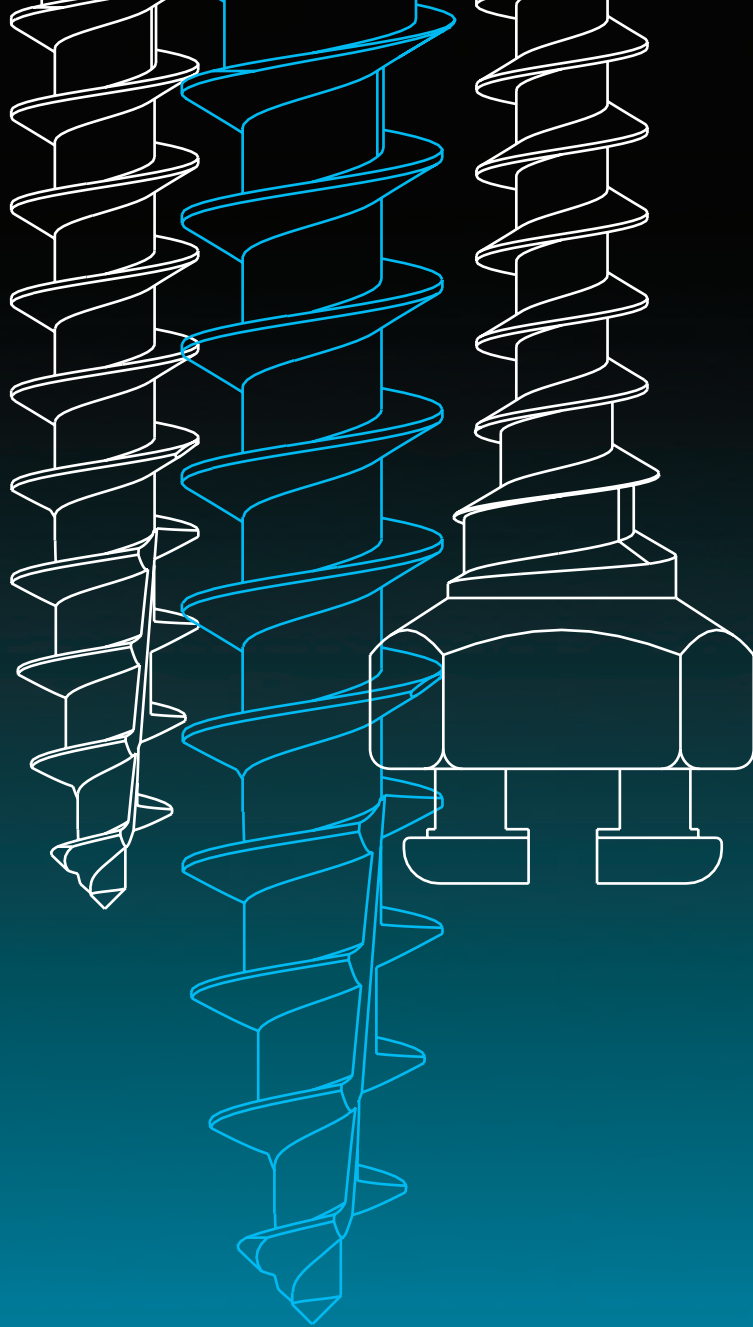




infinitasTM

mini implant system

clinical instruction manual

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infinitas

Why choose *Infinitas*?



The simple, yet comprehensive, Orthodontic mini implant system for an infinite number of anchorage applications.

Infinitas mini implant system from DB Orthodontics.

DB Orthodontics' mission is to provide the Orthodontic profession around the world with the best 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 is a Consultant Orthodontist working in the UK hospital service and private practice. He has published papers and lectured widely on the technical aspects of bone anchorage, and developed the Infinitas mini implants system to overcome some of the limitations of existing mini implants, especially in terms of their lack of insertion precision, limited head features, and overly complex inventories.

A combination of clinical and laboratory trials have proven that the Infinitas mini implant system is reliable and provides comfort to both patient and clinician.

International patent pending.

U.S. patent pending

FDA Cleared for marketing in the US

CE Marked



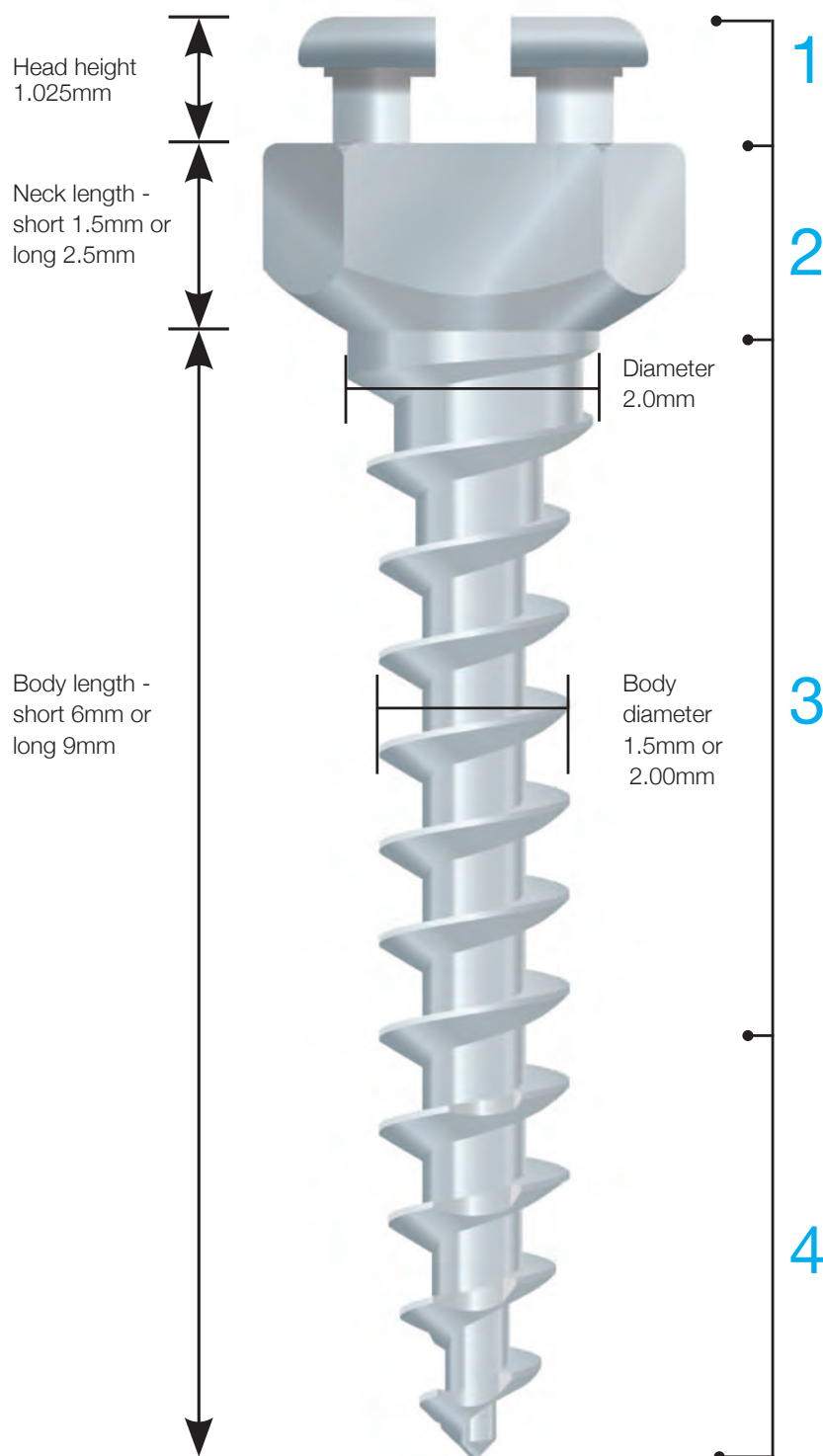
Dr Richard Cousley

Features of the System

When deciding which mini implant system to purchase there are a number of clinical details to consider: How easily will auxiliaries such as closing coil springs or elastomeric chain attach to the head? How comfortable will it be for the patient? How easily will it integrate with my current treatment mechanics? Will I need to drill a pilot hole or will the mini implants self-drill?

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.



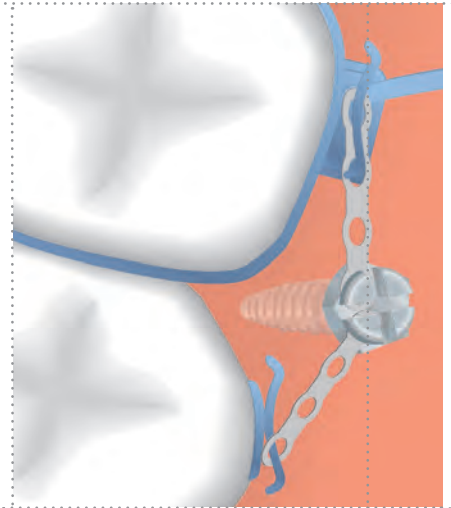
(Image shown 1.5mm $\varnothing$ 9mm Shortneck Infinitas mini implant)

1 Unique head design for universal applications

(patent pending)

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.

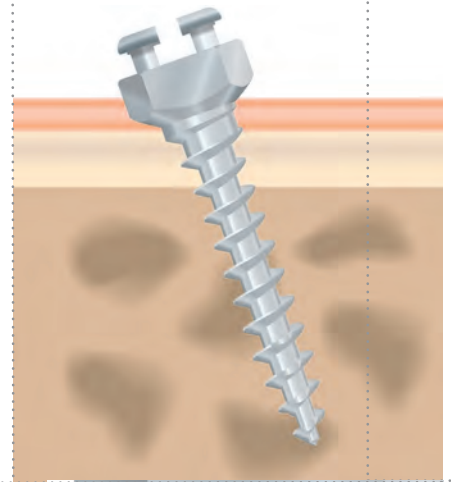
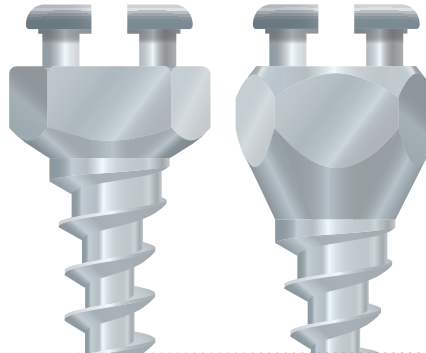


2 Transmucosal neck design

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:

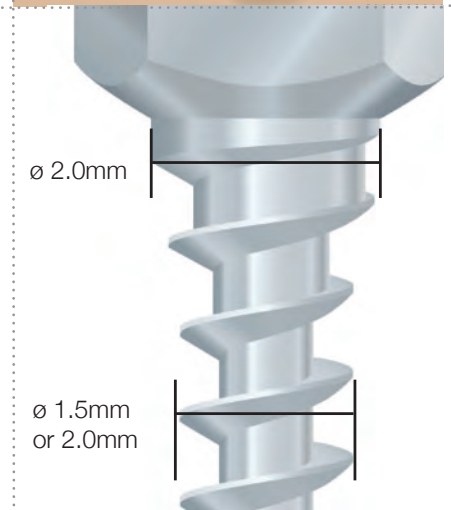
- Short neck for areas of thin mucosa.
- Long neck for areas of thick mucosa.



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.

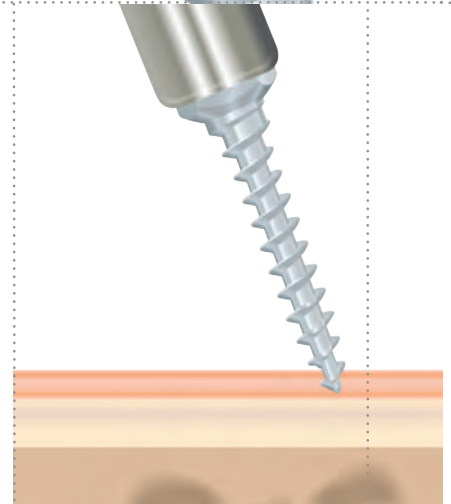
ii) The unique tapered design of the 1.5mm diameter mini implant ensures that the coronal end of the body has a diameter of 2mm for optimum engagement of the cortical bone, whilst still permitting easy interproximal placement.



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 bone punch. Details on page 5.



clinical kits



Introductory Kits

DB10-0063

Sterile contains 5 sterile implants

DB10-0064

Non Sterile contains 5 non-sterile implants

Contents:

DB10-0020	Infinitas Standard Handle (each)	
DB10-0021	Infinitas Screwdriver Standard Insert (each)	
DB10-0022	Infinitas Mucotome Standard Insert (each)	
DB10-0023	Infinitas Cortical Punch Standard Insert (each)	
DB10-0029	Infinitas Surgical Aluminium Tray (each)	
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:

DB10-0025	Infinitas Mini Screwdriver (Manual)	
DB10-0026	Infinitas Screwdriver Mini Insert	
DB10-0027	Infinitas Mucotome Mini Insert	
DB10-0028	Infinitas Cortical Punch Mini Insert	

DB10-0060

Sterile contains 5 sterile implants

DB10-0065

Non Sterile contains 5 non-sterile implants

guidance *kit*



Infinitas is the only truly complete system featuring mini implants combined with highly specialised instruments and a unique 3D guidance system. The stent contains a guide cylinder which accurately guides all instrumentation to the prescribed position. Patented 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)

Guidance Kit Contains:

DB10-0030	Infinitas Stent Analogue (packet of 5)	
DB10-0031	Infinitas Stent Abutment (packet of 5)	
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)	
DB10-0040R or DB10-0040S	Infinitas Baseplate - Round (packet of 5) Infinitas Baseplate - Square (packet of 5)	
DB10-0045	Infinitas Plastic Guidance kit box	



Clinical Procedure

indications/ contraindications

Indications

- 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)
- Changing tooth positions for pre-prosthetic treatment
- Inter-maxillary traction (and fixation during orthognathic surgery)

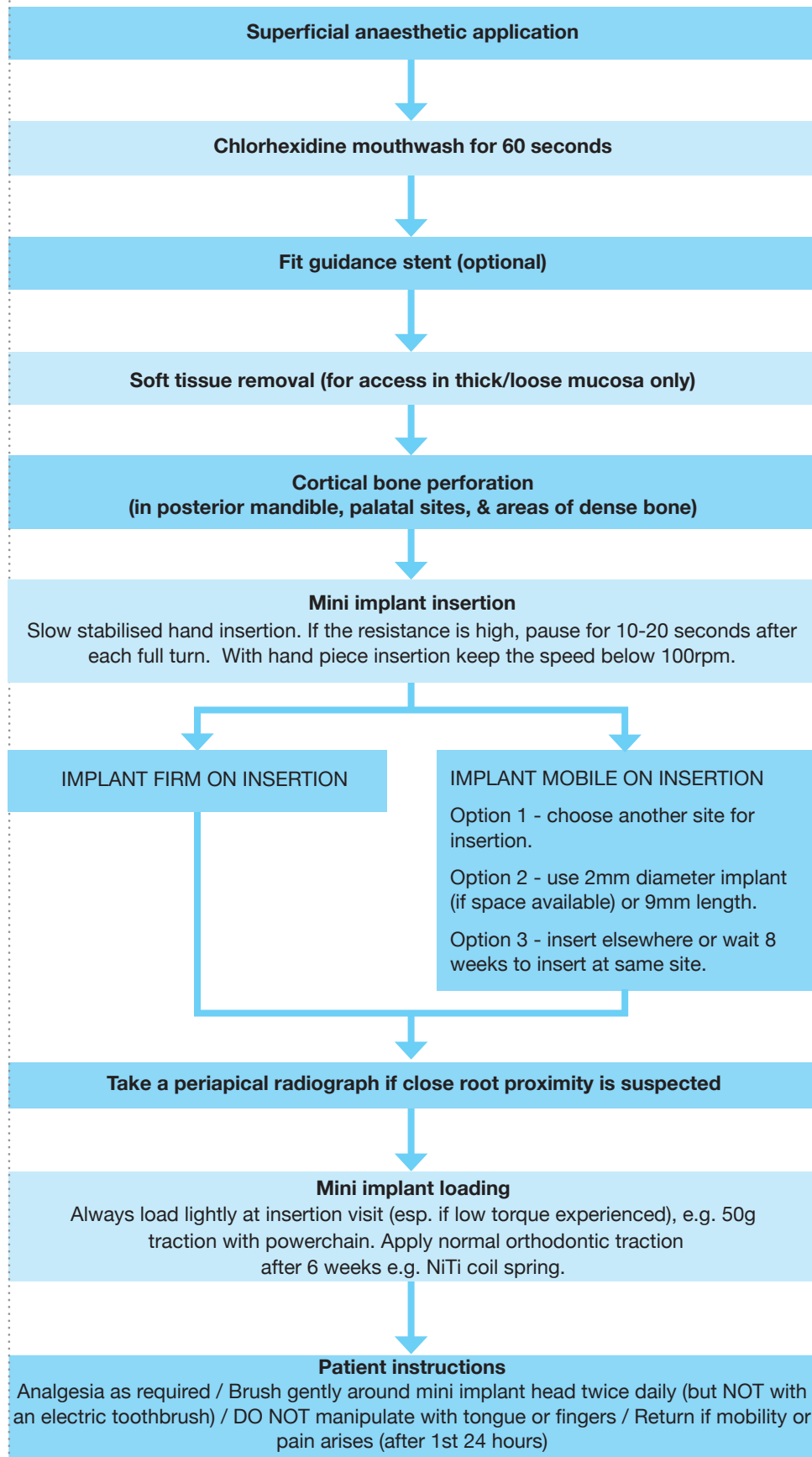
General Contraindications

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.

placement protocol



clinical procedure

1 Selecting the Insertion Area

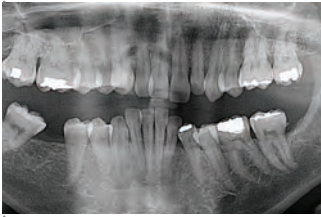


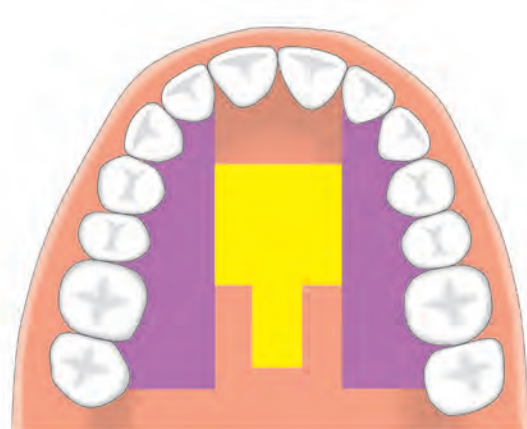
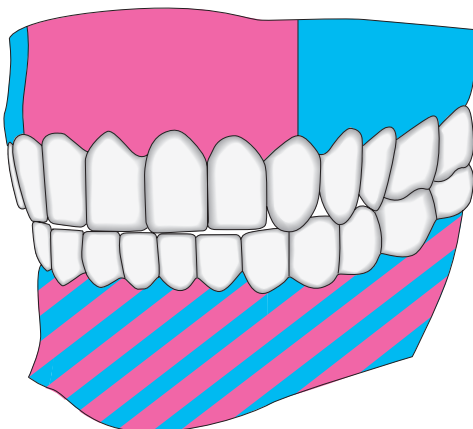
Fig. 1 Use Xrays to determine insertion sites

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	Diam.	Body Length	Neck Length	Non-Sterile Code	Sterile Code	Typical Insertion Sites
	1.5	6	Short	DB10-0001	DB10-0009	Anterior maxilla - perpendicular insertions Mandible - perpendicular insertions
	1.5	9	Short	DB10-0002	DB10-0010	Anterior maxilla - oblique insertions Posterior maxilla - buccal alveolus Mandible - oblique insertions
	1.5	9	Long	DB10-0004	DB10-0012	Maxilla - palatal alveolus
	2.0	6	Long	DB10-0007	DB10-0015	Mid-palate
	2.0	9	Long	DB10-0008	DB10-0016	Edentulous areas Temporary restorative abutment

2 Determining the optimum Infinitas 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.



DB10-0001/9 and DB10-0002/10 may be used in this area



Not shown in diagram as used in edentulous areas

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).

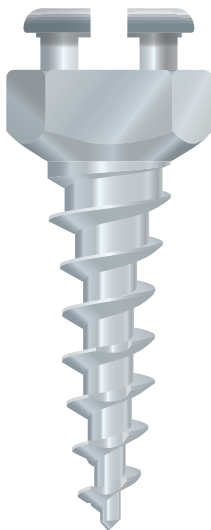
A long (9mm) body length is ideal for posterior maxillary sites whereas the short (6mm) length is better suited in sites with increased cortical depth and/or limited total bone depth e.g. anterior alveolus and mid-palate.

Determine the optimum Infinitas mini implant neck length.

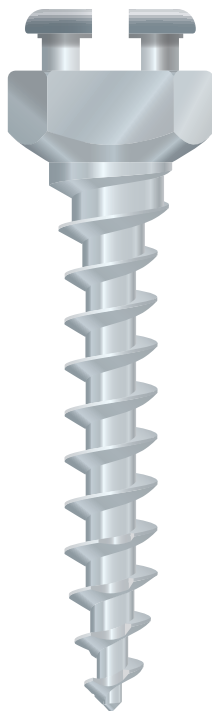
The short neck versions are typically used in labial/buccal sites, where the mucosa is thin, and the long neck versions in edentulous and palatal sites. The tissue thickness may be checked using a periodontal probe (with or without an endodontic stopper on the probe).

Sterile
Non-sterile

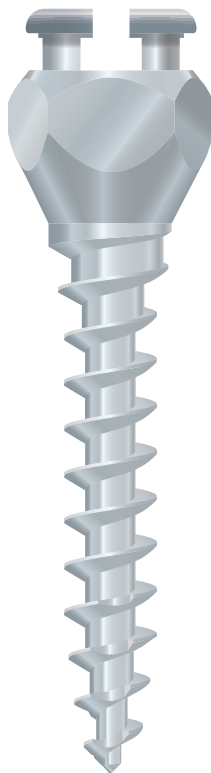
DB10-0001
DB10-0009



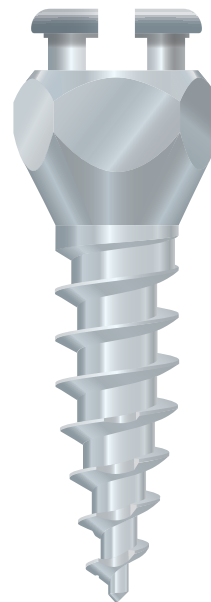
DB10-0002
DB10-0010



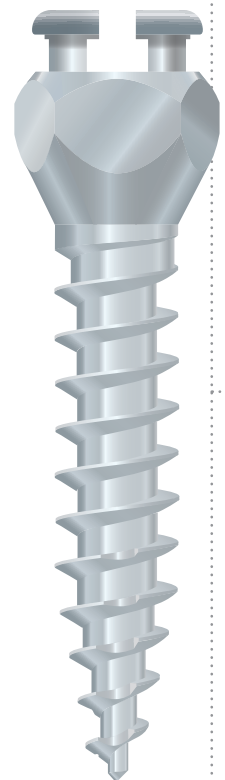
DB10-0004
DB10-0012



DB10-0007
DB10-0015



DB10-0008
DB10-0016





3 Inter-maxillary Traction Range

These two additional mini implants are specifically designed for intermaxillary fixation and/or traction.

Product Code (Non-Sterile)	Diameter	Body Length	Neck Length	Typical Insertion Sites
DB10-0101	1.5	9	Short	Buccal sites
DB10-0100	1.5	6	Short	Incisor sites

4 Stent Production (optional)

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



Fig. 2 Infinitas Stent in clinical use



Fig. 3 Anaesthetic application

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% chlorhexidine 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 Tissue Punch (optional)

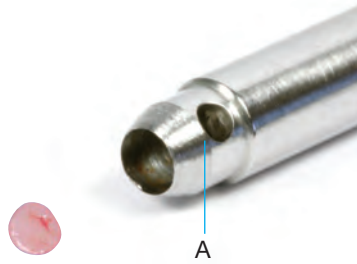


Fig. 4 Mucotome Tissue Punch
A. Hole for probe application to remove mucosa.

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. 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)

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 tissue punch (DB10-0027) in a speed reduction (e.g. 128:1) contra angle handpiece.

9 Cortical Bone 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 bone 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 diamond hard tip. The punch should be placed at the planned insertion angles.

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 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 bone 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 Cortical Bone Punch Insert in the Standard Handle

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 implant may be inserted manually using either the standard screwdriver, or mechanically using the screwdriver mini insert in a contra angle handpiece. The standard screwdriver (DB10-0021) is used for most buccal insertions, whilst the mini screwdriver insert (DB10-0026) used in a speed reduction (e.g. 128:1) 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 Infinitas mini implant.



Fig. 6 Mini Implant in position in the Standard Screwdriver



Fig. 7 Initial insertion



Fig. 8 Insertion using Infinitas Stent



Fig. 9 Inserted 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. The mini implant is slowly inserted by rotating the screwdriver handle 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. 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 insertion should either be paused for 20 seconds (allowing the viscoelastic bone to expand around the mini implant), or the mini implant should be unscrewed by 1 to 2 anticlockwise turns before inserting it further as normal. These measures 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.

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



Fig 10. Niti Coil spring attached directly to the Infinitas Mini Implant

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

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. 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).

Decontamination

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.

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 (HTM2030) 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.

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 (HTM2010) according to the standard routines for non-sterile 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 (HTM 2030). Do not exceed manufacturers stated maximum load. Use only validated autoclaves (HTM 2010).

U.S.A

With pre-vacuum:

Temperature 121°C

Time: 20 minutes

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.

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 sterilized in accordance with the instructions above.

warranty

DB Orthodontics warrants to the dental professional who purchases its products that all reasonable care has been taken in the choice of materials, method of manufacture, coating and packaging. DB Orthodontics shall not be liable for any incidental or consequential loss, damage or expense, directly or indirectly arising from the use of its products. The foregoing warranty, as conditioned and limited, is in lieu of and excludes all other warranties, whether expressed or implied, including but not limited to any implied warranties of merchantability or fitness-for-use, and of any other obligation on the part of the seller. DB Orthodontics neither assumes, nor authorises any other person to assume for it any additional liability or responsibility in connection with its products. No agent, employee or representative of DB Orthodontics has any authority to bind DB Orthodontics to any affirmation, representation or warranty concerning its products and any such representation or warranty shall not be enforceable by the buyer. Liability under this warranty is limited to replacement of any defective materials, manufacture or packaging. Damage to any DB Orthodontics product through misuse, neglect, accident or failure to follow recommended procedures or instructions for use by the buyer or user voids any DB Orthodontics warranty. Product replacement under DB Orthodontics' warranty shall be effected by promptly contacting DB Orthodontics at the phone numbers provided. Nothing in DB Orthodontics' warranty shall be construed to extend the rights or remedies of a patient into whom a DB Orthodontics product is implanted.

CAUTION: UK laws restrict the sale of any Infinitas product or device to licensed physicians, dentists or dental specialists. Use by any other person is strictly prohibited.

delivery and returns *policy*

1. DB Orthodontics will endeavour to despatch on the same day, all orders received by 4pm.
2. Delivery will be by next day carrier or first class post to mainland UK.
3. Customers should carefully check the carrier's documentation to ensure they are signing for the correct amount of parcels. If the incorrect amount of parcels are signed for, DB Orthodontics can not compensate the customer for the loss of goods unless reported within 2 hours of delivery.
4. Shortages and breakages must be reported to DB Orthodontics within 2 working days of receipt of the goods and confirmed in writing within 14 days.

Returns

1. Any returned item lost, damaged or defaced in transit to DB Orthodontics will not be credited. If the buyer has not received an acknowledgement or credit note within 14 days, they should notify DB Orthodontics.
2. Any returned items must be packed in a cardboard box and suitably labelled to DB Orthodontics.
3. Any item can only be returned for full credit if unused, complete, and in the original packaging.
4. Subject to conditions 1-4 above, DB Orthodontics will accept for credit at a sum equal to that which the buyer paid for the goods:
 - a) Items returned to and received by DB Orthodontics in a re-saleable condition provided they are received within 28 days of invoice date.
 - b) Any item received damaged or unusable provided DB Orthodontics is notified according to condition.
5. A handling charge of 25% may be raised on any return of saleable goods received after 28 days from invoice date.
6. DB Orthodontics reserves the right to charge carriage on returns where collection is arranged by DB Orthodontics.



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Class 11a and 11b medical devices
Amtac Certification Services Limited
Davy Avenue
Knowhill
Milton Keynes
MK5 8NL



Class 1 medical devices



NOTES

NOTES



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