

Astra Tech Implant System®

Washtray EV

Instructions for sterilization and instrument care

Processing/reprocessing in the Washtray Astra Tech Implant System EV and the Washtray GS Astra Tech Implant System EV

Mechanical/automated processing

The following describes automated processing and sterilization according to DIN EN ISO 17664.

- All drills, except the single use Precision Drill EV, can be used for approximately ten cases. If drills are not reused, dispose them in a sharps container immediately after the implant procedure is completed. For guided surgery: Remove the sleeve from the drill. The sleeve is for single use only. For detailed information please refer to the instructions for use.
- Remove coarse contamination such as blood, tissue and bone residue immediately after use. For this purpose, remove the instruments from the instrument tray and rinse them under cold running water while removing coarse contamination with a fine, soft nylon brush.
- For automated processing, place the instruments in the appropriate positions provided in the basket of the Washtray.
- Disassemble instruments that can be disassembled before cleaning and place them in the sieve basket of the Washtray.

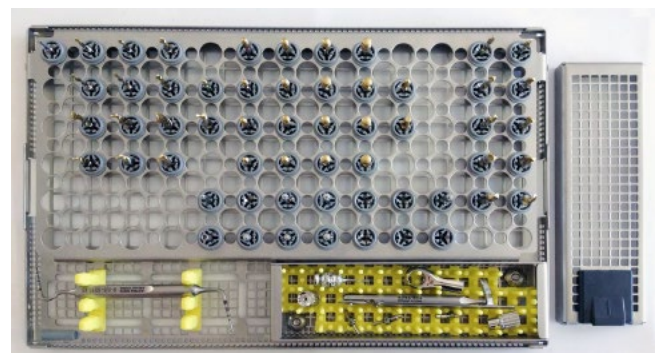
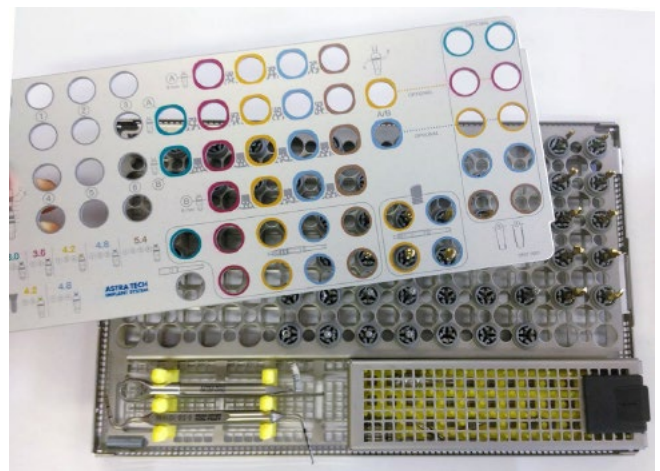
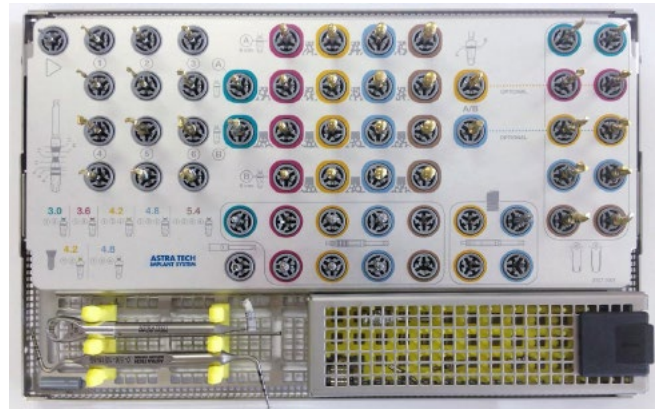
Ultrasonic pre-cleaning

To ensure efficient automated processing instruments need to be pre-cleaned in an ultrasonic bath.

- Remove the Overlay from the Washtray and close the loaded Washtray with the lid of the basket.
- Place the closed Washtray in an ultrasonic bath filled with cleaning agent (neodisher® MediClean forte). The Washtray must be entirely covered by the cleaning agent.
- Adhere to the concentrations and exposure times recommended by the manufacturer of the cleaning agent (minimum duration of ultrasonic cleaning 5 minutes).
- Ensure that the liquid levels recommended by the manufacturer of the ultrasonic bath are observed.

Automated cleaning

Suitable washer-disinfectors are to be used for automated cleaning, which are to be validated by the user as part of the established cleaning processes.



Loading

- Insert the Miele E 327 mobile unit into the washer-disinfector.
- Place the closed Washtray without the Overlay in the mobile unit.
- Clean the overlay separately from the Washtray.
- Follow the instructions of the manufacturer of the washer-disinfector.

Cleaning and neutralization agents

The following agents are recommended for cleaning:

- Cleaning agent neodisher® MediClean forte.
- Neutralization agent neodisher® Z.
- Cleaning and neutralization agents are to be dosed and used according to the manufacturer's instructions.

Water quality

The water quality recommended for cleaning (especially for the final rinse phase) is fully demineralized water or water which corresponds to this level of purity.

Cleaning program

The recommended cleaning program is the Vario TD program with thermal disinfection which operates at the optimum temperature of 45–55 °C for the removal of blood, or any other adequate and validated program.

Thermal disinfection

Thermal disinfection is part of the Vario TD program and takes into account the A_0 value ($A_0 \geq 3000$). The A_0 value is a measure for the reduction of microorganisms in steam disinfection processes.

Drying prior to sterilization

The instruments are dried automatically during the drying cycle in the washer disinfector.

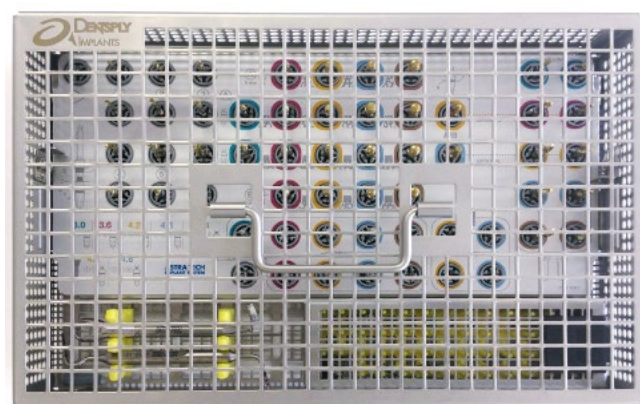
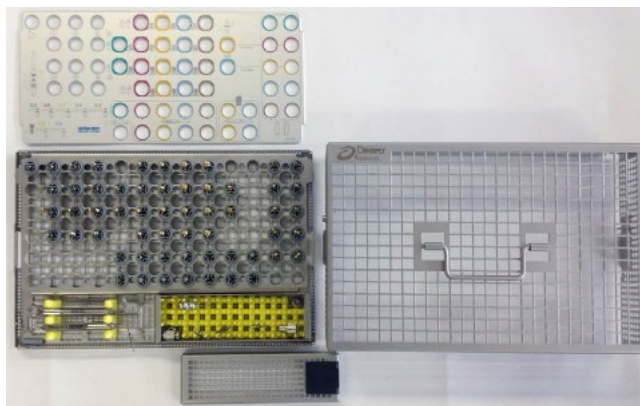
- Use residueless compressed air for drying drill holes/through-holes.
- Then check the cleaned and disinfected medical devices for damage and any corrosion.
- Replace damaged or corroded medical devices.

Sterilization

- Prior to sterilization reassemble the disassembled medical devices and sort them into the holders provided in the Washtray for sterilization.

Note: Medical devices that were cleaned in the Washtray can also be placed back into the Surgical Tray EV for sterilization.

- Place the Overlay in the Washtray, close the Washtray with the lid and lock it in place.
- Pack the loaded Washtray in a single-use sterilization (single or double) package or in a sterilization container suitable for steam sterilization.



Every sterile packaging should display a sterilization indicator and be marked with the date of sterilization. Packaging suitable for steam sterilization must comply with the requirements according to DIN EN ISO 11607/ ANSI/AAMI ST79/AAMI TIR12:2010, e.g. disposable sterilization packages (single or double packages) temperature-resistant up to at least 137 °C (279 °F) and sufficient steam permeability, which provide sufficient protection against mechanical damage, or sterilization containers which need to be maintained according to the manufacturer's instructions. Sterilization is performed in the autoclave. For sterilization parameters see table.

Method	Cycle	Temperature	Exposure time*	Drying time
Steam	Dynamic air removal (prevacuum)	132 °C (270 °F)	4 min.	20 min.
		135 °C (275 °F)	3 min.	20 min.
Steam	Gravity displacement	121 °C (250 °F)	30 min.	20 min.

* Minimum exposure times, the operating times are longer and may vary depending on the device.

Storage

Store the sterilized medical devices at room temperature in a dry and dust-free place.

About Dentsply Sirona Implants

Dentsply Sirona Implants offers comprehensive solutions for all phases of implant therapy, including Ankylos®, Astra Tech Implant System® and Xive® implant lines, digital technologies, such as Atlantis® patient-specific solutions and Simplant® guided surgery, Symbios® regenerative solutions, and professional and business development programs, such as STEPPS™. Dentsply Sirona Implants creates value for dental professionals and allows for predictable and lasting implant treatment outcomes, resulting in enhanced quality of life for patients.

About Dentsply Sirona

Dentsply Sirona is the world's largest manufacturer of professional dental products and technologies, with a 130-year history of innovation and service to the dental industry and patients worldwide. Dentsply Sirona develops, manufactures, and markets a comprehensive solutions offering including dental and oral health products as well as other consumable medical devices under a strong portfolio of world class brands. As The Dental Solutions Company™, Dentsply Sirona's products provide innovative, high-quality and effective solutions to advance patient care and deliver better, safer and faster dentistry. Dentsply Sirona's global headquarters is located in York, Pennsylvania, and the international headquarters is based in Salzburg, Austria. The company's shares are listed in the United States on NASDAQ under the symbol XRAY.

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