



Guidance System Manual

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infinitas



Infinitas™
guidance kit

Infinitas
GUIDE
CYLINDER
DB10-0032

Infinitas
ANALOGUE
DB10-0030

Infinitas
ABUTMENT
DB10-0031

TC 171L FG
TC 171L RR

Infinitas Mini Implant System



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 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.

Infinitas mini implants 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 and overly complex inventories.



Dr. Richard Cousley

A combination of clinical and computerised 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

Guidance Kit

Infinitas Guidance kit:

DB10-0049R (Round Baseplates)










DB10-0049S (Square Baseplate)



(Image shows Infinitas Guidance Kit DB10-0049S)

Product description and order information for individual components.

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) 1.5mm Infinitas Baseplate - Square (packet of 5) 1.5mm	
	Infinitas Plastic Guidance kit box	
	Infinitas Guidance System Instructions (1 each)	

Mini Implant Planning and Stent Fabrication

1.1 Determine the Insertion Details Using a Dental Model and Radiographs

The optimum three-dimensional position for each Infitas mini implant is determined using both plain radiographs (e.g. a panoramic tomograph or intra-oral views) and a plaster model of the dental arch. Ideally, the mini implant should be located where there is a maximum depth of cortical and cancellous bone, whilst avoiding structures such as adjacent dental roots, the gingival papilla, neurovascular tissues and nasal/maxillary cavities. As such, a balance is struck between three parameters:

- the topographical entry point of the implant
- the angulation: antero-posterior (AP) angle of entry
- the inclination: vertical angle of entry.

For example, where a patient requires retraction of the anterior teeth into a first premolar space then the mini-implant is commonly located buccally between the second premolar and first molar teeth in this quadrant. The insertion point and angles will be influenced by the position and morphology of the adjacent dental roots. The vertical level and angulation of the entry point affect the implant head's proximity to the gingivae and emergence angle. These, in turn, influence the prominence of the implant head and the ease of application of traction components.

If a dental technician is to insert the mini implant analogue then the planned location and angulations should be prescribed in writing by the orthodontist, and ideally an ink mark placed on the dental model to indicate the exact insertion site.



Fig.1 X-rays used to determine place of insertion.

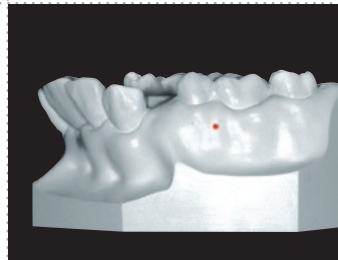


Fig.2 Model with location mark.

1.2 Drill a Pilot Hole in the Model

A pilot hole is drilled in the patient's dental model, using an Analogue Drill (DB10-0035 or DB10-0036) in either a straight or contra-angle dental hand piece, or in a laboratory hand piece (DB10-0037), to a depth of approximately 10 mm. It is critical that the drill is held at the correct 3D angulations to ensure that the desired vertical and mesio-distal insertion angles are produced. This procedure is normally performed 'free hand', but if desired, a technician may use the Analogue Drill in a vertical pillar drill with the model set on an adjustable angled table (as described in Cousley RRJ, Parberry DJ. Surgical stents for accurate miniscrew insertion. *Journal of Clinical Orthodontics* 2006; 40: 412-417).



Fig.3 Analogue drill in Model.

1.3 Place Mini Implant Analogue in Model

The mini implant analogue (DB10-0030) is inserted manually and fully seated using the Analogue Screwdriver (DB10-0038) rotated in a clockwise direction. The location and angulations of the analogue should then be checked. If the 3D position of the analogue is dissimilar to the planned details then the analogue should be removed and the drilling and insertion process repeated.



Fig.4 Analogue screw in place.

1.4 Fit Abutment onto Analogue

The Infinitas Stent Abutment (DB10-0031) is manually fitted onto the head of the analogue by matching its internal pentagonal sides to the external configuration of the analogue's neck.

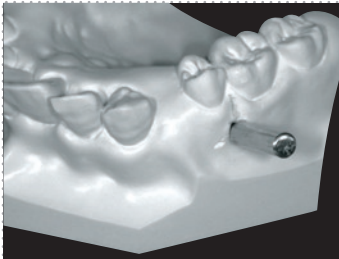


Fig.5 Abutment over analogue.

1.5 Fit Guide Cylinder onto Analogue

The Infinitas Stent Guide Cylinder (DB10-0032) is fitted by sliding it over the surface of the Infinitas abutment until it contacts the plaster model surface.

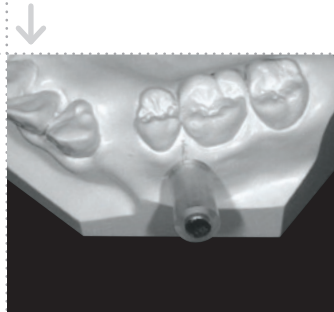


Fig.6 Guidance cylinder over Abutment.

1.6 Fabricate the Stent Baseplate

Plaster separator (cold mould seal) is applied to the plaster model. A 1.5 mm thermoforming baseplate, such as the Infinitas Baseplate which is available in Round or Square versions (DB10-0040R or DB10-0040S) is placed on top of the assembled model, abutment and guide cylinder components. It is then pressure-formed onto the model using a machine conventionally used for retainer fabrication.

When placing the model into the pressure forming machine the guide cylinder should be in a vertical position (standing upright (Fig.7a), this helps to create a fold in the base plate material from the guidance cylinder to the palatal or buccal surface of the stent (see Fig.8), (to help with removal of the stent from the plaster model it may be necessary to block out all undercuts).



Fig.7a Model placed in pressure forming machine with guide cylinder in vertical position



Fig.7b Baseplate & cylinder after thermoforming.

The baseplate now incorporates the guide cylinder and they are removed en masse from the model and abutment (Fig.7b). The baseplate's labial and lingual edges are trimmed, and the superficial end of the guide cylinder is opened by cutting through the covering baseplate layer.

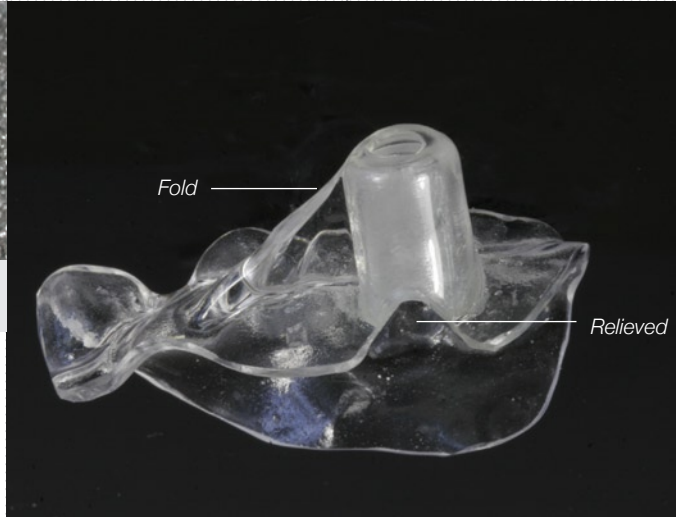


Fig.8 Trimmed baseplate to form stent with both superficial end & fitting surface of guide cylinder relieved.

The mini implant insertion site is exposed by relieving 3-4 mm of the fitting surface of the guide cylinder and adjacent baseplate (Fig.8). This provides open visual access of the insertion site without detracting from the positive guidance that the cylinder provides for the screwdriver. It also makes it easier to remove the stent from over the mini-implant head when the latter is not yet fully seated (during clinical insertion).





Fig.9 Stent fitted to model allowing open visual access of insertion site.

1.7 Pre-form Attachments (optional)

The Infinitas guidance system enables the orthodontist or dental technician to accurately fabricate wire attachments (e.g. 0.021x0.025 archwire) in advance of the clinical stage. In particular, if it is planned to provide indirect anchorage with a transpalatal arch then this can be made using the analogue(s) fitted in the patient's dental model. This also includes soldering bondable bonding bases to the wire.



Fig.10 Infinitas head with 0.021 x 0.025 wire.

Quality Control, Packing & Warranty

Quality Control

DB Orthodontics operates a Quality Management System in accordance with BS EN ISO 9002. 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' Infitas mini implants are provided sterile. Infitas mini implants are also provided non sterile together with dental instrumentation and components.

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 Infitas product or device to licensed physicians, dentists or dental specialists. Use by any other person is strictly prohibited.

Delivery, Returns Policy & Distributors

Delivery

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.

Distributors

For an updated list of Infitas Mini Implant Distributors log onto our web site: **www.infitas-miniimplant.com** or contact the head office.



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