

Maxso[®]

X92

Implant Handpiece



Instruction For Use

CE
0197

Beyes[®]
The Next Standard[®]

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Symbols



WARNING!
(Risk of injury)



CAUTION!
(To prevent damage)



Thermal washer
disinfectable



Sterilizable
up to the stated
temperature



Manufacturer



Authorized representative
in the European community.



CAUTION

This handpiece is intended for use only with surgical units with torque calibration system. Using this product with other surgical units may damage the handpiece or bone.

1. User and Indications for Use



User: Qualified Professionals

Indications for Use: This medical device is intended for transmitting rotation of the power source at the direct drive ratio or at a different gear ratio, thereby running the instrument such as a surgical bur or a surgical drill to cut teeth or maxillary/mandibular bones during oral surgery.

2. Precautions for handling and operation


Please 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 seriousness of the risk.


CLASS	Degree of Risk
 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

 **WARNING**

- Immediately after a surgery, the handpiece should be cleaned, lubricated and sterilized. Failure to properly maintain the handpiece can lead to contaminants remaining inside the handpiece. Unremoved blood may result in product failure due to the internal blood coagulation. Improper maintenance may also lead to overheating, causing burn injuries, product failure, or difficulty in attaching and detaching the bur/drill.
- Depressing the push button while the handpiece is in rotation may lead to overheating, causing burn injuries or product failure. Avoid the push button to contact with any oral tissue.
- Supply coolant water through the spray nozzle while using the handpiece. Other water supply methods than recommended may lead to overheating causing burn injuries, or product failure.

 **WARNING**

- Do not use the handpiece for polishing purposes. Polishing paste could enter the handpiece, causing the failure of the push button or cause burn injuries due to the overheating of the handpiece head.
- Keep any debris or other foreign materials away from inside the gear or the handpiece. Foreign materials remaining inside may lead to overheating, causing burn injuries or other accidents.
- Ball bearing, in time, will become worn and will require replacement. Be sure to inspect the handpiece before use. If abnormal vibration or noise are found, the bearing or other internal parts may require replacement. Damaged parts may lead to handpiece overheating causing burn injuries. If overheating is suspected, stop using the handpiece immediately and contact your Authorized Beyes dealer.

 **CAUTION**

- When operating the product always consider patient safety.
- Users are responsible for the operational control, maintenance and continual inspection of this product.
- Prior to clinical use, inspect the handpiece. Check for vibration, noise and overheating. If any abnormalities are found, stop using the handpiece immediately and contact your Authorized Beyes Dealer.



CAUTION

- Do not disassemble or alter the handpiece except as recommended by Beyes in this Operation Manual.
- Do not allow any impact on to the product. Do not drop the product.
- Operators and all others in the area must wear eye protection and a mask when operating this handpiece.
- Do not use bur/drills with problems listed below as the bur/drill may break, seize up or disengage from the chuck.
 - Bent, deformed, worn, rusted, broken, deficient bur/drill.
 - Bur/drill which is cracked on the edge or axis.
 - Non-ISO(EN ISO) standard, or tampered bur/drill.
- Do not use bur/drills other than specified in “10. Specifications” as such bur/drills may be accidentally released or break during rotation.
- Always keep the bur/drill shank clean. Dirt or debris in the chuck could cause poor bur/drill concentricity or low chuck retention force.
- Always insert the bur/drill all the way into the chuck. If insertion is insufficient, premature failure of the bearings or accidental release of the bur may occur.
- Do not exceed Max. Bur/Drill Length shown in “10. Specifications”.
- Always follow the instructions provided by the bur/Drill manufacturer.



CAUTION

- Do not exceed the bur/drill speed recommended by the bur/drill manufacturer.
- Should the handpiece function abnormally during use, stop using the handpiece immediately and contact your Authorized Beyes Dealer.
- Do not use the following fluids to wipe, immerse or clean the product; strong / super acid water, strong acid / alkaline chemicals, chlorine-containing solutions, solvents such as benzine or thinner.
- The handpiece is delivered in a non-sterile condition and must be autoclaved prior to use.
- Perform regular function and maintenance checks. (Refer to "9. Periodical Maintenance Checks")
- If the handpiece has not been used for a long period, rotate the handpiece and check for noise, vibration and overheating before use.
- To avoid clinical downtime it is recommended that a spare be kept on hand in case of a breakdown during treatment.
- The operation of the handpiece is permitted only on dental units which correspond to the standards IEC 60601-1 (EN 60601-1) and IEC 60601-1-2 (EN 60601-1-2).
- Do not use a surgical bur with its maximum length of 25mm or longer. Using such bur with this handpiece may lead to premature abrasion of the bearings. In addition, sudden release, bend or breakage of the bur may occur.

3. Accessory List

No.	Part Name	Quantity
1	Internal Spray Nozzle	1
2	Nozzle Holder	1
3	Y-Connector	1
4	Cleaning Wire	1
5	E-Type Spray Nozzle	1

4. Connecting and Disconnecting the Handpiece from the Motor

4-1 Connecting

- 1) Insert the handpiece direct into the motor (Fig.1). Turn the handpiece until it clicks and locks into position.
- 2) Confirm that the handpiece is securely connected to the motor.

4-2 Disconnecting

Hold the motor and the handpiece, then pull apart.

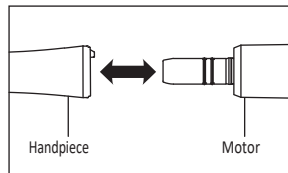


Fig.1



CAUTION

- Do not connect or disconnect the handpiece until the motor has completely stopped.
- Connect ONLY to E type motors (ISO 3964 (EN ISO 3964)).
- Do not exceed the Max. Rotation Speed (Motor) shown in "10. Specifications".
- The handpiece is designed for connection to a Beyes Non-optic motor or to a motor with a stopper pin. Connection to any other type of motor cannot lock the handpiece.

5. Inserting and Removing the Bur/Drill

5-1 Inserting the Bur/Drill

(Fig. 2)

- 1) Insert the bur/drill until it is correctly secured in place.
- 2) Depress the Push Button and insert the bur into the chuck until the bur "notch" mechanism engages. Release the button.
- 3) Confirm that the bur/drill is secure by gently pulling and pushing the bur/drill without depressing the Push Button.

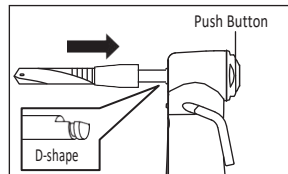


Fig.2

(Fig. 3)

- 1) Insert the bur into the chuck.
- 2) Depress the Push Button to open the chuck (①).
- 3) Insert the bur fully into the chuck until it stops (②) then release the Push Button.
- 4) Confirm that the bur is secure by gently pulling and pushing the bur without depressing the Push Button.

NOTICE

For easy operation of the Chuck Release Button, simply grip the handpiece and use your thumb tip to press the Chuck Release Button.

5-2 Removing the Bur

Depress the Push Button to open the chuck (①) and, while the chuck is open, remove the bur/drill (②).

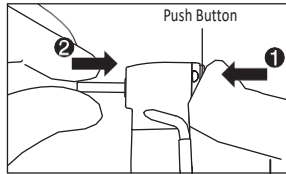


Fig.3

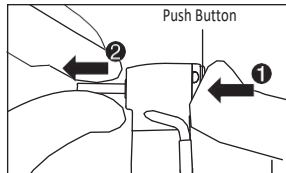


Fig.4



CAUTION

- Do not use bur/drills with problems listed below as the bur/drill may break, seize up or disengage from the chuck.
 - Bent, deformed, worn, rusted, broken, deficient bur/drill.
 - Bur/drill which is cracked on the edge or axis.
 - Non-ISO(EN ISO) standard, or tampered bur/drill.
- Do not use bur/drills other than specified in "10. Specifications" as such bur/drills may be accidentally released or break during rotation.
- Always keep the bur/drill shank clean. Debris in the chuck could cause poor bur/drill concentricity or low chuck retention force.
- Always insert the bur/drill all the way into the chuck. If insertion is insufficient, premature failure of the handpiece head bearings, or accidental release of the bur/drill, may occur.
- Do not exceed Max. Bur/Drill Length shown in "10. Specifications".
- Do not exceed the bur/drill speed recommended by the bur/drill manufacturer.
- Do not insert or remove the bur/drill until rotation has completely stopped.
- Do not apply excess pressure to the bur/drill as it may break or bend and become difficult to remove.
- After the bur/drill is locked in place, pull and push the bur/drill to make sure the bur/drill is locked.
- Depress the push button until it is almost parallel to the head cap.
- If removing the bur/drill is difficult, grip the bur with fine pliers while depressing the Push-button, and gently remove the bur/ drill. This situation can be avoided by frequently mounting and removing the bur/drill.

6. Spray Nozzle

Three irrigation methods are available for X92; External, Internal or both simultaneously, depending on the instrument and operation procedure.

6-1 External Spray Nozzle

Connect the Irrigation Tube to the External Spray Nozzle firmly. (Fig. 5)

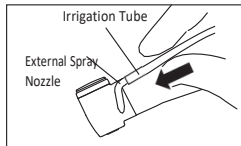


Fig.5

6-2 Internal Spray Nozzle

Only for a drill with internal irrigation system.

1) Attach the Nozzle Holder. (Fig.6)

2) Connect the Irrigation Tube to the Internal Spray Nozzle firmly. (Fig.7)

3) Insert the end of the Internal Spray Nozzle into the hole at the top of the handpiece head, then attach the Internal Spray Nozzle into the slot on the Nozzle Holder. (Fig.8)

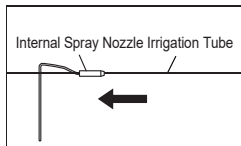


Fig.7

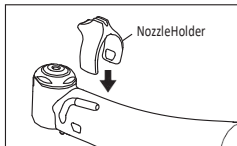


Fig.6

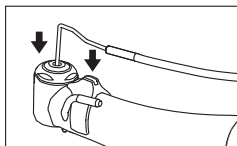


Fig.8

6-3 Simultaneous External and Internal Irrigation

- 1) Connect one end of the Y-Connector to the External Spray Nozzle and the other end into the Internal Spray Nozzle. (Refer to "6-1, 6-2")
- 2) Connect the Irrigation Tube to the Y-Connector firmly. (Fig.9)

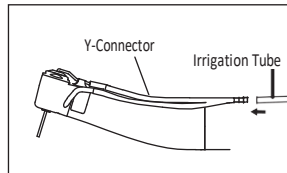


Fig.9

7. Checking the Handpiece Before Each Use

Follow the check procedure below before use. If any abnormalities are found, stop using the handpiece immediately and contact your Authorized Beyes Dealer.

- 1) Check the Head Cap is firmly tightened.
- 2) Check coolant water is flowing properly.
- 3) Insert the bur. (Refer to "5. Inserting and Removing the Bur/Drill")
- 4) Rotate the handpiece for about one minute, using coolant water, and with the motor operating at full speed. During rotation, check for abnormalities such as abnormal rotation, vibration, noise.
- 5) After the handpiece rotation has completely stopped, touch the handpiece head to confirm the head is NOT heating abnormally (Fig. 10).

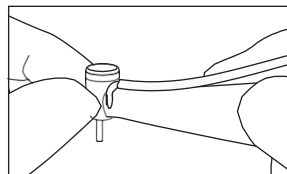


Fig.10



CAUTION

To avoid injury, keep your hands away from the bur/drill during rotation.

8. Post-use Maintenance

After each patient maintain the product as follows.



WARNING

Immediately after a surgery, the handpiece should be cleaned, lubricated and sterilized. Failure to properly maintain the handpiece can lead to contaminants remaining inside the handpiece. Unremoved blood may result in product failure due to the internal blood coagulation. Improper maintenance may also lead to overheating, causing burn injuries, product failure, or difficulty in attaching and detaching the bur/drill.



CAUTION

Do not use the following fluids to wipe, immerse or clean the product; strong / super acid water, strong acid / alkaline chemicals, chlorine-containing solutions, solvents such as benzene or thinner.

8-1 Preparation

- 1) Wear eye protection, a mask and gloves to avoid infection.
- 2) Remove the bur/drill.
- 3) (Only for X92) Immerse about 20mm of the handpiece head in water, and rotate the handpiece for about 15 seconds while switching the Forward/Reverse rotation direction (Fig. 11)
- 4) Disconnect the handpiece from the motor.

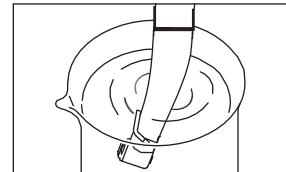


Fig.11

8-2 Cleaning

• Manual Cleaning (External Surface)

- 1) Remove debris on the handpiece surface using a brush under running water (at 38°C or less). Do NOT use a wire brush.
- 2) Wipe off moisture on the surface using an absorbent cloth.



CAUTION

If water enters the handpiece, using an air syringe, blow air into the rear of the handpiece to remove the internal water.

• Automatic Cleaning (External and Internal Surfaces)

Use a thermo-disinfector in accordance with ISO 15883 (EN ISO 15883). Refer to the thermo-disinfector manual.

CAUTION

After washing with thermo-disinfector, prior to lubrication, dry the product until all internal moisture is completely removed. Thermo-disinfector moisture remaining inside the product could reduce the effect of lubrication and could cause corrosion inside of the product.

8-3 Cleaning of Optic Illumination Points

Wipe clean all Optic Illumination Points (Glass Rod) using an alcohol-immersed cotton swab. Remove all debris and oil.

CAUTION

Do not use a sharp tool to clean the Glass Rod. It could damage the glass and reduce the light transmission.

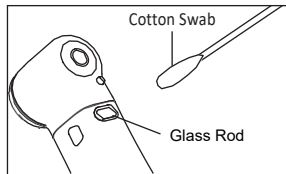


Fig.12

8-4 Cleaning (Spray Port)

1) Internally clean the Internal Spray Nozzle and/ or the External Spray Nozzle by using Cleaning Wire.

2) Connect the Irrigation Tube to each Spray Nozzle, and wash the inside with clean water.

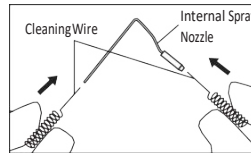


Fig.13

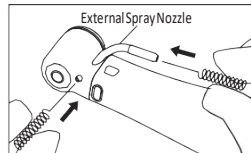


Fig.14

CAUTION

Do not forcibly insert the cleaning wire into the Spray Nozzle. Resultant port damage could cause the spray to be directed away from the bur/drill, and cause reduction of cooling efficiency.

8-5 Disinfection

• Manual Disinfection (External Surface)

Wipe the surface with cloth soaked in disinfectant solution such as alcohol.

- Automatic Disinfection (External and Internal Surfaces)

Use a thermo-disinfector in accordance with ISO 15883 (EN ISO 15883).

Refer to the thermo-disinfector manual.

8-6 Lubrication

BeyesLube® SPRAY

Apply BeyesLube® SPRAY every time after each use and/or before autoclaving.

1) Attach the CORRECT Spray Nozzle onto the spray port nozzle on the can.

2) Insert the Spray Nozzle into the rear of the handpiece. Hold the handpiece and spray 2-3 times for approximately 2-3 seconds each time. Apply lubricant until it expels from the handpiece head for at least 2 seconds (Fig. 15).

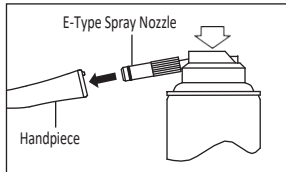


Fig.15



CAUTION

- Hold the spray can upright.
- Firmly hold the handpiece to prevent it slipping when spray pressure is applied.
- Spray lubricant until it expels from the handpiece head.
- If you wish to purge excessive oil from inside the handpiece, rotate the handpiece for approx 15 seconds without a bur/ file. During the rotation, do not depress the chuck release button, especially when using absorbent cloth to prevent oil from scattering. Depressing the push button during rotation may damage the chuck mechanism.

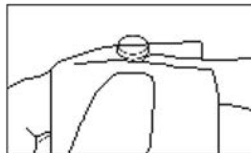


Fig.16

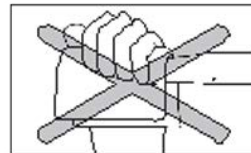


Fig.17

NOTICE

Beyes recommends the use of "Spray Mist Absorber" to prevent oil mist expelling out of the handpiece head.

• Chuck cleaning

Clean the Push Button chuck once a week.

- 1) Mount the Tip Nozzle onto the spray can port.
- 2) Lubricate the chuck directly where the bur is inserted (Fig. 18).
- 3) Lubricate handpiece by using BeyesLube® SPRAY (Fig. 15) or Beyes automatic handpiece cleaning and lubrication system.

CAUTION

If the chuck is not regularly cleaned the chuck grip may be weakened and the bur may be accidentally released during use.

8-7 Sterilization

Sterilization of instruments by applying a fractionated pre-vacuum steam sterilization process (according to EN285/EN 13060/EN ISO 17665) under consideration of the respective country requirements.

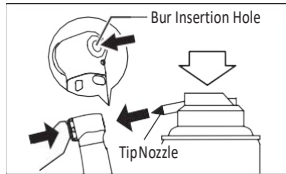




Fig.18

- 1) Insert into an autoclave pouch. Seal the pouch.
- 2) Recommended sterilization temperature: 135°C(±2°C), holding time: 5 min.

 Minimum drying time after sterilization: 8 minutes.

 Flash sterilization is not allowed on lumen instruments!

- 3) The handpiece should remain in the autoclave pouch until required for use.



CAUTION

- Clean and lubricate the handpiece prior to autoclaving. If blood remains on the internal surface it can become clotted and cause product failure.
- Do not autoclave the product with other instruments even when it is in a pouch. This is to prevent possible discoloration and damage to the product from chemical residue on other instruments.
- Do not heat or cool the product too quickly. Rapid change in temperature could cause damage to the product.
- To avoid product failure, do not use a sterilizer that exceeds a cycle temperature of 138°C, including the dry cycle. In some sterilizers, the chamber temperature may exceed 138°C. Contact the sterilizer manufacturer for detailed information about cycle temperatures.
- Keep the product in suitable atmospheric pressure, temperature, humidity, ventilation, and sunlight. The air should be free from dust, salt and sulphur.
- Do not touch the product immediately after autoclaving as it will be very hot and must remain in a sterile condition.



CAUTION

- Autoclave sterilization is recommended for the product. The validity of other sterilization methods is not confirmed.
- Only Handpiece, Internal Spray Nozzle and Nozzle Holder can be autoclaved. Do not autoclave other components (Y-Connector, Irrigation Tube, etc.).

NOTICE

Beyes recommends Class B sterilizers as stated in EN 13060.

9. Periodical Maintenance Checks

Every 3 months perform periodical maintenance checks, referring to the check sheet below. If any abnormalities are found, contact your Authorized Beyes Dealer.

Points to check	Details
Head cap is loose	Check that the Head Cap is firmly tightened.
Rotation	Rotate the handpiece and check for abnormalities such as abnormal rotation, vibration, noise, and overheating.

10. Specifications

Gear Ratio	20:1 Reduction
Connection	ISO E-Type
Water Spray	External
Body Material	Stainless Steel
Max Speed	2,000 min-1
Max Torque	80 Ncm
Sterilization	Autoclavable up to 135°C

11. Beyes Limited Warranty Statement

11.1 SCOPE OF WARRANTY

BEYES Dental Canada Inc. warrants to the original retail purchaser that it will be at BEYES option to repair or replace components of the dental products manufactured by BEYES (except for components not warranted under 'Exclusions') that are defective in material or workmanship under normal use and service. BEYES' obligation under this limited warranty is limited to the repair or replacement of the applicable components. This limited warranty shall only apply to defects that are reported to BEYES within the applicable warranty period and which, upon examination by Beyes, prove to be defective. This warranty extends only to the first retail purchaser of a product and is not transferable or assignable. Replacement components or products may be used and/or refurbished components or products, provided they are of like quality and specifications as new components or products.

11.2 APPLICABLE WARRANTY PERIOD

The applicable warranty period, measured from the date of invoice to the original user, shall be as follows X92 implant handpiece are warranted for a period of 12 months.

11.3 EXCLUSIONS

This limited warranty does not cover and BEYES shall not be liable for the following;

- 1) Defects, damage or other conditions caused, in whole or in part, by misuse, abuse, negligence, alteration, accident, freight damage, negligent storage, tampering or failure to seek and obtain repair or replacement in a timely manner;
- 2) Products which are not installed, used, and properly cleaned and maintained as required or recommended in the BEYES 'Installation' and/or 'Installation/Operation Manual' for the applicable product, including the specified structural and operational environment conditions and electrical power requirements;
- 3) Products considered to be of a consumable or sterile nature;
- 4) Accessories or parts not manufactured by BEYES;
- 5) Charges by anyone for adjustments, repairs, replacement parts, installation or other work performed upon or in connection with such products which are not expressly authorized in writing in advance by BEYES;
- 6) Costs and expenses of routine maintenance and cleaning;
- 7) Representations and warranties made by any person or entity other than BEYES;
- 8) Matching of color, grain or texture except to commercially acceptable standards;
- 9) Changes in color caused by natural or artificial light;
- 10) Custom manufactured products;

- 11) Alterations or modifications to the product by any person or entity other than BEYES;
- 12) Products that would otherwise be covered under Sections 1 and 2 of this limited warranty, but are acquired: (i) from a person or entity that is not BEYES or one of its authorized dealers; or (ii) from a BEYES dealer that is not authorized to sell the product at issue in the geographic territory where the purchaser is located, or is not authorized to sell the product at issue within the medical, animal health or dental market, as the case may be, in which purchaser intends to use the product.

11.4 exclusive remedy; consequential damages disclaimer

Beyes' obligation under this limited warranty is the repair or replacement of defective parts. Beyes shall not be liable for and hereby disclaims any direct, special, indirect, incidental, exemplary or consequential damages or delays, including, but not limited to, damages for loss of profits or income, loss of use, downtime, cover and employee or independent contractor wages, payments and benefits.

11.5 Warranty disclaimer

This limited warranty is Beyes only warranty and is in lieu of all other warranties, express or implied. Beyes makes no implied warranties of any kind including any implied warranties of merchantability or fitness for a particular purpose. This warranty is limited to the repair or replacement of defective parts.

11.6 Statue of limitations

No actions may be brought against beyes for breach of this limited warranty, or implied warranty, if any, or for any other claims arising out of or relating to the products, more than ninety (90) days following expiration of the limited warranty period.

* This device is not field repairable

* All brands are holders of their respective trademarks.



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Federal law restricts this device to sale by or on the order of a dentist, physician, or any other practitioner licensed by the law of the states in which he or she practices to use or order the use of this device.

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