

**E-ASP1**



**Dental Contra-angle Handpiece**

**USER MANUAL**

Changzhou Sifary Medical Technology Co., Ltd.

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# Scope of Dental Contra-angle Handpiece

## Structure

Dental Contra-angle Handpiece consists of head and handle, the structure diagram is as follows:



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| The bur is used to prevent the handpiece from damage during transportation, and should be removed before use. |

**1.2** **Components**

1.充电底座

2.主机

3.弯机头

4.机头套

5.锉夹（2件）

6.唇钩（2件）

7.测量线

8.电源适配器

9.注油嘴

|  |  |  |
| --- | --- | --- |
| Dental Contra-angle Handpiece (1pcs) | Spray Nozzle (1pcs) | Needle (1pcs) |

**1.3 Performance**

Dental Contra-angle Handpiece has the features of low radial run-out, anti-sterilization and corrosion resistance.

# Symbols used

|  |  |
| --- | --- |
|  | General warning sign |
|  | Caution |
|  | Serial number |
|  | Catalogue number |
|  | Manufacturer |
|  | Country of manufacture+ Date of manufacture |
|  | Batch code |
|  | Dispose of in accordance with the WEEE directive |
|  | Keep dry |
|  | Sterilizable in a steam sterilizer (autoclave) at the temperature specified |
|  | Washer-disinfector for thermal disinfection |
|  | Temperature limit |
|  | Humidity limitation |
|  | Atmospheric pressure limitation |
|  | Manufacturer's LOGO |
|  | Consult instructions for use |

# Before use

## Intended purpose

The E-ASP1 Dental Contra-angle Handpiece is intended for professional use only, it’s used in general dentistry such as restoration procedures for patients who need dental treatment.   
This device must only be used in hospital environments, clinics or dental offices by trained and qualified personnel.

## Contra-indications

The E-ASP1 is contraindicated in: Patients with hemophilia; Patients and doctors with pacemakers; Pregnant women, children and patients with heart disease.

The device must not be used if any open lesions or damaged soft tissue are present or if a recent extraction has taken place. The air flow could propel infected material into the wounds, causing infection and a risk of embolism.

## Precautions, warnings and informative instructions

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| * Read this User Manual before use to fully understand the product functions and files for future reference. * Follow all warnings and instructions during operation. * This product is intended for dental treatment only. Any other use of the handpiece is impermissible and can be hazardous. * This product is a high-speed rotating handpiece, please pay attention to safety when using it. * This product is driven by a dental low-voltage electric motor that has been legally marketed. * This product can only be used by trained and qualified professionals (dentists) in hospitals or clinics. * Please pre-operate the product outside the patient’s mouth before use. Should any abnormal situation occurs, such as looseness, vibration, noise or heating, please stop using the handpiece immediately and contact your authorized dealer. * Do not hit or drop the handpiece to avoid serious damage to it. * The bur applied should conform to the standards of ISO 3823-1:1997. Make sure that the specified speed and specifications of the bur applied are consistent with the handpiece. Do not use bent, cracked, deformed burs as the burs may break or disengage from the chunk, or causing damages to the handpiece or injuries. * The three-hole nozzle can be cleaned with the Needle. * The product should be maintained by the professional and cannot be repaired on site. * The product should be stored in a dry, clean environment away from harmful chemicals and gases such as acids and alkalis. Avoid pressure, collisions, rain and snow during transportation. * Entry of debris into the chunk, via the bur shank, could cause bur rotation slip and also prevent the bur from being securely located in the chunk. * Make sure that the handpiece completely stops when inserting or removing the bur. Depressing the Push button while the handpiece is in operation may cause overheating, serious technical damage and possible premature handpiece failure. During operation, avoid any actions that may cause the Push button to be depressed while the handpiece is in operation. * Do not exceed the maximum speed recom-   mended by the manufacturer during operation.   * Make sure the bur is firmly loaded before use. * Make sure the spray water and gas (cooling gas) of the handpiece are normal. Or the handpiece head surface temperature will exceed 41°C. Insufficient spray water and gas can cause the medical device to overheat and damage the handpiece. * If the temperature of handpiece rises obviously, please stop using. * If the handpiece is damaged or seriously abrased, it will cause cutting efficiency, abnormal rotation, excessive vibration, irregular running noise and overheating. The operator should perform regular function and maintenance check, and replace the handpiece according to clinical use. * Press the Push button to release the internal chunk while removing the bur. Don’t remove the bur by force if the internal chunk is not fully released, otherwise, it will damage the handpiece. * The clamping shaft length should not be too short, otherwise it will cause uneven bearing load and accelerate bearing abrasion. * Do not use non Sifary accessories to avoid damage to the handpiece or other hazards. |

# 4. Assembly and disassembly

## 4.1 Connection and disconnection of the handpiece and motor

**Connection：**Connect the handpiece direct to the motor and twist the handpiece until it locks into position with a “clicking” sound. Make sure the handpiece is firmly connected to the motor. Refer to the figure below:

**Disconnection：**Hold the motor and the handpiece separately, and disconnect with care. Refer to the figure below:



## 4.2 Insertion and removal of the bur

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| **Insertion：**Insert the bur until it is correctly seated in place. Depress the Push button and insert the bur into the chunk until the bur “notch” mechanism engages. Release the button. Make sure the bur is secure by gently pulling and pushing the bur without depressing the Push button.  Refer to the figure below: |
|  |
| **Removal：**Depress the Push button and remove the bur after the internal chunk is fully released. Refer to the figure below. |
|  |

# Maintenance

## 5.1 Foreword

For hygiene and sanitary safety purpose, the Dental Contra-angle Handpiece must be cleaned, disinfected and sterilized before each use to prevent any contamination. This concerns the first use as well as the subsequent uses. Comply with your national guidelines, standards and requirements for cleaning, disinfection and sterilization.

Reprocessing procedures have only limited implications to this dental device. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. From the processing side there is no maximum number of allowable reprocessing. The device should no longer be reused in case of signs of material degradation.

In case of damage the device should be reprocessed before sending back to the manufacturer for repair.

## 5.2 General recommendations

* The user is responsible for the sterility of the product for the first cycle and each further usage as well as for the usage of damaged or dirty instruments, where applicable after sterility.
* Clean the products within two hours after each use.
* For your own safety, please wear personal protective equipment (gloves, safety glasses, etc.).
* Use only a disinfecting solution which is approved for its efficacy (VAH/DGHM-listing, CE marking, and FDA approval) and in accordance with the DFU of the disinfecting solution manufacturer.
* The water quality has to be convenient to the local regulations especially for the last rinsing step or with a washer-disinfector.
* Thoroughly clean and wash the components before autoclaving.
* Do not lubricate the motor handpiece.
* Do not clean the Dental Contra-angle Handpiece with an ultrasonic cleaning device.
* Do not use bleach or chloride disinfectant materials.

## 5.3 Autoclavable components

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| **Autoclavable components** |
| Contra-angle Handpiece |
| * The Contra-angle Handpiece can be autoclaved. * Before first use and after each use, sterilize the handpiece. |
| **Reprocessing instructions** |
| **Preparation at the point of use:** Disconnect the components (bur/drill) from the handpiece. Refer to "Chapter 4-Assembly and Disassembly" of this manual for disassembly instructions. Remove gross contaminations from the components with code water (<40°C) immediately after use. Don’t use a fixating detergent or hot water (>40°C) as this can cause the fixation of residuals which may influence the result of the reprocessing process.  Do not store the instruments in a humid surrounding. |
| Do not submerge the handpiece or wipe it with any of the following functional water (acidic electrolyzed water, strong alkaline solution, or ozone water), medical agents (glutaral, etc.), or any other special types of water or commercial cleaning liquids. Such liquids may result in metal corrosion and adhesion of the residual medical agents to the components. |
| **Transportation:** Save storage and transportation to the reprocessing area to avoid any damage and contamination to the environment. |
| **Preparation for Decontamination:**  The device must be reprocessed in a disassembled state. |
| * Do not fail to take out the bur/needle before cleaning the Dental Contra-angle Handpiece. * Take suitable personal protective measures. |
| **Pre-Cleaning:** Do a manual pre-cleaning, until the handpiece is visually clean. Clean the surfaces with a soft bristle brush. And clean the chuck with a fine soft bristle brush. |
| **Cleaning**：Regarding cleaning/disinfection, rinsing and drying, it is to distinguish between manual and automated reprocessing methods. Preference is to be given to automated reprocessing methods, especially due to the better standardizing potential and industrial safety.  **Automated cleaning:**  Carefully put the components into the washer-disinfector on a tray and set the parameters as follows, then start the program:  4 min pre-washing with cold water (<40°C);  emptying  5 min washing with a mild alkaline cleaner at 55°C;  emptying  3 min neutralising with warm water (>40°C);  emptying  5 min intermediate rinsing with warm water (>40°C);  Emptying  The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr. Weigert).  Note Acc. to EN ISO 17664 no manual reprocessing methods are required for these devices. If a manual reprocessing method has to be used, please validate it prior to use. |
| * Use only approved wash-disinfectors according to EN ISO 15883, maintain and calibrate it regularly. * Follow instructions and observe concentrations given by the manufacturer (refer to general recommendations). * Avoid any contact between the Dental Contra-angle Handpiece and any instrument, kit, support or container. |
| **Disinfection:** Automated Thermal Disinfection in washer/disinfector under consideration of national requirements with regard to A0 value (refer to EN ISO 15883).  A disinfection cycle of 5mins disinfection at 93°C has been validated for the device to achieve an A0 value of 3000.  After manual cleaning, the instruments should be automated disinfected of sterilized immediately. A manual disinfection is not recommended. |
| **Automated drying:** Drying of outside of instrument through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel. Insufficient cavities of instruments by using sterile compressed air. |
| **Functional testing:** Visual inspection for cleanliness of the instruments and reassembling. Functional testing according to instructions of use. If necessary, perform reprocessing process again until instrument is visibly clean. |
| **Lubricating:** Insert the spray nozzle in rear of the handpiece, and apply the handpiece professional lubricant for lubricating and maintenance. Press the lubricant button (for 2-3 seconds) until the lubricant expels from the handpiece head. Press repeatedly until no black lubricant expels from the handpiece head. Refer to the figure below: |
| Before packaging and autoclaving, the handpiece must be lubricated according to manufacturer’s instruction. |
| **Packaging：**Pack the instruments in an appropriate packaging material for sterilization. |
| * Check the validity period of pouch given by the manufacturer to determine the service life. * Use pouches which resist to a temperature up to 141℃ and in accordance with EN 868-5. |
| **Sterilization:**  Sterilization of instruments by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN 13060/EN ISO 17665) under consideration of the respective country requirements.  Minimum requirements: 3 min at 134℃(in EU: 5 min at 134℃). Dry for at least 8 minutes after sterilization |
| * Use only approved autoclave devices according to EN 13060 or EN 285. * Use a validated sterilization procedure according to EN ISO 17665. * Follow the maintenance procedure of the autoclave device given by the manufacturer. * Use only this recommended sterilization procedure. * Control the efficiency (packaging integrity, no humidity, color change of sterilization indicators, physicochemical integrators, digital records of cycles parameters). * 6. Wait for cooling before touching. |
| **Storage：**Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use. |
| * Sterility cannot be guaranteed if packaging is open, damaged or wet. * 2. Check the packaging and the handpiece before using it (packaging integrity, no humidity and validity period). |
| Reprocessing validation study information: The above-mentioned reprocessing process (cleaning, disinfection, sterilization) has been successfully validated. |
| The instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for use. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences. |

# Troubleshooting

When trouble is found, check the following points before contacting your distributor. If none of these are applicable or the trouble is not remedied even after action has been taken, the product may have failed. Contact your distributor.

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| Problem | Cause | Solution |
| The bur cannot be clamped or the bur cannot be inserted | The bur does not meet the standard | Apply the bur that meets the standard |
| Rust or residual stains on the chuck | Lubricate and clean the inner hole |
| Poor spray or spray on the machine head | The three-hole nozzle of the handpiece is blocked by impurities | Clean and dredge the three-hole nozzle with a needle |

# Technical data

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| Manufacturer | Changzhou Sifary Medical Technology Co., Ltd |
| Model | E-ASP1 |
| Minimum fitting length of shank | 11mm |
| Maximum length of bur | 25mm |
| Shank type and size | Comply with ISO 1797:2017 requirements for type 3 shank, diametermm |
| Motor connector | Comply with ISO 3964：2016 requirements for type 3 motor |
| spray water flow | ≥50mL/min（200kPa） |
| spray air flow | ≥1.5NL/min（200kPa） |
| Maximum speed | 200000RPM |
| Chuck type | Push-button chuck |
| Gear ratio | 1:5 |
| Operation conditions | Use: in enclosed spaces  Ambient temperature: 5°C ~ 40 °C  Relative humidity: <80%  Operating altitude < 3000m |
| Transport and storage conditions | Ambient temperature: -20 °C ~ +55 °C  Relative humidity: 20% ~ 80 %  Atmospheric pressure: 70kPa ~ 106kPa |

# 8. Warranty

1. E-ASP 1 is warranted against manufacturing errors and defects in materials, and the warranty period is 6 months starting from the day of delivery to the customer.

2. E-ASP1 should be repaired by the equipment technology department of Changzhou Sifary Medical Technology Co., Ltd. or maintenance service partners authorized by Changzhou Sifary Medical Technology Co., Ltd. Do not provide circuit diagram, bill of material, legends, calibration rules, and other maintenance materials to other organizations.

3. Should the quality assurance complaint be reasonable, Changzhou Sifary Medical Technology Co., Ltd. or maintenance service partner authorized by Changzhou Sifary Medical Technology Co., Ltd shall provide repairing service as soon as possible.

4. Should the damage be proved to be caused by the user's negligence in daily maintenance, warranty is then voided.

5. Changzhou Sifary Medical Technology Co., Ltd reserves the right to analyze and determine the cause of any problem.

# 9. Statement

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| **Expected Service Life**  The expected service life of Dental Contra-angle Handpiece is 5 years.  To ensure continued safe use of E-ASP1. It is recommended that the equipment be checked and repaired at the dealer once a year |
| **Maintenance**  Reprocessing should be carried out according to this manual, such as cleaning, disinfection, sterilization and maintenance. Operation and maintenance were carried out only by authorized person. |
| **Disposal**  The Dental Contra-angle Handpiece contains no harmful ingredients itself. The bur applied with this product should be disposed as medical waste which has contact with the human body; the optical fiber(light guide rod) is made of glass, should be disposed in accordance with the environmental protection requirements of glass products at the end of the product's service life, and the rest of the metal can be classified and recycled; For the cleaning, disposable waste products generated from disinfection and sterilization should be disposed in accordance with local environmental protection laws and regulations. |
| **Rights**  All rights of modifying the product are reserved to the manufacturer without further notice. The pictures are only for reference. The final interpretation rights belong to CHANGZHOU SIFARY MEDICAL TECHNOLOGY CO., LTD. The industrial design, inner structure, etc, have claimed for several patents by SIFARY, any copy or fake product must take legal responsibilities. |
| Any serious incident should be reported to manufacturer and competent authority |

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