EN

# CITO mini®

## Surgery + Prosthetics Manual.

DENTAURUM IMPLANTS

# Content.

## Treatment procedure



## Dental technical variants



## General instructions



## Reusability of surgical instruments

# Safety notes.

## Manufacturer.

Dentaurum Implants GmbH
Turnstr. 31 I 75228 Ispringen I Germany

## Brief description.

CITO mini® implants are designed for insertion in the endosteal region of the maxilla or mandible. Depending on the indication, the relevant matrixes with the appropriate degrees of freedom are secured on the 1.8 mm ball diameter implants and fitted with a prosthetic restoration. The CITO mini® implant system contains specially coordinated instruments, abutments and accessories for insertion of the implant and fabrication of the prosthetic restoration. Only original components of the CITO mini® implant system should be used in combination according to the instructions for use/manual.

## Further information.

Though insertion of dental implants has a high rate of success and implants have a high survival rate, successful treatment cannot be guaranteed. The operator should note and document any problem cases and inform the manufacturer.

An inadequate number of implants, implants with an insufficient length or diameter, unfavourable positioning of the implants or an unstable prosthetic restoration can cause fatigue fracture in implants, abutments and prosthetic screws under biomechanical loading. The particular oral situation should be taken into account during implant insertion and fabrication of the prosthetic restoration to avoid overloading the components.

Use of components in combinations that are not clearly defined in the instructions for use/manual can also cause mechanical failure, damage to the tissue or unsatisfactory aesthetic results.

CITO mini® implants are not known to have any side effects or cause any interaction. It cannot, however, be ruled out that in rare cases allergies to components used in the materials of the CITO mini® implant system may occur or that there may be electrochemically induced discomfort.

## Application, availability, precautions, documentation.

The CITO mini® product range is supplied exclusively to doctors, dentists and dental technicians. It should only be used by doctors, dentists or dental technicians who are familiar with dental implantological procedures, including diagnosis, preoperative planning, surgical technique and prosthetic treatment.

Before using the system, operators should ensure that they have carefully read and understood all the information in the instructions for use / manuals. Operators are also strongly advised to attend one of the training courses on the CITO mini® system offered by Dentaurum Implants to learn the correct techniques because the instructions for use/user manuals cannot cover all possible clinical situations to allow immediate use.

When choosing the number of implants to be inserted, it is important to consider the bone quality and whether the implants will be loaded immediately. To fixate total prostheses, Dentaurum Implants recommends at least four implants in the mandible and six implants in the maxilla.

When positioning the implants, adhere to the minimum distance between the implants. Consider the size of the female part (matrix) of the connection.
Immediate implant loading is only possible, if a torque of 35 Ncm was reached during insertion. The torque of 40 Ncm should not be exceeded during insertion.

- Refer to the Base Folder and Surgery + Prosthetics Manual for information on precautionary measures and the selection of components for the prosthetic procedure.

**Before using this product, the operator must give the patient a thorough examination and a detailed explanation of the procedure. Dentaurum Implants recommends full clinical, radiological, photographic and statistical documentation.**
**The CITO mini® implant system components used can be documented in the patient file with the additional labels. The operator should ensure the products cannot be aspirated during intraoral use.**

Not all components are available in all countries.

## Quality, warranty, liability, development.

Development, clinical testing, production and quality control of the CITO mini® product range are in accordance with the Medical Device Directive 93/42/EEC.

Sections 9 and 10 of our General Terms of Delivery and Payment apply with regard to warranty and liability – unless otherwise stated in the instructions for use/ manuals.

Warranty and liability are rendered void if the products are not used by the operator or a third party in accordance with the instructions for use; this also applies if the CITO mini® product range is used in conjunction with the products of other manufacturers which have not been specifically recommended for use by Dentaurum Implants.

Dentaurum Implants has no control over processing and application of the product, which are the sole responsibility of the user.

Technical advice (oral and written) is based on the scientific and technical knowledge available when the product is put on the market. It does not release the user from the responsibility of personally checking the suitability of the products for the intended indication and application. Advice is only given as a non-binding recommendation, which cannot be assumed to provide any form of assurance or guarantee.

All products are subject to continuous development based on current scientific knowledge and we reserve the right to make changes in the construction, design or material of the products.

# The CITO mini® implant system.

Polished gingival shoulder.

Optimal soft tissue support.

Crestal fine thread.

Time-tested surface conditioning.

FEM-optimized thread geometry[1].

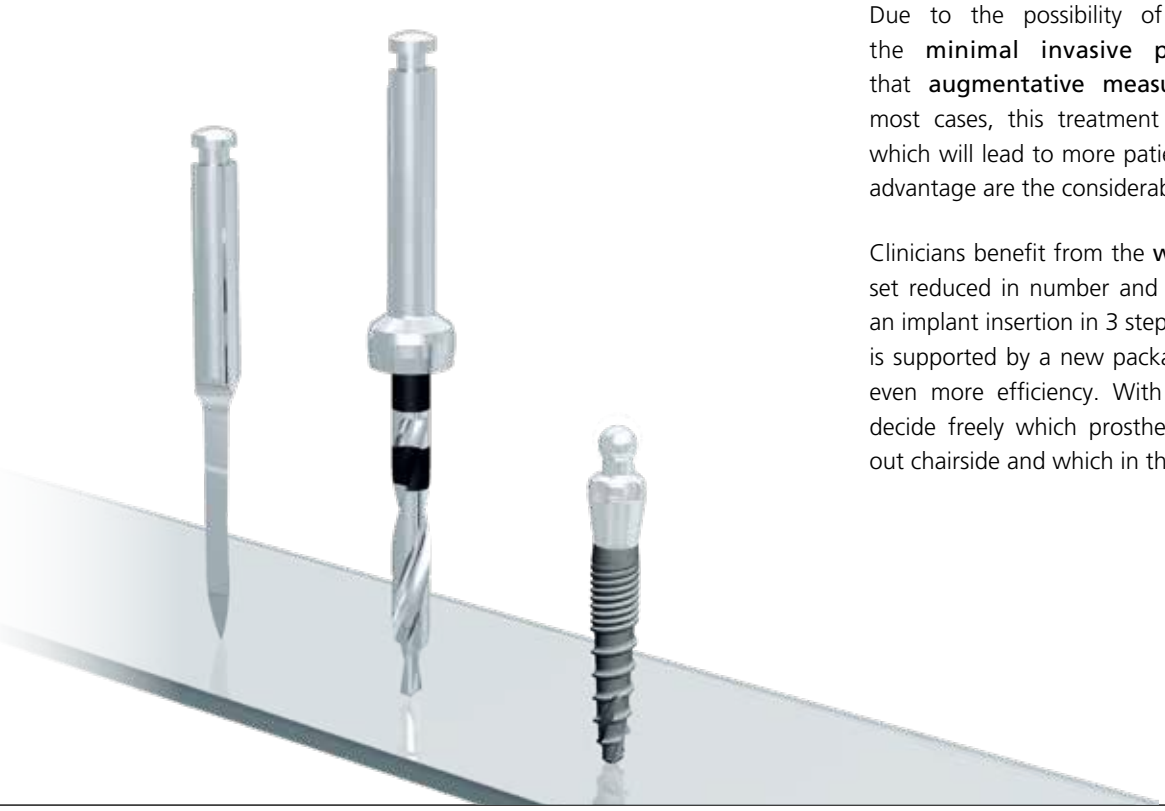
Self-tapping thread.

[1] I. Hasan, C. Bourauel: Biomechanische Untersuchungen des Einflusses von Geometrievarianten des CITO mini® Implantats [Biomechanical analyses of the influence of CITO mini® implant geometry variations]; University of Bonn 2014.

# CITO mini®

## CITO mini® – the solution for patients and clinicians.

Building on 25 years of experience in oral implantology, Dentaurum Implants has created the CITO mini® implant family.



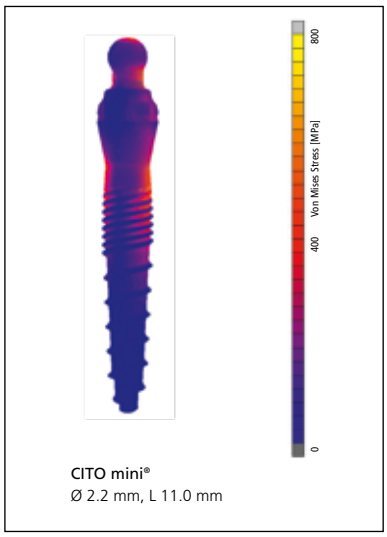
These small diameter implants are designed especially for patients with **reduced bone availability**. They can now be treated with implant-supported partial and total prostheses and benefit from the advantages. As an **immediate implant loading** is possible in many cases, patients can enjoy their new quality of life a lot sooner.

Due to the possibility of **transgingival insertion**, the **minimal invasive procedure** and the fact that **augmentative measures can be avoided** in most cases, this treatment causes less patient stress, which will lead to more patients agreeing to it. Another advantage are the considerably **lower costs**.

Clinicians benefit from the **well-organized instrument** set reduced in number and still **variable**, which allows an implant insertion in 3 steps. This **efficient procedure** is supported by a new packaging concept, that enables even more efficiency. With CITO mini®, clinicians can decide freely which prosthetic steps should be carried out chairside and which in the laboratory.

# The CITO mini® implant.

FEM-optimized implant shape and
thread geometry for optimal load distribution.[1]




CITO mini®
Ø 2.2 mm, L 11.0 mm

## CITO mini® implant.

The CITO mini® implant shape and the thread geometry were calculated using FEM analyses[1]. These tests show a uniform, gentle loading of the bone which prevents local overloading and stress peaks that could damage the bone.

CITO mini® implants have a cylindrical-conical external geometry. The polished gingival shoulder provides optimal gingival contouring.

The self-tapping thread and the thread pitch of the CITO mini® implants enable a quick and atraumatic implant insertion at a steady insertion torque and a high primary stability. The endosseous region of the CITO mini® implant has a blasted and etched surface.

[1] I. Hasan, C. Bourauel: Biomechanische Untersuchungen des Einflusses von Geometrievarianten des CITO mini® Implantats [Biomechanical analyses of the influence of CITO mini® implant geometry variations]; University of Bonn 2014.

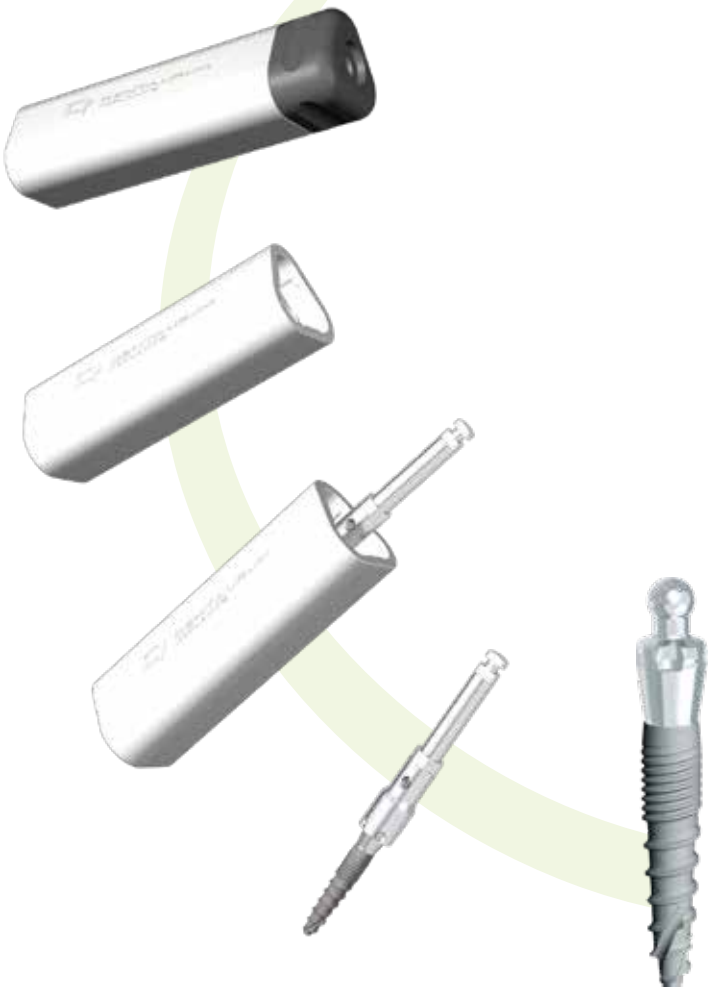
3 steps to success.

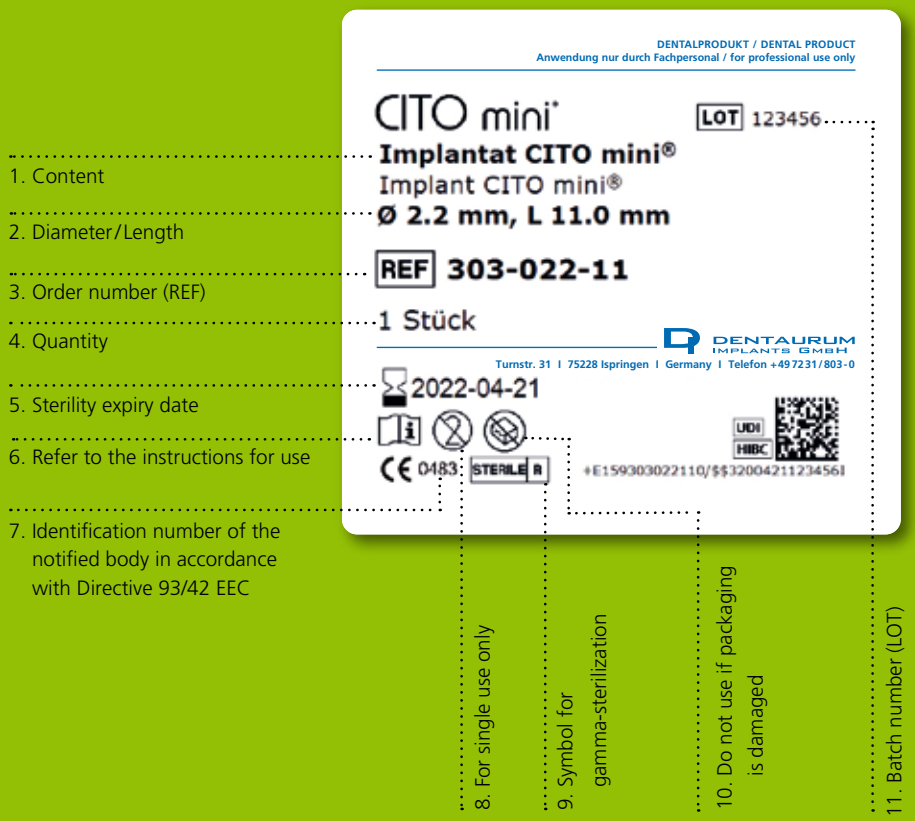
## Surgical tray for CITO mini®.

The instrument set of the surgical tray for CITO mini® provides maximum flexibility during implant site preparation while reducing the number of instruments. The drilling protocol for the CITO mini® instruments thus enables atraumatic, minimal invasive preparation specially tailored to the bone quality and individual regulation of the drilling depth for attaining the maximum primary stability of the implant with only one drill.

Not all items shown are included in the tray at delivery.

# The packaging system.






## Sterile packaging system.

All CITO mini® implants are supplied individually in gamma-sterilized double packaging. They are intended for single use only.The double packaging (foil and blister packaging) protects the inner container with the sterile implant against contamination. The contents remain sterile as long as the packaging is undamaged. The product should not be used if the double packaging is damaged.

It can be removed and placed directly contact-free with the PentaGrip insertion key. If necessary, a manual insertion can be performed using an intermediate adaptor.

The label on the outer packaging gives the order number, the description, length and diameter of the implant, the sterility expiry date and LOT number. There are four additional labels in the packaging with peel-off REF and LOT numbers for documentation in the patient file and the surgical protocol.

# Diagnosis and planning.

## General instructions.

### Indications.

CITO mini® implants help stabilize the denture in an edentulous maxilla or mandible. The possible benefits and disadvantages as well as the risks involved in implant treatment and alternative treatments should be taken into account when considering whether implant treatment is indicated.

In any implantological case the implant diameter and length of the CITO mini® implants should be in proportion to the prosthetic restoration

When choosing the number of implants to be inserted, it is important to consider the bone quality and whether the implants will be loaded immediately. To fixate total prostheses, Dentaurum Implants recommends at least four implants in the mandible and six implants in the maxilla*.

The insertion of CITO mini® implants in soft bones is not indicated. With restorations in the maxilla with CITO mini® implants, ø 2.2 mm, ø 2.5 mm must be used.

When positioning the implants, adhere to the minimum distance between the implants. Consider the size of the female part (matrix) of the connection**.

Immediate implant loading is only possible, if a torque of 35 Ncm was reached during insertion. The torque of 40 Ncm should not be exceeded during insertion.

* see planning template CITO mini® (989-502-45) or go to www.dentaurum.de

** Take here also the size of the matrix into consideration

This section provides a general overview of diagnosis and planning. For more detailed information on these aspects refer to current literature. Implantologists and dental technicians with many years of experience are available to answer any questions that you may have.

The integrated training programme also ensures that all the dentists, dental technicians and dental assistants involved in the implant procedure are optimally prepared by experienced lecturers. Dentaurum Implants provides numerous training courses at different levels tailored to the target group, level of knowledge and individual interests.

## Contraindications.

General contraindications for dental surgery apply. These include:

- reduced immunodeficiency
- steroid treatment
- blood coagulation disorders
- uncontrolled endocrine diseases
- rheumatic disorders
- bone system diseases
- cirrhosis of the liver
- drug, alcohol or tobacco abuse
- depression, psychopathic disorders
- poor patient compliance
- chronic inflammatory diseases

**Local contraindications / personal contraindications.**

- osteomyelitis
- radiotherapy in the head region
- recurring mucosal diseases
- temporomandibular joint dysfunctions
- parafunctions
- lack of vertical or horizontal bone availability, jaw defects, inadequate bone quality
- poor oral hygiene

It should be taken into account that these contraindications may be long or short term depending on the extent, duration and individual conditions. The current position of scientific implantological associations relating to indications and contraindications and current literature should be taken into consideration when planning implant treatment.

# Treatment procedure.

Rotary instruments.

## General information.

When choosing the number of implants to be inserted, it is important to consider the bone quality and whether the implants will be loaded immediately. To fixate total prostheses, Dentaurum Implants recommends at least four implants in the mandible and six implants in the maxilla.

When positioning the implants, adhere to the minimum distance between the implants. Consider the size of the female part (matrix) of the connection.

The CITO mini® implant must be surrounded by at least 1.0 mm of bone according to the implant diameter and inserted over the entire blasted and etched part.

Immediate implant loading is only possible, if a torque of 35 Ncm was reached during insertion. The torque of 40 Ncm should not be exceeded during insertion.
Rotary instruments required for the preparation of the implant site and their drilling sequence must be selected depending on the bone quality.

There is a preparation protocol (p. 18 and 19) for the user that is tailored to different bone qualities (soft, middle, dense). It is the responsibility of the user to determine the bone quality.

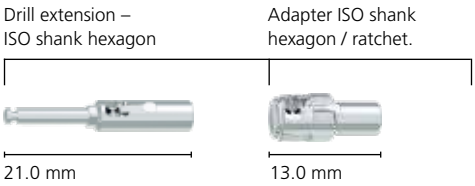
## Instruments.

The handpiece instruments can also be used manually as required using an adapter (max. permitted torque 40 Ncm). The instruments should be inserted rotationally secure and the fit checked. The manual adapter can be used with the torque ratchet set at the relevant torque.

Components should be secured with a sterile safety cord to prevent aspiration during use.

## Exposing.

The mucosa is cut through with a mucosa punch (e.g. Dentaurum, REF 307-001-00) and removed. When placing implants in the mandible, the position of the foramina mentales must be clarified.




## Marking drill.

To illustrate the exact functionality of every rotating instrument, hereafter the preparation is explained independently to the bone quality.

Thin crestal bone in the region of implant insertion can be smoothed slightly with a round bur.

The insertion point of the CITO mini® implant can be marked using the marking drill.

Preparation is continued using the appropriate stepped drill depending on the diameter of the implant.

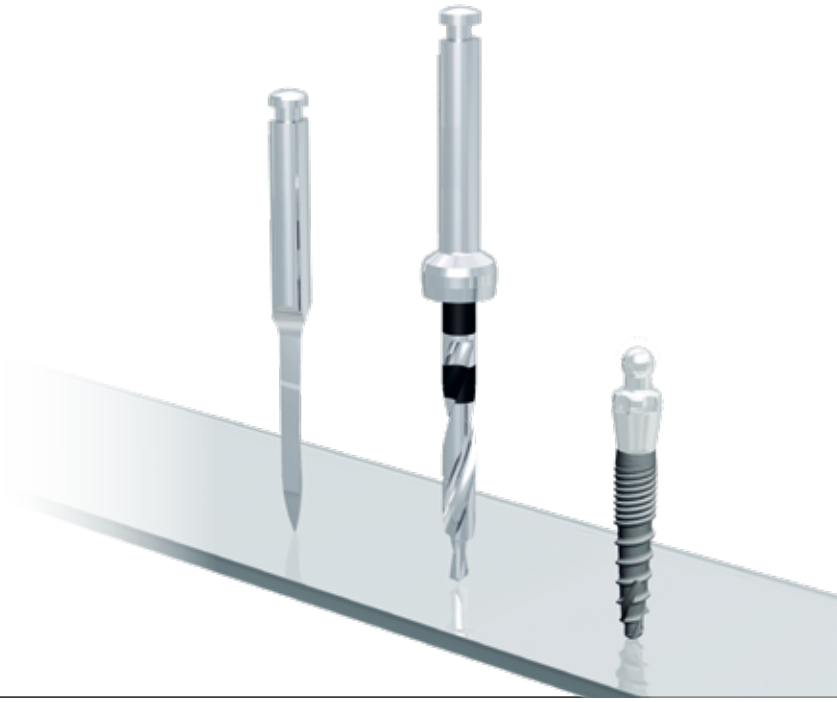
The green handpiece (500 – 800 $min^{-1}$) is used for drilling with external cooling using a sterile, cooled physiological saline solution (5 °C / 41 °F).

## Stepped countersinking.

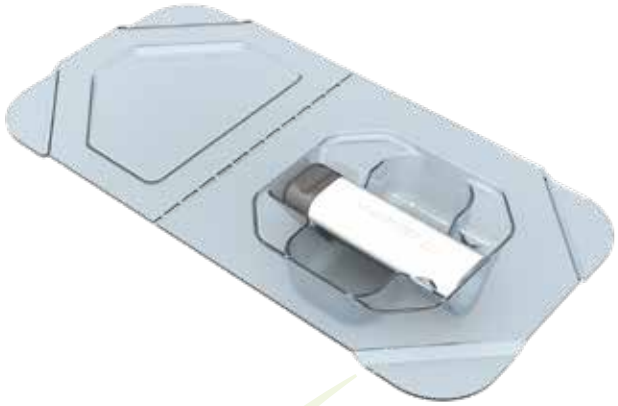
For technical reasons, the stepped countersink is 0.6 mm longer than the given preparation length. This should be taken into account during diagnosis and preparation.

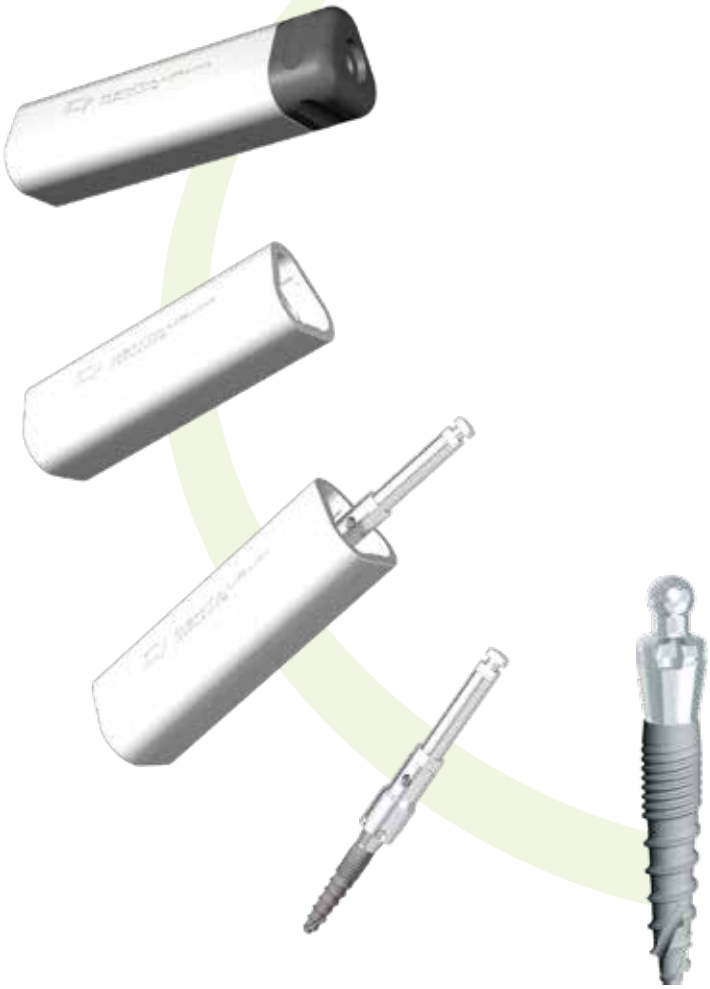
The green handpiece (500 – 800 $min^{-1}$) is used for drilling with external cooling using a sterile, cooled physiological saline solution (5 °C / 41 °F). Drilling should be intermittent without applying pressure to ensure that the tip of the drill can cool.

Should the bone be very hard, it may be necessary to use a stepped drill one size larger to ream the cortical bone.



# Treatment procedure.





## Sterile packaging.

All CITO mini® implants are supplied individually in gamma-sterilized double packaging. They are intended for single use only. The double packaging (foil and blister packaging) protects the inner container with the sterile implant against contamination. The contents remain sterile as long as the packaging is undamaged (p. 10).

**Handling.**

The blister packaging, which is shrink wrapped in foil, is removed from outer packaging. The foil is opened in the non-sterile area and the sterile blister packaging is transferred into the sterile area or taken by the operator or qualified personnel.

The cover of the sterile blister packaging is peeled back and the sterile inner tank removed.

The silicone closure is taken off. The implant is then picked up with the PentaGrip insertion key.

PentaGrip insertion key.

## Implant insertion.

The PentaGrip insertion key is designed to ensure contact-free insertion.

### Insertion with the PentaGrip insertion key.

The CITO mini® implant picked up with the PentaGrip insertion key is inserted into the prepared implant site. The PentaGrip insertion key can be extended using a drill extension and manually inserted by putting on an intermediate adapter.

A torque of 40 Ncm should not be exceeded with any insertion procedure. A prerequisite for immediate loading is a torque of at least 35 Ncm. The motor speed during handpiece insertion should not exceed 10 $min^{-1}$. Use of an excessive torque or min-1 can damage the implant site. Manual insertion is performed using an adapter ISO shank hexagon/ratchet for torque ratchet or sure-grip wheel. To this end, the adapter is mounted on the PentaGrip insertion key.

The CITO mini® implant should be inserted into the bone up to the planned and prepared position. Ensure that epithelial tissue does not enter the implant site during insertion. If the implant is difficult to insert, the implant site should be rinsed again.

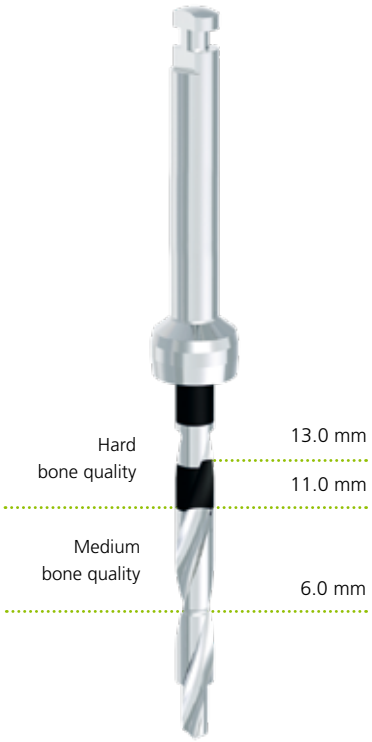
### Starting torque

- depending on the bone quality
  max. 40 Ncm
- for immediate implant loading min. 35 Ncm

# The preparation protocol.

Preparation protocol with CITO mini® preparation instruments.
Taking into account different bones qualities.

Adapt preparation protocol according to the indication and situation of each patient.
The insertion of CITO mini® implants in soft bone is not indicated.




Marking drill[2]

Stepped drill
for ø 1.8 mm[1]


Stepped drill
for ø 2.2 mm[1]


Stepped drill
for ø 2.5 mm[1]


| Soft bone quality | | | Medium bone quality | | | Hard bone quality | | |
|---|---|---|---|---|---|---|---|---|
| ø 1.8[3] | ø 2.2 | ø 2.5 | ø 1.8[3] | ø 2.2 | ø 2.5 | ø 1.8[3] | ø 2.2 | ø 2.5 |
| | | | X | X | X | X | X | X |
| The insertion of CITO mini® implants in soft bones is **not indicated**. | | | min. 6.0 mm | | | X[4] | | |
| | | | | min. 6.0 mm | | | X[4] | |
| | | | | | min. 6.0 mm | | | X[4] |

[1] The insertion depth / length of the stepped drill depends on the desired primary stability and the bone quality. The depth markings / scaling help to avoid damaging neighboring structures (e.g. nerves) due to perforations that are too deep.

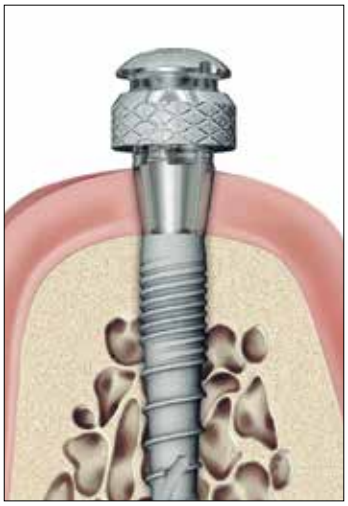
[2] Optional use.

[3] Not intended for maxillary prostheses.

[4] Should the bone be very hard, it may be necessary to use a stepped drill one size larger to ream the cortical bone.

# Dental technical variants.

## Removable restorations.



Ball head with matrix.

### Ball restoration.

Ball-anchored dentures are implant-borne, mucosa-supported. When using ball abutments existing coverdentures can be used as temporary dentures or modified with a chrome cobalt framework – alternatively a new coverdenture can be fabricated. Due to the way the CITO mini® implants function, it is advisable to use a prosthetic restoration on at least four implant abutments in the mandible and six in the maxilla. The implants must not diverge/converge by more than 25°.

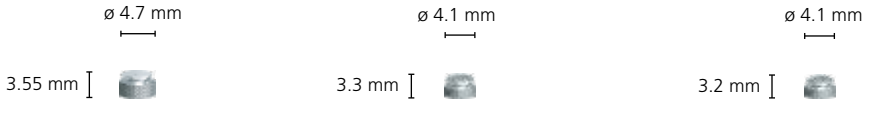
The lower edge of the ball head should be placed approx. 1.8 mm above the gingival line. To achieve optimum retention, all ball heads should be positioned at the same level.

The ball is 1.8 mm in diameter. The ball heads and their components must not be modified.

**Matrixes.**

O-ring matrix 1 CITO mini®: 0° – 25°/3 N*
O-ring matrix 2 CITO mini®: 0° – 15°/4 N*
O-ring matrix 3 CITO mini®: 0° – 5°/4 N*

* *Angle tolerance / holding force*




O-ring matrix 1. O-ring matrix 2. O-ring matrix 3.

## Working procedures (direct / indirect).

The direct technique involves processing the matrix into an existing denture directly in the patient's mouth without fabricating a model (case 1). No laboratory implant is required.

The indirect technique requires an impression and a model. The matrix is processed into the denture in the laboratory (case 2).

**Case 1 direct version.**

During the clinical procedures, the undercuts should be protected with spacers. It is positioned between the gingiva and the edge of the matrix to prevent cold-curing resin filling the undercuts in the mouth which would prevent the denture being removed after the resin has cured. Please adhere to the resin manufacturer's instructions.

**Case 2 indirect version. Impression.**

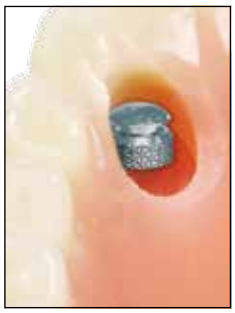
With the indirect version, the impression can be taken directly over the ball heads. Impression material is applied around all ball heads, the closed impression tray loaded with impression material and the impression taken. As soon as the impression material has set, the tray can be removed. Ensure that the impression has captured the ball heads exactly.

The ball head is then repositioned in the impression in the laboratory. The undercut beneath the ball ensures that the implant axes are transfererred precisely. To fabricate the model, the impression is cast with plaster and based. The laboratory implants must sit in the model without any free play. Once the plaster has cured, the impression can be carefully taken from the model. A ball abutment laboratory implant is available for all CITO mini® implants, as all balls have a 1.8 mm diameter.

# Dental technical variants.

## Removable restorations.

Blocking out the undercuts prior to polymerising.



Opening in the denture for finishing.

### Laboratory procedures.

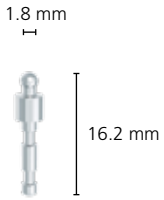
In the laboratory the ball laboratory implants are repositioned in the impression and the model fabricated.

The matrices are placed over them and their angle of insertion aligned parallel and axially to one another.

In order to protect the balls against acrylic seeping in and ensure that the matrices are parallel with the angle of insertion, the undercuts must be blocked out with spacers or wax.

The denture must be relieved adequately above the ball heads to allow sufficient clearance for the matrices. To permit the matrices to be checked for exact fit, an opning should be drilled in the lingual or palatal aspect of the denture.

Spacer.




Ball head laboratory implant.

Cold-curing resin is applied through the opening to secure the matrices in the denture. The instructions for the resin should be adhered to strictly. Once the resin has cured, the denture is removed from the model. The excess resin on the lower margins of the matrices must be removed before smoothing and polishing the denture.

The ball heads should be checked for correct functioning on the working model.

A new full denture is fabricated using exactly the same procedures except that the matrices are processed into the denture base.

## Recall appointment.

Dentures and their retention units must be examined at six-monthly intervals. Among others, the following points must be taken into account:

- Eliminate unfavourable movements of the denture (reline the denture to optimize it, activate or replace the matrices)
- Oral hygiene (remove plaque and calculus and, if necessary, reinstruct the patient on cleaning implants)
- Changing the o-rings in the matrices regularly ensures optimal retention of the denture

# General instructions.

## Cleaning and disinfection – Basic instructions.

A mechanical procedure (disinfector) should be used if possible for cleaning and disinfection. Because of its inferior efficacy and reproducibility a manual procedure – even with an ultrasonic cleaner – should only be used if a mechanical procedure is not an option.

**Preconditioning is required in both cases.**

## Application.

For reuse all instruments should be cleaned, disinfected and sterilized before each use. This applies in particular to initial use, as all instruments are supplied non-sterile (clean and disinfect after removing the transport packaging). Thorough cleaning and disinfection is essential for effective sterilization.

The operator is responsible for the sterility of the instruments and should always ensure that only properly validated procedures relating to the unit and the product are used for cleaning, disinfection and sterilization, that the units used (disinfector, sterilizer) are regularly serviced and checked and that the validated parameters are maintained during each cycle.

When using the instruments, ensure that dirty instruments are collected separately and not replaced in the tray. This is to avoid heavier contamination of the loaded tray. Dirty instruments should be cleaned, disinfected and placed in position in the tray. The fully loaded tray should then be sterilized.

The current legal regulations in the relevant country as well as the hygiene regulations of the dental practice or hospital should be adhered to. This applies in particular to the different instructions regarding effective inactivation of prions.

Special measures are required with certain instruments.
Please refer to section Reusability of surgical instruments p. 30!

## Preconditioning.

Loose dirt should be removed from the instruments immediately after use (within maximum two hours).

Loose dirt should be removed under running water or using a disinfectant solution; the disinfectant should not contain aldehyde (may cause fixation of blood debris) and should have certified efficacy (e.g. DGHM or FDA approved and CE marking); it should also be suitable for disinfection of the instruments and compatible with the instruments (p. 29 section Material resistance). Only a soft brush or a clean, soft cloth should be used for removing dirt manually; metal brushes or steel wool should never be used.

If applicable: rinse all hollow sections of the instruments 5 times using a disposable syringe (minimum volume 5.0 ml).

Note that the disinfectant used for preconditioning is only for personal protection and cannot be regarded as a substitute for subsequent disinfection after cleaning.

**Mechanical cleaning/ disinfection (disinfector or cleaner/ disinfector).**

When choosing and using a disinfector, ensure that

- the efficacy of the disinfector has been certified (e.g. DGHM or FDA approved and CE marking according to DIN EN ISO 15883),
- a certified programme for thermal disinfection (minimum 5 min. at 90 °C/194 °F or an A0 > 3000) is used (with chemical disinfection there is the risk of disinfectant residue on the instruments),
- the programme used is suitable for the instruments and has an adequate number of rinse cycles,
- it uses only water that is sterile or has a low bacteria count (max. 10 bacteria/ml) and is low in endotoxins (max. 0.25 endotoxin units/ml) (e.g. purified water/highly purified water) for rinsing,
- the air used for drying is filtered,
- the disinfector is regularly serviced and checked.

# General instructions.

**Cleaning supplies.**

When choosing a cleaning agent system, ensure that

- it is suitable for cleaning metal and plastic instruments,
- – provided that thermal sterilization is not used – an additional disinfectant with certified efficacy (e.g. DGHM or FDA approved and CE marking) is used and that it is compatible with the cleaning agent used,
- the chemicals used are compatible with the instruments (p. 29 section Material resistance),
- the concentrations given by the cleaning agent and disinfectant manufacturer must be strictly adhered to.

**Sequence.**

1. Dismantle the instruments if applicable.
2. Place the dismantled instruments in the disinfector. Ensure that the instruments do not come into contact with one another.
3. Start the programme.
4. Remove the instruments from the disinfector when the programme is complete.
5. Check and pack the instruments in a clean area as soon as possible after removal (p. 28 section Care, checking, maintenance, packaging), if necessary after additional drying

## Manual cleaning and disinfection.

When choosing a cleaning agent and disinfectant, ensure that

- they are suitable for cleaning and disinfecting metal and plastic instruments,
- the cleaning agent, if used, is suitable for ultrasonic cleaning (no foaming),
- a disinfectant with certified efficacy (e.g. DGHM or FDA approved and CE marking) is used and that it is compatible with the cleaning agent used,
- the chemicals used are compatible with the instruments (p. 29 section Material resistance),
- combined cleaning agents/disinfectants should not be used,
- the concentrations and reaction times given by the cleaning agent and disinfectant manufacturer should be strictly adhered to. Always use freshly prepared solutions, water that is sterile or has a low bacteria count (max. 10 bacteria/ml) and is low in endotoxins (max. 0.25 endotoxin units/ml) (e.g. purified water/highly purified water) and always use filtered air for drying.

Special measures are required with certain instruments.
Please refer to section Reusability of surgical instruments p. 30!

**Sequence – Cleaning.**

1. Dismantle the instruments if applicable.
2. Immerse the dismantled instruments fully in the cleaning solution for the recommended reaction time (if required use an ultrasonic cleaner or brush carefully with a soft brush). Ensure that the instruments do not come into contact with one another.

   If applicable: rinse all hollow sections of the instruments 5 times at the beginning and at the end of the reaction time using a disposable syringe (minimum volume 5.0 ml).
3. Then remove the instruments from the cleaning solution and rinse thoroughly at least three times with water.

   If applicable: rinse all hollow sections of the instruments 5 times using a disposable syringe (minimum volume 5.0 ml).
4. Check the instruments (p. 28 section Care, checking, maintenance, packaging).

**Sequence – Disinfection.**

5. Immerse the dismantled, cleaned and checked instruments fully in the disinfectant for the recommended reaction time. Ensure that the instruments do not come into contact with one another.
   If applicable: rinse all hollow sections of the instruments 5 times at the beginning and at the end of the reaction time using a disposable syringe (minimum volume 5.0 ml).
6. Then remove the instruments from the disinfectant and rinse thoroughly at least three times with water.
   If applicable: rinse all hollow sections of the instruments using a disposable syringe (minimum volume 5.0 ml).
7. Pack the instruments in a clean area as soon as possible after removal (p. 28 section Care, checking, maintenance, packaging), if necessary after additional drying.

Proof of basic suitability for effective manual cleaning and disinfecting was provided by an independent, accredited test laboratory using Bodedex® forte cleaning agent and Korsolex® plus disinfectant (Bode Chemie, Hamburg, Germany). The procedure described above was taken into account during the tests.

# General instructions.

## Care, checking.

Instruments should be checked after cleaning or cleaning/disinfection for corrosion, damaged surfaces, chipped edges and contamination. Damaged instruments should be discarded (p. 30 section Reusability of surgical instruments). Instruments that are still contaminated should be cleaned and disinfected again.

## Maintenance.

Reassembly of instruments (p. 30 section Reusability of surgical instruments).

If possible, instrument oils should not be used. If oil is to be used, ensure that only instrument oils (white oil) are used, which – depending on the maximum sterilization temperature used – are approved for steam sterilization and certified biocompatible.

## Packaging.

Arrange the cleaned and disinfected instruments as required in the sterilization tray.

Wrap the instruments and sterilization tray in disposable sterilization packing (single or double wrap) and/or pack in sterilization containers that meet the following requirements:

- DIN EN ISO/ANSI AAMI ISO 11607-1/2 (formerly: DIN EN 868/ANSI ISO 11607)
- suitable for steam sterilization (temperature resistant to min. 134 °C/273 °F adequate steam permeability)
- adequate protection of the instruments and sterilization packaging against mechanical damage
- regularly maintained according to the manufacturer's instructions (sterilization containers)

Special measures are required with certain instruments.
Please refer to section Reusability of surgical instruments p. 30!

## Sterilization procedures.[1]

Sterilization should only be completed using the sterilization procedures listed below; other sterilization procedures are not approved.

**Steam sterilization.**

- fractional vacuum method
- steam sterilizer in accordance with DIN EN 13060 or DIN EN 285
- validated in accordance with DIN EN ISO/ANSI AAMI ISO 17665 (formerly: DIN EN 554/ANSI AAMI ISO 11134) (valid commissioning and product-specific performance evaluation)
- maximum sterilization temperature 134 °C/ 273 °F; including tolerance in accordance with DIN EN ISO/ANSI AAMI ISO 17665 (formerly: DIN EN 554/ANSI AAMI ISO 11134)
- sterilization time (exposure time at the sterilization temperature) minimum 20 min at 134 °C/273 °F

Flash sterilization or gravitational method should never be used.

Do not use hot-air sterilization, X-ray sterilization, formaldehyde or ethylene oxide sterilization or plasma sterilization.

## Correct storage.

After sterilization the instruments should be stored dry and dust free in the sterilization packaging.

## Material resistance.

When choosing the cleaning agent and disinfectant, ensure that they do not contain the following components:

- organic, mineral or oxidizing acids (maximum permitted pH 9.5, a neutral/ enzymatic cleaner is recommended)
- strong alkali
- organic solvents (e.g. alcohol, ether, ketones, benzene)
- oxidation agents (e.g. hydrogen peroxide)
- halogens (chlorine, iodine, bromine)
- aromatic/ halogenated hydrocarbons
- heavy metal salts

Never clean instruments and sterilization trays with metal brushes or steel wool.

[1] Proof of basic suitability for effective steam sterilization was provided by an independent, accredited test laboratory using a EuroSelectomat steam sterilizer (MMM Münchener Medizin Mechanik GmbH, Planegg, Germany) as well as a Systec V-150 steam sterilizer (Systec GmbH Labor- Systemtechnik, Wettenberg, Germany). The procedure described above was taken into account during the tests.

# Surgical instruments.

## Reusability of surgical instruments.

Rotary instruments can be reused a maximum of 30 to 40 times in the hard bone – with proper care and provided that they are not damaged or contaminated; the operator is deemed responsible for any further reuse or the use of damaged and/or contaminated instruments. We do not accept any liability if these instructions are disregarded.

## Torque ratchet.

### Disassembling.

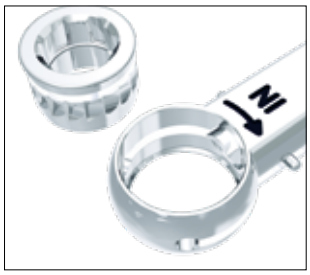
Completely loosen torque adjustment screw ⑤ and remove the spring ④. Pull ratchet head ② with the threaded rod from the scale sleeve ③.

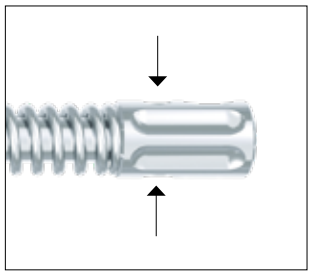
### Removing ratchet wheel

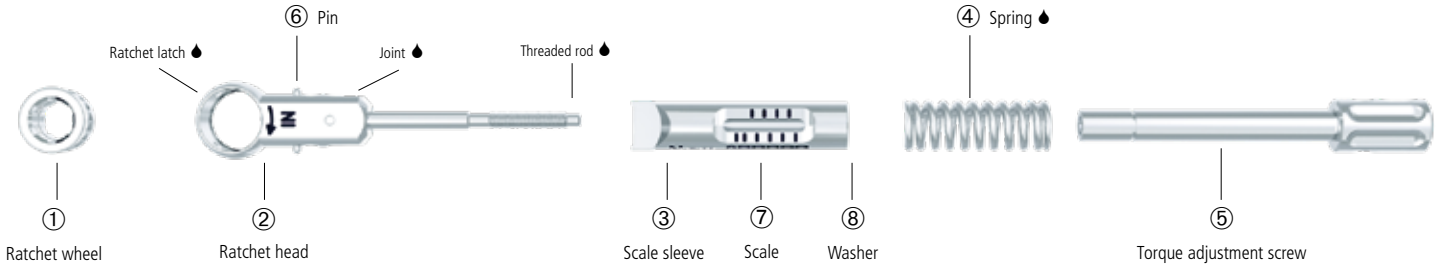
Pull back the pin ⑥ in the direction of the arrow using your thumb and index finger and remove the ratchet wheel ① .

Block function – „∞"-symbol.


Ratchet head, assembled.


Ratchet head, disassembled.


Do not loosen these 2 screws,
as the ratchet will lose its torque function.




### Assembling.

To assemble the torque ratchet correctly, connect the components in the following order: first remove the pin ⑥ as described above and insert the ratchet wheel ①.

Note: To avoid mistakes, the ratchet wheel ① can only be inserted on one side.

### Lubricating points (♦)

Lubricate the areas marked with the drop symbol using care oil for handpieces. Then assemble the ratchet components as described below and perform a function test.

**Slide the spring ④ over the torque adjustment screw ⑤. Pass the ratchet head ② with the threaded rod through the scale sleeve ③ and screw to torque adjustment screw ⑤.**

After assembly and before each use, check the correct function of the torque ratchet. If there is an audible regular ratchet noise and the mechanism of the torque limit functions, the instrument is functioning correctly.

### Sterilization.

The instrument must be sterilized with steam at 134 °C / 273 °F for 18 min.

Apply the regulations in force in the country where the torque ratchet is used.

Before sterilization, the torque ratchet must be completely assembled and set to the lowest torque.

Sterilize the key according to cycles of sterilization recommended by the manufacturer of the autoclave. We recommend the use of devices equipped with a vacuum pump (type B) to decrease the risk of air pockets.

We advise against the use of a hot air sterilizer because it can lead to ageing of the spring and subsequently bring about a change of the torque value. Find more information on the preparation of medical devices at www.rki.de or www.a-k-i.org.

# Overview.

Surgical restoration possibilities
and components.

## Surgical tray

REF 307-000-00

Surgical tray for CITO mini®

Content:
- Marking drill
- Stepped drill for ø 1.8 mm
- Stepped drill for ø 2.2 mm
- Stepped drill for ø 2.5 mm
- PentaGrip insertion key - ISO shank

## Rotating instruments

| | | | | |
|---|---|---|---|---|
| REF 382-015-00 |  | Marking drill | Ø 1.5 mm | |
| REF 302-118-00 |  | Stepped drill for Ø 1.8 mm | Ø 1.5 mm | L 17.0 mm |
| REF 302-122-00 |  | Stepped drill for Ø 2.2 mm | Ø 1.9 mm | L 17.0 mm |
| REF 302-125-00 |  | Stepped drill for Ø 2.5 mm | Ø 2.1 mm | L 17.0 mm |

## Implants

| | | | | |
|---|---|---|---|---|
| REF 303-018-11 |  | CITO mini® implant | Ø 1.8 mm | L 11.0 mm |
| REF 303-018-13 |  | CITO mini® implant | Ø 1.8 mm | L 13.0 mm |
| REF 303-022-11 |  | CITO mini® implant | Ø 2.2 mm | L 11.0 mm |
| REF 303-022-13 |  | CITO mini® implant | Ø 2.2 mm | L 13.0 mm |
| REF 303-025-11 |  | CITO mini® implant | Ø 2.5 mm | L 11.0 mm |
| REF 303-025-13 |  | CITO mini® implant | Ø 2.5 mm | L 13.0 mm |

## Prosthetics ball abutments

| | | |
|---|---|---|
| REF 306-614-00 |  | Ball head laboratory implant CITO mini® |
| REF 306-616-00 |  | O-ring matrix 1 CITO mini® |
| REF 306-618-00 |  | O-ring matrix 2 CITO mini® |
| REF 306-620-00 |  | O-ring matrix 3 CITO mini® |
| REF 306-626-00 |  | O-ring for matrix 1 CITO mini®, 1 Stück |
| REF 306-627-00 |  | O-ring for matrix 1 CITO mini®, 10 Stück |
| REF 306-628-00 |  | O-ring for matrix 2 + 3 CITO mini®, 1 Stück |
| REF 306-629-00 |  | O-ring for matrix 2 + 3 CITO mini®, 10 Stück |
| REF 306-632-00 |  | Spacer |

## Accessories – Surgical prosthetics

| | | |
|---|---|---|
| REF 387-511-00 |  | Adapter – ISO shank hexagon / ratchet |
| REF 307-646-00 |  | PentaGrip insertion key – ISO shank CITO mini® |
| REF 387-800-00 |  | Torque ratchet with blocking function |
| REF 307-001-00 |  | Gingiva punch, ø 1.0 mm |

## Demo-Modell

| | | |
|---|---|---|
| REF 308-420-00 |  | Demo implant CITO mini® 5:1 |

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