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Dentsply Sirona

Info File Hygiene

Instrument reprocessing in the dental practice

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DAC Universal Advantages

Professional care

- Cleaning, lubrication – if necessary –disinfection and sterilization in a single cycle
- Internal and external cleaning of straight and contra-angle handpieces, turbines, ultrasonic handpieces and tips as well as the nozzles of multi-functional syringes and powder jet devices
- Disinfection and sterilization of instruments

Cost-effective reprocessing

- Low operating and consumption costs – no use of cleaning and disinfection chemicals
- Low investment costs in instruments thanks to quick return to service

Fully automatic reprocessing

- Six instruments in next to no time
- Reliable processing and time-saving
- Simple operation
- An interface for electronic, documentation systems

Legal certainty

- Cleaning, disinfection and sterilization process which can be validated
- Cleaning, disinfection and sterilization process in accordance with ISO 15883-5 and EN 13060 class S

Switch off hygiene risks: Switch on DAC Universal

Comply with hygiene standards at the touch of a button and avoid cross contamination: Completely safe with DAC Universal. Your patients and employees can rely on this all-round protection and put their complete trust in the treatment with the reprocessed, disinfected or sterilized instruments.

Conformity with standards

The sterilization process of the DAC Universal meets the requirements of the European standard EN 13060 for small steam sterilizers. The cleaning and disinfection process is carried out in compliance with the international standard ISO 15883-5 for cleaning and disinfection devices.

The fully automated reprocessing process

The DAC Universal cleans, lubricates and disinfects/sterilizes up to six straight and contra-angle handpieces and turbines in a fully automated process. Furthermore, ultrasonic handpieces and tips as well as the nozzles of multifunctional syringes and powder jet devices as well as solid instruments can be reprocessed at a very high level of hygienic safety in the DAC Universal.

Reprocessing of rotating instruments in a single cycle (Standard lid)

Internal cleaning with cold water

1: Leak test

2: Internal cleaning: The internal channels are rinsed with water

Fully automated lubrication

3: Lubrication: The drive channels are lubricated (only sufficient for the next treatment).

External cleaning with cold and hot water

4: Instruments are cleaned in the pulse-wash procedure (multi-cyclical cleaning procedure)

5: Warm external cleaning

6: Heating to 134°C

7: Back-flush: Saturated steam is directed through the instruments

Sterilization and drying

8: Sterilization: three minutes at 134°C

9: Back-flush: Saturated steam is directed through the instruments

10: Drying

11: Lid opens slightly

12: Lid opens completely when the “C” button (DAC Universal Standard) or the “down arrow” button (DAC Universal Advanced) is pressed.

Reprocessing with the Flex lid (identical process to the Standard lid, but without lubrication)

Internal cleaning with cold water

External cleaning with cold and hot water

Disinfection and drying

Information on the validation of the DAC Universal

The following information is provided in line with the statutory requirements

Validation is a process that tests the effectiveness and reproducibility of the reprocessing procedure. It is composed of installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ).

If the relevant authorities demand complete and **comprehensive initial validation** on-site in the practice, there are various dental depots and service providers that offer such on-site validation services. Complete initial validation locally in the practice includes a comprehensive performance qualification in addition to the installation qualification and operational qualification.

The renewed performance qualification (revalidation) must be carried out after two years or 3,000 cycles at the latest. Revalidation is also required after changes have been made to the device that influence the process parameters or after a change in loading. The inspection qualification and operation qualification are omitted in the renewed performance qualification.

For the batch-related test, an indicator holder (Standard lid Ref. 60 51 788 / Flex lid Ref. 65 42 489) and a chemical indicator of class 5 (Ref. 58 92 059) are available for the inspection. The Class 5 chemical indicator monitors the time, temperature and pressure parameters.

A PCD test phantom (Ref. 60 51 820) is also available **for routine testing**. This is placed on an ISO/INTRAmatic adapter, contains a class 5 chemical indicator and is used once weekly as part of the reprocessing cycle according to the manufacturer's recommendations. As part of this procedure a steam penetration test is conducted. Using access via a tiny hole, this method simulates the hollow cavity of a contra-angle handpiece or turbine.

Batches must be documented; this can be carried out with a printer, using the practice software (also via a network) or via a USB data-logger system.

The declaration of conformity confirms that the device satisfies the necessary cleaning and sterilization standards. This must be verified by hygiene certification from an accredited hygiene laboratory and is arranged by the manufacturer. The proof of origin of the DAC Universal confirms the effectiveness of cleaning as per ISO 15883-5, and the effectiveness of sterilization as per EN 13060, class S. In contrast to Class B devices with which the steam penetrates into the hollow spaces via a vacuum, as a Class S device, the DAC Universal is based on a circulating steam penetration process.

Maintenance as recommended by the manufacturer must, in addition to the repeated performance qualification, also be performed at the latest after two years or 3,000 cycles. A replacement parts set is available (Ref. 60 80 480). The depot technician must be allowed approx. four working hours.

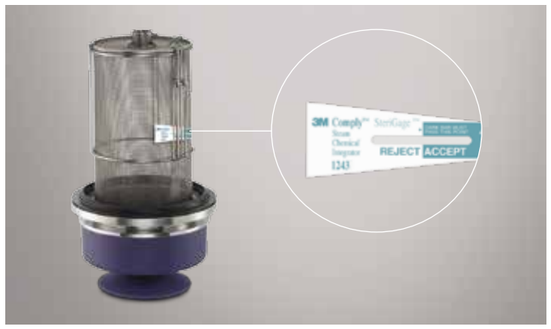
Batch control and release

Semi-critical – Standard lid

- For all semi-critical applications of turbines, straight and contra-angle handpieces and contra-angle handpiece heads
- Release: Batch control is performed using a class 5 chemical indicator
- Indicator holder (Ref. 60 51 788) with class 5 chemical indicator (Ref. 58 92 059)

Semi-critical – Flex lid

- For all semi-critical applications of ultrasonic tips, handpieces and the nozzles of powder jet devices
- Release: Batch control is performed using a class 5 chemical indicator
- Indicator holder (Ref. 65 42 489) with class 5 chemical indicator (Ref. 58 92 059)



Semi-critical – Basket lid

- Up to five solid instruments (without cavities) can be cleaned and sterilized in the sterilization basket
- Release: Batch control is performed using a class 5 chemical indicator
- Class 5 chemical indicator (Ref. 58 92 059)

Release of the batch documents the success of sterilization by:

- Assessing the process with a protocol printout, software output or display
- Inspecting the chemical indicator
- Visually examining for cleanliness
- Then, a written release from the specialist employee is issued
- Issuing a written release from the specialist employee (if release is not possible due to an objection, the entire preparation process must be again carried out)

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