



INSTRUCTIONS FOR USE

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

Contra Angle Handpiece

A-dec CLASS A A11

A-dec CLASS A A41

A-dec CLASS A A41P

Rx Only

MADE IN JAPAN

OM-DC0904EN 000

1 User and Indications for Use

A11 / A41

User: Qualified Professionals (Dentist)

Indications for Use:

Contra Angle Handpiece is intended for the following application(s):

Caries removal, Cavity and crown preparation, Removal of dental restorations (fillings and prostheses), Finishing of teeth and dental restorations (preparation/adjustment).

A41P

User: Qualified Professionals (Dentist/Dental hygienist)

Indications for Use:

Contra Angle Handpiece is intended for the following application(s):

Removal of accretions/deposits (excluding calculus) from the surface of teeth and dental restorations (fillings and prostheses), Polishing of the surface of teeth and dental restorations.

▲ CAUTION

- Connect ONLY to E type motors (ISO 3964 (EN ISO 3964)).

For identification of symbols, refer to *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.

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 “7 Post-use Maintenance”)
- If blood infiltrates inside a handpiece, clean immediately.

⚠ WARNING

- 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. (Except for A41P)
- Supply Air Coolant (AC) while using handpiece. Not supplying Air Coolant may lead to overheating, causing burn injuries or product failure. (Except for A41P)
- Do not use the handpiece for polishing purposes. Polishing paste could enter the handpiece, causing the failure of the Push Button or burn injuries due to the overheating of the handpiece head. (Except for A41P)

⚠ 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 “6 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.

▲ 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 “6 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.
- Never use Counter Clockwise. It may run out the Rubber Cup/Brush and cause an injury.(A41P)

▲ CAUTION

- Operators and all others in the area must wear eye protection and a mask when operating this handpiece.
- Do not use burs/cups/brushes with problems listed below as the bur/cup/brush may break, seize up or disengage from the chuck/screw hole.
 - Bent, deformed, worn, rusted, broken, deficient bur/cup/brush.
 - Bur which is cracked on the edge or axis.
 - Non-ISO (EN ISO) standard, or tampered bur.
- Do not use burs/cups/brushes other than specified in “9 Specifications” as such burs/cups/brushes may be accidentally released or break during rotation.
- Always keep the bur shank/cup and brush screw thread clean. Dirt or debris in the chuck/screw hole could cause poor bur/cup/brush concentricity or low chuck/screw hole retention force.

▲ CAUTION

- Always insert the bur/cup/brush all the way into the chuck/screw hole. If insertion is insufficient, premature failure of the bearings or accidental release of the bur/cup/brush may occur.
- Do not exceed Max. Bur Length shown in “9 Specifications”.
- Always follow the instructions provided by the bur/cup/brush manufacturer.
- Do not exceed the bur/cup/brush speed recommended by the bur/cup/brush 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.

▲ CAUTION

- The handpiece is delivered in a non-sterile condition and must be autoclaved prior to use.
- Perform regular function and maintenance checks. (Refer to “8 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, 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.

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.

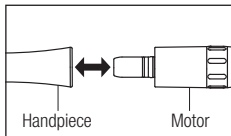


Fig. 1

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 "9 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 Bur/Cup/Brush

5-1 Mounting the Bur (A11 / A41)

- 1) Insert the bur until it is correctly seated in place. (Fig.2)
- 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 is not removed by gently pulling and pushing the bur without depressing the Push Button.

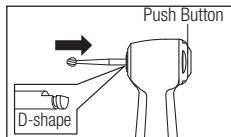


Fig. 2

5-2 Removing the Bur (A11 / A41)

Depress the Push Button to open the chuck (1) and remove the bur (2). (Fig.3)

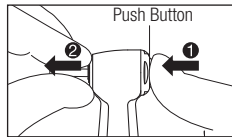


Fig. 3

5-3 Mounting the Cup/Brush (A41P)

- 1) Insert the screw shank of the cup or brush into the screw hole of the handpiece head.
- 2) Turn cup/brush in a clockwise direction to fix the screw shank.
- 3) Check that the screw part of the cup or brush is inserted to the end. (Fig.4)

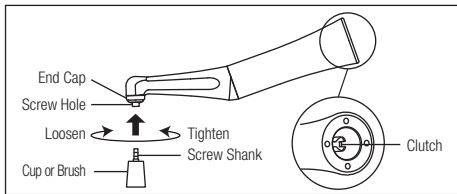


Fig. 4

5-4 Removing the Cup/Brush (A41P)

Remove the handpiece from the motor, hold the cup or brush firmly while the handpiece clutch is fixed, and turn it in the loosening direction as shown in Fig. 4.

▲ WARNING

- Always use a clean, sterile bur/cup/brush. Be sure to wear sterile gloves before mounting the bur/cup/brush.
- When changing the bur/cup/brush during treatment, remove the bur/cup/brush and wipe around the bur insertion hole or screw hole with a dry lint free cloth until it is visually clean, then mount a clean and sterile bur/cup/brush. Residual blood or debris may enter the handpiece while changing bur/cup/brush, which could lead to higher risk of cross-contamination.

⚠ CAUTION

- Do not use burs/cups/brushes with problems listed below as the bur/cup/brush may break, seize up or disengage from the chuck/screw hole.
 - Bent, deformed, worn, rusted, broken, deficient bur/cup/brush.
 - Bur which is cracked on the edge or axis.
 - Non-ISO (EN ISO) standard, or tampered bur.
- Do not use burs/cups/brushes other than specified in “9 Specifications” as such burs/cups/brushes may be accidentally released or break during rotation.
- Insert a sterilized bur/cup/brush and always keep the bur/cup/brush shank clean. When changing bur/cup/brush, make sure that there is no dirt or debris in and around the bur/cup/brush insertion hole of the handpiece. Debris in the chuck/screw hole could cause infection, heating, poor bur/cup/brush concentricity or low chuck/screw hole retention force.

⚠ CAUTION

- Always insert the bur/cup/brush all the way into the chuck/screw hole. If insertion is insufficient, premature failure of the bearings or accidental release of the bur/cup/brush may occur.
- Do not exceed Max. Bur Length shown in “9 Specifications”.
- Always follow the instructions provided by the bur/cup/brush manufacturer.
- Do not exceed the bur/cup/brush speed recommended by the bur/cup/brush manufacturer.
- Do not mount or remove the bur/cup/brush until the motor has completely stopped.
- Do not apply excess pressure to the bur/cup/brush as it may break or bend or become difficult to remove.

6 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) Check the head cap is firmly tightened.
- 2) Mount the bur/cup/brush and make sure that it is securely connected. (Refer to “5 Mounting and Removing the Bur/Cup/Brush”)
- 3) Rotate the handpiece for about one minute at the Max. rotation speed of the attached motor. During rotation, check for abnormalities such as abnormal rotation, vibration, noise.

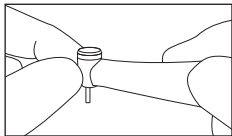


Fig. 5

- 4) After the handpiece rotation has completely stopped, touch the handpiece head to confirm it is NOT heating abnormally (Fig. 5).

▲ CAUTION

- To avoid injury, keep your hands away from the bur during rotation.
- If the bur/cup/brush connection is loose, the part may fall out, which could result in accidental ingestion.
- Heat generation of the handpiece may cause burn injuries.
- If the head cap or end cap is loose, the part may fall out, which could result in accidental ingestion.

7 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.

7-1

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 benzene 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. 6)

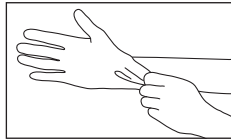


Fig. 6

- 2) Remove the bur/cup/brush.
(Fig. 7)

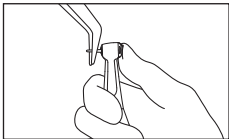


Fig. 7

- 3) 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.

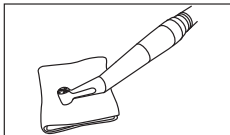


Fig. 8

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)

- 4) Operate the handpiece at the chair-side for at least 20 seconds. After the handpiece rotation has completely stopped, touch the handpiece head to confirm it is NOT heating abnormally.

⚠ CAUTION

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

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

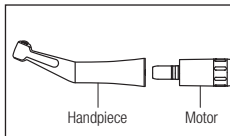


Fig. 9

- 6) Carry the handpiece to the decontamination area.

7-2 Cleaning and Drying

Wash the handpiece under running water following the procedures below.

(Water condition: $\leq 100^{\circ}\text{F}$ (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)

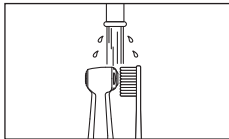


Fig. 10

- 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 (EN ISO 16409). (Fig. 11)

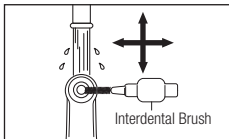


Fig. 11

- 3) 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.

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

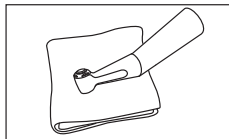


Fig. 12

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 (≤ 50 psi (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 "7-3 Cleaning and Lubrication".

7-3 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 etc.
- 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.

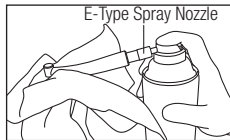


Fig. 13

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.
- If you wish to purge excessive oil from inside the handpiece, rotate the handpiece for approx 15 seconds without a bur. During the rotation, do not depress the push button, especially when using absorbent cloth to prevent oil from scattering. Depressing the push button during rotation may damage the chuck mechanism (Fig.14, Fig.15).

⚠ CAUTION

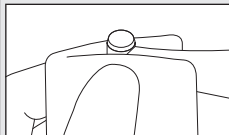


Fig. 14

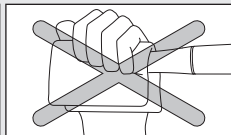


Fig. 15

7-4 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.
- 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.

▲ 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.

7-5 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 “9 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.

8 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

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.
Connection	Check the connection between the cup or brush, motor and handpiece for any problems.

9 Specifications

Model	A11	A41	A41P
Max. Rotation Speed (Motor)	40,000rpm		20,000rpm
Max. Rotation Speed (Handpiece)	40,000rpm	10,000rpm	5,000rpm
Gear Ratio	1:1 Direct Drive	4:1 Reduction	4:1 Reduction
Bur/ Rotary Instrument Type	ISO 1797 (EN ISO 1797) Type1, Ø2.334-2.35mm CA Bur		Screw-in cup/brush (Screw thread in accordance with ISO 13295 (EN ISO 13295) Type 5 1.8×0.35 (No.1-64UNC / No.1-72UNF))
Chuck Length	12.7mm		-
Max. Bur Length	22.5mm		-
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.

10 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.

11 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.



Manufactured for A-dec

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