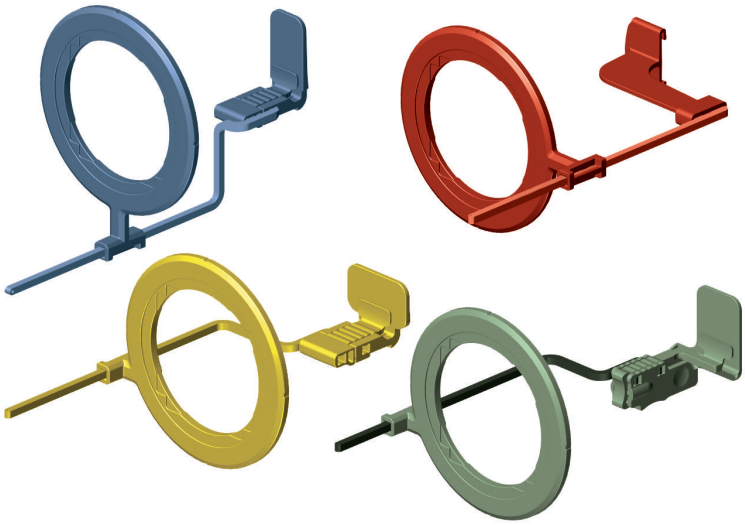
VistaPosition PSP Holder System

RWT01...



EN-US Operating instructions

Rx Only

AIR TECHNIQUES equipped for life®

2130100498L29 G3704 2408V002

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Important information

1 About this document

These operating instructions are an integral part of the product.

The manufacturer shall not be held liable and offers no guarantees of the safe and smooth operation of this product you fail to comply with notes and instructions contained in these Installation and Operating Instructions.

The German version of the operating instructions is the original manual. All other languages are translations of the original manual.
These operating instructions apply to:
- **VistaPosition Anterior (RWT01.1A1)**
  REF: 2130100413
- **VistaPosition Posterior (RWT01.4A1)**
  REF: 2130100414
- **VistaPosition Anterior (RWT01.2A1)**
  REF: 2130100416
- **VistaPosition Anterior (RWT01.3A1)**
  REF: 2130100415

1.1 Warnings and symbols

Warnings

The warning notes in this document highlight possible injury to persons or damage to machinery.
They are marked with the following warning symbols:

General warning symbol

The warnings are structured as follows:

SIGNAL WORD

Description of type and source of danger

Here you will find the possible consequences of ignoring the warning

› Follow these measures to avoid the danger.

The signal word differentiates between different levels of danger:
- **DANGER**
  Direct danger of severe injury or death
- **WARNING**
  Possible danger of severe injury or death
- **CAUTION**
  Risk of minor injuries
- **NOTICE**
  Risk of extensive material/property damage

Miscellaneous symbols

These symbols are used in the document and on or in the unit:

Note, e.g. specific instructions regarding the efficient use of the unit.

Take note of the accompanying electronic documents.

Manufacturer

Distributor

Not sterile

Search

Sterilize with steam at 134 °C

LOT Batch name

MD Medical device

REF Part number

Model number

General Mandatory Sign

Wear hand protection.

Wear eye protection.


Use a mask.


Wear protective clothing.

HIBC Health Industry Bar Code (HIBC)


Recycling

CE mark

Rx Only Caution: By virtue of Federal Law, the device may only be sold to dentists or bought on behalf of a dentist.

Rinse with instrument cleaner.


Keep dry

Comply with the lower and upper humidity limits

Comply with the lower and upper temperature limits


Keep away from sunlight during storage

1.2 Copyright information

All circuits, processes, names, software programs and products mentioned in this document are protected by copyright.
The operating instructions must not be copied or reprinted, neither in full nor in part, without written authorization from the manufacturer.

2 Safety

The product has been developed and designed appropriately such that hazards are largely excluded if it is used in accordance with its intended use.
Despite this, the following residual risks can remain:
- Personal injury due to incorrect use/misuse
- Personal injury due to mechanical effects
- Personal injury due to lack of hygiene, e.g. infection

2.1 Indications for use

The holder system is intended for transient holding of image receptors for intraoral dental radiographs by parallel technique. The holder system is used for the following dental radiographs:
- anterior radiograph
- posterior radiograph
- bitewing radiograph
- endo radiograph

2.2 Contraindications

Patients who are not able to close their mouth in a controlled manner.

2.3 Intended use

The holding system is used for positioning the image receptors in the oral cavity and the correct alignment of the x-ray tube for intraoral dental radiographs in order to prevent repeat exposures. Therefore the anatomy of the patients oral cavity has to be considered appropriate.
The holding system is reusable. It is non-sterile and intended to be reprocessed before use.
The holders may only be used with image receptors approved by the manufacturer.

2.4 Improper use

Any other usage or usage beyond this scope is deemed to be improper.

2.5 General safety information

The sale or prescription of this device by a medical practitioner is subject to the restrictions of the applicable Federal Law. The device may be used only under permanent supervision by a dentist or licensed medical practitioner.

RxOnly Caution: By virtue of Federal Law, the device may only be sold to dentists or bought on behalf of a dentist.

2.6 Patient groups

Adults, adolescents as well as infants whose anatomy of the oral cavity an application allows.

2.7 Specialist personnel

Operating personnel such as dentists and dental staff. Based on their training and expertise, these individuals must be capable of handling the product safely and appropriately.

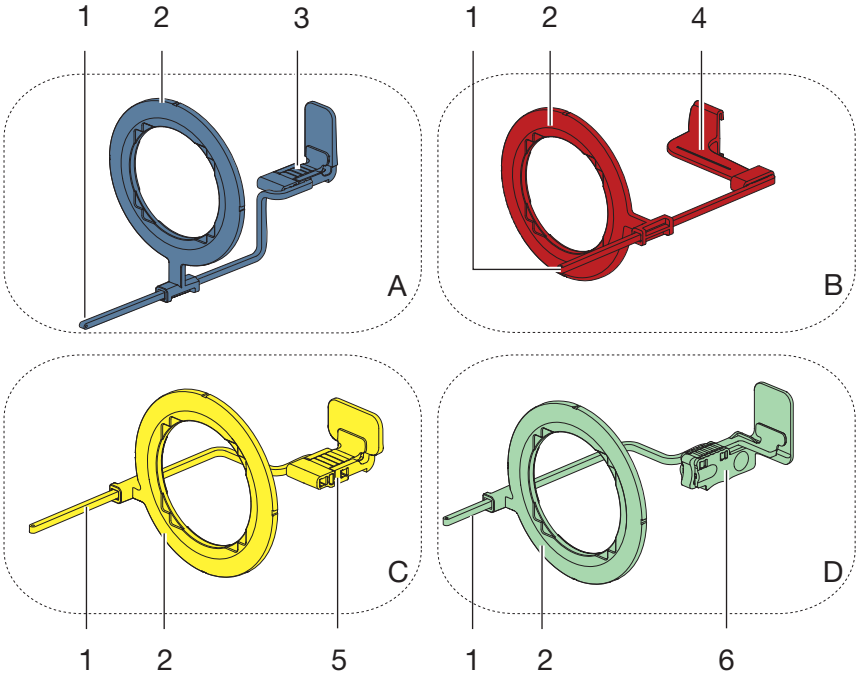
– Instruct or have every user instructed in handling the product.

2.8 Notification requirement of serious incidents

The operator/patient has to report any serious incident related the product to the manufacturer and the competent authority of the Member State, in which the operator and/or patient is established/resident.

Product description

3 Overview



A VistaPosition PSP Anterior/Posterior Kit (Anterior)
B VistaPosition PSP Bitewing Kit
C VistaPosition PSP Anterior/Posterior Kit (Posterior)
D VistaPosition PSP Endo Kit
1 Indicator arm
2 Aiming ring
3 Bite block Anterior *
4 Bite block Bitewing
5 Bite block Posterior *
6 Bite block Endo *

* consisting of fixing element and base element

3.1 Scope of delivery

The following items are included in the scope of delivery (possible variations may apply due to country-specific requirements and/or import regulations):

VistaPosition PSP
Anterior/Posterior Kit Titanium G3710
Anterior/Posterior Kit G3810

- Indicator arms
  - Anterior
  - Posterior
- Bite block Anterior
  - Fixing element
  - Base element
- Bite block Posterior
  - Fixing element
  - Base element
- Aiming rings
  - Anterior
  - Posterior

VistaPosition PSP
Bitewing Kit Titanium G3720
Bitewing Kit G3820

- Indicator arm Bite wing
- Bite block Bitewing
  - Bite wing S0/S1
  - Bite wing S2 Vertical
  - Bite wing S2 Horizontal
  - Bite wing S3
- Color aiming ring Bite wing

VistaPosition PSP
Endo Kit Titanium G3730
Endo Kit G3830

- Indicator arm Endo
- Bite block Endo
  - Fixing element (Endo Q2/Q4)
  - Fixing element (Endo Q1/Q3)
  - Base element (Endo Q2/Q4)
  - Base element (Endo Q1/Q3)
- Aiming ring Endo

3.2 Consumables

Cleaning and disinfection

Monarch Enzymatic Cleaner H6201

4 Technical data

4.1 VistaPosition (RWT01...)

Classification		
Medical Device Class (MDR)		I
FDA classification (CFR Title 21)		I

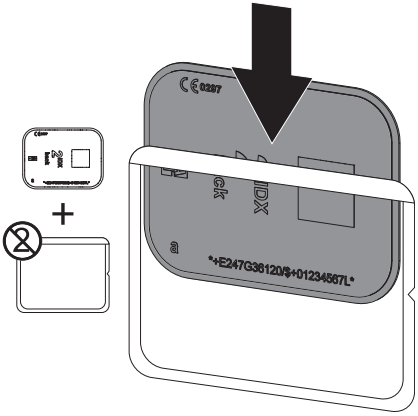
Ambient conditions during storage and transport		
Temperature	°C	-20 to + 60
	°F	-4 to +140
Relative humidity	%	10 - 95

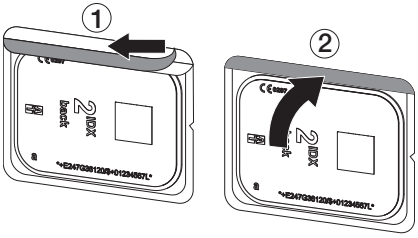
Installation

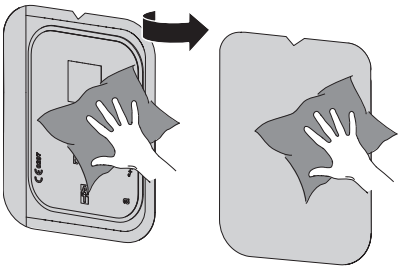
5 Preparation

For more information on how to use phosphor storage plates, please see:

https://qr.duerrdental.com/AirTechniques_IDX-PSP







6 Assembly of components

A light protection cover must be used to preserve the phosphor storage plate and ensure optimum image quality.

Use the phosphor storage plates and light protection covers made by Air Techniques exclusively.

For use, assemble the holder system as follows:

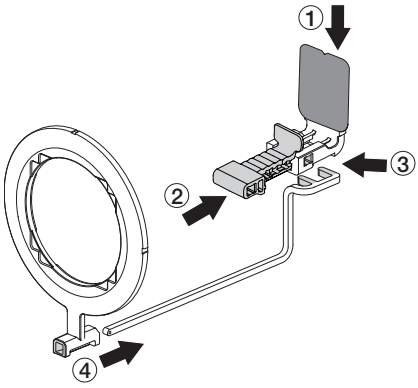
1. Position the phosphor storage plate (Note the position of the phosphor storage plate).
2. Assemble the bite blocks.
3. Insert the pins on the side of the indicator arm into the bite block until they reach the limit stop.
4. Slide the aiming ring onto the indicator arm.

6.1 Anterior/Posterior Kit

Note the following steps when you position the phosphor storage plate and assemble the bite blocks:

Anterior

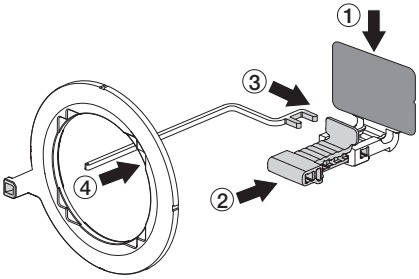
1. Positioning the phosphor storage plate vertically.
2. Slide the fixing element onto the base element and fix the phosphor storage plate in place.



Posterior

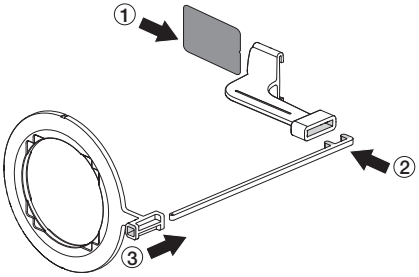
1. Positioning the phosphor storage plate horizontally.

2. Slide the fixation element onto the basic element and fix the phosphor storage plate in place.



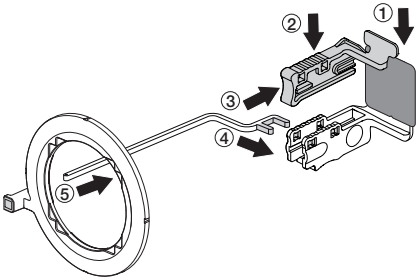
6.2 Bitewing Kit

1. Slide the phosphor storage plate in horizontal orientation into the bite block.
2. Position it in the center.



6.3 Endo Kit

1. Position the phosphor storage plate horizontally or vertically as needed.
2. Place the fixing element onto the base element from above.
3. Slide the fixing element onto the base element and fix the phosphor storage plate in place.



Usage

7 Application

The medical device must be reprocessed before first use and after each subsequent use in accordance with the manufacturer's instructions.

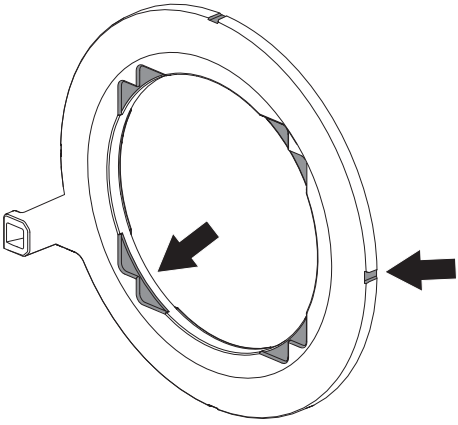
For correct positioning of the holder system, please note the following:

1. Position it in the mouth.
2. Slide the aiming ring as close to the cheek as possible.

For more information on the proper use of the holder system, please see:

https://www.airtechniques.com/product/vistaposition/

If you use a collimator, align the groove (outside) or the recesses (inside) on the aiming ring, as appropriate for the respective model of the X-ray device.



8 Reprocessing

The following components need to be reprocessed:

- **Aiming ring**
  - Pre-cleaning
  - Manual cleaning
  - Automatic cleaning and disinfection
  - Steam sterilization
- **Bite block**
  - Pre-cleaning
  - Manual cleaning
  - Automatic cleaning and disinfection
  - Steam sterilization
- **Indicator arm**
  - Pre-cleaning
  - Manual cleaning
  - Automatic cleaning and disinfection
  - Steam sterilization

In order to prevent damage, use the procedures described above exclusively.

8.1 Risk analysis and classification

A risk analysis and classification of medical devices that are common in dentistry must be performed before they are reprocessed by the operator. Comply with the country-specific guidelines, standards and regulations.

Classification recommendation indicator arm, bite block

Classification recommendation given Intended Use of the product: **semi-critical B**

Classification recommendation aiming ring

Classification recommendation given proper use of the product: **non-critical**

Non-critical medical device:
A medical device that only comes into contact with intact skin.
Semi-critical medical product:
A medical product which comes into contact with mucous membrane or pathologically changed skin.
The operator is responsible for correct classification of the medical products, defining the reprocessing steps and performing the reprocessing.

8.2 Reprocessing procedures

Perform the reprocessing procedure after each patient treatment and according to the reprocessing procedure:
- Pre-cleaning in accordance with AAMI TIR 30.
- Steam sterilization in accordance with ANSI/AAMI ST81.

Important information!

The reprocessing instructions according to FDA Guidance "Reprocessing Medical Devices in Health Care Settings - Validation Methods and Labeling" have been independently verified by the manufacturer for preparation of the device and its components for reuse.

The person conducting the reprocessing is responsible for ensuring that the reprocessing is performed using equipment, materials and personnel that attains the desired results. This requires validation and routine monitoring of the reprocessing process. Any negative consequences resulting from deviation from these instructions by the person conducting the reprocessing are the responsibility of the member of staff performing the reprocessing.

Frequent reprocessing has only a minor effect on the components of the device. The end of the product life cycle is mainly influenced by the amount of wear and tear or damage resulting from its use.

The use of soiled, contaminated and damaged components is at the sole responsibility of the person performing the reprocessing and the operator.

The reprocessing procedure was validated as follows:
- **Pre-cleaning:**
  - Tap water
- **Manual cleaning:**
  - Monarch Enzymatic Cleaner
  - Cleaning brushes
- **Automatic cleaning and disinfection** was performed in accordance with EN ISO 15883 with tested efficacy:
  - Cleaning agent: Neodisher MediClean Forte 0.4 %
  - Washer-disinfector: PG 8535 (Miele)
  - Programs: *Cleaning without neutralization* and *THERMAL DES*
- **Steam sterilization** was performed in accordance with ISO 17665 using the fractionated vacuum procedure:
  - Pre-vacuum: 3 x
  - Sterilization temperature: at least 270 °F (132 °C)
  - Sterilization time: 2 minutes (half-cycle)
  - Drying time: min. 20 minutes
- **Cleaning brush**
  Cleaning brush with nylon bristles, double-sided
  - Number of brush heads: 2
  - Brush material: nylon
  - Brush head length: 1 and 1.4 in
  - Bristle length: 0.2 and 0.4 in
- Example: Interlock cleaning brush, double-sided, green (REF 09098)
  Cleaning brush for lumen
  - Brush head length: 0.7 in
  - Brush head diameter: 0.1 in

  Example: Key Surgical Cleaning Brush, circular (REF 45912)

General information

1. Comply with all national directives, standards and specifications for the cleaning, disinfection and sterilization of medical devices as well as the specific specifications for dental practices and clinics.
2. When selecting the cleaning and disinfectant agents to be used, the information provided (see above) must be followed.

3. Comply with the concentrations, temperatures, residence times and post-rinsing specifications issued by the manufacturer of the cleaning agent and disinfectant.
4. Only use cleaning agents that are non-fixing and aldehyde-free and display material compatibility with the product.
5. Only use disinfectants that are aldehyde-free and display material compatibility with the product.
6. Do not use any rinse aid (danger of toxic residue on the components).
7. Only use freshly-produced solutions.
8. Only use distilled or de-ionized water with a low bacterial count (at least drinking water quality) that is free from facultatively pathogenic microorganisms (e.g. Legionella bacteria).
9. Use clean, dry, oil- and particle-free compressed air.
10. Do not exceed temperatures of 281 °F(138 °F).
11. Subject all devices used (e.g. ultrasonic bath, cleaning and disinfection device (washer-disinfector), sealing device, steam sterilizer) to regular maintenance and inspections.

8.3 Preparation at the operating location


Wear hand protection.


Wear eye protection.


Use a mask.


Wear protective clothing.

WARNING

Risk of infection from contaminated products

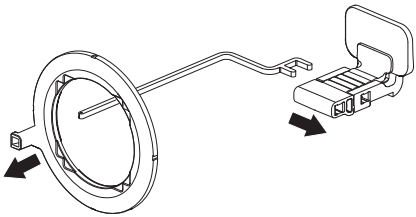
Risk of cross contamination

› Reprocess the product correctly and promptly before its first use and after every subsequent use.

1. Protect the unit from contamination when transporting it from the treatment chair to the reprocessing location.
2. Rinse all components with cold water for 1 minute.

8.4 Disassembly

1. Disassemble the holder system into its individual components (aiming ring, indicator arm, bite block) for reprocessing.

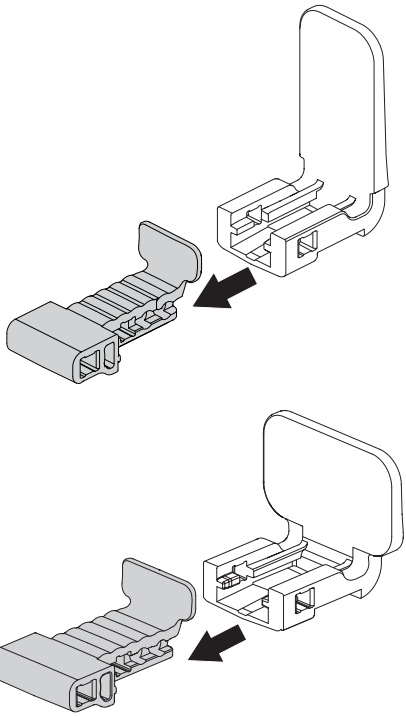


Bite blocks

Dismantle two-part bite blocks into their individual components (fixing element, base element):

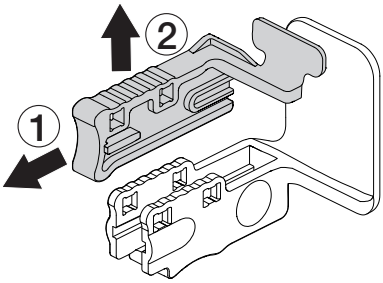
Anterior/Posterior Kit

1. Pull the fixing element out of the base element.



Endo Kit

1. Pull the fixing element out of the base element.
2. Remove the fixing element from above.



8.5 Clean manually, perform a final rinse, dry

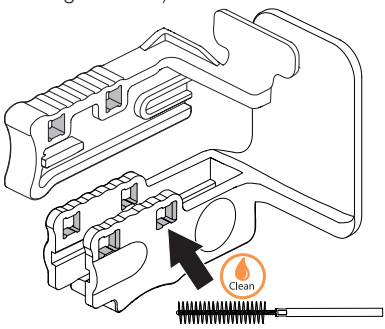
Cleaning agents with the following properties must be used for manual cleaning:

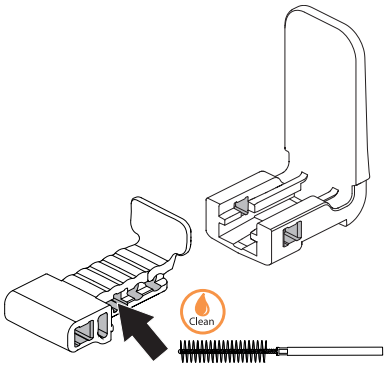
– only cleaning products approved by Air Techniques
– no aggressive or abrasive cleaning agents

For further information, see "General information".

Cleaning

1. Immerse the components in a cleaning bath making sure that all parts are covered.
2. Immerse the components in an ultrasonic bath containing cleaning agent making sure that all parts are covered (optional).
3. Note the action times of the cleaning agents (see "General information").
4. Brush all external and internal surfaces extensively with a hygienic brush below the surface of the ready-to-use solution until they are clean upon visual inspection.
5. Clean the inside of all hollow spaces 5x using the cleaning brush for lumen (see “Cleaning brushes”).





Final rinse

After the action time prescribed by the manufacturer has expired:

1. Rinse all components with water for at least 1 minute (temperature < 95 °F (35 °C)).

Drying

1. If necessary, re-dry at a clean location using a hygienic, lint-free cloth.

8.6 Automatic cleaning, intermediate rinsing, disinfection, final rinse, drying

Selection of the washer-disinfector

Automatic cleaning and disinfection requires a washer-disinfector with the following properties and validated processes:
– Satisfies ISO 15883, with verified efficacy
– Certified program for thermal disinfection (A_0 value ≥ 3000 or a minimum of 5 minutes at 200° F (93 °C))
– Program is suitable for the components and includes sufficient rinsing cycles.
Further information: "General information".

Selection of the machine cleaning agents and disinfectants

The following properties are required:
– Material compatibility with the product
– Compliance with the washer-disinfector manufacturer's specifications

For further information, see "General information".

Automatic cleaning and disinfecting

When arranging the parts in the washer-disinfector, make sure there are no areas missed by rinsing.

1. Place all components in small-component baskets and position these in the washer-disinfector (following the manufacturer's instructions).

8.7 Check for function

1. After the end of the cleaning and disinfection cycle, check the components for any residual soiling and residual moisture. If necessary, repeat the cycle.
2. If necessary, replace any damaged parts.
3. The components should be packaged as soon as possible after drying and checking.

8.8 Steam sterilization

Packing

For packaging of the components, only use sterile barrier systems made of transparent paper film that are approved for use for steam sterilization according to the instructions of the manufacturer. This includes:
– Temperature resistance up to 138 °F
– Standards EN ISO 11607-1/2
– The applicable sections of standard series EN 868

The sterile barrier system must be of sufficient size. The loaded sterile barrier system must not be exposed to any strain.

Steam sterilization

WARNING

Health risk due to improper sterilization

If the sterilization is not performed correctly, it may not be effective. The use of insufficiently sterilized instruments can be a health risk to the patient.

› Only steam sterilization is permissible.
› Comply with all process parameters.
› Comply with the manufacturer‘s instructions regarding the use of the steam sterilizer.
› Do not use any other procedures.

NOTICE

Damage to equipment due to improper sterilization

Product damage may be caused if the sterilization process is not performed correctly.

› Comply with the manufacturer‘s instructions regarding the use of the steam sterilizer.
› Comply with all process parameters.

Steam sterilizer requirements:
- Complies with EN 13060 or EN 285 and/or ANSI AAMI ST79
- Suitable programs for the products listed (e. g. with hollow bodies: fractionated vacuum procedure including three vacuum steps)
- Sufficient drying of the product
- Validated processes in accordance with ISO 17665 (valid IQ/OQ and product-specific performance appraisal (PQ))

Perform the following steps:

1. Sterilize the parts to be sterilized (at least 20 minutes at 250 °F (121 °C), at least 4 minutes at 270 °F (132 °C) or at least 5 minutes at 274 °F (134 °C)).
   Do not exceed a temperature of 281 °F (138 °C) in the process.

Marking

1. Mark the packaged, treated medical device appropriately such as to ensure its safe application.

8.9 Issue clearance for the parts for sterilization

The reprocessing of the medical device ends with the documented clearance for storage and renewed use.

1. Document the release of the medical device after reprocessing.

8.10 Storing parts for sterilization

1. Comply with the stated storage conditions:
   - Store the parts protected against contamination
   - Dust-protected, e.g. in a locked cabinet
   - Protected against moisture
   - Protected against excessive temperature fluctuations
   - Protected against damage

   The integrity of the packaging of a sterile medical device be lost as a result of a particular incident and the passage of time. Potential external contamination of the sterile barrier system should be taken into account in terms of aseptic preparation when establishing the storage conditions.

Assemble components that will come into contact with the patient immediately before use.

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