

CITO mini®

Surgery + Prosthetics Manual.



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General information.

Manufacturer.

Dentaurum GmbH & Co. KG
Turnstr. 31 | 75228 Ispringen | Germany

Brief description.

CITO mini® implant types are designed for insertion in the endosteal region of the maxilla or mandible. Depending on the indication, the matrices with the appropriate degrees of freedom are fixed on the implants with a ball diameter of 1.8 mm and provided with a prosthetic superstructure.

The CITO mini® implant system contains specially coordinated instruments, abutments and accessories for insertion of the implants and for the prosthetic restoration. Only original components of the CITO mini® implant system should be combined in accordance with the Instructions for use/manuals.

Further information.

Though placement of dental implants has a high rate of success and implants have a long durability, successful treatment cannot be guaranteed. The implantologist should note and document any problematic cases and inform the manufacturer.

An inadequate number of implants, implants with insufficient length or diameter, unfavorable positioning of the implants or a statically poor prosthetic restoration can cause premature implant loss and fatigue fractures in implants and abutments under biomechanical loading.

Placement of the implants and fabrication of the prosthetic restoration should take the situation of each individual patient into account to avoid overloading the components.

Using components which are not described in the Instructions for use / manual as being specifically combinable can also cause mechanical failure, damage to the tissue or unsatisfactory aesthetic results.

CITO mini® implant types are not known to have any side effects or produce 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.

Use, 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 implantology, including diagnosis, preoperative planning, surgical techniques and prosthetic restorations.



Before use, dental professionals should ensure that they have carefully read and understood the full Instructions for use / manuals. As the instructions and manuals cannot provide all information for immediate use, we strongly recommend that, before using the system, implantologists attend a CITO mini® implant system training course offered by Dentaaurum to learn the correct techniques.

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 full dentures, Dentaaurum 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 and take the size of the matrices into consideration.

Immediate implant loading is only possible if a torque of 35 Ncm was reached during insertion. Torque should not exceed 40 Ncm during insertion.

- Refer to this Surgery + Prosthetics Manual and the basic folder CITO mini® for information on precautions and the selection of components for the surgical and prosthetic procedure.

Before using this product, the patient must be thoroughly examined by the implantologist and given a detailed explanation of the product. Dentaaurum recommends full clinical, radiological, photographic and statistical documentation.

The CITO mini® implant system components can be documented, e. g. in the patient file, using the additional labels. The implantologist should ensure the products cannot be aspirated during intra-oral use.

Not all components are available in every country.

Quality, warranty and liability, development.

Development, clinical testing, production and quality control of the CITO mini® product range are completed 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 or liability – unless stated otherwise in the Instructions for use / manual.

Warranty and liability are rendered void in particular if the products are not used by the dental professional or a third party in accordance with the Instructions for use; this also applies if the CITO mini® product range is used in combination with products from other manufacturers which have not been specifically recommended for use by Dentaaurum.

Dentaaurum has no control over processing and use of the product. These are the sole responsibility of the dental professional.

Technical advice (oral and written) is based on the scientific and technical knowledge available at the time the product is put on the market. It does not release the dental professional from the responsibility of personally checking the suitability of the products for the intended indications and applications. 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 geometry¹.

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.

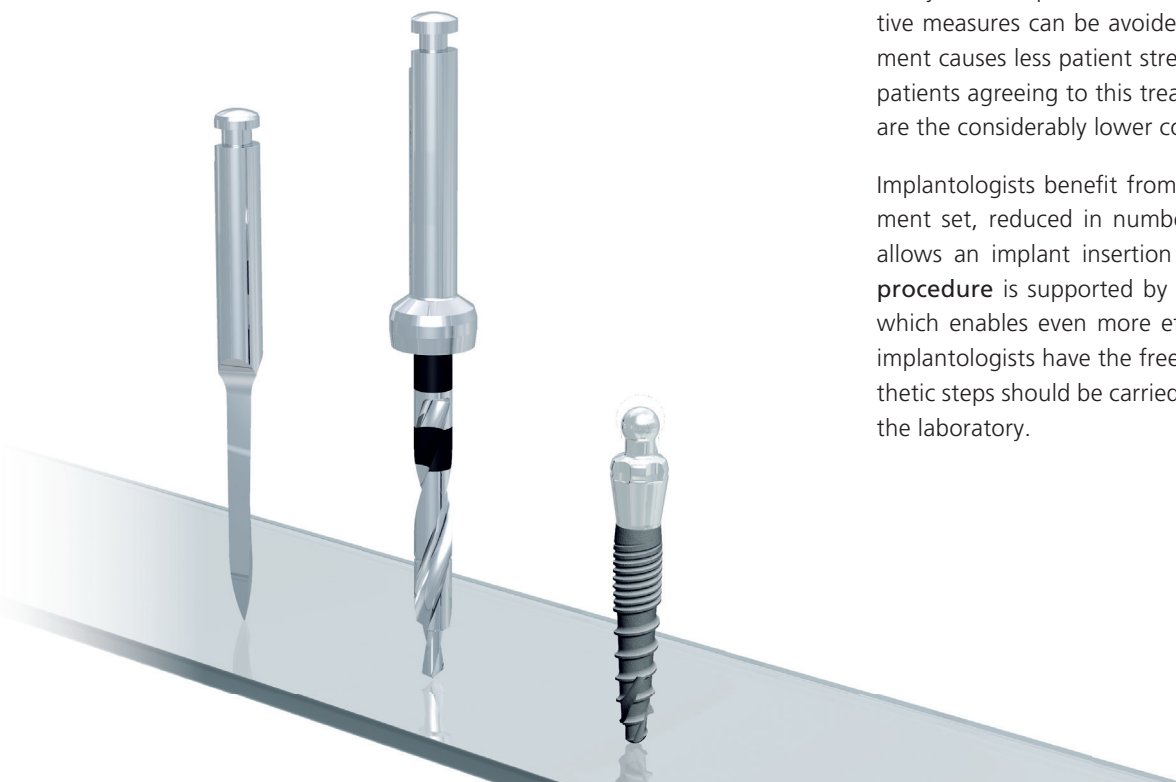
CITO mini® – the solution for patients and implantologists.

Dentaurum has developed the CITO mini® implant family, building on 25 years of experience in oral implantology.

These small diameter implants are designed especially for patients with **reduced bone availability**. They can now be treated with implant-supported partial or full dentures and benefit from the advantages. As many of these implant cases can be **loaded immediately**, patients can enjoy their new quality of life a lot sooner.

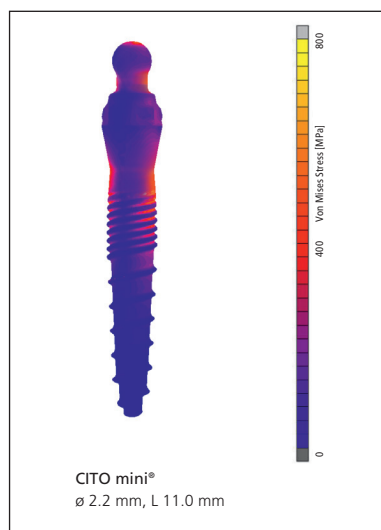
Due to the possibility of transgingival insertion, the minimally invasive procedure and the fact that augmentative measures can be avoided in most cases, this treatment causes less patient stress, which will lead to more patients agreeing to this treatment. Another advantage are the considerably lower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

Implantologists 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, which enables even more efficiency. With CITO mini®, implantologists have the freedom of choice 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[®] implant.

The CITO mini[®] implant shape and the thread geometry were calculated using FEM analyses¹. 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 osseous region of the CITO mini[®] implant surface is blast- and etched.

¹ I. Hasan, C. Bourauiel: 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, minimally 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.

Packaging system.



- 1 Content
- 2 Diameter / length
- 3 Article no. (REF)
- 4 Quantity
- 5 Refer to Instructions for use
- 6 For single use only
- 7 Do not use if packaging is damaged
- 8 Symbol for gamma-sterilization

- 9 Identification number of the notified body in accordance with Directive 93/42 EEC
- 10 Medical device
- 11 Sterility expiry date
- 12 Date of manufacture
- 13 Batch number (LOT)
- 14 Manufacturer

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9

DENTALPRODUKT / DENTAL PRODUCT
Anwendung nur durch Fachpersonal / for professional use only

CITO mini®  2025-06-20

Implantat CITO mini®  2023-06-20

Implant CITO mini®  123456

Ø 2.2 mm, L 11.0 mm

REF 303-022-11

1 Stück/piece

   **STERILE R** 

Turnstr. 31 | 75228 Ispringen | Germany | Tel. +49 72 31 / 803-0

CE 0483 **MD**   

+J011303022110/\$\$3250620123456G

- 11
- 12
- 13
- 14

Sterile packaging system.

All CITO mini® implants are delivered individually wrapped 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 only remain sterile as long as the packaging is undamaged. The product should not be used if the double packaging is damaged.

The implant can be taken out of the container without being touched by using the PentaGrip insertion key. It can then be inserted. Manual insertion is possible, if required, by means of an intermediate adapter.

The label on the outer packaging states the article number (REF), the name, length and diameter of the implant, the sterility expiry date and LOT number. There are four self-adhesive labels in the packaging with REF and LOT numbers for documentation in the surgical protocol, patient file etc.

Diagnosis and planning.

General overview.

Indications.

CITO mini® implant types are used to stabilize prostheses in the edentulous maxilla and 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 implantology in general, the implant diameter and length of the CITO mini® implant types 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 full dentures, Dentaureum recommends at least four implants in the mandible and six implants in the maxilla*.

The insertion of CITO mini® implants in soft bone is not indicated. For restorations in the maxilla, use CITO mini® implants $\varnothing$ 2.2 mm or $\varnothing$ 2.5 mm.

When positioning the implants, pay attention to keeping an adequate distance between the implants and to ensuring that the static force on the bone is optimally applied**.

Immediate implant loading is only possible if a torque of 35 Ncm was reached during insertion. Torque should not exceed 40 Ncm during insertion.

* see Planning Scheme CITO mini® (989-502-45) or www.dentaurum.de

** The size of the matrix should also be considered

This section provides a general overview of diagnosis and planning. For more detailed information on these aspects, please 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 Dentaurem training program also ensures that all the dentists, dental technicians and dental assistants involved in the implant procedure are optimally prepared by experienced lecturers. Dentaurem provides numerous training courses at different levels tailored to suit the target group, the level of knowledge and individual interests.

Contraindications.

General contraindications for dental surgery procedures 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
- incomplete physical growth of patient

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 circumstances. 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.

Rotating 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 full dentures, Dentauro 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 and take the size of the matrices into consideration.

In line with the implant diameter the CITO mini® implant must be surrounded by at least 1.0 mm bone and the blasted and etched section of the implant must be inserted in the bone.

Immediate implant loading is only possible if a torque of 35 Ncm was reached during insertion. Torque should not exceed 40 Ncm during insertion.

For the preparation of the implant site, the rotary instruments and their drilling sequence should be chosen depending on the bone quality.

A preparation protocol for different bone qualities (soft, medium, dense) is available for the implantologist (p. 18/19). Determination of the bone quality rests on the implantologist.

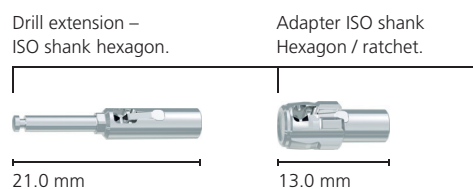
Instruments.

The handpiece instruments can also be used manually as required using an adapter (max. permitted torque 45 Ncm). The instruments should be inserted rotationally secure and the fit checked. The 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.

All CITO mini® rotary instruments are supplied non-sterile and should be sterilized before use. They should be thoroughly cleaned, disinfected and conditioned before using for the first time (brand new) and immediately after each use. Rotary instruments should always be checked to ensure that they are sharp, in good condition and the markings are legible, as they have a limited service life. Instruments can become blunt as a result of use and cleaning. Only instruments that are sharp and free from defects should be used (p. 24, General Information).

Rotary instruments – used with proper care and provided that they are not damaged or contam-



inated – can be reused in dense bone 15 to 20 times; any further reuse or the use of damaged and / or contaminated instruments must be avoided. The dental professional bears responsibility. No liability is accepted if these instructions are disregarded.

Bone exposure.

The mucosa is perforated and removed with a gingiva punch (e.g. Dentaurem REF 307-001-00). The position of the mental foramen should be clarified before placing implants in the mandible.

Drillpoint marking.

The following describes preparation regardless of the bone quality in order to show exactly how each of the rotary instruments work.

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 for the length of the implant.

The green contra angle (500 – 800 min⁻¹) is used for drilling with external cooling using a sterile, cooled physiological saline solution (5 °C / 41 °F).

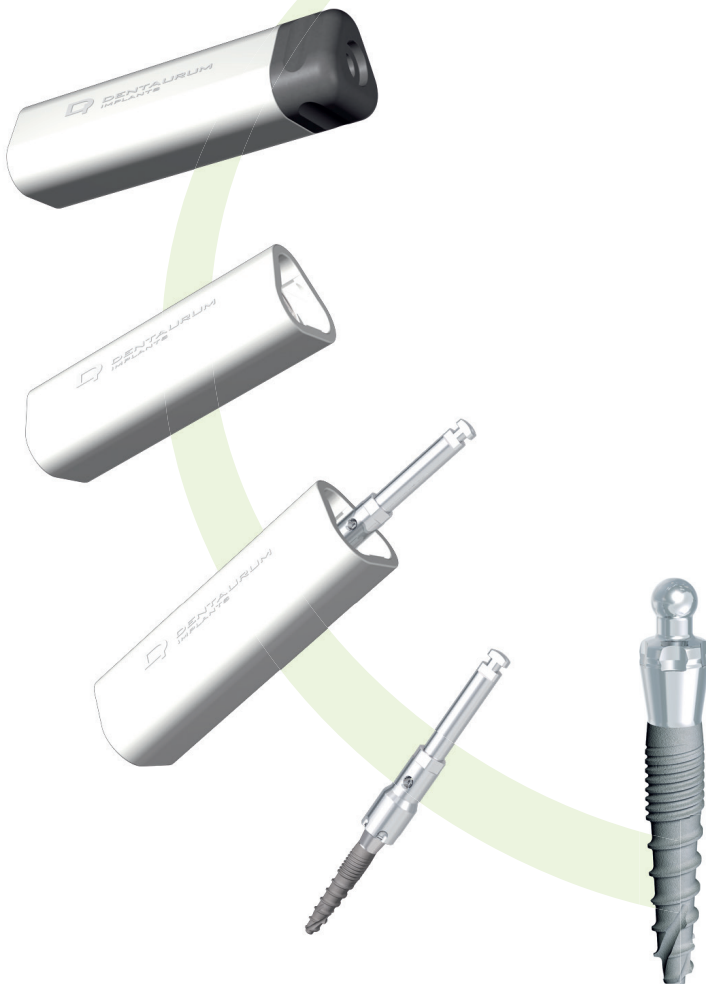
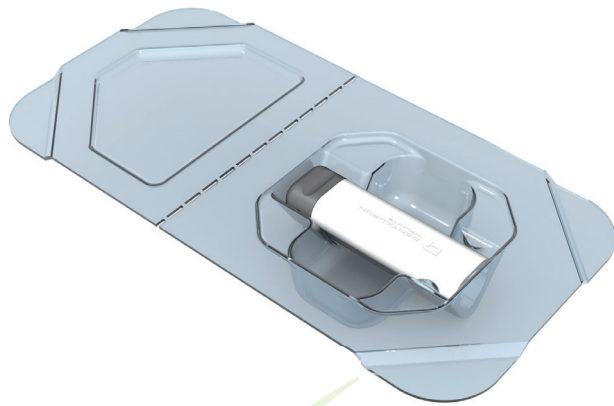
Stepped drilling.

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

The green contra angle (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 delivered individually wrapped 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 only remain sterile as long as the packaging is undamaged (p. 10).

Handling.

The blister packaging, which is shrink wrapped in foil, is removed from the 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 implantologist or qualified personnel.

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

The silicone seal is removed. The implant is then grasped using the PentaGrip insertion key.



PentaGrip insertion key.

Implant insertion.

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

Insertion with PentaGrip insertion key.

Following removal from the packaging with the PentaGrip insertion key, the CITO mini® implant is inserted into the prepared implant site. The PentaGrip insertion key can be extended using a drill extension and can be used manually by attaching the intermediate adapter.

A torque of 40 Ncm should not be exceeded with any insertion procedure. It is necessary to achieve a torque of min. 35 Ncm for immediate loading of the implant. The motor speed during handpiece insertion should not exceed 10 min⁻¹. Use of an excessive torque or motor speed can damage the implant site. For manual insertion, an adapter ISO shank hexagon/ratchet is available for use with the torque ratchet or sure-grip wheel. The adapter ISO shank/ratchet is placed on the PentaGrip insertion key.

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

Tightening torque

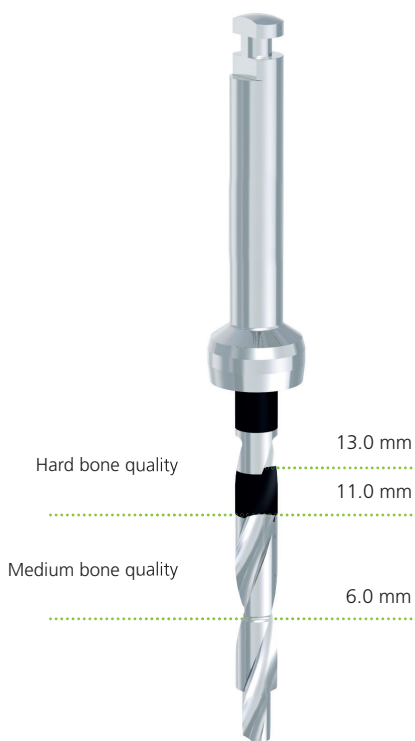
- depending on the bone quality max. 40 Ncm
- for immediate implant loading min. 35 Ncm

Preparation protocol.

Preparation protocol with CITO mini® preparation instruments.

Taking different bone qualities into account.

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 drill²



Stepped drill

for $\varnothing$ 1.8 mm¹



Stepped drill

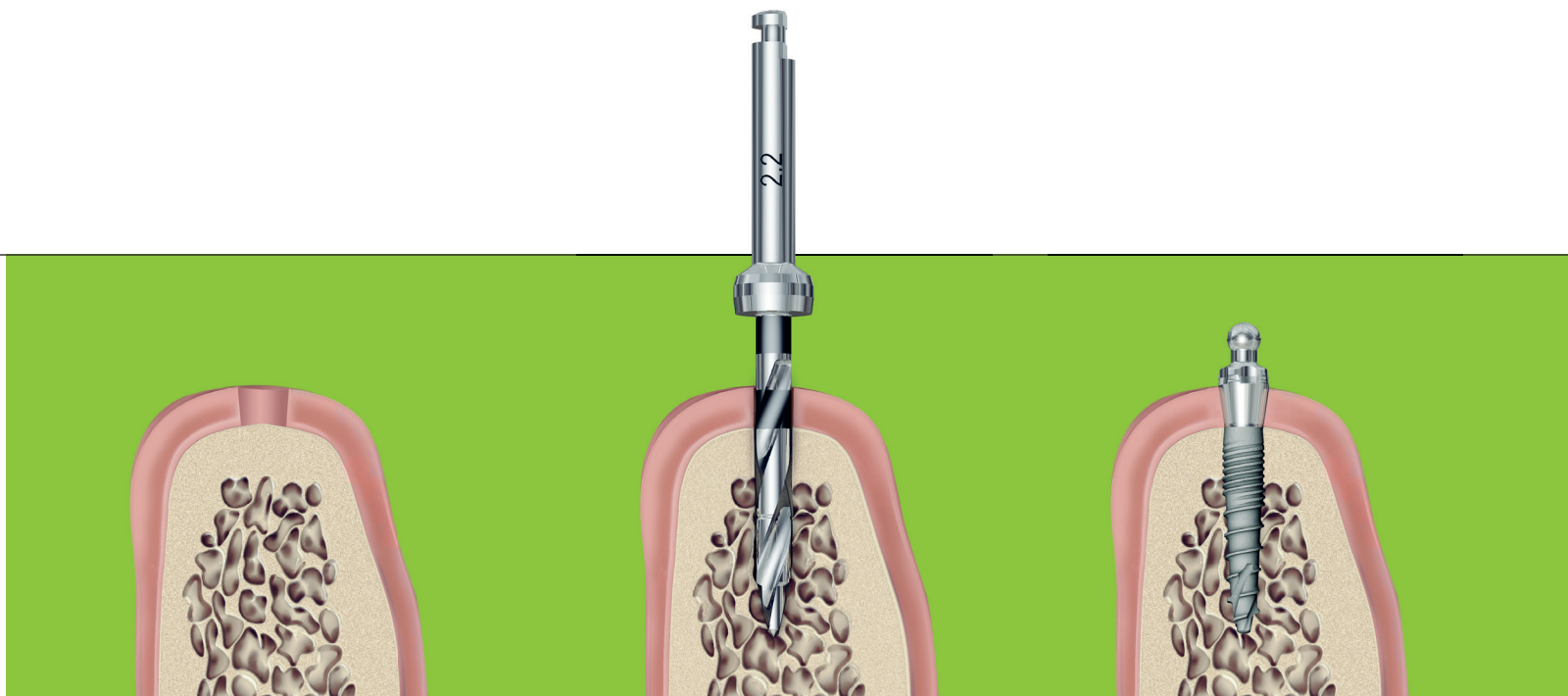
for $\varnothing$ 2.2 mm¹



Stepped drill

for $\varnothing$ 2.5 mm¹





Soft bone quality



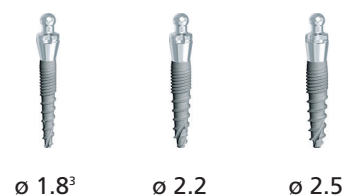
ø 1.8³ ø 2.2 ø 2.5

Medium bone quality



ø 1.8³ ø 2.2 ø 2.5

Hard bone quality



ø 1.8³ ø 2.2 ø 2.5

X

X

X

X

X

X

min.
6.0 mm

X⁴

The insertion of
CITO mini® implants in soft bone is
not indicated.

min.
6.0 mm

X⁴

min.
6.0 mm

X⁴

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.

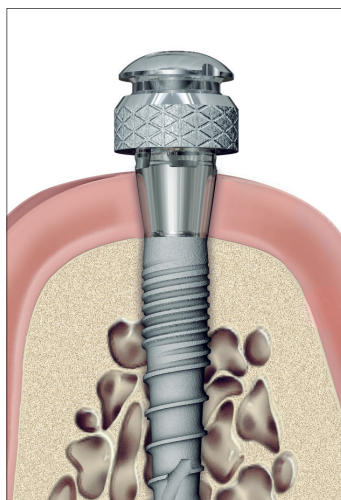
² Optional use.

³ Not intended for restorations in the maxilla.

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 abutment restorations.

Ball-anchored dentures are tissue-borne restorations. When using ball abutments, existing coverdentures can be used as temporary dentures or modified with a partial denture framework – alternatively a new coverdenture can be fabricated. CITO mini® implants function in such a manner that it is advisable to support the prosthetic restoration on at least four implants in the mandible and six implants in the maxilla. The implants may not diverge by more than 25°.

The lower edge of the ball head should be approx. 1.8 mm above the gingival line. To achieve optimum retention, all ball heads should be positioned at the same level. The ball head is 1.8 mm in diameter. The components of the ball head may not be modified.

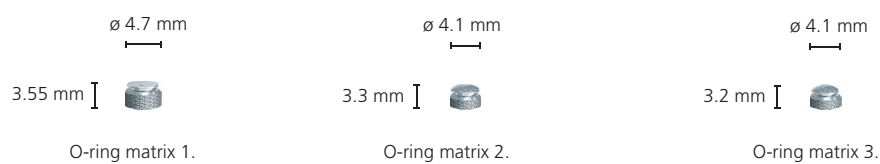
Matrices.

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/retentive force



Different versions of working procedures (direct / indirect).

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

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

Case 1 direct version.

During the clinical procedures, the undercuts are protected with the help of spacers. These are 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. Instructions for the resin should be adhered to strictly.

Case 2 indirect version. Impression-taking.

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 is loaded with impression material and the impression is taken. As soon as the impression material has set, the tray can be removed. Ensure that the impression has captured the ball heads exactly.

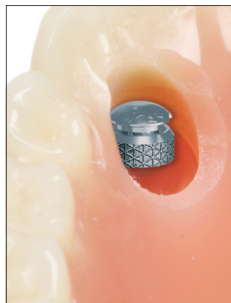
The ball laboratory implant is then repositioned in the impression in the laboratory. The surface beneath the ball ensures that the implant axes are transferred precisely. An impression is cast in plaster and given a base to make a model. The laboratory implant must fit precisely on the model. After the plaster has hardened, carefully remove the impression from the model. A ball laboratory implant is available for all CITO mini® implant types as all balls have a diameter of 1.8 mm.

Dental technical variants.

Removable restorations.



Blocking out the undercuts prior to polymerizing.



Opening in the denture for finishing.

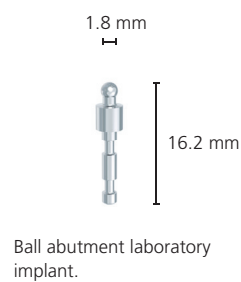
Laboratory.

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 to ensure that the matrices are parallel with the angle of insertion, the undercuts must be blocked out with wax.

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



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

Check that the ball abutments function correctly on the working cast.

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

Recall.

Dentures and their retention units must be monitored at six-monthly intervals. The following points, inter alia, must be taken into account:

- Eliminate unfavorable movements of the denture (optimize relining of the denture or replace the matrices)
- Oral hygiene (remove plaque and calculus and, if necessary, re-instruct the patient on cleaning implants)
- regularly changing the O-rings in the matrices guarantees optimum retention of the denture

General information.

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.

Use.

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 are essential for an effective sterilization.

The implantologist 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 equipment used (disinfector, sterilizer) is regularly serviced and checked and that the validated parameters are maintained during each cycle.

When using the instruments, ensure that contaminated instruments are collected separately and not put back into the tray. This is to avoid heavier contamination of the loaded tray. Contaminated 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 the chapter Reusability of surgical instruments, p. 30.

Preconditioning.

Remove coarse impurities from the instruments immediately after use (within maximum 2 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 be compatible with the instruments (p. 29 Material resistance). Only a soft brush or a clean, soft cloth should be used for removing impurities manually; metal brushes or steel wool should never be used.

If applicable: rinse all cavities of the instruments five 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.

Machine-based cleaning and disinfection.

(disinfector or washer disinfector).

When choosing 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 program 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 program 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 information.

Cleaning agents.

When choosing a cleaning agent system, ensure that

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

Procedure.

1. Dismantle the instruments as far as possible.
2. Place the dismantled instruments in the disinfectant. Ensure that the instruments do not come into contact with one another.
3. Start the program.
4. Remove the instruments from the disinfectant when the program is complete.

5. Check and pack the instruments in a clean area as soon as possible after removal (p. 28, chapter Care, monitoring, 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, chapter Material resistance).
- combined cleaning agents / disinfectants should not be used.

Special measures are required with certain instruments.

Please refer to the chapter Reusability of surgical instruments, p. 30.

- 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.

Procedure - cleaning.

1. Dismantle the instruments as far as possible.
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 cavities of the instruments five 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 cavities of the instruments five times using a disposable syringe (minimum volume 5.0 ml).

4. Check the instruments (p. 28, Care, monitoring, maintenance, packaging).

Procedure - disinfecting.

5. Immerse the dismantled, cleaned and checked instruments fully in the disinfectant solution for the recommended reaction time. Ensure that the instruments do not come into contact with one another.
If applicable: rinse all cavities of the instruments five 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 solution and rinse thoroughly at least three times with water.
If applicable: rinse all cavities of the instruments using a disposable syringe (minimum volume 5.0 ml).
7. Assemble, if appropriate, and pack the instruments in a clean area as soon as possible after removal (p. 28, chapter Care, monitoring, 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 information.

Care, monitoring.

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

Maintenance.

Reassembly of instruments (p. 30, chapter Reusability of surgical instruments).

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

- fractionated vacuum process
- 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 (plus 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 18 mins at 134 °C / 273 °F

Flash sterilization or gravitational method should not be used.

Other procedures that should not be used are: 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 value 9.5, a neutral / enzymatic cleaner is recommended)
- strong alkali
- organic solvents (e.g. alcohol, ether, ketones, benzines)
- 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) and a Systec V-150 steam sterilizer (Systec GmbH Labor-Systemtechnik, Wetztenberg, Germany). The procedure described above was taken into account during the tests.

Surgical instruments.

Reusability of surgical instruments.

Rotary instruments – used with proper care and provided that they are not damaged or contaminated – can be reused in dense bone 15 to 20 times; it is the implantologist's responsibility to ensure that they are not used beyond this and that no damaged and / or contaminated instruments are used. No liability is accepted if these instructions are disregarded.

Torque ratchet.

Disassembly.

Before cleaning (regardless of the selected cleaning method), the torque ratchet must be dismantled into the individual parts. This can be done without tools. Completely unscrew the torque adjustment screw ⑤, and remove the spring ④ and the ratchet head ② with threaded rod.

Take care not to lose the plastic washer ⑧ as this

would have a negative impact on the instrument's precision. (The plastic washer needs only to be removed if there is visible contamination. It can be pulled off if necessary and replaced after cleaning).

Remove 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.

Monitoring.

The best method to identify and remove defect instruments is by examining them and carrying out functional tests before and after each use. Specific functional areas (e.g. connection for adapter, torque initiator) and moving parts require special attention.

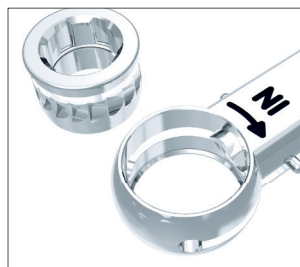
Allow the parts to cool down to room temperature.
Parts with damaged surfaces, chippings, con-



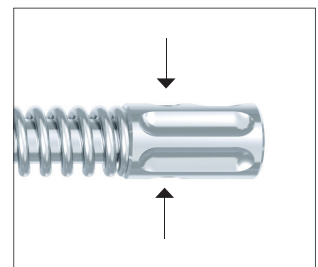
Blocking function – „∞“ mark.



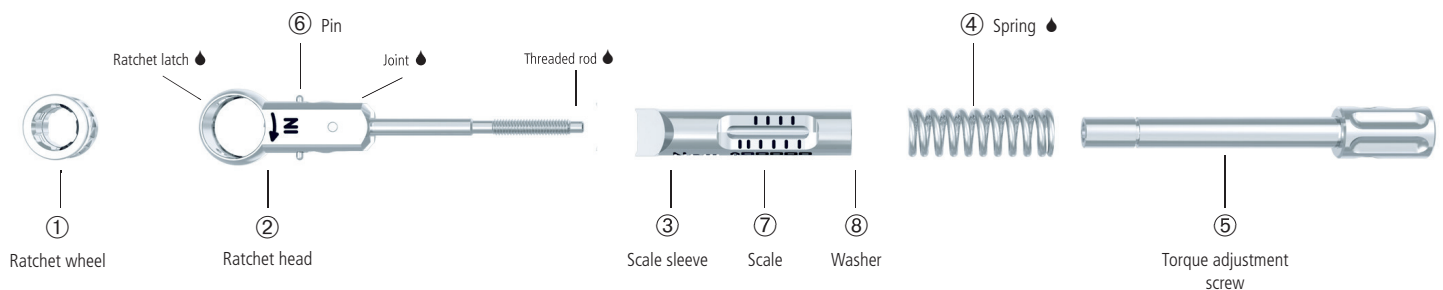
Ratchet head, assembled.



Ratchet head, disassembled.



Never loosen these screws as the ratchet will lose its torque function.



tamination, discoloration or corrosion must be removed. Discard any instruments that are deformed, worn in their functionality or otherwise damaged.

Instruments that are still contaminated should be cleaned and sterilized again.

Maintenance.

If several torque ratchets are in use, do not interchange the individual parts. Each individual part belongs to one instrument.

Lubricating points (◆)

Lubricate the areas marked with the "drop" symbol lightly with maintenance oil for instruments.

Ensure that only instrument oils (paraffinic white oil without corrosion inhibitor or other additives) are used, which – depending on the maximum sterilization temperature used – are approved for steam sterilization and are certified as biocompatible. The oil should be used sparingly.

Reassemble the ratchet and perform a function test.

Assembly.

To assemble the torque ratchet correctly, connect the components in the following order: first pull back the pin ⑥ as described above and

insert the ratchet wheel ①.

Caution:

To avoid confusion, the ratchet wheel ① can only be inserted on one side.

Slide the spring ④ back 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. The instrument is ready for use when there is an audible regular ratchet noise and the mechanism of the torque limit functions.

After reassembly and before sterilization, the torque ratchet should be stress-relieved at max. 10 Ncm.

Sterilization:

Additional information can be found at www.dentaurum.de (Processing Instructions Instruments and Accessories REF 989-801-09).

Overview.

Surgical restoration possibilities and components.



Surgical tray

REF 307-000-00



Surgical tray for CITO mini®

- Content:
- Marking drill
 - Stepped drill for CITO mini®, ø 1.8 mm
 - Stepped drill for CITO mini®, ø 2.2 mm
 - Stepped drill for CITO mini®, 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 CITO mini®, ø 1.8 mm	ø 1.5 mm	L 17.0 mm
REF 302-122-00		Stepped drill for CITO mini®, ø 2.2 mm	ø 1.9 mm	L 17.0 mm
REF 302-125-00		Stepped drill for CITO mini®, 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 abutment laboratory implant CITO mini® ø 1.8 mm
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 piece
REF 306-627-00		O-ring for matrix 1 CITO mini® – 10 pieces
REF 306-628-00		O-ring for matrix 2 + 3 CITO mini® – 1 piece
REF 306-629-00		O-ring for matrix 2 + 3 CITO mini® – 10 pieces

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

Demo model

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

Turnstr. 31 | 75228 Ispringen | Germany | Tel. +49 72 31/803-0 | Fax +49 72 31/803-295
www.dentaurum.com | info@dentaurum.com