



**Clinical Instruction Manual** 

Date: 11/02/2020



### WHY CHOOSE INFINITAS?



INFINITAS: The simple, yet comprehensive, Orthodontic mini implant system for a wide range of anchorage applications.

DB Orthodontics' mission is to provide the Orthodontic profession around the world with the ultimate mini implant system. We have strived for absolute perfection from the design stage to the manufacturing of the Infinitas mini implant system. We are continually developing the Infinitas mini implant system, working with leading Orthodontic experts to ensure that our mini implants meet the highest standards expected by today's Orthodontic profession. In essence, the Infinitas mini implant system has been designed by an Orthodontist, for Orthodontists, so that precise, reliable bone anchorage can be achieved using as simple a clinical process as possible.



The Infinitas mini implant system has been designed with Dr Richard Cousley who has a wealth of experience treating complex cases both as a Consultant Orthodontist in the UK hospital service and in private practice. He has published a landmark textbook on mini-implant anchorage (second edition published in 2020) plus numerous papers on clinical and technical innovations in orthodontic bone anchorage and biomechanics, and lectures widely on the this topic. He developed the Infinitas mini implant system in 2007 in order to achieve a reliable yet relatively simple

mini implant system, especially in terms of insertion precision, multi-purpose head features, and ease of use in multiple clinical scenarios.

A combination of clinical and laboratory trials have proven that the Infinitas mini implant system is a safe and reliable treatment option for both patient and clinician.

International patent pending
U.S. patent pending
FDA
CE Marked



### FEATURES OF THE SYSTEM

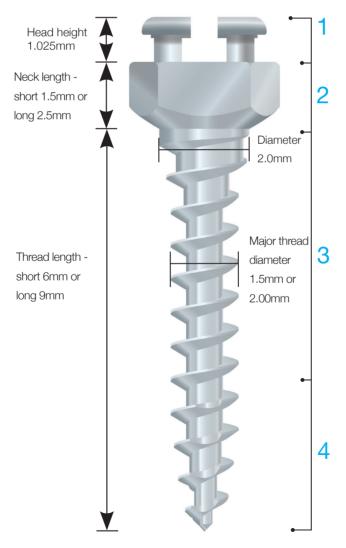


When deciding which mini implant system to purchase there are a number of clinical details to consider:

How easy will it be to insert? Can I use the same design in multiple clinical scenarios? Can I use my own traction auxiliaries or do I need to buy special closing coils etc to connect to the mini-implant?

With this in mind we have designed all components of the Infinitas mini implant system to meet all of the indications for use as we aim to exceed clinical expectations. This manual explains all of the features of this sophisticated and intelligently designed system which have already made it the system of choice for many Orthodontists.

Infinitas mini implants and IMT screw are manufactured screws from Titanium Grade 5, Ti 6A1 4V in accordance with ASTM F 136, ASTM B 348 and ISO 5832.3.

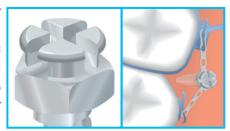


(Image shown 1.5mm Ø 9mm shortneck Infinitas mini implant)



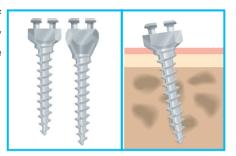
# 1) UNIQUE HEAD DESIGN FOR UNIVERSAL APPLICATIONS

The head of the Infinitas mini implant is designed for easy and direct attachment of all forms of traction. Auxillaries, such as closing coil springs, elastomeric chain and .021x.025 rectangular wire are held securely on one traction level, in the undercut of this sophisticated low profile head design. In particular there is no need for custom made closing coil springs.



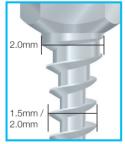
# 2) TRANSMUCOASAL NECK DESIGN

- i) Angled Transmucosal Neck ensuring ease of insertion and patient comfort when inserted at any angle due to the favourable contact between the mucosa and angled neck.
- ii) Two neck heights:
- Short neck for areas of thin mucosa.
- Long neck for areas of thick mucosa.



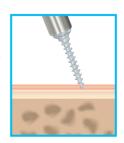
# 3) UNIQUE BODY DESIGN

- i) The unique Infinitas cutting thread continues the full length of the mini implant body and therefore through the cortical bone maximising self-drilling effects and increasing mini implant stability.
- ii) The unique tapered design of the 1.5mm diameter mini implant ensures that the coronal end of the body has a diameter of 2mm for optimum engagement of the cortical bone, whilst still permitting easy interproximal placement.



# 4) SELF DRILLING INSERTION TECHNIQUE

All Infinitas mini implants are self drilling, assuring easy insertion and maximum stability. Their self drilling thread avoids the need to pre-drill a full pilot hole. During placement in dense cortical bone excessive torque is avoided with the use of the unique Infinitas cortical punch. Details on page 5.











### **Introductory Kits**

Sterile contains 5 sterile implants

**DB10-0063** 

DB 10-0003

Non Sterile contains 5 non-sterile implants DB10-0064

### Contents:

DB10-0020	Infinitas Standard Handle (each)	
DB10-0021	Infinitas Screwdriver Standard Insert (each) (For use with short neck implants)	
DB10-0022	Infinitas Mucotome Standard Insert (each)	
DB10-0023	Infinitas Cortical Punch Standard Insert (each)	
DB10-0029	Infinitas Surgical Aluminium Tray (each)	E III
DB10-0001 - DB10-0008	Included in Non Sterile Kit Infinitas Mini Implants. Non Sterile (x5)	
DB10-0009 - DB10-0016	Included in Non Sterile Kit Infinitas Mini Implants. Sterile (x5)	······································

### **Complete Kits**

Contents as introductory Kit plus the following:

**Sterile** contains 5 sterile implants

**DB10-0060** 

Non Sterile contains 5 non-sterile implants DB10-0065

DB10-0026	Infinitas Screwdriver Mini Insert (For use with long neck implants)	s
DB10-0027	Infinitas Mucotome Mini Insert	A STATE OF THE STA
DB10-0028	Infinitas Cortical Punch Mini Insert	

Also available as an optional item

DB10-0025 Infinitas Mini Screwdriver (Manual)





The Infinitas system combines highly specialised instruments with a unique 3D guidance delivery system. Using the guidance stent will give confidence and peace of mind that the correct insertion site and angle is achieved. The stent contains a guide cylinder which accurately guides all instrumentation to the prescribed position. The stent components, available in the Infinitas Guidance Kit, simplify the production of a 3D stent and ensure effortless and accurate mini implant insertion in any location.



#### The infinitas Stent Guidance System:

- Provides a reproducible 3D insertion.
- Provides stable insertion point (no slippage of implant tip on bone) during oblique insertion and especially helpful in difficult to access sites e.g. palate.
- Reduces perforation risks.
- Inspires confidence in implant novices and difficult access insertions.
- Prescribes insertion details for other clinicians.
- · Reduces surgery time & stress.

#### Infinitas Guidance kit.

DB10-0049R (Round Baseplates)
DB10-0049S (Square Baseplate)





DB10-0030	Infinitas Stent Analogue (packet of 5)	-
DB10-0031	Infinitas Stent Abutment (packet of 5)	and the same of th
DB10-0032	Infinitas Stent Guide Cylinder (packet of 5)	
DB10-0035	Analogue C/A Drill for Plaster Model (1 each)	
DB10-0036	Analogue S/T Drill for Plaster Model (1 each)	
DB10-0037	Analogue Lab Drill for Plaster Model (1 each)	
DB10-0038	Analogue Screwdriver (1 each)	
DB10-0040S <b>OR</b>	Infinitas Baseplate - Round (packet of 5)	
DB10-0040R	Infinitas Baseplate - Square (packet of 5)	
DB10-0045	Infinitas Plastic Guidance kit box	



### INDICATIONS / CONTRAINDICATIONS



### INDICATIONS - INFINITAS MINI IMPLANTS

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 clinical a 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 and IMT Screw. 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.

### INDICATIONS - INTER MAXILLARY TRACTION SCREW

- inter-maxillary elastic or wire fixation during either orthognathic surgery or the temporary stabilisation of jaw fractures
- the application of post-operative and orthodontic inter-maxillary elastic traction.

### **GENERAL CONTRAINDICATIONS**

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 CONTRAINDICATIONS

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.

### WARNINGS

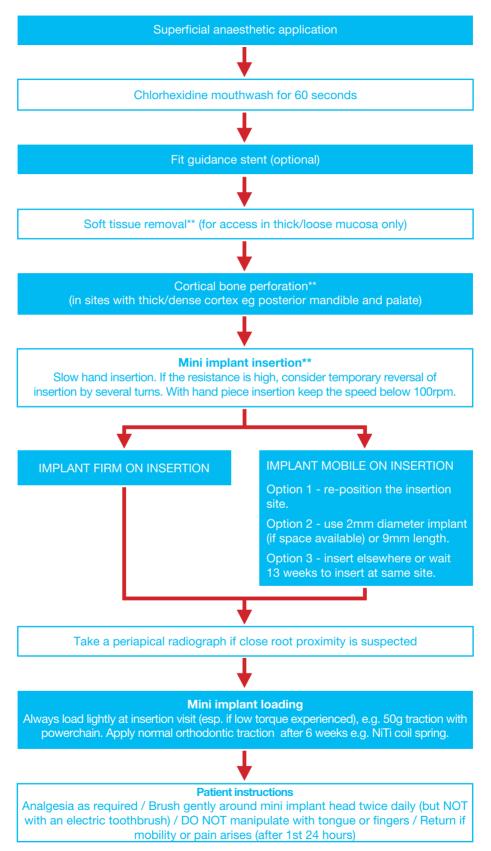
- Do not use if the Sterile Packaging is damaged.
- Do not re-use Infinitas sterile mini implants after their expiry date.
- Do not reprocess sterile implants.
- Infinitas Mini Implants are for single use only.
- Re-insertion of an Infinitas mini implant is not recommended.

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



### **PLACEMENT PROTOCOL**





<sup>\*</sup>Please note that the lot number of the implant selectedshould be retained with the patient records.

\*\*Use of the Infinitas instruments should be limited to 20 Ncm.





# 1) SELECTING THE INSERTION AREA

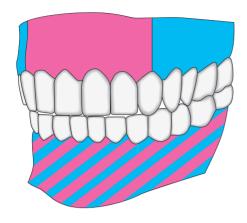
The Infinitas System can be used to provide bone anchorage in virtually any maxillary/mandibular interproximal site, although the most frequently utilised insertion site is buccal and mesial to the maxillary first molar. The insertion site is determined by individual anchorage demands and anatomical factors (e.g. bone quantity, root and sinus positions). The exact insertion site is selected by studying each patient's dental model and radiographs periapical views (+/- OPT) together. If there appears to be insufficient space then undertake a short period of root divergence prior to mini implant insertion.

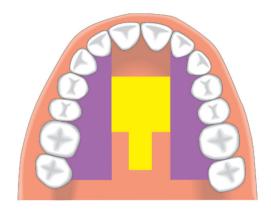


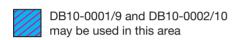
Colour Coded	Major Thread Diam	Thread Length	Neck Length	Overall Length	Non-Sterile Code	Sterile Code	Typical Ins	sertion Sites
	1.5	6	Short	8.53mm	DB10-0001	DB10-0009		erpendicular insertions endicular insertions
	1.5	9	Short	11.53mm	DB10-0002	DB10-0010	Posterior maxilla	- oblique insertions a - buccal alveolus blique insertions
	1.5	9	Long	12.53mm	DB10-0004	DB10-0012	Maxilla - pa	alatal alveolus
	2.0	6	Long	9.53mm	DB10-0007	DB10-0015	Mid-	-palate
	2.0	9	Long	12.53mm	DB10-0008	DB10-0016		ous areas torative abutment
Sterile Non-ster		810-0001		B10-0002 B10-0010		0-0004	DB10-0007 DB10-0015	DB10-0008 DB10-0016

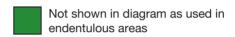
# 2) DETERMINING THE OPTIMUM INFINITAS MINI IMPLANT SIZE

A range of mini implants is available to suit all insertion sites and applications: This should be used as a guide only; patient anatomy may vary.









Determine the optimum Infinitas mini implant body size (length and diameter):

The 1.5mm diameter is selected for interproximal insertions whilst the 2.0mm size is reserved for edentulous sites (eg mid-palate and previous extraction sites).

A long (9mm) body length is ideal for posterior maxillary sites whereas the short (6mm) length is better suited in sites with increased cortical depth and/or limited total bone depth e.g. anterior alveolus and mid-palate.

Determine the optimum Infinitas mini implant neck length.

The short neck versions are typically used in labial/buccal sites, where the mucosa is thin, and the long neck versions in edentulous and palatal sites. The tissue thickness may be checked using a periodontal probe (with or without an endodontic stopper on the probe).

\*There is a risk of implant fracture or implant loosening if the incorrect screw is selected.

## 3) INTER-MAXILLARY TRACTION

The Infinitas system includes mini implants which are specifically designed for intermaxillary fixation and/or traction during and post surgical procedures.

Product Code (Non-Sterile)	Major Thread Diam	Thread Length	Overall Length (mm)	Neck Length	Typical Insertion Sites
DB10-0101	1.5	9	12.525	Short	Buccal sites
DB10-0100	1.5	6	9.525	Short	Incisor sites







The Infinitas IMT Screw is used to provide temporary bone anchorage in any maxillary and mandibular interproximal site where there is sufficient dental root clearance. The IMT mini-screw heads are designed for the application of inter-maxillary elastic or wire fixation during either orthognathic surgery or the temporary stabilisation of jaw fractures. They are also intended to provide bone-anchored inter-maxillary elastic traction during the post-operative (osteotomy / fracture) phase and during normal orthodontic treatment (where the application of traction on tooth-borne surgical / orthodontic appliances is either inappropriate or unfeasible).

## 4) STENT PRODUCTION (OPTIONAL)

Whilst the use of a guidance stent is optional, it is very useful in posterior and / or palatel areas which are often difficult to access, and by inexperienced clinicians for most locations. The process of stent production is described in detail in the Infinitas Guidance System manual.



# 5) ANAESTHETIC APPLICATION

Superficial anaesthesia is achieved using either local or topical anaesthesia. This aims to anaesthetise the mucosa and periosteum at the insertion site. However, deep levels of anaesthesia are both unnecessary and indeed unhelpful since pressure feedback from adjacent dental tissues and the opposite side of the alveolus can alert the clinician that the position/orientation of the mini implant needs to be altered during insertion.



# 6) CHLORHEXIDINE MOUTHWASH

The patient should rinse the insertion site(s) for one minute using 0.2% chlorhexdine gluconate mouthwash. This helps to reduce the bacterial levels immediately pre-insertion.

# 7) STENT APPLICATION (OPTIONAL)

If a stent is available it is fitted onto the dentition once adequate anaesthesia has been achieved. This guides all of the subsequent Infinitas instruments.

# 8) MUCOTOME (OPTIONAL)

The Infinitas mini implant is designed for transmucosal insertion, but the mucotome (soft tissue punch) is required when the mini implant will penetrate thick (e.g. palatal) or mobile mucosa. The mucotome is positioned perpendicular to the tissue surface and its cutting end is pressed through the soft tissue with clockwise rotations (limit force to 20 Ncm). Once the bone is contacted, the punch is rotated against its surface to fully incise the circle of tissue. If the tissue is cleanly incised, it

usually stays in the head of the punch. Otherwise the excision can be completed with a curette and Mosquito forceps / tweezers.

When a stent is used it is best to provisionally indent the mucosa with the mucotome in the guidance cylinder, then remove the stent to enable the mucotome to be applied perpendicular to the tissue surface. N.B. If the mucosa remains in the mucotome after use, this must be removed using a dental probe prior to instrument decontamination. (fig 4)



Fig. 4 Mucotome Tissue Punch A. Hole for probe application to remove mucosa.



Two versions of the mucotome are available:

- i) The standard mucotome (DB10-0022) fits into the standard handle (DB10-0020). Clockwise rotation of the screwdriver handles causes the punch tip to incise the tissue.
- ii) In palatal areas which are difficult to access, it is preferable to use the mini mucotome (DB10-0027) in a speed reduction (e.g. 128:1) contra angle handpiece.

### 9. CORTICAL PUNCH

Infinitas mini implants are self-drilling and may be inserted directly in many situations using the standard screwdriver (DB10-0021). However, it is important to use the cortical punch in areas of dense cortical bone e.g. the posterior mandible, the mid-palate, and the palatal alveolus. This facilitates implant insertion by reducing the generation of excessive insertion torque. Indentation of the cortical plate also prevents slippage of the mini implant tip when it is inserted at an oblique angle to the cortical plate. The cortical punch has a 2mm long tip. The punch should be placed at the planned insertion angles (limit force to 20 Ncm).

If a stent is used then the punch will fit precisely into the guidance channel to ensure accuracy. Two versions of the cortical punch are available:

- i) The standard cortical punch (DB10-0023) fits into the standard handle (DB10-0020). Clockwise rotation of the screwdriver handles causes the punch tip to perforate the cortical plate.
- ii) In those areas which are difficult to access, such as maxillary sites, it is preferable to use the mini cortical punch (DB10-0028) in a speed reduction (e.g. 128:1) contra angle handpiece. It is important not to exceed 100 RPM to avoid over-heating the bone, but irrigation is not required. To ensure the exact position of the cortical perforation, a stent is recommended in such limited access situations.



Fig. 5 Mini screwdriver insert in speed reducing handpiece

\*The tip of the Standard and Mini Cortical punch will gradually blunt against the bone surface, so therefore needs to be replaced when the operator notices that it begins to readily stop perforating the bone surface. The minimum acceptable number of uses for the Cortical Punch Mini Insert, Cortical Punch Standard Insert, Mucatome Mini Insert and Mucatome Standard Insert is 50 and the maximum 100.

Is recommended that the Infinitas instruments are routinely checked for wear and tear/damage prior to reprocessing.

### 10. 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, it gives a better feel for the clinician 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 minimplant threads, lock the screwdriver securely onto the head of the Infinitas 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.

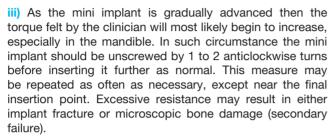






Fig. 8 Insertion using Infinitas Stent

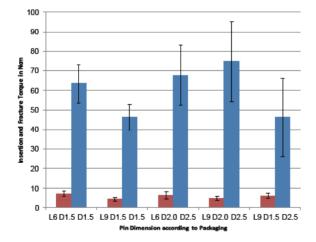
When a speed reduction contra angle handpiece is used care should be taken **NOT TO EXCEED 100 RPM**, to avoid microscopic bone necrosis. The Infinitas mini implant should be inserted such that the top section of its body firmly engages the cortical plate, whilst the neck lightly depresses

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.





### 11. 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



Fig 10. NiTi coil spring attached directly to the Infinitas Mini Implant

be secured with either a steel ligature or bonding composite (on the head).

### 12. PATIENT INSTRUCTIONS

It is advisable to provide the patient with both verbal and written instructions, in accordance with the Infinitas patient guidance sheet.

# 13. 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 Infinitas 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 explanated 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. Non-sterile Infinitas mini implants, hand held instruments and kit box 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.

### **DECONTAMINATION**



### **Washing 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 (up to 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.

#### **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 using validated autoclaves according to the standard routines for nonsterile instruments. Instruments should be loaded into perforated general instrument trays or the Infinitas surgical trays. When sterilizing more than one instrument care should be taken to prevent the instruments from touching as this may cause damage or corrosion.

#### UK

With pre-vacuum:

Temperature 134-137°C

Minimum time exposure:

3 - 3.5 minutes Drying Time:

Minimum 20 minutes

Without pre-vacuum:

Temperature: 134-137°C

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

#### U.S.A

With pre-vacuum:

Temperature 121°C Time: 20 minutes

Without pre-vacuum:

Temperature 121°C Time: 20 minutes

#### **Additional Information:**

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. 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.

#### **Quality Control**

DB Orthodontics operates a Quality Management System in accordance with ISO 13485. This encompasses a Batch/Lot Control system for full traceability of all medical devices and equipment sold by DB Orthodontics. Customers of DB Orthodontics should be reminded to retain product information for medical devices supplied by DB Orthodontics. Information should include Batch/Lot Number and Expiry date which would be required should the need arise to return the product or in the case of a product recall.

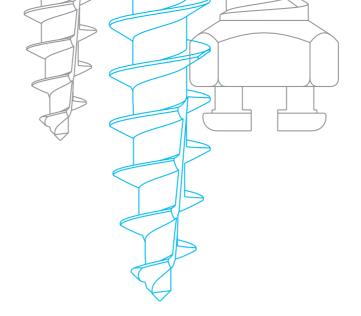
#### **Packing**

DB Orthodontics' Non-sterile Infinitas mini implants and Instrumentation are provided in unsterile packaging and should be steilized in accordance with the instructions above.

### WARRANTY

Sold under DB Orthodontics terms and conditions - please refer to www.dbortho.com for terms and conditions.









### **DB Orthodontics Limited**

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