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a-dec

Straight Handpiece

A-dec CLASS A A11S

INSTRUCTIONS FOR USE

Please read these Instructions For Use carefully before use, and file for future reference.

Rx Only MADE IN JAPAN

OM-DH0909EN 000

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1 User and Indications for Use

User: Qualified Professionals (Dentist/Dental hygienist)
Indications for Use:
Straight Handpiece is intended for the following application(s): Removal of dental restorations (fillings and prostheses), Finishing of teeth ((deciduous) central incisors - (deciduous) second molars) and dental restorations, that is, preparation/adjustment/polishing (including the case where a polishing tool such as prophy handpiece is used).

For identification of symbols, refer to the "11. Symbol" section on page 21 and *Regulatory Information, Specifications, and Warranty* document (p/n 86.0221.00), which is available in the Resource Center at www.a-dec.com.

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 the 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.

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NOTICE	General product specification information highlighted to avoid product malfunction and performance reduction.

⚠ WARNING

- Clean and lubricate the handpiece immediately (within 1 hour) after each treatment to remove residue. Failure to properly maintain the handpiece may cause infection, product failure or overheating, leading to burn injuries. (Refer to “8. Post-use Maintenance”.)
- If blood infiltrates inside a handpiece, clean immediately.

⚠ WARNING

- 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 bearings are wear items and may require replacement. Be sure to inspect the handpiece before use (Refer to “7. Checking the Handpiece Before Each Use”). If abnormal vibration or noise is found, the bearings or other internal parts may be worn out or damaged. Damaged parts may lead to handpiece overheating causing burn injuries. If overheating is suspected, stop using the handpiece immediately and contact your Authorized A-dec Dealer.

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⚠ CAUTION

- Read this Instructions For Use before use to fully understand the product functions and file for future reference.
- When operating the product, always consider the safety of the patient.
- 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 A-dec Dealer. (Refer to "7. Checking the Handpiece Before Each Use")
- Do not disassemble or alter the handpiece except as described in this Instructions For Use.
- Do not allow any impact to the product. Do not drop the product. Deformation may cause the handpiece to fail during use.

⚠ CAUTION

- Operators and all others in the area must wear eye protection and a mask when operating this handpiece.
- Do not use burs with problems listed below as the bur may break, seize up or disengage from the chuck.
  - Bent, deformed, worn, rusted, broken, deficient bur.
  - Bur which is cracked on the edge or axis.
  - Non-ISO (EN ISO) standard, or tampered bur.
- Do not use burs other than specified in "10. Specifications" as such burs may be accidentally released or break during rotation.
- Always keep the bur shank clean. Dirt or debris in the chuck could cause poor bur concentricity or low chuck retention force.
- Always insert the bur all the way into the chuck. If insertion is insufficient, premature failure of the bearings or accidental release of the bur may occur.

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⚠ CAUTION

- Do not exceed Max. Bur Length shown in "10. Specifications".
- Always follow the instructions provided by the bur manufacturer.
- Do not exceed the bur speed recommended by the bur manufacturer.
- Should the handpiece function abnormally during use, stop using the handpiece immediately and contact your Authorized A-dec 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".)

⚠ CAUTION

- 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, A-dec recommends that you keep a spare to replace one that breaks 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).
- U.S. Federal law restricts this device to sale by or on the order of a licensed physician.

NOTICE

- Repairs of this product are only to be performed by authorized service technicians according to A-dec requirements. Contact your Authorized A-dec Dealer if repairs are necessary.

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3 Accessory List

No.	Part Name	Quantity
1	E-Type Spray Nozzle	1

4 Connecting and Disconnecting the Handpiece from the Motor

4-1 Connecting

1) Insert the handpiece directly into the motor (Fig. 1).
2) Confirm that the handpiece is firmly connected to the motor.

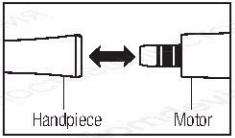


Fig. 1

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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.
- Do not exceed the Max. Rotation Speed (Motor) shown in "10. Specifications".
- Connect ONLY to E type motors (ISO 3964 (EN ISO 3964)).
- Make sure that the motor and handpiece are securely connected. The motor and coolant air pressure may cause the handpiece to jump out of the motor, which could result in injury.

5 Mounting and Removing the HP Bur

5-1 Mounting

1) Turn the Bur Lock Ring in the direction of the " 🔓 " mark until it clicks. (Fig. 2)
2) Insert the bur fully into the chuck then turn the Bur Lock Ring in the direction of the " 🔒 " mark until it clicks. (Fig. 2)
3) Confirm that the bur is secure by gently pulling and pushing the bur.

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5-2 Removing

Turn the Bur Lock Ring in the direction of the " " mark until it clicks then remove the bur (Fig. 2).

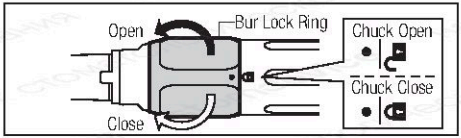


Fig. 2

6 Mounting and Removing the Prophy handpiece

6-1 Mounting

1) Turn the Bur Lock Ring in the direction of the " " mark until it clicks.
2) Align the prophy handpiece with the groove on the handpiece and insert it all the way into the chuck (Fig. 3).

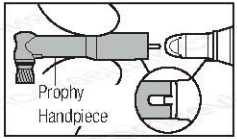


Fig. 3

3) Turn the Bur Lock Ring in the direction of the " " mark until the " " mark and the " • " mark align with a click.
4) Confirm that the prophy handpiece is secure by gently pulling and pushing the prophy handpiece.

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8-2 Removing

Turn the Bur Lock Ring in the direction of the " 🔓 " mark until it clicks then remove the prophy handpiece.

⚠ WARNING

- Always use a clean, sterile bur. Be sure to wear sterile gloves before mounting the bur.
- Do not rotate the motor when the Bur Lock Ring is at the OPEN position or when a bur is not mounted in the chuck. In either situation, it may cause burn injuries due to sudden heat generation. In addition, the motor insert could be damaged which may lead to difficulty in connecting and disconnecting the handpiece.

⚠ WARNING

- After mounting the bur in the chuck, be sure to confirm that the " • " mark and the " 🔒 " mark align. If these marks are not completely aligned, burn injuries may occur due to handpiece overheating during rotation.
- When changing burs during treatment, remove the bur and wipe around the bur insertion hole with a dry lint free cloth until it is visually clean, then mount a clean and sterile bur. Residual blood or debris may enter the handpiece while changing burs, which could lead to higher risk of cross-contamination.

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⚠ CAUTION

- Do not use burs with problems listed below as the bur may break, seize up or disengage from the chuck.
  - Bent, deformed, worn, rusted, broken, deficient bur.
  - Bur which is cracked on the edge or axis.
  - Non-ISO (EN ISO) standard, or tampered bur.
- Do not use burs other than specified in "10. Specifications" as such burs may be accidentally released or break during rotation.
- Insert a sterilized bur and always keep the bur shank clean. When changing burs, make sure that there is no dirt or debris in and around the bur insertion hole of the handpiece. Debris in the chuck could cause infection, heating, poor bur concentricity or low chuck retention force.

⚠ CAUTION

- Always insert the bur 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 Length shown in "10. Specifications".
- Always follow the instructions provided by the bur manufacturer.
- Do not exceed the bur speed recommended by the bur manufacturer.
- Do not mount or remove the bur until the motor has completely stopped.
- Do not apply excess pressure to the bur as it may break or bend or become difficult to remove.

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7 Checking the Handpiece Before Each Use

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

1) Mount the bur. (Refer to "5. Mounting and Removing the HP Bur".)
2) Rotate the handpiece for about one minute at the maximum rotation speed of the attached motor. During rotation, check for abnormalities such as abnormal rotation, vibration, noise.
3) After the handpiece rotation has completely stopped, touch the handpiece head and Bur Lock Ring to confirm they are NOT heating abnormally (Fig. 4).

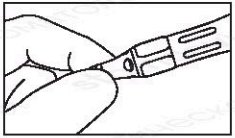


Fig. 4

⚠ CAUTION

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

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8 Post-use Maintenance

After each patient, maintain the product as follows.

⚠ WARNING

- To ensure cleaning and sterilization efficacy, use only the following procedures for reprocessing.
- Follow any additional local directives, standards, and guidelines for cleaning and sterilization.
- Clean and lubricate the handpiece immediately (within 1 hour) after each treatment to remove residue. Failure to properly maintain the handpiece may cause infection, product failure, overheating leading to burn injuries.

8-1 Cleaning at point-of-use

⚠ CAUTION

- Do not use the following liquids to wipe, immerse, or clean the product: strong/super acid water, strong acid/alkaline chemicals, chlorine-containing solutions, solvents such as benzine or thinner.
- Do not immerse A-dec instruments in disinfectant solution or clean in ultrasonic devices.

1) Always wear protective gloves, a mask, and protective goggles for safety purposes and to minimize the risk of infection. (Fig. 5)

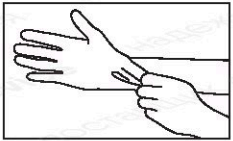


Fig. 5

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2) Operate the handpiece at the chair-side for at least 20 seconds (Fig. 6). After the handpiece rotation has completely stopped, touch the handpiece head and Bur Lock Ring to confirm they are NOT heating abnormally.

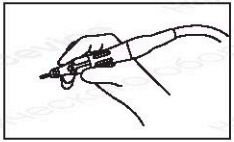


Fig. 6

⚠ CAUTION

- If the handpiece head is heating abnormally, stop using the handpiece immediately and contact your Authorized A-dec Distributor.

⚠ CAUTION

- Be sure to take the step "8-1 Cleaning at point-of-use 2)" before removing the bur. If the handpiece operates without the bur, it may cause burn injuries due to sudden heat generation. In addition, the motor insert could be damaged which may lead to difficulty in connecting and disconnecting the handpiece.

3) Remove the bur. (Fig. 7)

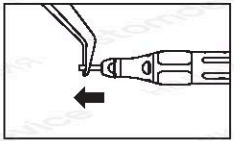


Fig. 7

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4) Wipe the exterior of the handpiece clean using a cloth moistened with disinfectant or ethanol with a concentration of 60-90%. (Fig. 8)
When using disinfectant, follow the instructions given by the manufacturer of the disinfectant.
Use a state-sanctioned disinfectant with proven bactericidal, fungicidal, and virucidal properties.
The following disinfectants can be used in the United States and Canada.
CaviCide®, CaviWipes® (manufactured by Metrex)

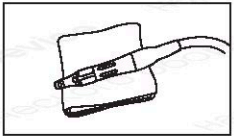


Fig. 8

5) Remove the handpiece from the motor. (Fig. 9)

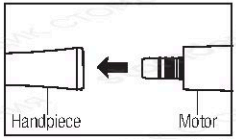


Fig. 9

6) Carry the handpiece to the decontamination area.

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8-2 Cleaning and Drying

Wash the handpiece under running water following the procedures below.
(Water condition: ≤100°F (38°C), ≥1 gal/min (3.5L/min); water should be of the same quality as drinking water)

1) Clean the external surfaces of the handpiece with a soft bristled toothbrush for 15 seconds or more. (Fig. 10)

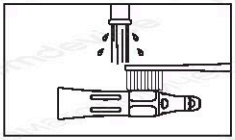


Fig. 10

2) Clean around the bur insertion hole for 15 seconds or more, using an interdental brush (wire thickness 0.7mm) that conforms to size 4 in ISO 16409. (Fig. 11)

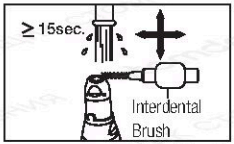


Fig. 11

Under appropriate lighting (natural office lighting, 500 lx or higher), inspect the handpiece for blood or other debris. If any visible debris remains, repeat the process until the handpiece is visually clean.

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3) Wipe the exterior of the handpiece clean using a cloth moistened with disinfectant or ethanol with a concentration of 60-90%. (Fig. 12)

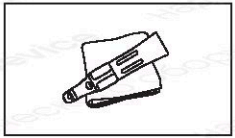


Fig. 12

When using disinfectant, follow the instructions given by the manufacturer of the disinfectant.
Use a state-sanctioned disinfectant with proven bactericidal, fungicidal, and virucidal properties.
The following disinfectants can be used in the United States and Canada.
CaviCide®, CaviWipes® (manufactured by Metrex)

After cleaning, if residual moisture is present, wipe off with dry cloth or blow it off with compressed air (≤50psi (0.35Mpa)) until there is no moisture in the interior and exterior.
When blowing off with compressed air, cover the handpiece with cloth to prevent scattering of water.
Proceed to "8-3 Cleaning and Lubrication".

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8-3. Cleaning and Lubrication

1) Attach an E-Type Spray Nozzle to the nozzle of the PANA SPRAY Plus.
2) Shake the can 3 or 4 times, and insert the E-Type spray nozzle into the rear of the handpiece while holding the handpiece head with a cloth.
3) Hold the handpiece, and spray for 2 or 3 seconds until oil comes out of the handpiece head (Fig. 13). Repeat lubrication until foreign material stops coming out of the tip.

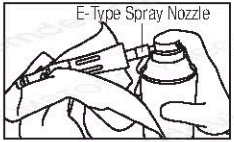


Fig. 13

Please contact your local dealer for PANA SPRAY Plus **REF** Z182600 and E-Type spray nozzle **REF** Z256090.

⚠ CAUTION

- Do not use sprays other than PANA SPRAY Plus. Using sprays other than PANA SPRAY Plus may cause the handpiece to overheat.
- 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.

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8-4 Packaging, Sterilizing, and Drying

1) Insert the handpiece into an FDA-approved sterilization pouch that conforms to ISO 11607-1 (EN ISO 11607-1), and seal the pouch.
2) Perform steam sterilization with the following conditions.

Type	Gravity Displacement	Dynamic Air Removal
Temperature	270°F (132°C)	270°F (132°C)
Full Cycle Time	15 min	4 min
Drying Time	30 min	30 min

⚠ CAUTION

- Use an FDA-approved steam sterilizer to perform sterilization.
- Follow local rules, regulations, and guidelines regarding the reprocessing of devices.

⚠ CAUTION

- Do not touch the product immediately after steam sterilization as it will be very hot and must remain in a sterile condition.
- Do not perform steam sterilization on 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.
- Clean and lubricate the handpiece prior to sterilization. If blood remains on the internal surface it can become clotted and cause product failure.
- Do not heat or cool the product too quickly. Rapid change in temperature could cause damage to the product.

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⚠ CAUTION

- Be sure to use sterilizers that can perform sterilization no higher than 275°F (135°C). In some sterilizers, the chamber temperature may exceed 275°F (135°C). Do not use these sterilizers as failure of the handpiece could occur. Contact the sterilizer manufacturer for detailed information about cycle temperatures.
- Steam sterilization is recommended for the product. The validity of other sterilization methods (such as plasma sterilization or EOG sterilization) is not confirmed.

8-5 Storage

Store the product in a dry, clean location.

⚠ CAUTION

- After the sterilization and drying cycles are complete, remove the handpiece immediately from the sterilizer to store it.
- Store the product in a well ventilated place out of direct sunlight and within the range of temperature, humidity and pressure specified in "10. Specifications".
- Sterilization is not guaranteed after the sterilization retention period specified by the manufacturer and seller of the sterilization pouch has elapsed. If the sterilization retention period has elapsed, perform sterilization again with a new sterilization pouch.

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9 Periodical Maintenance Checks

Perform periodical maintenance checks every three months, referring to the checklist below. If any abnormalities are found, contact your Authorized A-dec Dealer.

Points to check	Details
Rotation	Rotate the handpiece and check for abnormalities such as abnormal rotation, vibration, noise, and overheating.
Connection	Check the connection between the motor, bur and handpiece for any problems.

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10 Specifications

Model	A11S
Max. Rotation Speed (Motor)	40,000rpm
Max. Rotation Speed (Handpiece)	40,000rpm
Gear Ratio	1:1 Direct Drive
Bur Type	ISO 1797 (EN ISO 1797) Type2 Ø2.334-2.35mm HP Bur / ISO 14457 (EN ISO 14457) Prophy Handpiece
Chuck Length	30mm
Max. Bur Length	44.5mm
Max. Working Part Diameter	Ø4.0mm

Use Environment	Temperature: 50 - 95°F (10 - 35°C), Humidity: 30 - 75% (No Condensation)
Transportation and Store Environment	Temperature: 14 - 122°F (-10 - 50°C), Humidity: 10 - 85%, Pressure: 500 - 1,060hPa

NOTE Specifications are subject to change without notice. Requirements may vary depending on your location. For more information, contact your authorized A-dec dealer.

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11 Symbol

- Open
- Close
- Position

12 Warranty

IMPORTANT For warranty, electrical specifications, identification of symbols, and other regulatory requirements, see the *Regulatory Information, Specifications, and Warranty* document (p/n 86.0221.00), which is available in the Resource Center at www.a-dec.com.

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13 Disposing product

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 or a dentist is required to confirm the equipment is sterile. Ask specialist firms who are licensed to dispose of specially controlled medical wastes, to dispose the product for you.

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86.0942.00 Rev A

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