



 **infinitas**TM
mini implant system

Guidance System Manual

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Class 2a and 2b medical devices
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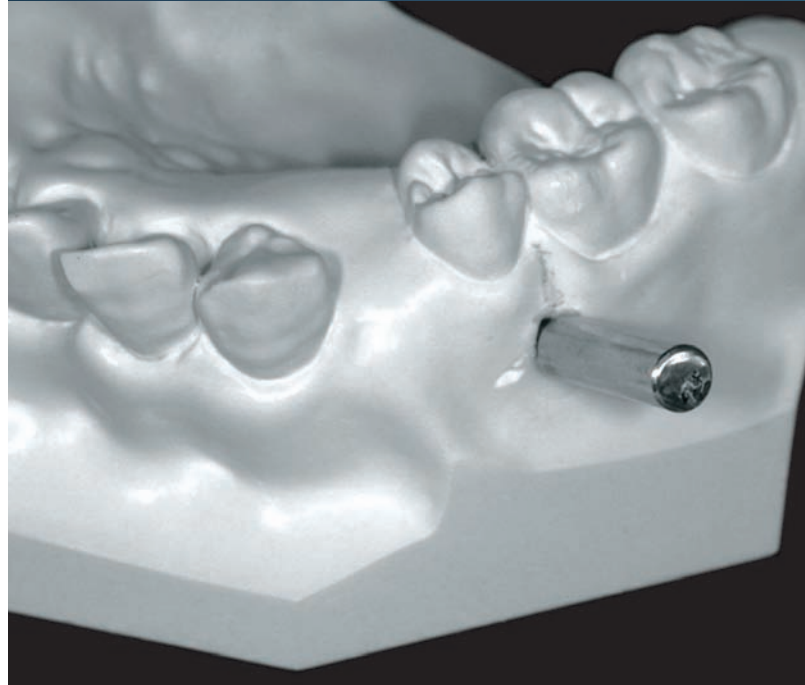
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Part Art. Part Science. All Orthodontics.

For better dentistry
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WARRANTY & CONTACT INFORMATION



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' Infinitas mini implants are provided sterile. Infinitas mini implants are also provided non sterile together with dental instrumentation and components.

Contact Information

For troubleshooting and/or service, please contact your local DENTSPLY GAC sales representative or DENTSPLY GAC Customer Service Department directly at 1-888-GACINTL (422-4685) or 1-631-419-1700.

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 authorizes 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.

GUIDANCE KIT

WHY CHOOSE INFINITAS?










Infinitas Guidance Kit: KIT95-010-49R (Round Baseplates) / KIT95-010-49S (Square Baseplate)

Product description and order information for individual components.

Guidance Kit contains:

(Image shows Infinitas Guidance Kit KIT95-010-49S)



95-010-30	Infinitas Stent Analogue (packet of 5)	
95-010-31	Infinitas Stent Abutment (packet of 5)	
95-010-32	Infinitas Stent Guide Cylinder (packet of 5)	
95-010-35	Analogue C/A Drill for Plaster Model (1 each)	
95-010-36	Analogue S/T Drill for Plaster Model (1 each)	
95-010-37	Analogue Lab Drill for Plaster Model (1 each)	
95-010-38	Analogue Screwdriver (1 each)	
95-010-40R or 95-010-40S	Infinitas Baseplate - Round (packet of 5) 1.5mm Infinitas Baseplate - Square (packet of 5) 1.5mm	
95-010-45	Infinitas Plastic Guidance kit box	



The Simple, Yet Comprehensive, Orthodontic Mini Implant System for a Wide Variety 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 Temporary Anchorage Device (TAD) System.

We are continually evolving the Infinitas TAD 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 TAD 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 TAD 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.

International patent pending.

U.S. patent pending

FDA Cleared for marketing in the US

CE Marked

GUIDANCE KIT DIRECTIONS FOR USE

Indications For Use

None Known

Contraindications

None Known

Warnings

For professional use only.

The Infinitas guidance kit is intended for use only with the Infinitas clinical kit and its related mini-implant insertion techniques. It does not replace the need for a full orthodontic diagnostic and treatment planning process.

Precautions

None Known

Adverse Reactions

None Known

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Part Art. Part Science. All Orthodontics.

MINI IMPLANT PLANNING AND STENT FABRICATION



Fig.10 Infinitas head with 0.021 x 0.025 wire.

1.7 Pre-form Attachments (optional)

The Infinitas guidance system enables the orthodontist or dental technician to accurately fabricate wire attachments (e.g. 0.021" x 0.025" 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 may also include soldering bondable bonding bases to the wire.



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

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MINI IMPLANT PLANNING AND STENT FABRICATION



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.

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1.6 Fabricate the Stent Baseplate

Plaster separator (cold mold 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 (95-010-40R or 95-010-40S) 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.

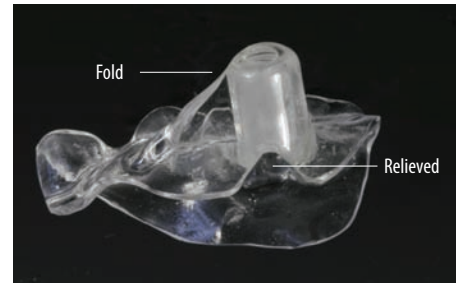


Fig.8 Trimmed baseplate to form stent with both superficial end & fitting surface of guide cylinder relieved.

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 allows for removal of the stent from over the mini-implant head when the latter is not yet fully seated (during clinical insertion).

MINI IMPLANT PLANNING AND STENT FABRICATION



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



Fig.2 Model with location mark.

Step-By-Step Instructions

1.1 Determine the Insertion Details Using a Dental Model and Radiographs

The optimum three-dimensional position for each Infinitas 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, at the same time, avoiding structures such as adjacent dental roots, the gingival papilla, neurovascular tissues and nasal/maxillary cavities. This results in a balance between the following three parameters:

- 1) the topographical entry point of the implant
- 2) the angulation: antero-posterior (AP) angle of entry
- 3) 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 gingiva and emergence angle. Maxillary buccal mini implants are typically inserted at 70-90 degrees to the bone surface.

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.

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MINI IMPLANT PLANNING AND STENT FABRICATION



Fig.3 Analogue drill in model.



Fig.4 Analogue screw in place.

1.2 Drill a Pilot Hole in the Model

A pilot hole is drilled in the patient's dental model, using an analogue drill (95-010-35 or 95-010-36) in either a straight or contra-angle dental hand piece, or in a laboratory hand piece (95-010-37), to a depth of approximately 10 mm. It is critical that the drill is held at the correct 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).

1.3 Place Mini Implant Analogue in Model

The mini implant analogue (95-010-30) is inserted manually and fully seated using the analogue screwdriver (95-010-38) 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.

MINI IMPLANT PLANNING AND STENT FABRICATION

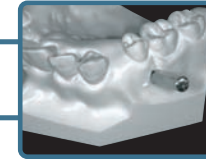


Fig.5 Abutment over analogue.



Fig.6 Guidance cylinder over abutment.

1.4 Fit Abutment onto Analogue

The Infinitas stent abutment (95-010-31) is manually fitted onto the head of the analogue. This acts as extension arm on the analogue and also makes it easier to double-check the insertion directions relative to the adjacent teeth.

1.5 Fit Guide Cylinder onto Analogue

The Infinitas stent guide cylinder (95-010-32) is fitted by sliding it over the Infinitas abutment until it contacts the plaster model surface.