



Instructions for use and safety precautions for rotary instruments in dental applications

All rotary instruments from Shofu Dental Corporation have been developed for their specific applications. Rotary instruments for dental applications may only be used by doctors and other specialist who are familiar with the use of these instruments due to their professional education or experience in their practical use. Improper use may contribute to premature wear of the instruments, lead to poor results and pose a danger to the patients and the operators.

Intended application

Only technically and hygienically flawlessly, maintained and cleaned turbines as well as handpieces and contra-angle handpieces may be used.

Until their first use, they should be stored in the original packaging, at room temperature and sealed against dust and moisture.

Prior to the first use on the patient, the rotary instruments should be disinfected, cleaned and – if appropriate – sterilized.

Damaged, deformed or unbalanced instruments should be immediately disposed of and no longer used.

The instruments should be inserted as far as possible and brought to the required rotational speed prior to applying to the object surface. Avoid tilting or levering the instruments, as this may increase the risk of breakage.

Depending on the type of application, protective glasses should be used.

During the application of diamond cutting tools, the use of a disc guard is recommended.

When processing dry materials, you should use a dust suction device to reduce the formation of dust. Unprotected contact with the instruments by the operator should be avoided.

Rotational speeds

The recommended speed range on the packaging and the package insert should be strictly adhered to.

Adherence to the recommended speed range ensures optimal working results. Exceeding or going below this speed range may lead to inferior work results.

Non-adherence to the maximum permissible rotational speed results in increased material loss and safety hazard for the operators and the patients.

Long and pointed instruments tend to oscillate when exceeding the maximum permissible rotational speed, which may lead to the destruction of the instrument.

Pressing forces

Excessive pressing forces should be strictly avoided as they may damage the working sections of the instruments resulting in chipping of the blades and at the same time leading to excessive heat development.

In the case of grinding instruments, excessive pressing forces may lead to tearing out of the abrasive grains or loading of the instrument and increased heat development.

Excessive pressing forces may also lead to injury of the dental pulp due to overheating or to undesirable rough surfaces due to chipped

blades. Even breakage of the instrument cannot be excluded.

Cooling

In order to avoid excessive heat development during preparation, sufficient air / water cooling (at least 50 ml / min) should be utilized.

Insufficient cooling may lead to irreversible damage of the tooth/bone and/or tissue.

Reconditioning Storage, disinfection, cleaning and sterilization

Used instruments must always be disinfected prior to cleaning.

All instruments and components are packaged under non-sterile conditions and must be sterilized according to the purpose of use prior to the application.

In case of improper cleaning and sterilization of the instruments, the patient may be infected with harmful germs.

All materials can be sterilized in accordance with EN DIN 554 and DIN EN 13060 – moist heat sterilization in the steam autoclave (at 134 °C for a minimum residence time of 3 minutes with fractioned pre-vacuum and at least 10 minutes drying period).

Please adhere strictly to the operating instructions from the instrument manufacturer during sterilization.

Prior to sterilization, the instruments should be sufficiently disinfected and cleaned. The disinfection can be carried out manually or mechanically.

The manual cleaning/disinfectant suitability of SHOFU instruments has been validated and documented.

Use a suitable brush to thoroughly remove surface soiling under flowing water.

Place the instruments in a holding device (such as Bur Block, SHOFU) and: put **carbide and diamond instruments into an ultrasound bath**, put **abrasive stones and polishers into a thermal bath**

that are filled with the required amount of water including 2% of the cleaning and disinfection chemicals Stammopur DR8 (Dr. H Stamm GmbH, Berlin).

The exposure period is 10 minutes at a bath temperature of 45 °C.

After the exposure period, thoroughly rinse off with water and dry with compressed air.

Then make a visual inspection for cleanliness and integrity.

If residual contamination can still be seen, repeat cleaning and chemical disinfection until the contamination is no longer visible.

The suitability of SHOFU instruments for mechanical cleaning and disinfection in standard disinfectants is validated and proven: cleaning / disinfection machine MIELE G7735 CD with an alkaline detergent (0.5 % Neodisher FA, Dr. Weigert) without pre-cleaning and using the Bur Block (SHOFU) with the VARIO TD program.

After cleaning, the instruments should be thoroughly rinsed with water and immediately dried. Contact between the instruments during the cleaning/disinfection process may cause damage and should thus be avoided.

Use of protective gloves during the cleaning of contaminated instruments is highly recommended.

The thermo-disinfector is neither suitable for polishers or for other rotary instruments. The instruments are attacked and damaged. As a matter of principle, polishers are not suitable for disinfection at temperatures over 135 °C.

The instructions for use, reaction time and suitability of disinfectants and detergents for certain types of instruments should be obtained from the instructions of the

manufacturers of these agents and strictly adhered to. We also remind you of the list of disinfection methods tested in accordance with the guidelines for the testing of chemical disinfectants and proven to be effective by the German Association for Hygiene and Microbiology (DGHM). The same applies to the list of the Robert Koch Institute (RKI). Information on suitable disinfection agents and methods is also available on the internet at <http://www.rki.de> or www.dghm.de.

The instruments should be stored in suitable, hygienic containers. The same applies to sterilized instruments. They should be stored and sealed against dust, moisture and recontamination. The maximum storage period must not be exceeded.

The above-mentioned instructions have been validated as SUITABLE by the manufacturer of the medical equipment for the preparation of that equipment for reutilization.

The onus is on the operator to ensure that the preparation for re-use performed in the processing plant uses appropriate equipment, materials and personnel produces the required results. This usually requires validation and continuous monitoring of the process. Similarly, any deviation from the supplied instructions by the processing person should be carefully evaluated to ensure effectiveness and avoid any potentially negative consequences.

On the basis of the respective case of application as well as the possible wear of the instruments, the doctor or specialist using these instruments is solely responsible for the decision of reusing the instrument set and the frequency of use. In doubt, the instrument should always be prematurely disposed of and replaced.

Rotary instruments are subject to wear. As a result of this, the functioning guarantee for all rotary tools expires after frequent use.