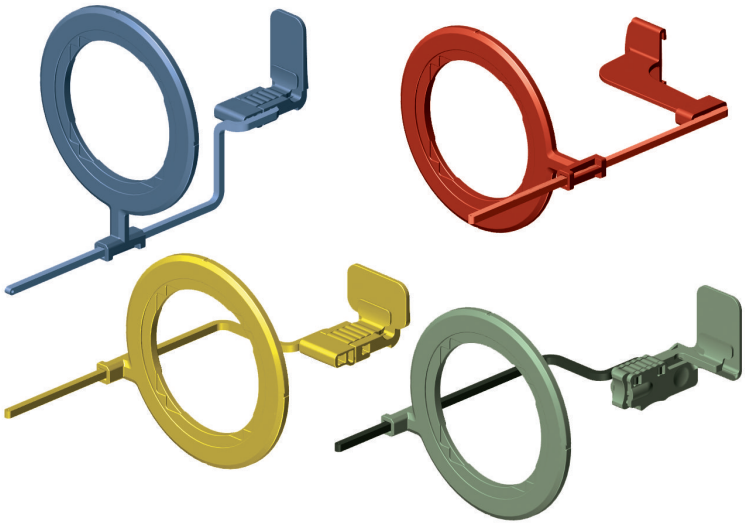
VistaPosition PSP Holding System

RWT01...



EN Operating instructions

CE

DÜRR DENTAL

2130100384L02 2408V003

Contents

Important information

Product description

Assembly

Usage

Appendix

Important information

1 About this document

These operating instructions form part of the product.

If the instructions and information in these operating instructions are not followed, Dürr Dental will not be able to offer any warranty or assume any liability for the safe operation and the safe functioning of the product.

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 (RWT01.1D1)**
  REF: 2130100329
- **VistaPosition Posterior (RWT01.4D1)**
  REF: 2130100330
- **VistaPosition Bitewing (RWT01.2D1)**
  REF: 2130100333
- **VistaPosition Endo (RWT01.3D1)**
  REF: 2130100332

1.1 Warnings and symbols

Warnings

The warnings in this document are intended to draw your attention to possible injury to persons or damage to machinery.
The following warning symbols are used:

General warning symbol

The warnings are structured as follows:

SIGNAL WORD

Description of the 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 four levels of danger:
- **DANGER**
  Immediate 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

Other symbols

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

Note, e.g. specific instructions regarding efficient and cost-effective use of the unit.

Refer to the accompanying electronic documents.

Manufacturer

CE labelling

Conformity mark for the United Kingdom of Great Britain and Northern Ireland

CH REP Authorised representative for Switzerland

Ukrainian conformity mark

Search

NON STERILE Not sterile

134 °C Steam sterilise at 134 °C

LOT Lot designation

MD Medical device

REF Order number

Model number

HIBC Health Industry Bar Code (HIBC)


Recycling


General mandatory sign


Wear protective gloves.


Wear protective goggles.


Use a mask.


Use protective clothing.

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

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 authorisation from Dürr Dental.

2 Safety

The product has been developed and designed in such a way that dangers are effectively ruled out if used in accordance with the 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 Intended purpose

The holder system is intended for transient holding of image receptors for intraoral dental radiographs by parallel technique.

2.2 Indications

The holder system is used for the following dental radiographs:
– anterior radiograph
– posterior radiograph
– bitewing radiograph
– endo radiograph

2.3 Contraindication

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

2.4 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.

2.5 Improper use

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

2.6 Patient groups

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

2.7 Specialist personnel

Operating persons for the product are dentists and dental personnel. They must ensure safe and appropriate handling on the basis of their training and know-how.

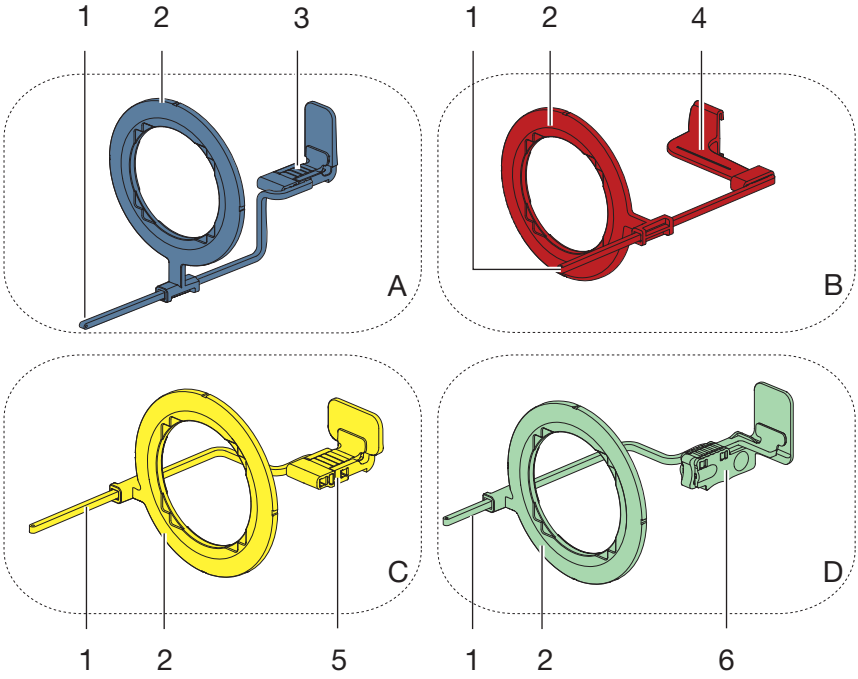
– Instruct or have every user instructed in handling the product.

2.8 Notification requirement of serious incidents

The operator/patient is required to report any serious incident that occurs in connection with the device to the manufacturer and to 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 variant-specific deviations due to country-specific requirements and/or import regulations):

VistaPosition PSP

Anterior/Posterior Kit Titanium . . 2130100500
Anterior/Posterior Kit 2130101500

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

VistaPosition PSP

Bitewing Kit Titanium 2130100600
Bitewing Kit 2130101600

- Indicator arm bite wing
- Bitewing bite block
  - Bite wing S0/ S1
  - Bite wing S2 horizontal
  - Bite wing S3
- Aiming ring bite wing

VistaPosition PSP

Endo Kit Titanium 2130100700
Endo Kit 2130101700

- Endo indicator arm
- Endo bite block
  - Fixing element (Endo Q2/Q4)
  - Fixing element (Endo Q1/Q3)
  - Base element (Endo Q2/Q4)
  - Base element (Endo Q1/Q3)
- Endo aiming ring

VistaPosition PSP

Universal Kit 2130101800

- Indicator arms
  - Anterior
  - Posterior
  - Bitewing
- Aiming rings
  - Anterior
  - Posterior
  - Bitewing
- Anterior bite block
  - Fixing element
  - Base element
- Posterior bite block
  - Fixing element
  - Base element
- Bitewing bite block
  - Bite wing S2 horizontal

3.2 Consumables

Cleaning and disinfection

ID 212
Instrument disinfection CDI212C6150

4 Technical data

4.1 VistaPosition (RWT01...)

Classification		
Medical Device Class (MDR)		I

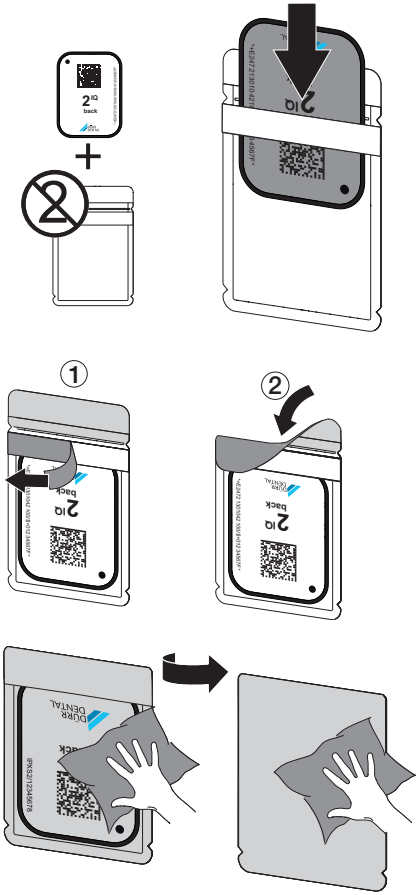
Ambient conditions during storage and transport		
Temperature	°C	-20 to 60
	°F	-4 to +140
Relative humidity	%	10 - 95

Assembly

5 Preparation

More information on the use of image plates can be found in the download centre at:

http://qr.duerrdental.com/2130100137



6 Assembling components

To preserve the image plates and for optimum image quality the light protection cover must always be used.

Only use the image plates and light protection covers manufactured by Dürr Dental.

Assemble the holding system for use as follows:

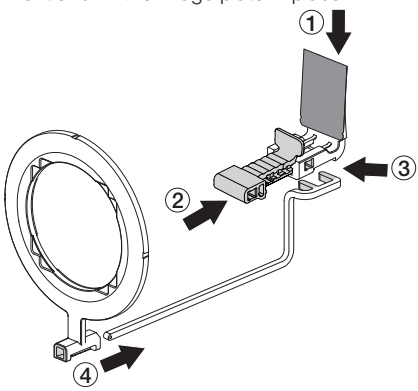
1. Position the image plate (pay attention to the position of the image plate).
2. Assemble the bite blocks.
3. Insert the pins on the side of the indicator arm into the bite block as far as they will go.
4. Slide the aiming ring onto the indicator arm.

6.1 Anterior/Posterior Kit

Observe the following steps for positioning the image plate and assembling the bite blocks:

Anterior

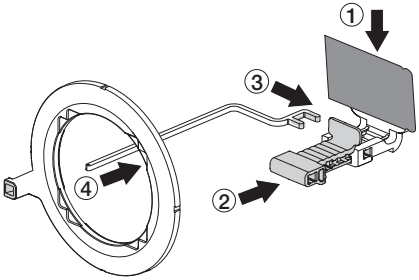
1. Attach the image plate vertically.
2. Slide the fixing element onto the base element and fix the image plate in place.



Posterior

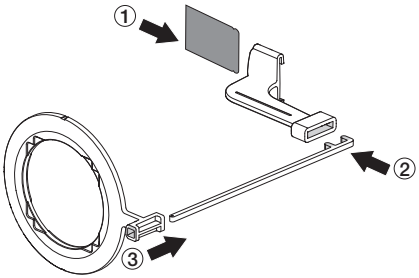
1. Attach the image plate horizontally.

2. Slide the fixing element onto the base element and fix the image plate in place.



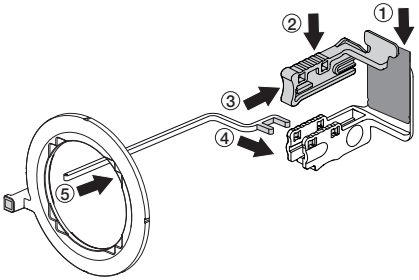
6.2 Bitewing Kit

1. Push the image plate horizontally into the bite block.
2. Position in the centre.



6.3 Endo Kit

1. Position the image plate horizontally or vertically as required.
2. Place the fixing element on the base element from above.
3. Slide the fixing element onto the base element and fix the image plate in place.



Usage

7 Application

The medical device must be prepared and conditioned prior to the first and after every subsequent application in accordance with the manufacturer's information.

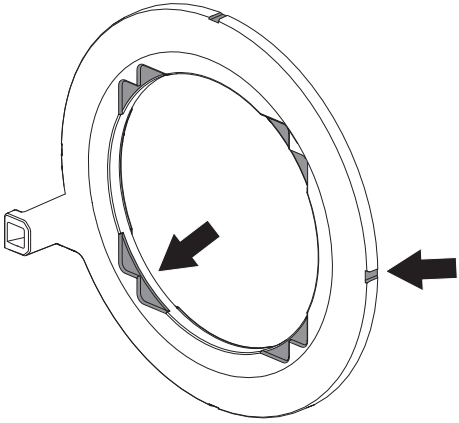
Observe the following points for the correct positioning of the holding system:

1. Place in the oral cavity.
2. Slide the aiming ring as close to the cheek as possible.

More information on the correct use of the holding system can be found at:

www.duerrdental.com/intraoral-positioning

When using a collimator, align the groove (external) or the recesses (interior) on the aiming ring according to the respective model of the X-ray unit.



8 Reprocessing

The following components need to be reprocessed:

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

In order to prevent damage, only the methods described above must be used.

8.1 Risk analysis and categorisation

A risk analysis and categorisation of medical products often used in dentistry must be performed before their reprocessing by the operator. Comply with all national directives, standards and specifications such as e. g. the "Recommendations from the Commission for Hospital Hygiene and Infection Prevention".

Classification recommendation indicator arm, bite block

Classification recommendation given intended use of the product: **semi-critical B**

Classification recommendation aiming ring

Classification recommendation given intended 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 affected skin.
The operator is responsible for correct classification of the medical products, defining the reprocessing steps and performing the reprocessing.

8.2 Preparation process in accordance with ISO 17664

Carry out the procedure for reprocessing after every treatment in accordance with the preparation process set out in ISO 17664.

Important information!

The reprocessing notes in accordance with ISO 17664 have been independently tested by Dürr Dental for the preparation of the product and its components for their reuse.

The person conducing the reprocessing is responsible for ensuring the reprocessing performed using the equipment, materials and personnel achieves the desired results. This requires validation and routine monitoring of the reprocessing process. Any deviation from the instructions described herein by the staff preparing the equipment could lead to lower effectiveness and possible negative consequences: these lie solely with the staff responsible.

Frequent reprocessing has little effect on the device components. The end of the product life cycle is especially 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**
  - ID 212 Instrument disinfection (Dürr Dental)
  - Cleaning brushes
- **Manual disinfection**
  - ID 212 Instrument disinfection (Dürr Dental)
- **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)
  - Programmes: "Cleaning without neutralisation" and "THERMAL DES"
- **Steam sterilisation**
  was performed in accordance with EN ISO 17665 with the fractionated vacuum procedure.
  - Pre-vacuum: 3 x
  - Sterilisation temperature: 132°C
  - Sterilisation time: 1.5 minutes (half-cycle)
  - Drying time: min. 20 minutes
- **Cleaning brushes**
  Cleaning brush with nylon bristles, double-sided
  - Number of brush heads: 2
  - Brush material: nylon
  - Brush head length: 25 and 35 mm
  - Brush length: 5 and 10 mm

  Example: Interlock cleaning brush double-sided green (REF 09098)
  Cleaning brush for lumen
  - Brush head length: 18 mm
  - Brush head diameter: 3 mm

  Example: Key Surgical cleaning brush, round (REF 45912)

General information

1. Comply with all national directives, standards and specifications for the cleaning, disinfection and sterilisation of medical products as well as the specific specifications for dental practices and clinics.

2. Comply with the specifications (see "8.5 Manual cleaning, intermediate rinsing, disinfection, final rinse, drying" and "8.6 Automatic cleaning, intermediate rinsing, disinfection, final rinse, drying") when selecting the cleaning and disinfectant agents to be used.
3. Comply with the concentration, temperature, residence time and post-rinsing specifications issued by the manufacturer of the cleaning and disinfectant agent.
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 deionised 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 138 °C.
11. Subject all devices used (ultrasonic bath, cleaning and disinfection device (CD), sealing device, steam steriliser) to regular maintenance and inspections.

8.3 Preparation at the operating location


Wear protective gloves.


Wear protective goggles.


Use a mask.


Use protective clothing.

WARNING

Risk of infection from contaminated products

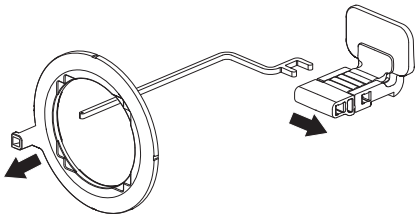
Danger of cross contamination

› 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 holding system into its individual pieces (aiming ring, indicator arm, bite block) for reprocessing.

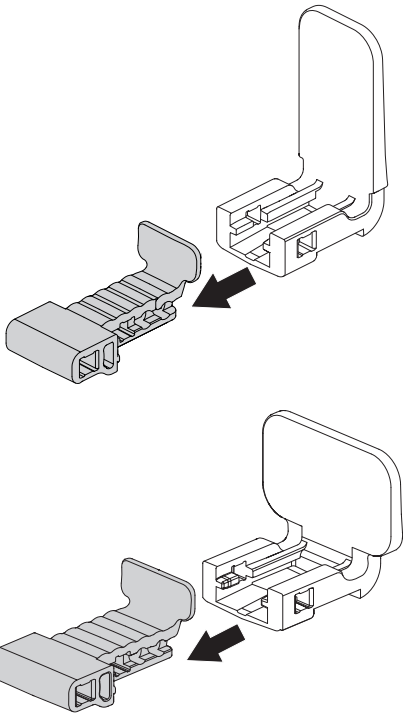


Bite blocks

Disassemble two-piece bite blocks into their individual components (fixing element, base element):

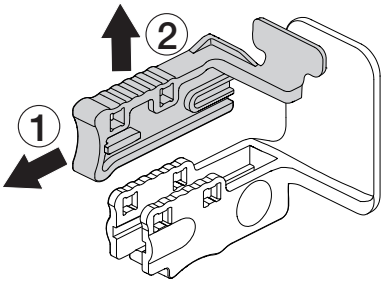
Anterior/Posterior Kit

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 Manual cleaning, intermediate rinsing, disinfection, final rinse, drying

A disinfectant or combined cleaning and disinfectant agent is required for manual disinfection. It must have the following properties:

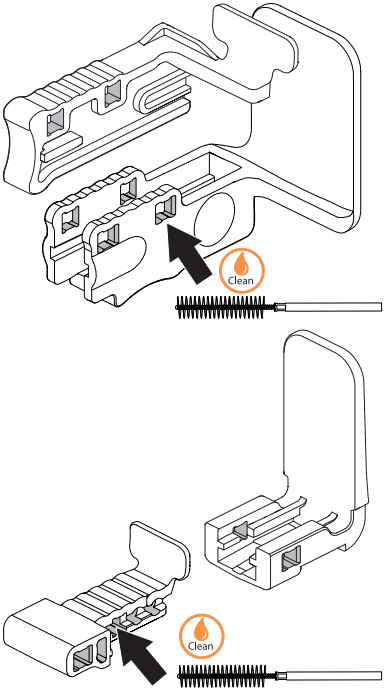
– certified, possibly virucidal efficacy (DVV/RKI, VAH or European Standards)

For further information, see: "General information".

Cleaning

1. Place the individual components in a disinfectant bath (non-fixing/aldehyde-free, see "General information") so that all parts are covered.
2. Place the components in an ultrasonic bath containing cleaning agent and disinfectant (non-fixing/aldehyde-free, see "General information"), making sure that all parts are covered (optional).
3. Comply with the reaction times of the cleaning and disinfecting agents (see "General information").
4. Brush all exterior and interior surfaces completely with a hygienic brush under the surface of the ready-to-use solution, until visibly clean.

5. Clean cavities 5x per lumen with a cleaning brush for lumen (see “Cleaning brushes”).



Intermediate rinsing

After the action time prescribed by the manufacturer:

1. Rinse off all components under water for at least 1 minute (temperature < 35°C).

Disinfection

1. Place individual components in a cleaning and disinfectant bath so that all parts are covered.
2. Note the action time for the disinfectant.

Final rinse

After the action time prescribed by the manufacturer:

1. Rinse off all components under water for at least 1 minute (temperature < 35°C).

Drying

1. Dry all components in 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:

– Corresponds to and tested in accordance with ISO 15883
– Certified program for thermal disinfection (A_0 value ≥ 3000 or at least 5 minutes at 93°C)
– Programme is suitable for the components and provides sufficient rinsing cycles.
  For more information: "General information".

Selection of the machine cleaning agents and disinfectants

The following properties are required:

– Material compatibility with the product
– Corresponds with the manufacturer's specifications of the CD

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 parts baskets and put in the washer-disinfector (follow 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 sterilising

Packing

For packaging of the components, use only sterile barrier systems made of transparent paper film that are approved for use in steam sterilisation according to the manufacturer information. This includes:

- Temperature resistance up to 138°C
- Standards EN ISO 11607-1/2
- The applicable sections of the standard series EN 868

The sterile barrier system must be large enough. Once it is loaded, the sterile barrier system must not be under any strain.

Steam sterilising

WARNING

Health risk due to incorrect sterilisation

If the sterilisation not performed correctly, it may not be effective. The use of instruments that have not been properly sterilised can pose a health risk to the patient..

- › Only steam sterilisation must be used.
- › Comply with all of the specified process parameters.
- › Comply with the manufacturer's instructions regarding use of the steam steriliser.
- › Do not use any other methods.

NOTICE

Damage to equipment due to incorrect sterilisation

If the sterilisation process is not performed correctly, this can cause damage to the product.

- › Comply with the manufacturer's instructions regarding use of the steam steriliser.
- › Comply with all of the specified process parameters.

Requirements placed on the steam steriliser:

- Corresponds to EN 13060 or EN 285 and/or ANSI AAMI ST79
- Suitable programme for the products listed (e. g. with hollow bodies, fractionated vacuum procedure in three vacuum steps)
- Sufficient product drying
- Validated process in accordance with ISO 17665 (valid IQ/OQ and product-specific performance appraisal (PQ))

Perform the following steps:

1. Sterilise the parts for sterilisation(at least 20 minutes at 121°C, at least 4 minutes at 270°F or at least 5 minutes at 134°C).
   Do not exceed 138°C.

Marking

1. Mark the packaged, treated medical product in such a way as to ensure safe application.

8.9 Issue clearance for the parts for sterilisation

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

1. Document the clearance of the medical product after reprocessing.

8.10 Storing parts for sterilisation

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

   Packaging for a sterile medical device can suffer damage 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 the components with patient contact immediately before use.

Appendix

9 Country representatives

Country		Address
GB	UK CA	**UK Responsible Person:** Duerr Dental (Products) UK Ltd. 14 Linnell Way Telford Way Industrial Estate Kettering, Northants NN 16 8PS
CH	CH REP	**Schweizer Bevollmächtigter:** DÜRR DENTAL SCHWEIZ AG Grabenackerstraße 27 8156 Oberhasli Switzerland
UA		**Уповноважений представник в Україні:** Приватне підприємство “Галіт” вул. 15 квітня, 6Є, с. Байківці, Тернопільський р-н, 47711, Україна тел.: 0800 502 998; +38 050 338 10 64 www.galit.te.ua; e-mail: office@galit.te.ua Виробник: Дюрр Дентал ЕсЕ Хьопфігхаймер Штрассе 17, Д-74321 Бітігхайм-Біссінген, Німеччина email: info@duerrdental.com
CN		**备**案人/生**产**企**业**： DÜRR DENTAL SE 德国迪珥**齿**科股份公司 住所/生**产**地址： Höpfigheimer Str. 17, 74321 Bietigheim-Bissingen, Germany **联**系方式： **电话**： + 49 7142 705-0 **邮**箱： info@duerrdental.com 网址： www.duerrdental.com 代理人/售后服**务单**位：迪珥医**疗**器械（上海）有限公司 住所：上海市**长**宁区天山路 641 号 2 号楼 (20 幢) 303 室 **联**系方式： **电话**：+ 86 21 6381 0270 **传**真：+ 86 21 6381 0290 **邮**箱：info@duerr.cn 网址：http://www.duerrdental.com

Hersteller / Manufacturer:

DÜRR DENTAL SE
Höpfigheimer Str. 17
74321 Bietigheim-Bissingen
Germany
Fon: +49 7142 705-0
www.duerrdental.com
info@duerrdental.com

DÜRR DENTAL