

INFINITAS ORTHODONTIC MINI IMPLANT - NON STERILE

DISTRIBUTED WORLDWIDE BY:
DB Orthodontics Limited
Ryefield Way
Silsden
West Yorkshire, BD20 0EF
United Kingdom
Phone: +44 (0) 1535 656999
Fax: +44 (0) 1535 656969
Web: www.infinitas-miniimplant.co.uk

DISTRIBUTED IN U.S., CANADA, CENTRAL
AMERICA AND SOUTH AMERICA BY:
Dentsply International
GAC Division, 1 CA Plaza, Suite 100
Islandia,
NY 11749
U.S.A
Phone: 001 631 419 1500
Fax: 001 631 419 1599



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GB

**ALL OF THESE INSTRUCTIONS FOR USE MUST BE
READ CAREFULLY PRIOR TO CLINICAL USE**

USA

DESCRIPTION

•Infinitas Mini-Implant (REF DB10-0001 - DB10-0016)

To achieve temporary anchorage during orthodontic treatment with the aid of intraosseous anchorage of the Infinitas mini implant. The head of the Infinitas implant can be used with various orthodontic appliances, according to each indication, in order to achieve or support the required tooth movement.

Material Information:

The Infinitas implant system consists of various matching components to insert the implant. Infinitas implants are made from grade 5 titanium alloy (acc. to ASTM F67, ASTM F136/ISO 5832-2). This material is biocompatible, corrosion resistant and non-toxic in the biological environment, it also produces negligible artefacts by X-ray, CT and MRI.

INDICATIONS

•Temporary anchorage point for the attachment of orthodontic appliances.

GENERAL CONTRA-INDICATIONS

The Infinitas implant must not be used if the patient has a recent history of immune deficiency, steroid therapy, problems with blood clotting, uncontrolled endocrinological disease, rheumatic disease, bone disease, bisphosphonate treatment, cirrhosis of the liver or any other acute disease. The Infinitas implant must not be used if the patient has a titanium-related metal allergy or foreign body sensitivity or if the patient has unstable mental or neurological conditions, is severely non-compliant, and is unwilling or incapable of following postoperative care instructions.

LOCAL CONTRA-INDICATIONS

The Infinitas implant must not be used if the patient suffers from an active local infection or osteomyelitis, has insufficient quality or quantity of bone, a limited blood supply or history of radiotherapy of the jaws, has active periodontal disease, or unsatisfactory oral hygiene.

POSSIBLE SYSTEM ADVERSE EFFECTS

In many instances, adverse results may be clinically related rather than implant related.

- Loosening of an implant as a result of insecure insertion or unfavourable loading.
- Metal sensitivities or allergic reaction.
- Severe bending and/or fracture of an implant.
- Bony necrosis, osteoporosis, inhibited revascularisation, bone resorption, and poor bone quality/quantity can cause premature loss of an implant.
- Neurovascular damage due to surgical trauma.
- Early or late infection, both deep and/or superficial.

IMPLANT PRESENTATION

The Mini-implants and other components are delivered non-sterile and must be sterilized prior to use.

WARNINGS AND PRECAUTIONS

Responsibility for proper selection of patients, adequate training, expertise in the choice and placement of implants and the decision to leave or remove implants post-operatively, rests with the clinician. The Infinitas implant may only be inserted by orthodontists, dentists and oral/maxillofacial surgeons. The user must read and have understood the instructions for use supplied with the product.

Only original Infinitas implant components may be used according to the instructions for use. Each patient must be examined and informed about the Infinitas implant before use.

The Infinitas implant is designed for single use only. Once applied, the product should never be reused. Although it may appear undamaged, previous stresses may have created imperfections that could reduce its service life.

EXPLANATION OF SYMBOLS



Expiration Date



Please observe instructions
for use

R_x only
for professional use.



Single use only



Lot-number

Issue 7 16/06/16

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INSERTION AND REMOVAL OF THE INFINITAS IMPLANTS

Insertion:

- Select the insertion area
- Apply local/topical anaesthetic
- Fit surgical stent (optional)
- Punch a hole in the gingiva (optional) where it is thick or loose, using the mucatome (REF DB10-0022)
- Infinitas implants are self-drilling; however drilling should precede implant insertion in areas of dense cortical bone e.g. the mandible.
- For cortical plate penetration use either a drill (REF DB10-0028) in a contra-angled speed reducing hand piece (maximum RPM 1500); or bone punch (REF DB10-0023) on the standard screwdriver handle (REF DB10-0020). By turning the mid section of the handle, the bone punch will penetrate the cortical plate to a depth of up to 2mm.
- Remove the Infinitas implant from the packaging and sterilize according to our sterilizing instructions before use. Insert into the screw driver head. Insertion into the bone is achieved in a clockwise direction either manually using the Infinitas screwdriver (REF DB10-0020) or the Infinitas mini-screwdriver (REF DB10-0021); or mechanically, using a contra-angled speed-reducing hand-piece with the torque set to 20 Ncm and the RPM to a maximum of 25.

Removal:

- Apply local anaesthetic (optional).
- Unscrew the Infinitas implant in a counter-clockwise direction from the bone using either the standard screwdriver and insert or the mini-screwdriver. If unscrewing mechanically use the mini-insert with a contra-angled speed reducing hand piece with fixed RPM. The torque must be set to 20 Ncm and the RPM to a maximum of 25.

* PLEASE REFER TO THE CLINICAL INSTRUCTION MANUAL FOR FURTHER INFORMATION

VALIDATED WASHING, HANDLING AND STERILIZATION INSTRUCTIONS FOR INFINITAS INSTRUMENTS AND MINI-IMPLANTS

Infinitas mini-implants and Infinitas hand held instruments are not sterile upon receipt and must be sterilized before use in accordance with the following instructions. Remove all packaging prior to cleaning and sterilization.

Cleaning Instructions:

New and used products must be carefully cleaned before initial sterilization. Trained personnel must perform cleaning along with maintenance and mechanical inspection prior to initial sterilization. Remove any excess oil with a disposable paper towel.

Manual:

Brush using a validated cleaning agent and ensure that the instrument is cleaned thoroughly on all surfaces and joints. Special attention should be taken when washing part numbers DB10-0022, DB10-0023, DB10-0027, and DB10-0028 as these parts come into contact with bone and tissue (a fine brush should be used).

All parts should be rinsed under clean running water for 3 minutes. Repeat full process if necessary. Dry using a paper towel.

Automatic:

Use only validated washing machines and validated cleaning agents suitable for the instruments and washing machine (upto PH 14) Do not exceed 160°C. When removing the instruments from the washing machines check for cleanliness and repeat the cycle if necessary. Check for any damage or corrosion. When removing the instruments from the washing machines check for cleanliness and repeat the cycle if necessary. Check for any damage or corrosion.

Drying Process:

Remove the implant trays upon completion of the cleaning process. If the cleaning process does not include a drying cycle, thoroughly dry the implant instruments in an oven at a temperature below 110°C (230°F). Please note: Instruments left standing wet may corrode!

Sterilization:

All devices must be sterilized according to the standard routines for non-sterile instruments. Instruments should be loaded into perforated general instrument trays or the Infinitas sterilization trays. When sterilizing more than one instrument care should be taken to prevent the instruments from touching as this may cause damage or corrosion.

With pre-vacuum:
Sterilization cycle with pre-vacuum:
Temperature 134-137°C (273-279°F)
Minimum time exposure: 3 - 3.5 minutes
Drying Time: Minimum 20 minutes

Without pre-vacuum:
Sterilization cycle without pre-vacuum:
Temperature 134-137°C (273-279°F)
Minimum time exposure: 20 minutes
Drying Time: Minimum 30 minutes

The UK Department of Health recommends that validated, pre-vacuum autoclaves are used for sterilizing wrapped instruments. Autoclaves drawing only a post sterilization vacuum for drying purposes are not suitable for processing wrapped instruments.

Use only validated autoclaves. Do not exceed manufacturers stated maximum load.

U.S.A

With pre-vacuum:
Sterilization cycle with pre-vacuum:
Temperature 121°C
Time: 20 minutes

Without pre-vacuum:
Sterilization cycle without pre-vacuum:
Temperature 121°C
Time: 20 minutes

Additional Information:

Validated ultrasonic baths may be used with validated cleaning agents. Follow instructions for use issued by the equipment and cleaning manufacturer. It remains the responsibility of the trained personnel to ensure that the reprocessing has actually achieved the desired result. This normally requires validation and routine monitoring of the process. Caution: Federal law in the USA restricts the device to sale by or on the order of a physician or hospital.

DB Orthodontics recommends automatic cleaning requirements should be done following the requirements of CFPP, NI/CFPP, SHTM and WHTM publications as applicable. Infinitas washing and sterilization processes have been validated by DB Orthodontics and are in compliance with ISO 17665-1.

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