infinitas™
mini implant system

STERILE

DB Orthodontics Limited
Ryefield Way, Silsden, West Yorkshire, BD20 0EF, United Kingdom

Phone: +44 (0) 1535 656999 **I Fax:** +44 (0) 1535 656969
Email: Sales@dbortho.com **I Web:** www.dbortho.com

CE 0123 EC REP
EMERGO EUROPE
Westervoortsedijk 60
6827 AT, Arnhem
The Netherlands

DESCRIPTION

Infinitas mini-implant
(REF DB10-0009 - DB10-0019)
To achieve temporary anchorage during orthodontic treatment with the aid of intraosseous anchorage of the mini-implant. The head of the mini-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 mini-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

The Infinitas mini-implant is used to provide bone anchorage in virtually any maxillary/mandibular interproximal site and in the hard palate. It has been designed so that reliable bone anchorage can be achieved using as simple a clinical technique as possible and can be used for a number of anchorage applications. The Infinitas instrumentation has been designed for use with the Infinitas mini-implant . The devices are intended for use as follows: The Inifinitas
mini-implant system is intended to be used in a healthcare environment by suitably qualified Clinicians who are familiar with, and have experience of, the devices and surgical techniques used.

- Space closure in class I, II, III malocclusions
- Retraction of anterior teeth
- Distalisation and uprighting of molars
- Mesialisation of molars
- Intrusion of anterior or posterior teeth (anterior openbite cases)
- Bone anchored rapid maxillary expansion
- Inter-maxillary traction (and fixation during orthognathic surgery)
- Asymmetric anchorage for large centreline and occlusal cant corrections.

GENERAL CONTRA-INDICATIONS

The Infinitas mini-implant may not be used if the patient has a recent history of immune deficiency, systemic steroid therapy, problems with blood clotting, metabolic bone disease, bisphosphonate treatment, cirrhosis of the liver or any other acute systemic disease. The Infinitas mini-implant must not be used if the patient has a titanium allergy or related foreign body sensitivity, or if the patient has unstable mental or neurological conditions, is non-compliant, and is unwilling or incapable of following post-operative care instructions. Patients who smoke tobacco should be warned that this is linked to an increased risk of mini-implant failure.

LOCAL CONTRA-INDICATIONS

The Infinitas mini-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

Sterile Infinitas implants are delivered wrapped in blister foil packaging in a plastic sheath. The packaging should be removed just prior to insertion. The non-sterile mini-implants and other components are delivered non-sterile and must be sterilized prior to use.

WARNINGS AND PRECAUTIONS

- Do not use if the sterile packaging is damaged.
- Do not re-use Infinitas sterile mini-implants after their expiry date.
- Do not reprocess sterile implants.
- Infinitas mini-implants are for single use only.
- Re-insertion of an Infinitas mini-implant is not recommended.

Any serious incident that has been caused in relation to the device should be immediately reported to DB Orthodontics and the competent authority of the member state in which the user and / or patient is established.

IMPLANT INSERTION

The location and angles at which each mini-implant is inserted determine the position of its head (for attachment purposes) but crucially should be planned to avoid root proximity and maximise the bone quantity around the body. The short neck implant may be inserted manually using either the standard screwdriver, or mechanically using the screwdriver mini insert in a contra angle handpiece. We recommend long neck implants are placed using the mini-insert.

The standard screwdriver (DB10-0021) is always used for buccal insertions. The cinician has greater control of the force application and is less likely to create excessive torque (limit force to 20 Ncm). The mini screwdriver insert (DB10-0026) used in a speed reduction handpiece is recommended in palatal areas and in the posterior alveolus. The principles, similar for both, are as follows:

i) Using light pressure, and without directly touching the mini-implant threads, lock the screwdriver securely onto the head of the mini-implant.

ii) The tip of the mini-implant is placed onto the mucosa or exposed cortical surface at the desired position and 3D orientation. If a stent is used then this positional information will be dictated by the engagement of the screwdriver within the guidance cylinder. Firm pressure is used to penetrate the cortical plate, but once resistance lessens then the mini-implant should be inserted primarily by rotational means.

iii) As the mini-implant is gradually advanced then the torque felt by the clinician will most likely begin to increase, especially in the mandible. In such circumstance the mini-implant should be unscrewed by 1 to 2 anticlockwise turns before inserting it further as normal. This measure may be repeated as often as necessary. Excessive resistance may result in either implant fracture or microscopic bone damage (secondary failure).

When a speed reduction contra angle handpiece is used care should be taken not to exceed 100 RPM, to avoid microscopic bone necrosis. The Infinitas mini-implant should be inserted such that the top section of its body firmly engages the cortical plate, whilst the neck lightly depresses the mucosa, leaving the head fully accessible (yet not prominent). Notably, if primary stability is unsatisfactory then the mini-implant should be removed and the insertion process repeated at a different site. Also, it may be useful to take a radiograph to check the mini-implant position in relation to adjacent structures, especially if the patient felt discomfort and/or the adjacent teeth are tender to percussion, and re-position it if necessary.

Insertion and fracture torque. Measured according to ISO 19023 : 2018.

LOADING THE INFINITAS MINI -IMPLANT

Infinitas mini-implants can be loaded immediately after insertion. The applied force should be perpendicular to the long axis of the mini-implant. There is no need to wait for either soft tissue or bony healing, although light loading, e.g. 50g, is advisable for the first 6 weeks. Various kinds of attachments, e.g. preformed nickel titanium coil springs and elastomeric chains, can be placed into the external and/or internal undercuts. These can apply continuous forces up to 200g. The internal undercut can also accommodate standard archwires up to 0.021 x 0.025 size, and these may be secured with either a steel ligature or bonding composite (on the head).

INFINITAS MINI-IMPLANT EXPLANTATION AFTER TREATMENT OR IF LOOSE

The Infinitas mini-implant is generally removed once the need for anchorage reinforcement is complete, although in some cases it may be desirable to leave the unloaded mini-implant in place for several months as a precaution in the event that further anchorage is required. Due to the polished surface of the Infinitas mini-implant osseointegration does not occur and it is removed by simply engaging the screwdriver, usually without the need for local anaesthesia.

This removal is performed by fully engaging the screwdriver onto the mini -implant head and turning it counter-clockwise ensuring the screwdriver remains lightly pressed onto the mini-implant during the entire removal process. Minimal pain is associated with the mini-implant removal and analgesics are not indicated. No special post-removal treatment, e.g. suturing, is indicated and both the soft tissues and bone heal uneventfully (the former within days). In the case of a loose implant the loss of mini-implant stability is self-limiting since the problem is resolved by removal of a loose implant.

The Infinitas mini-implant is slowly extracted by rotating the screwdriver handle counter clockwise with one's fingers and with firm seating pressure at the base of the handle. It is essential that one's wrist is stabilised and that the rotations are produced by digit movements only.


Expiration Date


Consult Instructions for use.

Gamma Sterilised

Medical Device


Single Use Only

LOT Number


DO NOT USE IF PACKAGING IS DAMAGED