Instructions for Sterilization and Instrument Care

Dentsply Sirona

General requirements for the processing/reprocessing of medical devices

- Observe the legal regulations of your country applicable at a time as well as the hygiene guidelines for practices and clinics.
  This applies in particular for the guidelines regarding the effective inactivation of prions.
- The ever-present risk of contamination and infection during treatment must be excluded or reduced by specific preventive measures.

  These include:
  - Assessment of the risks and dangers in connection with medical practice and definition of appropriate precautions
  - Schematization and systematization of work routines with the predominant aim of avoiding contamination and injuries
  - Careful anamnesis with special regard to patient-induced risks of infection
- All used as well as unpacked but previously unused medical devices have to be considered contaminated and must therefore be processed hygienically without exception.
- During transport it has to be assured that neither staff nor third parties are at risk. For their own safety, staff members must wear appropriate protective clothing and protective gloves.
- Medical devices should not be stored in physiological saline solution as prolonged exposure may lead to corrosion. The parts must be moistened completely and bubble-free in a bath. Demineralized water is required under all circumstances for final rinsing after disinfection to avoid water stains and crystal seeding which may interfere with the subsequent process of sterilization.
- As your responsibility includes the sterility of the medical devices used, please bear in mind that only validated procedures must be used for cleaning, disinfection and sterilization. All equipment needs to be serviced at regular intervals, and all parameters must be observed in every cycle. Please observe the shelf-life indicated on the sterile packaging of devices (see manufacturer's instructions). Processing ends with the release for use.
- All medical devices for single use that are supplied sterile must not be resterilized.
- All medical devices that are supplied non-sterile must be processed prior to their first use on a patient.
- All reusable medical devices must be repocessed after every use according to the described validated procedure.
- When using reprocessing procedures that are different from those described in this manual, this procedure must be validated by the respective practice or hospital.
- Not all medical devices are made for multiple use. Medical devices that must not be re-used are marked for single use only on the product label.
- All cutting or abrasive devices must be replaced at the most after the usage cycles prescribed in the instructions for use or as occasion demands (e.g. due to bluntness).
- For information whether a medical device has to be disassembled prior to processing/reprocessing or whether it is suitable for sterilization in the autoclave please refer to the instructions for use.
- Detailed specifications related to the materials of the medical devices will be made available on request.

Specific remarks on the processing/reprocessing of Dentsply Sirona medical devices*

- For medical devices where Dentsply Implants Manufacturing GmbH is not named as manufacturer, please check the specific directions regarding preparation and re-usability in the manufacturer's instructions for use.
  The manufacturer name is given on the product label.
- All dismountable medical devices must be disassembled for cleaning and disinfection and assembled prior to sterilization.
- If using an ultrasonic bath, place the drills in a drill organizer.

* Ankylos®, Astra Tech Implant System®, Xive®, Frialit®, Friadent®, Frios®, Ziteron®

Note: The proper reprocessing of instruments has little influence on the lifetime of the instruments. The end of product lifetime is usually determined by wear and tear and damage during use (cutting instruments are an exception). Therefore, instruments can be reused with proper care. A prerequisite for reuse is that the products are not damaged, free of contamination and tested for faultless function before use.

Validated procedure for the processing/reprocessing of Dentsply Sirona medical devices

According to a recommendation by the Robert Koch-Institute [2.] one distinguishes between manual and mechanical/automated procedures for processing, whereby the automated procedure is always to be preferred.
The following gives a guideline for automated and manual processing as well as for sterilization.

Materials

The following materials and equipment were used for the validation of the manual and automated processing/reprocessing procedures:

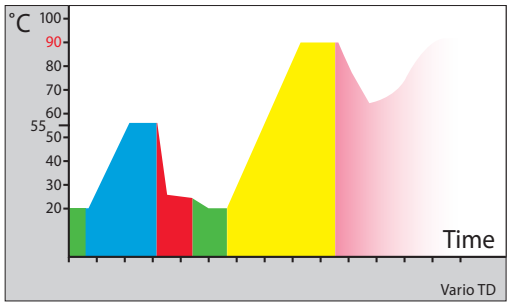
- Friadent Drill Cleaning Instrument

Washer-disinfector

- Washer-disinfector
  Type: G 7836 CD; Manufacturer: Miele & Cie. KG, Gütersloh, Germany
- E 450 mobile injector unit for MIC instrument set (Miele)
- E 327 mobile unit M-No.1274658 04/50 (Miele)
- E 473/1 mesh insert with lid
  (mesh basket with lid for small instruments/Miele)
- 3mach®-rinsing module
  Manufacturer: 3mach GmbH, Germany

Cleaning program

The recommended cleaning program is the VARIO-TD program with thermal disinfection which operates at the optimum temperature of 45 – 55 °C (113 °F – 131 °F) for the removal of blood, or any other adequate and validated program.



VARIO-TD program by Miele Professional

The VARIO-TD program is divided into the following phases:

Pre-rinsing	4 min.
Cleaning with alkaline detergent at max. 55 °C (131 °F)	10 min.
Neutralization	6 min.
Intermediate rinsing	3 min.
Thermal disinfection at 90°C (195 °F)	5 min.
Drying	30 min.

Cleaning, neutralization and disinfecting agents

The following commercially available cleaning, neutralization agents and disinfectants were used:

- Cleaning agent neodisher® MediClean forte
  Manufacturer: Dr. Weigert, Hamburg, Germany
  Ingredients for cleaning agents according to the Regulation (EC) No 648/2004 on Detergents:
  <5% non-ionic or anionic surfactants, and enzymes
- neodisher® Z
  Manufacturer: Dr. Weigert, Hamburg, Germany
  Ingredients for detergents and cleaning agents according to EC Recommendation 89/542/EEC: organic acids
- ID 213 Instrument disinfection Manufacturer:
  DÜRR SYSTEM-HYGIENE, Germany
  Ingredients: alkylamines, quaternary ammonium compounds, non-ionic surfactants, complexing angents, auxiliary substances as well as citronellol and coumarin; DGHM-/VAH (2011) listed
- FDA listed: CIDEX® OPA
  Manufacturer: Johnson & Johnson
  High level disinfectant for semi-critical medical devices
  Ingredients: ortho-phtalaldehyde, dipotassium hydrogen phosphate, potassium dihydrogen phosphate, benzotriazole, citric acid, D&C Green Dye #5, N-(hydroxyethyl) -ethylenediaminetriacetic acid (HEDTA)
- Adhere to the concentrations and exposure times recommended by the manufacturer of the cleaning, neutralization and disinfecting agents.

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 [2.][3.].

Instrument oil

- InstruCare instrument oil, highly pure medical white oils
  Manufacturer: Laboratorium Dr. Deppe, Kempen, Germany
  Ingredients according to DAB 10 2nd Ed, BP 1993, USP XXII, NF XVII, FDA 172 – 878, steam resistant up to 200 °C (392 °F).

Mechanical/automated processing [1.][4.][6.]

Manual pre-cleaning is necessary to ensure efficient automated cleaning, so that the automated reprocessing of medical devices begins with a manual cleaning step as well.

Manual pre-cleaning

Coarse contamination such as blood, tissue and bone residue must be removed immediately (within two hours) 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 soft nylon brush.
- Then place the instruments to be cleaned mechanically in the sieve basket of the washer-disinfector.

Ultrasonic cleaning

Ultrasonic pre-cleaning is required for instruments with critical design features, e.g. movable parts or blind holes.
If the medical devices are heavily contaminated or if coarse contamination proves difficult to remove manually (as described above), pre-cleaning in an ultrasonic bath is recommended.
Care should be taken to ensure that the exposure times and concentrations recommended by the manufacturer are adhered to.
Please also ensure that the liquid levels recommended by the manufacturer of the ultrasonic bath are observed.

Cleaning of medical devices with through-holes, e.g. irrigation cannulas or cooling capillaries

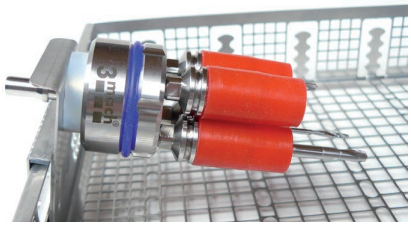
Medical devices with cooling capillaries or drills with internal irrigation make high demands on reprocessing due to the small diameters of the through-holes.
To ensure safe processing of such delicate instruments, these need to be pre-cleaned manually. Hereby it is essential to observe the following points:

- Immediately (within two hours) after use, clean the capillary from coarse contamination using the Friadent Drill Cleaning Instrument and check it for obstructions.
- Rinse the capillaries several times with distilled water using a disposable syringe (10 ml).
- Then proceed to automated cleaning of the medical devices.
- After automated cleaning, rinse the capillaries several times with distilled water using a disposable syringe (10 ml).

Cleaning of drills and millers with cooling capillaries using the 3mach® rinsing concept

Due to the small diameters of the through-holes, medical devices with cooling capillaries or drills with internal irrigation make high demands on reprocessing. To ensure safe processing of such delicate instruments, these need to be pre-cleaned manually. Hereby it is essential to observe the following points:

- Immediately (within two hours) after use, clean the capillary from coarse contamination using the Friadent Drill Cleaning Instrument and check it for obstructions.
- When no obstructions are present, automated processing of the instruments by using 3mach® rinsing modules is possible.
- Insert the shaft of the instrument in the silicone sleeve of the rinsing module.



3mach rinsing module (3mach GmbH)

- Place the rinsing module in the sieve basket or fix it to the basket.
- Connect the rinsing module to the tubing system of the E 450 mobile injector unit for instrument set (Miele) and continue with automated cleaning.

Mechanical/automated processing [1.][4.][6.]

Automated cleaning

Suitable washer-disinfectors type G 7836 CD (Miele) are to be used for automated cleaning, which need to be validated by the user in the scope of the cleaning processes in place.

Loading

- Insert the mobile/mobile injector unit in the washer-disinfector.
- Place the instruments and/or their disassembled parts to be cleaned in the basket.
- Place the lid on the sieve basket and lock it in place.
- Follow the instructions of the manufacturer of the washer-disinfector.

Cleaning and neutralization agents

The following cleaning and neutralization agents are recommended for cleaning:

- Cleaning agent neodisher® MediClean forte
- Neutralization agent neodisher® Z
- Cleaning and neutralization agents are to be dosed and used in accordance with 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 [2.][3.].

Cleaning program

The recommended cleaning program is the VARIO-TD program with thermal disinfection which operates at the optimum temperature of 45 – 55 °C (113 °F – 131 °F) 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>=3000). The A_0 value is a measure for the reduction of microorganisms in steam disinfection processes [2.][3.].

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.

Manual processing [1.][2.]

Note: Manual processing is not applicable for EU customers. EU customers are required to use the automated processing.

Pretreatment (to avoid cross contamination)

Important: Dried contamination may severely impede the reprocessing of medical devices. Therefore start the pretreatment as early as possible to achieve effective reprocessing.

- To prevent drying and for reasons of personal protection, place the medical devices in disinfectant solution (bactericidal, fungicidal, sporicidal and antiviral effects) immediately (within two hours) after use**.
  Shake thoroughly at least three times.
- Then remove coarse contamination such as blood, tissue and bone residue.
- For this purpose, remove the instruments from the instrument tray and rinse off all visible residues of surgery and adhering contamination under cold running water or in a disinfectant solution with a soft nylon brush or a clean, soft cloth which is only used for this purpose. Never use metal brushes or steel wool.

Cleaning/disinfection should then take place within the next 2 hours.

Important: At temperatures exceeding 40 °C (104 °F) there is a risk of protein coagulation. The optimum operating temperature for a disinfectant bath is room temperature. This initial disinfection cannot replace the disinfection step which is carried out after cleaning!

Ultrasonic cleaning (optional)

If the medical devices are heavily contaminated or if coarse contamination proves difficult to remove manually (as described above), pre-cleaning in an ultrasonic bath is recommended.
Care should be taken to ensure that the cleaning agent is compatible with the products and that the exposure times and concentrations recommended by the manufacturer are adhered to. Also ensure that the liquid levels recommended by the manufacturer of the ultrasonic bath are adhered to.

Cleaning

- Prior to cleaning rinse the products with running cold water.
- Disassemble all dismountable parts.

The water quality recommended for cleaning is distilled water or fully demineralized water [2.][3.]. neodisher® MediClean forte is, for example, a suitable cleaning agent.

Important: Cleaning is carried out at a maximum temperature of 40 °C (104 °F). The optimum operating temperature is room temperature.

- Place the disassembled medical devices in a freshly prepared cleaning bath in accordance with the manufacturer's instructions and then clean with an instrument cleaning brush made of plastic/nylon.
- Clean medical devices with through-holes, for example, irrigation cannulas or cooling capillaries, with the Friadent Drill Cleaning Instrument and rinse several times with distilled water using a disposable syringe (min. 10 ml) at the beginning and end of the exposure time. Ensure there are no obstructions in the through-holes.
- After cleaning, rinse the medical devices several times with distilled or fully demineralized water.
- After cleaning, examine the products for damage or any signs of corrosion.
- Replace damaged medical devices.

Disinfection

- For the disinfection place the medical devices in a freshly prepared disinfection bath** (shake thoroughly at least three times).

Important: The medical devices must be fully immersed/wetted by the disinfectant solution.

For example, a suitable disinfectant with bactericidal, tuberculocidal, fungicidal and virucidal effects (enveloped viruses such as vaccina viruses including HBV, HCV and HIV, as well as enveloped viruses such as adeno, polyoma SV 40, polio viruses) is ID 213 Instrument Disinfectant, and for the USA FDA-listed as high-level disinfectants for semi-critical medical devices, e.g. CIDEX OPA.

Rinsing and drying

- Following disinfection, rinse the instruments thoroughly three times with distilled water.
- Dry the instruments and the drill holes using clean compressed air.

** Observe information provided by the manufacturer of the instrument disinfection/ cleaning agent with regard to concentration/ exposure time and, if given, temperature. Only disinfectants not containing chlorine, ammonia and aldehydes and with proven efficacy against HBV, HCV and HIV may be used, and which comply with the respective current national regulations on disinfectants (e.g. FDA approval, DDGHM (2002)/VAH (2011) listed, CE marking, etc.). Disinfection should be performed using aldehyde-free agents due to the protein-binding properties of aldehyde-containing disinfectants

Maintenance and functionality

A prerequisite for reuse is that the products are not damaged, free of contamination and tested for faultless function before use.

General recommendations

- Single-use products that must be cleaned, disinfected, and sterilized prior to use are not intended to be reused.
- Check for reusable products that are delivered non-sterile and need to be processed before first use that the product has not reached the end of its shelf life.
- All dismountable products must be disassembled for cleaning and disinfection and assembled prior to sterilization.
- Before preparing for sterilization, all products should be inspected with the naked eye for visible soil, impairments, and/or corrosion. Particular attention should be paid to design features such as channels, blind holes, threads, deep undercuts, and mating surfaces.
- Check products for visibility and readability of all markings by inspection with the naked eye.
- To ensure proper functionality, perform a functional check for products having movable parts or consisting of multiple parts.

Perform functional check

Careful inspection and functional testing of the products before use is the best method for determining the end of serviceable life for the medical device.

- Check drills for sharpness and damages.
- Check mating products for proper assembly and functionality, e.g.:
  - Ratchets: check if switching is possible and verify correct fit of ratchet insert
  - Frios seating instruments: check for sufficient clamping force between instrument working part and membrane tacks
- Check device with movable parts for correct operation, e.g.:
  - Frios Drilling and Positioning Tool for Membrane Tacks: check if tongue is movable to required position.
- Check devices containing PTFE or O-rings for lost or damaged rings. Verify friction of instrument with counterpart, e.g.:
  - Insertion instruments – check sufficient clamping force between insertion instrument and placement head
- **Note:** If PTFE or O-ring is lost or damaged, a new ring must be installed before further use of the instrument.

Replace damaged and corroded products.

For disposal of the products comply with the currently applicable national waste disposal regulations in your country.

Sterilization [1.][2.]

- Reassemble all disassembled instruments prior to sterilization.
- Place the separately cleaned and disinfected instruments in the sterilization tray. Instruments can also be sterilized individually.
- Pack the loaded trays and/or the individual instruments in a single-use (single or double) package that is suitable for steam sterilization or in a sterilization container.

Packaging suitable for steam sterilization must comply with the requirements according to DIN EN ISO 11607/ ANSI/AAMI ST79/AAMI TIR12, 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

Sterilization is performed in the autoclave. For sterilization parameters see table below:

Storage

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

Method	Cycle	Temperature	Exposure time*	Drying time
Steam (**EU****)	Dynamic air removal (prevacuum)	134 °C	3 min.	20 min.
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.

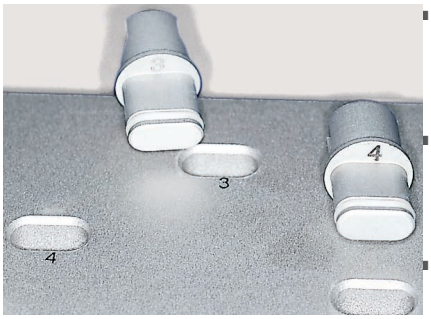
* Minimum exposure times, the operating times are longer and may vary depending on the device.
** EU customers are required to use these steam sterilization parameters.

[1.] DIN EN ISO 17664 Sterilization of medical devices – Information to be provided by the manufacturer for the preparation of re-sterilizable medical devices (ISO 17664:2017); German version EN ISO 17664:2017
[2.] RKI Guideline 2012: Hygiene requirements for the reprocessing of medical devices (German Federal Health Gazette 2012; 55: 1244-1310)
[3.] Guidelines of the DGKH (German Association for Hospital Hygiene), DGSV (German Association for Sterile Services) and AKI (Working party instrument preparation) for the validation and routine monitoring of mechanical cleaning and thermal disinfection processes for medical devices , 4th edition 2014
[4.] Guidance for Industry and FDA Staff – Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, March 17, 2015
[5.] AAMI TIR12:2010, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
[6.] DIN EN ISO 15883-1 (2014-10) Cleaning and disinfection appliances – Part 1: General requirements, definitions and test methods (ISO 15883-1:2014-10); German version EN ISO 15883-1:2014-10
[7.] EN 13060 "Small steam sterilizers"
[8.] EN 285 "Sterilization – Steam sterilizers – Large sterilizers"
[9.] ISO 17665 "Sterilization of health care products" – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

Processing/reprocessing of trays/aluminum kits

Trays/kits have to be reprocessed after each use. For this purpose, disassemble the trays/kits according to the following instructions.

- Remove all medical devices from the tray/kit for reprocessing (cleaning/disinfection).
- Then disassemble the tray/kit completely into its individual components. Remove the base plate and the accessory box, if present, from the tray or the kit.
- Remove the aluminum insert for separate cleaning.
- Perform **"Mechanical/automated processing"** with washer-disinfector (see page 5) or **"Manual processing"** (see page 7).



Note: For Ankylos kits (see picture) please also disassemble the plastic straps.

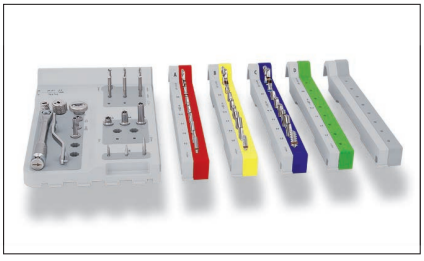
- Reassemble the cleaned and disinfected tray/kit for maintenance and assembly. Do not use instrument oil. Replace damaged trays.
- For preparation of sterilization place the separately cleaned and disinfected instruments back into the tray.
- Pack the tray in a single-use sterilization (single or double) package or a sterilization container that conform to the requirements of DIN EN ISO 11607/ANSI/AAMI ST79 /AAMI TIR12.
- Perform "Sterilization" as described (see page 9).

Important:

- The transparent cover in the Ankylos kits must not be sterilized.
- The bath-shaped insert (small box) in the Frialit trays is not a sterile container.

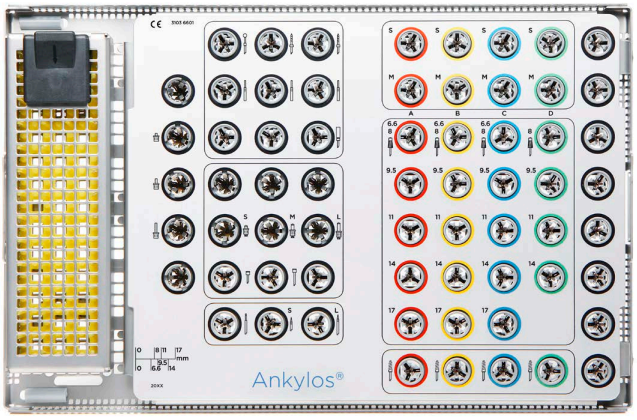
Reprocessing of plastic trays

- Remove all products from the tray for reprocessing (cleaning/ disinfection).
- Disassemble the tray completely into its individual components.
- Perform **"Mechanical/automated processing"** with washer-disinfector (see page 5) or **"Manual processing"** (see page 7).
- Reassemble the cleaned and disinfected tray/kit for maintenance and assembly. Do not use instrument oil. Replace damaged trays.
- For preparation of sterilization place the separately cleaned and disinfected instruments back into the tray.
- Pack the tray in a single-use sterilization (single or double) package or a sterilization container that conform to the requirements of DIN EN ISO 11607/ANSI/AAMI ST79 /AAMI TIR12.
- Perform **"Sterilization"** as described (see page 9).

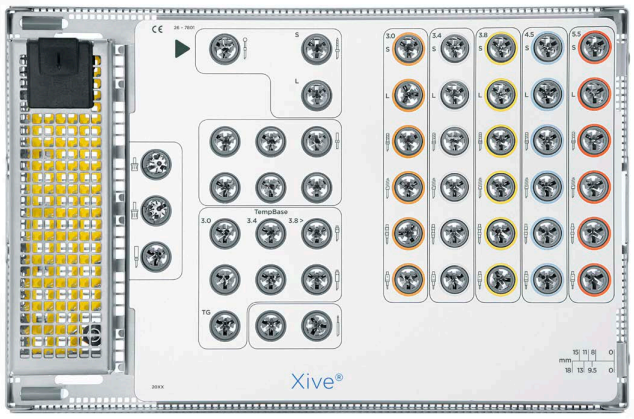


Important:
The interior pad insert is solely for protection during transport and is to be removed prior to first use. The pad insert must under no circumstances be sterilized. All trays must be cleaned, disinfected and sterilized prior to first use and after each use. Cleaning/disinfection of loaded trays is not permissible.
Please already ensure that contaminated instruments are collected separately during use and not returned to the tray.

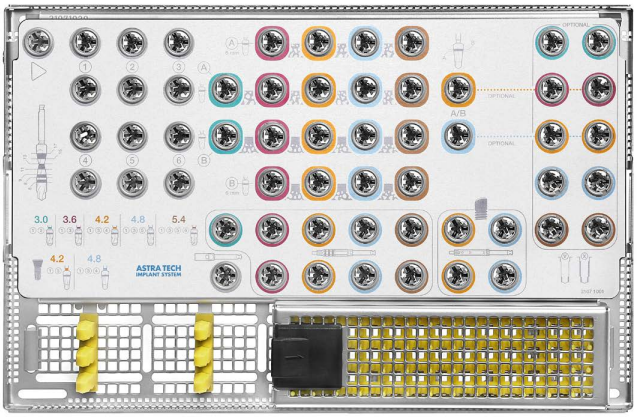
Processing/reprocessing in the Washtray



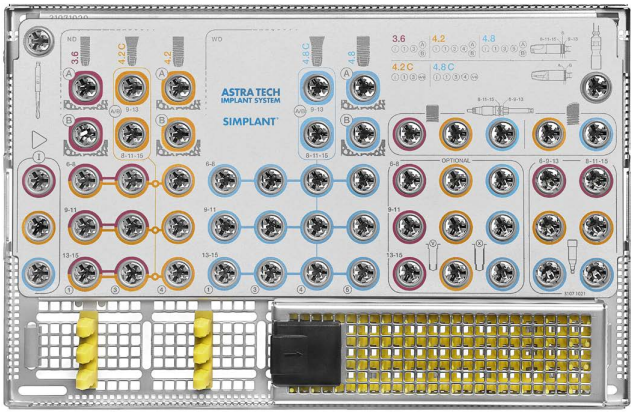
Washtray
with Ankylos Overlay



Washtray
with Xive Overlay



Washtray
with Overlay Astra Tech Implant System EV

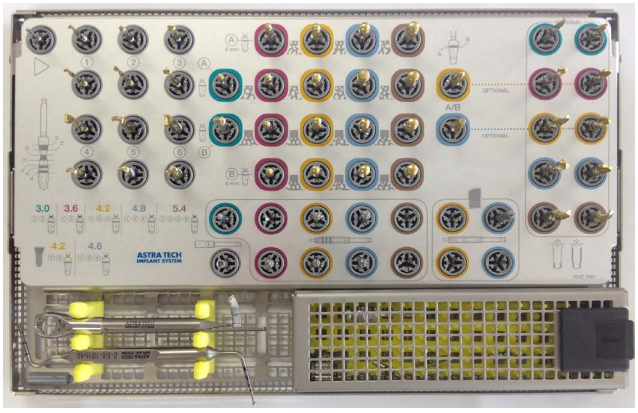


Washtray
with Overlay GS Astra Tech Implant System EV

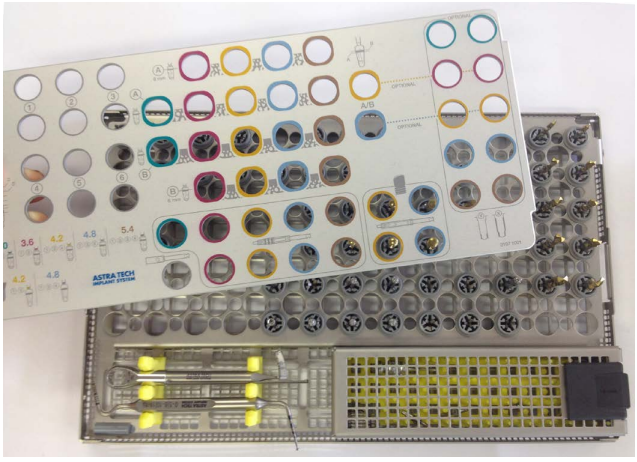
Mechanical/automated processing [1.][4.][6.]

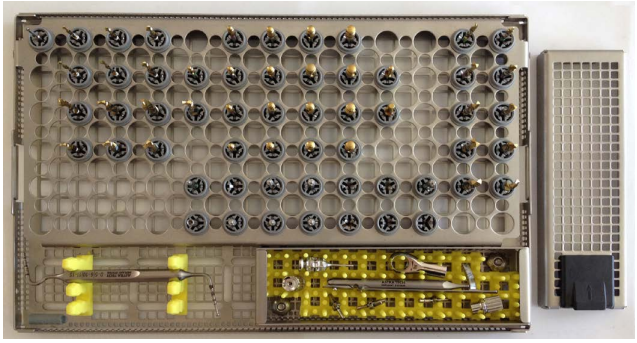
The following describes automated processing and sterilization according to DIN EN ISO 17664.

- Remove coarse contamination such as blood, tissue and bone residue immediately (within two hours) 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.



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.

Mechanical/automated processing [1.][4.][6.]

Automated cleaning

Suitable washer-disinfectors type G 7836 CD (Miele) are to be used for automated cleaning, which need to be validated by the user in the scope of the cleaning processes in place.

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 [2.][3.].

Cleaning program

The recommended cleaning program is the VARIO-TD program with thermal disinfection which operates at the optimum temperature of 45 – 55 °C (113 °F – 131 °F) for the removal of blood, or any other adequate and validated program.

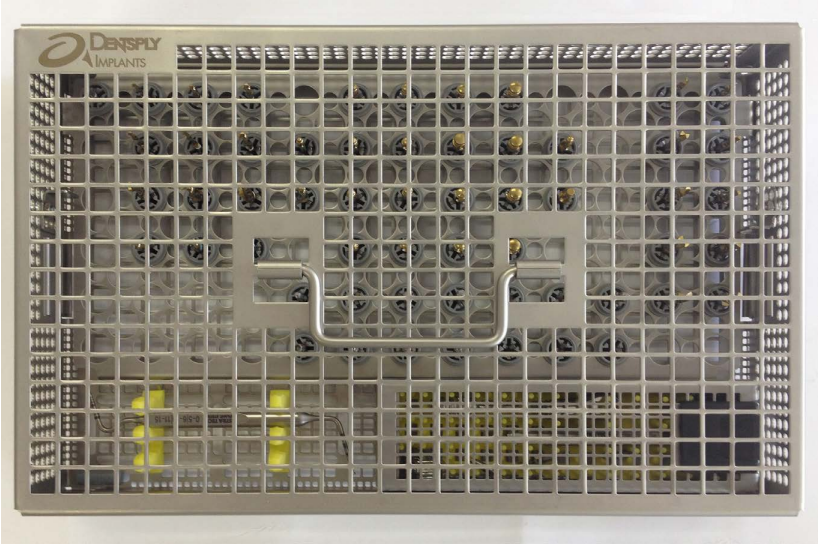
Thermal disinfection

Thermal disinfection is part of the VARIO-TD program and takes into account the A_0 value (A_0>=3000). The A_0 value is a measure for the reduction of microorganisms in steam disinfection processes [2.][3.].

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.



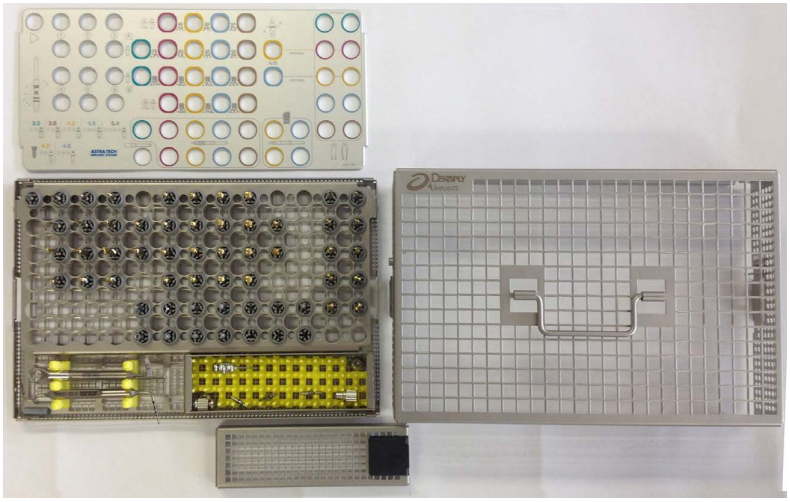
Sterilization [1.][2.]

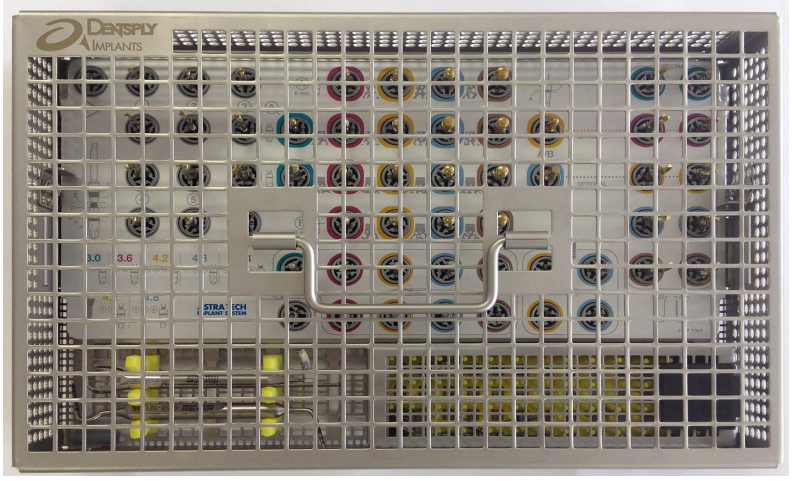
- Prior to sterilization reassemble the disassembled medical devices and sort them into the holders provided in the Washtray for sterilization.
- Place the Overlay in the Washtray, close the Washtray with the lid and lock it in place.
- Pack the loaded Washtray in a single-use sterilization (single or double) package or in a sterilization container suitable for steam sterilization.

Every sterilization package must have a sterilization indicator and sterilzation date.

Packaging suitable for steam sterilization must comply with the requirements according to DIN EN ISO 11607/ANSI/AAMI ST79/AAMI TIR12, 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 auto-clave. For sterilization parameters see table.





Storage

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

Method	Cycle	Temperature	Exposure time*	Drying time
Steam (**EU****)	Dynamic air removal (prevacuum)	134 °C	3 min.	20 min.
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.
** EU customers are required to use these steam sterilization parameters.

Disassembly/assembly of Dentsply Sirona medical devices

Ankylos® Ratchet/Xive® Ratchet

Disassembly

- Twist the reverse button.
- Then press the reverse button down and loosen it by turning counterclockwise.
- Release the milled ring nut from the ratchet by turning it counter-clockwise (Fig. 1).
- Remove the sprocket with the return spring from the ratchet (Fig. 2).
- Remove the return spring from the sprocket (Fig. 3).
- Prior to sterilization, lubricate the parts with a thin layer of instrument oil. Let excess oil drip off.

Assembly

- To reassemble proceed in reverse order.

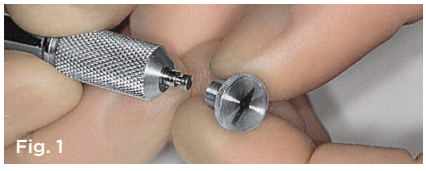


Fig. 1

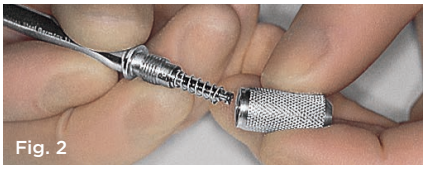
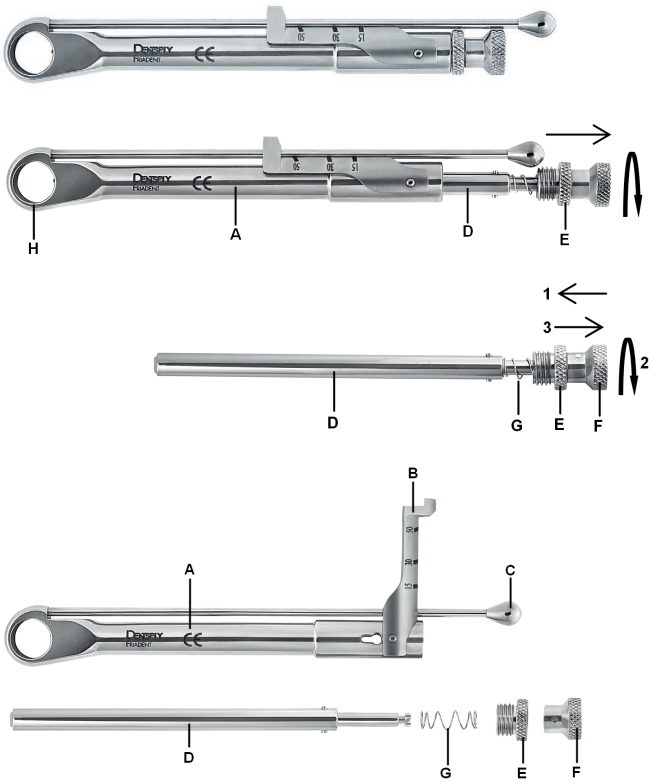


Fig. 2


Fig. 3

Xive® & Ankylos® Surgical Ratchet with Torque Indication



Disassembly

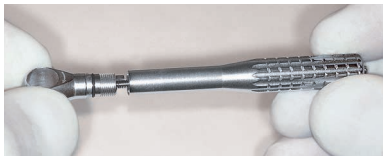
- Turn the knurled screw E counterclockwise and release.
- Pull the pawl D out of the ratchet body A and open out the indicator B for cleaning or sterilization.
- For disassembly, press the toggle button F to the stop in the direction of the pawl D.
- Hold the toggle button down and turn 180°, counterclockwise.
- Disengage the toggle button from the pawl, remove the knurled screw E and pull the compression spring G from the pawl.

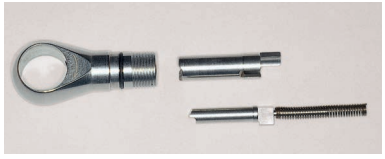
Assembly

- Prior to sterilization, lubricate all parts with a thin layer of instrument oil. Let excess oil drip off.
- Slide the compression spring G and the knurled screw E onto the pawl D.
- Push the toggle button F onto the pawl, hold down and turn clockwise, until the toggle button engages with an audible click.
- Slide the pawl into the ratchet body A and screw clockwise into the ratchet body using the knurled screw E.
- Then fold down the indicator B.

Disassembly/assembly of Dentsply Sirona medical devices

Ankylos® Prosthetic Ratchet/Friadent® Ratchet





Disassembly

- First unscrew the ratchet head (1) from the handle (5).
- Then remove the ratchet insert for implant driver or the torque driver from the ratchet head.
- Remove the sleeve (2), guide (3) and recoil spring (4) from the ratchet head.
- Remove the recoil spring from the sprocket.
- Prior to sterilization, lubricate the parts with a thin layer of instrument oil and let excess oil drip off.

Assembly

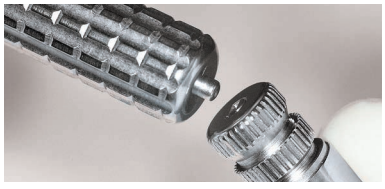
- To assemble the ratchet proceed in reverse order.

1 2 3 4 5

Ankylos® & Friadent® Torque Driver Inserts for Prosthetic Ratchet

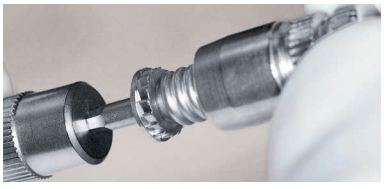
Disassembly

- Press the mandrel at the end of the ratchet handle into the recess at the housing of the torque driver insert until the working part detaches from the housing.



Assembly

- Insert the working part of the torque driver insert carefully while turning it clockwise into the housing.



- Turn the working part in the housing and press it until it engages with an audible click.

Disassembly/assembly of Dentsply Sirona medical devices

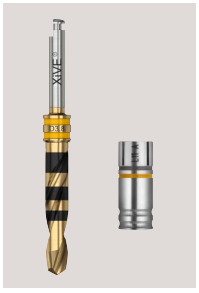
Xive® Depth Stops for Twist Drills

Disassembly

- Place the tip of the drill on a soft pad (e.g. surgical cloth).
- Remove the depth stop manually over the tip of the drill.

Assembly

- Push the depth stop manually over the tip of the drill.



Note:
The depth stops of Xive twist drills are not pre-mounted.

Frialit® Drill Depth Stop Tool (D 3.4 or higher)

Disassembly

- Place the shaft of the drill on a soft surface (Fig. 1).
- Remove the depth stop from the drill using the long depth stop tool (Fig. 2).

Assembly

- Place the tip of the drill on a soft surface (Fig. 3).
- Mount the short depth stop onto the drill (Fig. 4) using the short stop tool.

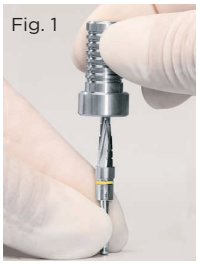


Fig. 1


Fig. 2

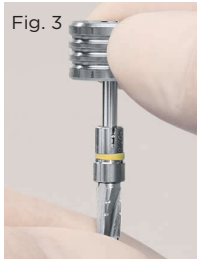


Fig. 3

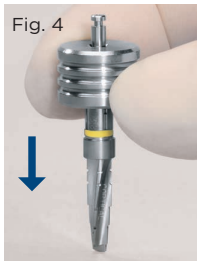


Fig. 4

Note:
The depth stops of the Frialit stepped drills universal are not pre-mounted.

Ankylos® Implant Driver GS

Disassembly

- Unscrew the sleeve from the implant driver for cleaning.

Assembly

- Screw the sleeve back on the implant driver prior to sterilization.

Note:
The sleeves of the Ankylos implant driver GS can be re-used, but should be exchanged when damaged.
The Ankylos sleeves for implant driver GS are available separately as spare parts.

Xive® Implant Driver GS

Disassembly

- Unscrew the sleeve from the implant driver for cleaning.

Assembly

- Screw the sleeve back on the implant driver prior to sterilization.

Note:
The sleeves of the Xive implant driver GS can be re-used, but should be exchanged when damaged.
The Xive sleeves for implant driver GS are available separately as spare parts.

Disassembly/assembly of Dentsply Sirona medical devices

Ankylos® ATP-Punch

Disassembly

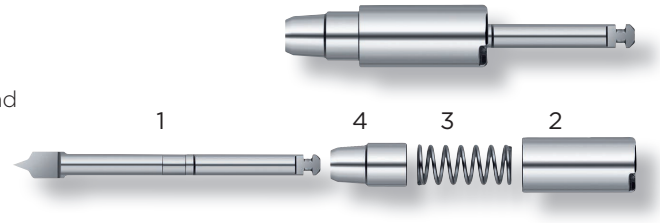
The ATP-Punch is held together by a bayonet fitting and can be disassembled by just twisting.

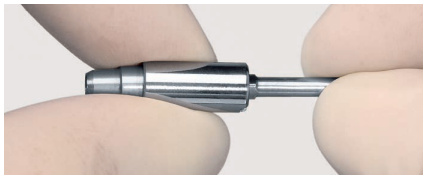
- Hold the housing of the ATP-Punch and turn the milling tool (1) clockwise.
- Remove housing (2) and spring (3) from the milling tool.
- Slide the punch sleeve (4) from the milling tool.

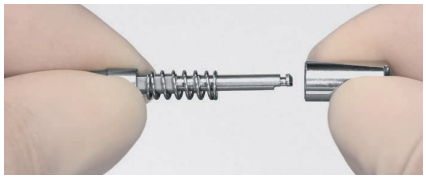
Note:
The punch sleeve is for single use only and needs to be replaced after use.

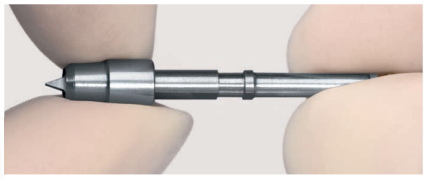
Assembly

- Slide the sleeve for the ATP-Punch onto the milling tool.
- Turn the sleeve and the milling tool clockwise.
- Slide the spring and the housing onto the milling tool.
- Turn the housing and milling tool clockwise.









Disassembly/assembly of Dentsply Sirona medical devices

Frios® BoneCollector

Disassembly

- Remove the disposable suction tube (1) from the particulate container (2).
- Strip the suction unit adapter (3) from the suction unit (4).
- Unscrew the particulate container from the suction unit.
- Remove the titanium filter (5) from the suction unit adapter.

Assembly

- To assemble proceed in reverse order.

Note:
The suction tube and titanium filter have to be disposed after use. Insert the sterile titanium filter and the sterile disposable suction tube into the BoneCollector housing immediately prior to use.

Friadent® Periotome

Disassembly

- Loosen the head of the instrument counterclockwise from the handle.
- Remove the blade from the working part.

Assembly

- To assemble proceed in reverse order.

Note:
During assembly, the driving stud of the blade must be inserted in one of the grooves in the working part.

Disassembly/assembly of Dentsply Sirona medical devices

Conometric Fixation Tool

Disassembly

Note: The Fixation Tool must be disassembled for cleaning and may be assembled again for sterilization only in a dry condition.

- In case a plastic Fixation Tool Tip is mounted, remove it before disassembling the Fixation Tool.
- Hold the Fixation Tool with the Top Body (1) pointing upwards.
- Unscrew the Top Body (1) from the Middle Body (4) by turning counterclockwise.
- Remove the Compression Spring (2).
- Tilt the Middle Body (4) until the Hammer (3) glides into your hand.
- Turn the Fixation Tool until the Front Sting (9) is facing upwards.
- Hold the Lower Body (8) and unscrew the Front Sting (9) by turning counterclockwise.
- Hold the Middle Body (4) and unscrew the Lower Body (8) by turning counterclockwise.

- Remove the Lower Body (8) carefully to prevent the Guide Sting (7) from dropping out.
- Remove the Guide Sting (7) from the Middle Body (4).
- Tilt the Middle Body (4) until the Guide Pin (6) and the Guide Spring (5) glide into your hands.
- Remove the Guide Spring (5) from the Guide Pin (6).

Assembly

To assemble proceed in reverse order.

Note: When inserting the Guide Sting into the Middle Body, make sure that it fits into the triangular form of the Middle Body. The Lower Body can only be fully screwed down if the Guide Sting is in the correct position.

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.

Visit www.dentsplysirona.com for more information about Dentsply Sirona and its products.

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