount the Irrigation Nozzle to the Attachment/Handpiece after removing the Bur/Drill.
- Do not use irrigation nozzles other than those specified by NSK.
- Also see the Operation Manual of Primado2 Control Unit.

- 1) Insert the Irrigation Nozzle onto the Bur Guard of the Attachment/Handpiece, making sure the correct end of the Irrigation Nozzle goes in (Fig. 9).
- 2) Insert the Irrigation Tube into the Irrigation Nozzle (Fig. 10).
- 3) For the related connection and the setting of the Control Unit, see the Operation Manual of Primado2 Control Unit.



6 Cleaning / Sterilization



CAUTION

- Perform cleaning and sterilization after every use.
- Clean and lubricate the Attachment/Handpiece before autoclaving. Autoclaving an Attachment/Handpiece stained with blood or debris could cause damage to the Attachment/Handpiece.
- In order to prevent infection, wear a mask, rubber gloves and glasses.
- For detailed information on cleaning and sterilizing the Motor, refer to the Operation Manual of Primado2 Motor.

6-1 Preparation before cleaning

- 1) Remove the Bur/Drill from the Attachment/Handpiece. Dispose the Bur/Drill as it cannot be reused.
- 2) Remove the Attachment/Handpiece from each Motor.
- 3) Confirm that there are no abnormalities, damages or deterioration in its appearance. Confirm that the connection of the Motor is not damaged or broken.

6-2 Cleaning

- 1) Clean the surface of each component, using a lint-free cloth or brush moistened with a neutral detergent for medical treatment. Do not use a wire brush.
- 2) Remove the detergent from the surface using a lint-free cloth moistened with distilled, deionized or demineralized water.

6-3 Washing



CAUTION

- Prior to use of a Thermo Disinfector, read the Operation Manual of the Thermo Disinfector carefully.
- Do not use a chlorinated cleaner.
- Do not clean Attachments/Handpieces by an ultrasonic cleaning apparatus.



The Attachment/Handpiece can be washed via Thermo Disinfector.

Disinfect the Attachment/Handpiece by either using a Thermo Disinfector or by soaking.

6-3-1 Auto disinfection (It is recommended to use a Thermo Disinfector compatible with ISO 15883)

The following conditions are recommended for a Thermo Disinfector:

- a. Cleaning: 45°C for 3 minutes
- b. Intermediate rinse: At least 1 minute (using distilled, deionized or demineralized water).
- c. Thermal disinfecting: 93°C for 5 minutes (using distilled, deionized or demineralized water).
- d. Drying: at least 10 minutes

6-3-2 Manual disinfection

1) Soaking: Soak the Attachment/Handpiece in a neutral enzymatic detergent.

Example: 20 to 30 minutes at 40 to 50°C

(Follow the time and temperature recommended by the manufacturer of the neutral enzymatic detergent)

2) Rinse: Remove debris and detergent from the Attachment/Handpiece by rinsing with distilled, demineralized or deionized water.

3) Drying: Wipe the Attachment/Handpiece dry with a lint-free cloth.

6-4 Lubrication

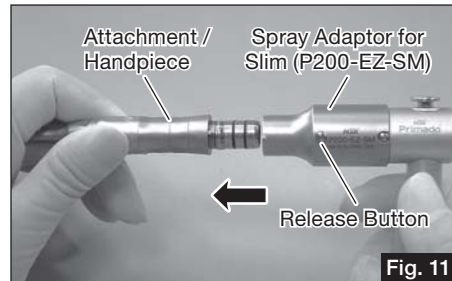


CAUTION

- Do not use anything other than PANA SPRAY Plus for lubrication.
- Continue spraying PANA SPRAY Plus until it comes out clear at the tip of the Attachment/Handpiece. Due to its structure, PANA SPRAY Plus comes out from the tip of the Attachment/Handpiece and the Twist Collet part.
To prevent the dispersal of the lubrication oil in the surrounding area, it is recommended to use a Spray Mist Absorber (Order Code: Y900084).
- Shake PANA SPRAY Plus well before use.
- If the Attachment/Handpiece is sterilized in an autoclave while unclean with remaining blood, etc. in its interior, the debris may solidify leading to a malfunction of the Attachment/Handpiece. Please thoroughly clean and lubricate the Attachment/Handpiece before autoclave sterilization.
- After cleaning and prior to sterilization, check the Attachment/Handpiece in the same method as in Step 2 " Check before Operation ".

Lubricate the Attachment/Handpiece using the separately sold EZ Spray Adaptor (Order Code: PD-EZ-M)/E-Type Spray Nozzle (Order Code: Z019090) and PANA SPRAY Plus (Order Code: Z182600).

- 1) Insert the Spray Adaptor for Slim (P200-EZ-SM) accompanying the Motor straight into the EZ Spray Grip.
- 2) Push the Spray Adaptor for Slim (P200-EZ-SM) into the rear part of the Attachment/Handpiece and turn either clockwise or counterclockwise. When the Alignment Pin clicks into position, the Spray is securely connected (Fig. 11).
- 3) Spray until the oil coming out of the tip of the Attachment/Handpiece is clear of any debris or foreign substance (approximately 3 seconds).
- 4) Remove the Attachment/Handpiece by depressing the Release Button on the Spray Adaptor for Slim (P200-EZ-SM).
- 5) Remove the Spray Adaptor for Slim (P200-EZ-SM) from the EZ Spray Grip.



6-5 Sterilization



CAUTION

- The sterilization parameters are indicated for sterilization and immediate use only.
- Attachments/Handpieces cannot be sterilized using the EOG sterilization method.
- Sterilize Attachments/Handpieces after each patient use.
- Do not clean Attachments/Handpieces by a washer sterilizer.

Autoclavable products: Standard Handpiece 200, SlimHandpiece 200, Super Slim Handpiece 200, Drill Handpiece 200, Metal Cutting Handpiece 200, Contra Angle Handpiece 200, Irrigation Nozzle, Wrench.

We verify the effectiveness of product sterilization under the following conditions.

- 1) By placing the autoclavable products in a Primado2 Sterilization Cassette.
- 2) Autoclave under the following conditions;
 - Pre-vacuum Autoclave: at 134°C for 3 minutes or longer
 - Gravity-displacement Autoclave: at 132°C for 15 minutes or longer

6-6 Storage

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

7 Troubleshooting

If you are suspecting 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 dealer to fix the problem.

Symptoms	Causes/Points of checking	Countermeasures
Cannot be connected to the Motor.	The '▼' symbol of the Attachment/Handpiece and '●' symbol of the Motor are not aligned.	Align the '▼' symbol of the Attachment/Handpiece and '●' symbol of the Motor, then push the Attachment/Handpiece in until it clicks to connect firmly.
	Connection part has been deformed.	Contact your dealer.
The Bur or Drill cannot be firmly mounted.	The Bur or Drill has not been inserted deep enough.	Insert the Bur/Drill all the way through.
	The Twist Collet/Latch is in ' OPEN '.	After inserting the Bur/Drill, fasten the Twist Collet/Latch.
	Twist Collet/Latch has been damaged or deformed.	Contact your dealer.
No rotation when the Bur/Drill has been securely mounted.	The Twist Collet/Latch is in ' OPEN '.	After inserting the Bur/Drill, fasten the Twist Collet/Latch.
	<ul style="list-style-type: none"> · The bearing has overheated. · Foreign materials inside. · The bearing has worn out. 	Contact your dealer.

Symptoms	Causes/Points of checking	Countermeasures
Overheating (during operation).	Continuous operation for long period of time.	Stop operating the Attachment/Handpiece and Motor immediately. Wait until the Attachment/Handpiece and Motor cool down before continuing to operate.
	<ul style="list-style-type: none"> · The bearing has overheated. · Foreign materials inside. · The bearing has worn out. 	Contact your dealer.
Abnormal vibration and noise. Bur run-out.	<ul style="list-style-type: none"> · The bearing has overheated. · Foreign materials inside. · The bearing has worn out. 	

8 Specifications

Standard Handpiece 200 (Straight)

Model	P200-2SMS	P200-2SES	P200-2SS	P200-2SM	P200-2SL
Rotational Speed	80,000min ⁻¹	80,000min ⁻¹	80,000min ⁻¹	80,000min ⁻¹	80,000min ⁻¹
Handpiece Type	Straight (MS)	Straight (ES)	Straight (S)	Straight (M)	Straight (L)
Suitable Bur	Ø2.35mm Primado Bur (MS)	Ø2.35mm Primado Bur (ES)	Ø2.35mm Primado Bur (S)	Ø2.35mm Primado Bur(M)	Ø2.35mm Primado Bur (L)

Standard Handpiece 200 (Angled)

Model	P200-2AMS	P200-2AES	P200-2AS	P200-2AM	P200-2AL
Rotational Speed	80,000min ⁻¹	80,000min ⁻¹	80,000min ⁻¹	80,000min ⁻¹	80,000min ⁻¹
Handpiece Type	Angled (MS)	Angled (ES)	Angled (S)	Angled (M)	Angled (L)
Suitable Bur	Ø2.35mm Primado Bur (MS)	Ø2.35mm Primado Bur (ES)	Ø2.35mm Primado Bur (S)	Ø2.35mm Primado Bur (M)	Ø2.35mm Primado Bur (L)

Slim Handpiece 200

Model	P200-1A135	P200-1A155	P200-1A155-C	P200-1A175	P200-1A175-C
Rotational Speed	80,000min ⁻¹	80,000min ⁻¹	80,000min ⁻¹	80,000min ⁻¹	80,000min ⁻¹
Handpiece Type	Angled (L)	Angled (EL)	Angled (EL/Curve)	Angled (SL)	Angled (SL/Curve)
Suitable Bur	Ø1mm Primado Bur (L)	Ø1mm Primado Bur (EL)	Ø1mm Primado Bur (EL)	Ø1mm Primado Bur (SL)	Ø1mm Primado Bur (SL)

Super Slim Handpiece 200

Model	P200-RA330	P200-RA330-L
Rotational Speed	20,000min ⁻¹	20,000min ⁻¹
Handpiece Type	Angled (SPL)	Angled (SPL)
Suitable Bur	Ø1mm Primado Bur (SPL)	Ø1mm Primado Bur (SPL)

Drill Handpiece 200

Model	P200-2SD
Rotational Speed	80,000min ⁻¹
Handpiece Type	Straight
Suitable Bur	Ø 2.35mm Primado Twist Drill

Contra Angle Handpiece 200

Model	P200-CA-4
Rotational Speed	20,000min ⁻¹
Gear Ratio	4 : 1
Suitable Bur	Commercially available Ø2.35mm Contra Burs

Metal Cutting Handpiece 200

Model	P200-3MC
Rotational Speed	80,000min ⁻¹
Handpiece Type	Straight
Suitable Bur	Ø3.17mm Primado Metal Cutting Carbide Bur (1.6/3.0) Ø3.17mm Primado Metal Cutting Diamond Disk (25.4)

Adapted Motor (Optional)

Model	Product Name
P200-SMH	Primado2 Slim Motor
P200-SMH-HS	Primado2 Slim Motor (with Hand Control)

	Temperature	Humidity	Atmospheric pressure
Use environment	0 - 40°C (no condensation)	30 - 75%RH	700 - 1,060hPa
Store and transportation environment	-10 - 50°C	10 - 85%RH	500 - 1,060hPa

9 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.

10 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 dealer from whom the product was purchased.

Guarantee period.....One year

- In the following cases, the repair has to be paid for even if it 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 dealer from whom the product was purchased.

11 Symbols



Manufacturer.



Conforms to CE European Directive of " Medical device directive 93/42/EEC ".



This product is Autoclavable up to Max.135°C. * For details see Step 6 " Cleaning/Sterilization ".



This product can be washed via Thermo Disinfector.



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

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Specifications are subject to change without notice.

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

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