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Ultrasonic Scaler

REPROCESSING INSTRUCTIONS

URIT Medical Electronic Co.,Ltd.

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1. PLEASE READ THIS BEFORE BEGINNING WORK

Please read these operating instructions carefully as they explain all the most important details and procedures. Please pay special attention to the safety precautions.

Always keep this instruction close at hand.

To prevent injury to people and damage to property, please heed the corresponding directives. They are marked as follows:

 Danger

Risk of injury

 Caution

Risk of property damage or environmental harm

2. INTRODUCTION

The instructions provides instructions for cleaning,sterilization and packaging of Ultrasonic Scaler intended to be reprocessed in medical facilities.Reprocessing components include tip，wrench and handpiece.

The goal of reprocessing reusable products is to reduce bioburden and to achieve sterility of those products in order to eliminate the risk of product reuse related infection.Decisions regarding cleaning or sterilizing dental instruments are based on the potential risk of infection associated with

their use.

It is recommended to use steam sterilization. Remember that sterilization cannot be achieved unless the elements of the assembly are cleaned first.

If there is anything in the following instructions that is not clear, do not hesitate to contact.

We encourage you to report adverse events related to device reprocessing. Report such events directly to URIT Medical Electronic Co.,Ltd.

3. REPROCESSING INSTRUCTIONS FOR REUSABLE PRODUCTS

The instructions are binding for the reprocessing of Ultrasonic Scaler. When necessary, additional product–specific instructions are included with the product to provide additional information.

Application

Important

 Before use, carefully read the operating instructions of Ultrasonic Scaler and devices with which the product will be used.

 Reusable products must be cleaned and sterilized prior to first use. They must be replaced after the number of operations specified by the manufacturer. Disposable products (single use) cannot be reused.

4. PREPARATION

Basic principles

It is only possible to carry out effective sterilization after the completion of effective cleaning. Please ensure that, as part of your responsibility for the sterility of products during use, only sufficiently validated equipment and product–specific procedures are used for cleaning and sterilization, and that the validated parameters are adhered to during every cycle.Please also observe the applicable legal requirements in your country as well as the hygiene regulations of the hospital or clinic.

5. INITIAL TREATMENT AT THE POINT OF USE

⚠ The treatment must be carried out immediately, no later than 30 minutes after the completion of the operation. Additional information, where necessary, is provided in the respective product–specific usage instructions.

Steps

1. Completely disassemble the tips and handpiece from Ultrasonic Scaler, if applicable. Rinse away any surface soiling of them with distilled deionized water or cleaning agent.
2. Rinse through all lumina (e.g. irrigation and aspiration connection) at least 3 times in the

normal direction of flow (no back rinsing) using a disposable syringe (min. volume 50 ml) filled with distilled/deionized water applied to the back nozzle.

3. An aldehyde–free cleaning and disinfection solution that is compatible with the products may also be used as an alternative rinsing solution. In such cases, it is necessary to rinse thoroughly afterwards at least 3 times with distilled, or deionized water.

6. CLEANING

Preparation

When selecting the cleaning agent to be used, ensure that:

• These are fundamentally suitable for the cleaning of the products and compatible with one another,

• The chemicals used are compatible with the products.

⚠ It is absolutely essential that the concentrations and contact times specified by the manufacturer of the cleaning agent are adhered to. Only freshly prepared solutions may be used. The solution is not permitted to foam.Only sterilized or low microbe count distilled/deionized water (< 10 cfu/ml) can be used for all rinsing steps.

Steps for manual cleaning

1. Completely disassemble the handpiece and instruments, if applicable.
2. Place the products in 75% ethyl alcohol for at least 3mins.
3. Remove any externally–attached soiling by brushing carefully with a soft brush or a soft cloth for at least 3 mins.
4. Rinse the products vigorously at least five times, each time with fresh distilled or deionized water (each product lunmen with at least 50 ml of water). Repeat the cleaning process if the last rinsing does not run clear, or if stains are still visible on the product.

⚠ The product adopts manual cleaning and it has been verified. Please do not modify the cleaning method without authorization, such as using disinfector for automated cleaned.

Notice: No automatic cleaning for the product.

7. DRYING

After cleaning, put the handpiece, wrench and tips into the oven for drying.The recommended drying condition is 138℃ for 20 minutes.

8. INSPECTION AND MAINTENANCE

⚠ If stains are still visible on the product after cleaning, the entire cleaning procedure must be repeated. Products with visible damage, chip/flake loss, corrosion or bent out of shape must be

disposed of (no further use is permissible).

9. PACKAGING

Only cleaned products are permitted to be sterilized. Prior to sterilization, the products need to be placed in a suitable sterilization container:

• Resistant to 138℃, with adequate steam permeability,

• Maintained on a regular basis.

If single–use sterilization packaging is to be used, this must be suitable for steam sterilization (temperature resistant to 138℃ with adequate steam permeability).The material of sterilization packaging is made of medical paper and PET/CPP. The packaging material complies with the requirements of EN ISO 11607–1.

Step:

1. Select a suitable sterilization packaging according to the size of the sterilized item and put the items in.

2. Place the sharp and specially shaped devices in the correct position for safe removal when opened.

3. Affix the strip of sterilization packaging(the strip of the packaging is sticky and it does not require

additional processing for sealing such as heat sealing) and mark the sterilization time.

4. Put the sealed sterilization packaging rightly into steam sterilizer.

5. Pay attention to the color–changing: if sterilization is really implemented, it will turn black /grey from initial blue under steam sterilization.

6. Open the strip along the direction printed on the packaging and then takes the items out.

10. STERILIZATION

⚠ The handpiece and tips can withstand 250 reprocessing cycles.Do not exceed the maximum number of reprocessing cycles.

Use only the following listed steam sterilization procedures for sterilization; other sterilization procedures are not permissible:

- Steam sterilizer in accordance with EN 13060 validated in compliance with EN IS0 17665,
- Maximum sterilization temperature 138℃.

Steps for sterilization

1. Sterilization at 134℃ for 4 minutes.
2. Sterilization at 134℃ for a maximum of 20 minutes is permissible.

⚠ The hot–air sterilization and radio–sterilization procedure may not be used (as it causes the

destruction of products). The manufacturer assumes no responsibility for the use of other sterilization procedures (e.g. ethylene oxide, formaldehyde and low temperature plasma sterilization).

11. SERVICE LIFE

The handpiece and tips have been designed for 250 reprocessing cycles.Ultrasonic Scaler has 10 years service life and tips have 5 years service life from start with production, if it exceeds reprocessing cycles or service life, it should be not used any more. The materials used in their manufacture were selected accordingly. However with every renewed preparation for use, thermal and chemical stresses will result in ageing of the products.The use of ultrasound baths and strong cleaning and disinfection fluids (alkaling pH > 9 or acid pH < 5) can reduce the life span of products. The manufacturer accepts no liability in such cases. The products may not be exposed to temperatures above 138℃.

12. STORAGE AND TRANSPORTATION

After sterilization, keep sterilization packaging and stored it in the following environment to avoid infection and sterilization failure:

- Temperature:–20~55 ℃,

- Humidity:10%–90%,
- Atmospheric pressure:70kPa~106 kPa.

The product can keep sterile for 6 months in sterilization packaging, when exceed the 6 months，it shall be reprocessed again before use.

⚠ After reprocessing, it is necessary to confirm that the products can work normally before use. If products with visible damage, chip/flake loss, corrosion, rust or bent out of shape must be disposed of (no further use is permissible).

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