Surgical Manual

Screw Internal Hex Implant System

AlphaBio TEC

Alpha-Bio Tec is committed to ensure that Alpha-Bio Tec's medical devices are in compliance with international standards and requirements.
In order to ensure constant adequacy and effectiveness in accordance with these standards and in order to comply with all regulatory requirements Alpha-Bio Tec maintains a high standard of Quality Assurance system.

Alpha-Bio Tec's Medical devices are:
- CE-approved.
- Cleared for marketing in the USA.

Alpha-Bio Tec complies with major quality system standards:
- ISO 13485:2003 including the Canadian Medical Devices Conformity Assessment System.
- ISO 9001:2000.
- Council Directive 93/42/EEC.

Table of Contents

Alpha-Bio Tec specializes in the development and production of advanced dental solutions, focusing on the fields of implants and prosthetics.

Since entering the market over 20 years ago, Alpha-Bio Tec has developed a long list of innovative products designed to provide the implant dentistry market with the most comprehensive and efficient array of solutions.

Alpha-Bio Tec develops, manufactures and markets implants, prosthetic parts, surgical instrumentation and accompanying aids for complete implantology solutions.

In order to assure that its products are optimally suited to meet changing needs, Alpha-Bio Tec has established a research and development team comprised of experts in the field of dentistry. Team members are dedicated to conducting thorough and on-going research and analysis, the results of which stand at the root of the methods and products developed by Alpha-Bio Tec.

The professional training and educational center operated by Alpha-Bio Tec provides a long list of professional courses ranging from training courses for beginners to advanced courses for experienced dentists. The center also conducts international advanced courses and worldwide lectures.

Alpha-Bio Tec operates local sale and service centers in many countries worldwide through a chain of carefully selected distributors.

Alpha-Bio Tec sustains a meticulous quality control system, complying with major quality system standards: ISO 13485:2003 including the Canadian Medical Devices Conformity Assessment System, ISO 9001:2000 and Council Directive 93/42/EEC. Alpha-Bio Tec's medical devices are CE-approved and are cleared for marketing in the USA.

Simplicity is the ultimate sophistication.

Designing a successful implant system requires a great deal of knowledge about biology and mechanics, as well as the understanding of how the two fields interact. Our advanced implant systems provide simple and predictable solutions for the implantologist's every need.

Our main goal is to gain the ultimate integration between the human body and the Alpha-Bio Tec implants. With the *NanoTec*™ Implant surface, we have taken it to the next level by helping our implants integrate naturally with the human body.

In Alpha-Bio Tec we believe that initial bone healing and long-term marginal bone stability are affected by the implant's design and surface properties.

Both short and long-term successful clinical results are directly related to the features of an implant.

With the right conditions, the Alpha-Bio Tec implant system is designed to provide the ultimate substitute for natural teeth where all of the system's parts work together successfully.

The system offers a wide range of products, including implants and prosthetic parts, designed in a "one-platform-fits-all" implant diameters.

The unique and simple system makes the dentist's work extremely convenient and offers several major advantages:

- Fast and easy insertion
- High primary stability
- High success rate in immediate loading
- High predictability
- Wide range of products with proven clinical biocompatibility

Alpha-Bio Tec Implant Systems

Screw Internal Hex Implant System
Standard 2.5 mm internal hex

Arrow Press Implant System
Trans gingival implants

Arrow Implant System
Provisional Implants

NanoTec™ Implant Surface

The implant surface is the key to achieving optimal osseointegration.

It is well documented that the surface characteristics of implanted materials can influence the healing and growth of tissues adjacent to the implant surface.

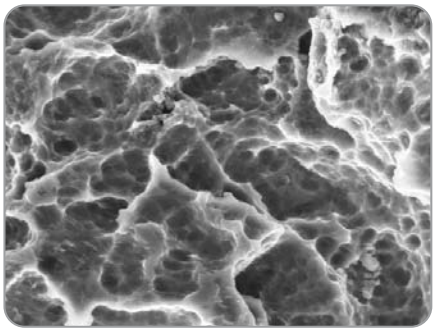
Following years of extensive research, Alpha-Bio Tec developed a superior *NanoTec*™ surface for its implants. Alpha-Bio Tec's *NanoTec*™ implant surface is treated with sand blasting to create a macro surface of 20-40 micron. Then it undergoes a double thermal acid etching process to create micro pitting between 1 to 5 microns with nano-pitting.

The Alpha-Bio Tec *NanoTec*™ implant surface enables the absorption of blood directly into its micropores immediately after the implant placement. It promotes healing and growth of tissues adjacent to the implant surface, thus accelerating and improving the osseointegration process. Retrospective clinical data shows that Alpha-Bio Tec's implants achieve an overall clinical success rate of 98.3% and 99.6% when using the immediate loading procedure.

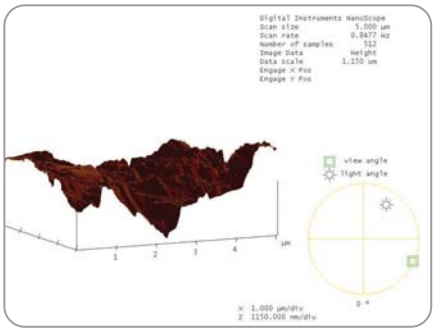
***NanoTec*™ advantages:**

- Increased early bone to implant contact
- Increased stability
- Shortened healing period
- Higher predictability

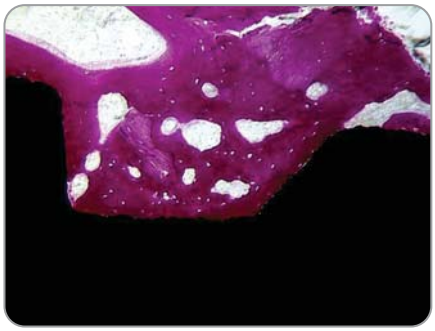
SEM of surface (x2,000)

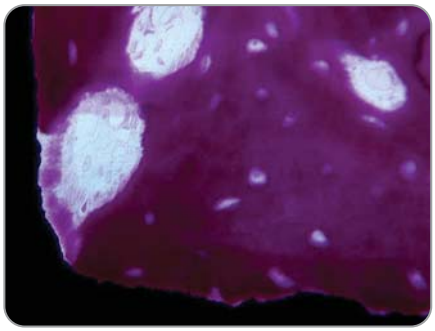


AFM roughness



Histology after 2 months showing excellent bone to implant contact





*Data on file

Flapless technique
Punching tissue
and marking drill

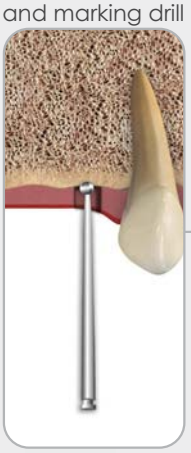


Fig. 1A

Flapless technique
Twist drill 2 mm

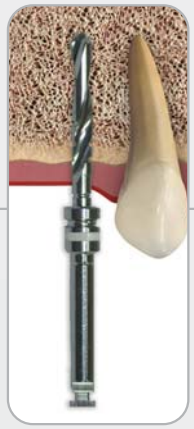


Fig. 2A

Flap technique
Marking drill

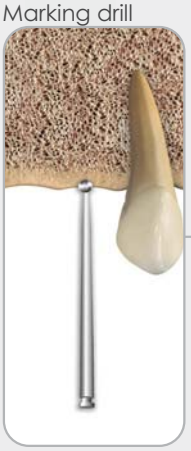


Fig. 1B

Flap technique
Twist drill 2 mm

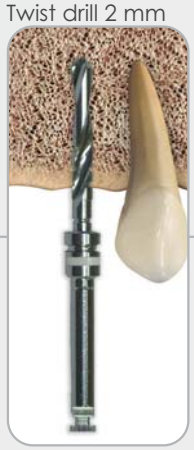


Fig. 2B

Twist drill 2.8 mm

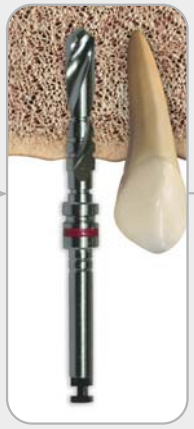


Fig. 3

Twist drill 3.2 mm

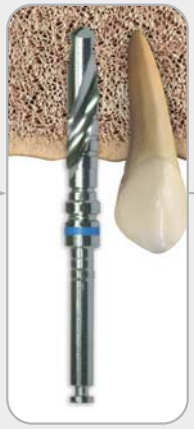


Fig. 4

Recommended drill sequence varies between different implant diameters and different bone types.
For recommended drill sequence for each implant please refer to pages 15, 21, 27.

Implant placement

Fig. 5

Two stage
Delayed
function

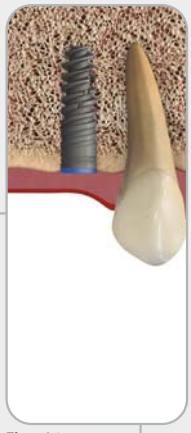


Fig. 6A

One stage
Delayed
function

Fig. 6B

One stage
Immediate
function

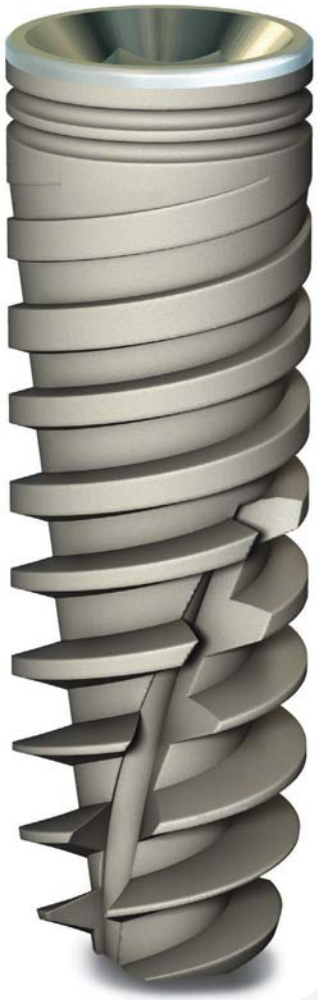
Fig. 6C

Abutment
Temporary crown

Fig. 7

SPI

The Original Spiral Implant



SPI - Spiral Implant

The SPI is a tapered internal hex implant with a unique combination of design features that enable easy insertion and very high initial stability.
The unique shape of the implant body and its variable thread design (double thread 2x2.1 mm) equip it with some exceptional abilities.
It is **self drilling, self tapping and self condensing**, yielding outstanding advantages in all bone types and in compromised situations.

The SPI spiral implant is therefore the exceptional solution for immediate placement and immediate loading.

Original Spiral

SPI Indications

The spiral implant is indicated for all situations, bone types and surgical protocols:

- Single missing tooth, partial edentulism, total edentulism
- Upper and lower jaws, anterior and posterior regions
- One stage and two stage surgical procedures
- Closed and open sinus lift procedures
- Simultaneous guided bone regeneration and/or splitting crest technique
- Immediate implantation and immediate loading

The clinical advantages of the SPI implant make it ideal for all implantology procedures - from the most simple single tooth restoration to the most complicated full mouth rehabilitation. Its unique qualities make it ideal for immediate implantation and for immediate loading procedures.

SPI Clinical Advantages

Clinical advantages of implant design:

- Bone condensing property and very high primary stability
- Self-directing in line of insertion
- Enables changing direction for optimal restorative position
- Enables smaller osteotomy which results in minimal bone loss and reduced trauma
- Enables narrow ridge expansion
- Reduces the risk of damaging neighboring teeth
- Reduces the risk of perforating the lingual or buccal cortex

SPI Spiral Implant | Features and Advantages

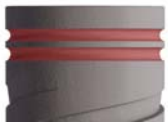
Improved Internal Hex

Design Features:
- Extremely precise internal hex
- One platform for all diameters

1

Advantages:
- Perfect implant-abutment connection
- Simple restoration process

Coronal Part

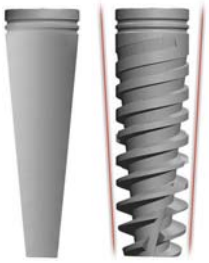


Design Features:
- Micro rings*
- Bone platform shifting
- Rough surface to the top
- Threads reaching the top of the implant

2

Advantages:
- Greater surface area
- Less crestal resorption
- Better load distribution
- Decreased crestal stress

Implant Body and Core



Design Features:
- Tapered body
- Tapered core – more pronounced than the threads
- Osteotome like condensing body

3

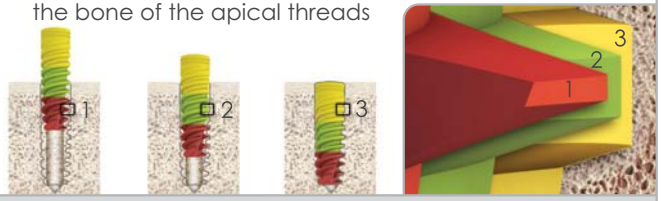
Advantages:
- Bone condensing
- Primary stabilization
- Easy insertion

Implant Threads

Design Features:
- Double thread design 2X2.1mm
- Wide thread step
- Threads increase in the apical direction
- Variable threads design:
  - Coronal – thick square threads
  - Middle – thinner square threads
  - Apical – V threads

4

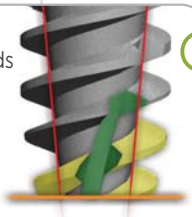
The coronal threads condense the bone of the apical threads



Advantages:
- Easy insertion
- High primary stability
- Bone condensing
- Self drilling
- Self tapping
- Primary stabilization
- Easy insertion

Apical Part

sesign Features:
- Sharp and deep threads
- Narrow core
- Apical blade
- Straight apical border
- Condensing tapper



5

Advantages:
- Self tapping
- Self drilling
- Easy insertion
- Helps prevent damage to anatomical structures
- Enables the implant to penetrate small diameter prepared sites

* The number of micro rings may vary between different implant diameters and/or lengths.

SPI Special Implant Qualities

The SPI's unique features and advantages facilitate its placement in clinically demanding situations and make it ideal for use in complicated cases, for immediate implantation, immediate loading and in soft bone.

Small changes in parallelism

The ability to redirect the implant's position during implant placement helps achieve parallelism between implants and optimize implant placement.

The unique self drilling capabilities of the SPI implant make it possible to change the direction of the implant during placement.

If a change in implant direction due to incorrect drilling angle (Fig. 1), is desired:

- Rotate the implant backwards 2-3 turns (Fig. 3)
- Begin inserting the implant into its desired position (Fig. 4)
- Continue the insertion until the implant is fully seated in the desired position (Fig. 5)


Fig. 1


Fig. 2


Fig. 3


Fig. 4


Fig. 5

Caution!

With any insertion tool, avoid over tightening the implant. Over tightening may compromise the integrity of internal connection and over compress the surrounding bone, compromising osseointegration.
It is recommended to place the implants using a torque lower than 60 Ncm.

Stabilization in wide sockets with minimal bone loss

The implant's ability to reach high primary stability in minimal bone after extraction is desirable in cases of immediate implantation. The unique SPI implant core, threads design and apical part allow it to be anchored and stabilized in minimal bone and after extraction due to the implant's ability to penetrate prepared sites much narrower in diameter than required for regular implants.

Site preparation and implantation process

- Drill 2-3 mm apically to the extraction socket, using a 2 mm twist drill (Fig. 6)
- Depending on the diameter of the implant, continue drilling according to the drilling protocol for soft bone on page 15
- Begin inserting the implant into the under prepared site (Fig. 7)
  The variable thread design and the bone condensing properties of the threads and core contribute to the achievement of sufficient retention, stabilization and position of the implant
- Continue inserting the implant to the final depth (Fig. 8). Changing direction is possible during insertion
- Bone augmentation may be immediately followed if indicated
- Place the cover screw and suture (Fig. 9)


Fig. 6


Fig. 7


Fig. 8


Fig. 9

Caution!
With any insertion tool, avoid over tightening the implant. Over tightening may compromise the integrity of internal connection and over compress the surrounding bone, compromising osseointegration.
It is recommended to place the implants using a torque lower than 60 Ncm.

Stabilization in very soft bone

The implant's ability to reach high primary stability in soft bone is desirable in most clinical cases.
The unique SPI implant core and thread design allow it to be anchored and stabilized in soft bone due to its ability to penetrate prepared sites that are much narrower in diameter (1-2 drills less) than required for regular implants.

Site preparation for implantation process in bone type IV

- Drill using a 2 mm Twist drill (Fig. 1)
- Drill using a 2.8 mm Twist drill. If the bone is very soft use the 2.8 mm Twist drill just to penetrate the cortex (Fig 2).
- Begin inserting the implant into the under prepared site. The variable thread design and the bone condensing properties of the threads and core contribute to the achievement of sufficient retention and stabilization surrounding the implant (Fig. 3)


Fig. 1


Fig. 2

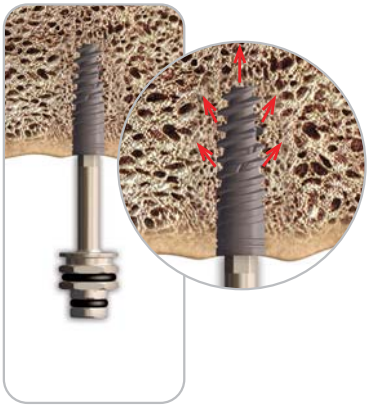
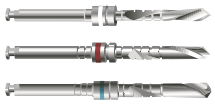
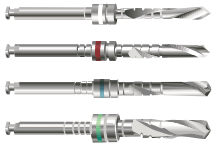
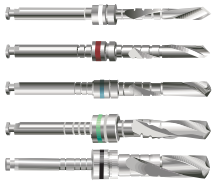
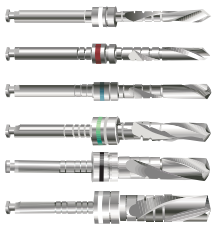
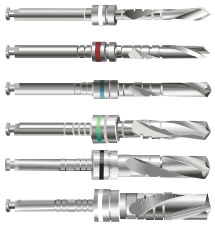


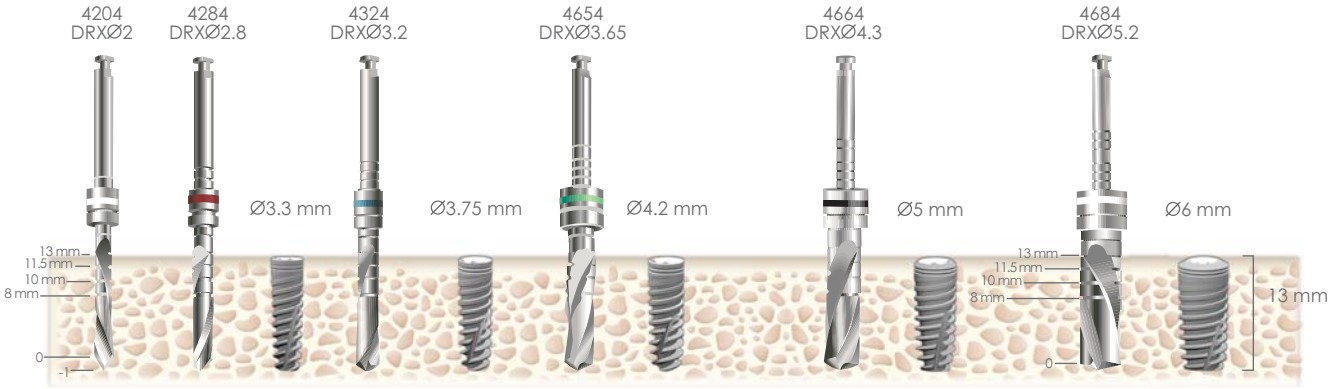
Fig. 3

Caution!
With any insertion tool, avoid over tightening the implant. Over tightening may compromise the integrity of internal connection and over compress the surrounding bone, compromising osseointegration.
It is recommended to place the implants using a torque lower than 60 Ncm.

SPI Drilling Sequences for All Bone Types

	Type IV	Type II, III	Type I	
SPI Ø 3.3 mm	Ø 2 mm	Ø 2 mm Ø 2.8 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm	
SPI Ø 3.75 mm	Ø 2 mm Ø 2.8 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm Ø 3.65 mm	
SPI Ø 4.2 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm Ø 3.65 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm Ø 3.65 mm Ø 4.3 mm	
SPI Ø 5 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm Ø 3.65 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm Ø 3.65 mm Ø 4.3 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm Ø 3.65 mm Ø 4.3 mm Ø 5.2 mm	
SPI Ø 6 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm Ø 3.65 mm Ø 4.3 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm Ø 3.65 mm Ø 4.3 mm Ø 5.2 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm Ø 3.65 mm Ø 4.3 mm Ø 5.2 mm	

The marked drills are used only to penetrate the cortex.
They are not to be used for drilling to the final depth.



Depth of drilled site

In soft bone, the implant is capable of drilling itself farther than the prepared depth. If it is desired to achieve higher primary stability, drill 2-4 mm less than the total implant length, insert the implant to the drilled depth and continue to insert. The implant will drill its way into the final depth.

DFI Dual Fit Implant

DFI - Dual Fit Implant

The DFI implant was especially designed to provide implantologists with a confident implant suitable for all procedures. It is a tapered internal hex implant with a variable thread design (2 x 1.2 mm).
The DFI is indicated for all situations, bone types and surgical protocols. Its tapered design allows it to be placed in the ideal position for improved esthetics and provides better load distribution. Its unique apical part with the cutting taper makes is easy to insert, even into very hard bone.

From the simplest single tooth rehabilitation to a full mouth restoration - the DFI is the confident implantology solution you need.

Simple sophisticated

DFI Indications

The DFI implant is indicated for all situations, bone types and surgical protocols:

- Single missing tooth, partial edentulism, total edentulism
- Upper and lower jaws, anterior and posterior regions
- One stage and two stage surgical procedures
- Closed and open sinus lift procedures
- Simultaneous guided bone regeneration and/or splitting crest technique
- Limited vertical bone volume

The DFI is a universal implant suitable for all situations and for all surgery levels. It can be used in simple cases of single tooth restoration or complex cases of full mouth rehabilitation.

DFI Clinical Advantages

Clinical advantages of implant design:

- Suitable for all bone types
- Easy insertion and better control during placement
- Bone condensing property and high primary stability
- Self directing in line of insertion
- Enables smaller osteotomy which results in minimal bone loss and reduces trauma

Improved Internal Hex

Design Features:
- Extremely precise internal hex
- One platform for all diameters

1

Advantages:
- Perfect implant-abutment connection
- Simple restoration process

Coronal Part

Design Features:
- Micro rings *
- Bone platform shifting
- Rough surface to the top
- Threads reaching the top of the implant

2

Advantages:
- Greater surface area
- Less crestal resorption
- Better load distribution
- Decreased crestal stress

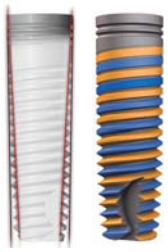
Implant Body and Core

Design Features:
- Tapered body
- Tapered core – more pronounced than the threads

3

Advantages:
- Primary stabilization
- Easy insertion

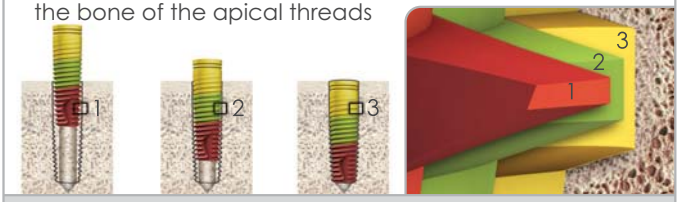
Implant Threads



Design Features:
- Double thread design 2X1.2mm
- Threads increase in the apical direction
- Variable threads design:
  Coronal – thick square threads
  Middle – thinner square threads
  Apical – V threads

4

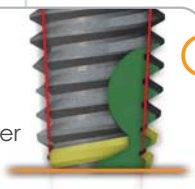
The coronal threads condense the bone of the apical threads



Advantages:
- Easy insertion
- High primary stability
- Bone condensing
- Self drilling
- Self tapping

Apical Part

Design Features:
- Sharp threads
- Apical blades
- Straight apical border
- Cutting taper



5

Advantages:
- Self tapping
- Self drilling
- Easy insertion
- Helps prevent damage to anatomical structures

* The number of micro rings may vary between different implant diameters and/or lengths.

Universal implant for all bone types and all clinical situations

The DFI is suitable for type I bone

The dual threads design and the cutting taper help the implant glide into hard bone and achieve very high primary stability without over compressing the bone. These unique features lower the risk of hard bone necrosis.


Fig. 1


Fig. 2


Fig. 3


Fig. 4

The DFI is ideal for type II & III bone

The slightly tapered body and variable threads design facilitate the DFI's easy insertion without over compressing the bone, but with enough bone condensing action to achieve high primary stability. The sharp 60° apical threads cut through the bone, followed by the middle and coronal threads that very gently condense the bone for better primary stability.


Fig. 5


Fig. 6


Fig. 7

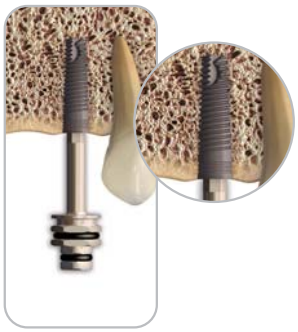


Fig. 8

The DFI is suitable for type IV bone

The DFI achieves good primary stability in type IV bone due to its tapered body and variable threads design. The tapered body enables the implant to penetrate smaller prepared sites in very soft bone, thus utilizing the implant's self drilling and self tapping features to achieve good primary stability.


Fig. 9

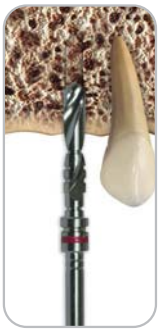
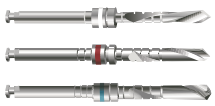
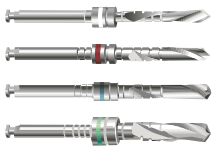
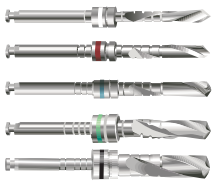
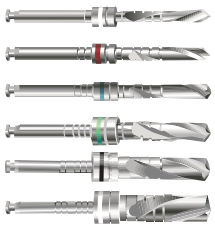


Fig. 10

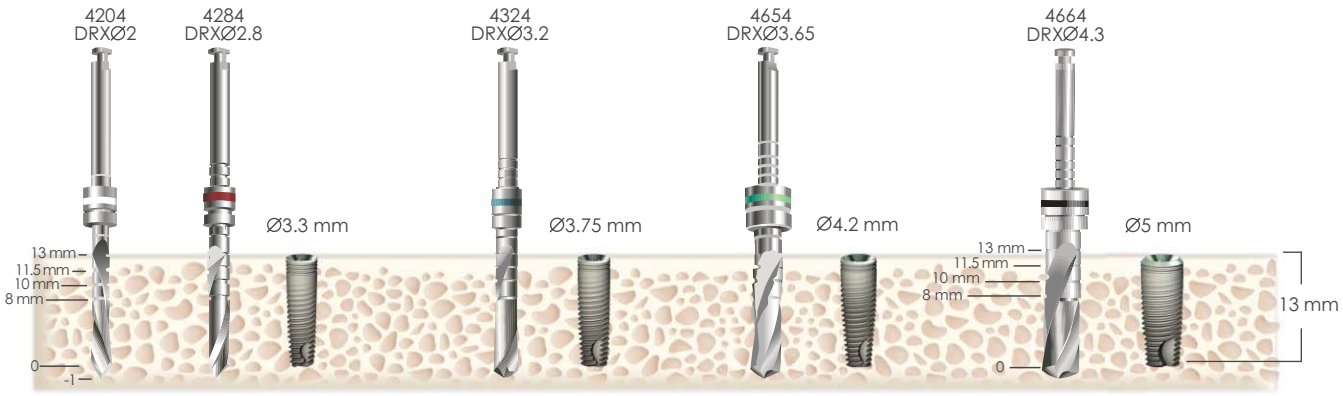

Fig. 11

* Images on this page refer to recommended drill sequence for 3.75 mmd implants. For other diameters, please refer to page 21.

DFI Drilling Sequences for All Bone Types

	Type IV	Type II, III	Type I	
DFI Ø 3.3 mm	Ø 2 mm	Ø 2 mm Ø 2.8 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm	
DFI Ø 3.75 mm	Ø 2 mm Ø 2.8 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm Ø 3.65 mm	
DFI Ø 4.2 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm Ø 3.65 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm Ø 3.65 mm Ø 4.3 mm	
DFI Ø 5 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm Ø 3.65 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm Ø 3.65 mm Ø 4.3 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm Ø 3.65 mm Ø 4.3 mm Ø 5.2 mm	

The marked drills are used only to penetrate the cortex.
They are not to be used for drilling to the final depth.



ATID Standard Implant

ATID - Standard Implant

The ATID is a standard cylindrical implant with a double 2 X 1.2 mm thread step. The ATID is a very simple and easy implant to use, with very good control during implant placement. It is suitable for all bone types, but is highly recommended for bone types I & II due to its cylindrical shape. This shape, combined with the implant's cutting taper enables easy insertion with minimal pressure to very hard bone.

The ATID features unique 6 mm short implants in ⌀ 5 mm and ⌀ 6 mm. These short implants enable a simple and easy implantation process in areas with limited vertical bone volume and help eliminate the need for guided bone regeneration, especially in the mandible.

The ATID is therefore an excellent solution for very hard bone and for limited vertical bone volume cases.

Standard Cylindrical

ATID Indications

The ATID implant is indicated for all situations, bone types and surgical protocols:

- Single missing tooth, partial edentulism, total edentulism
- Upper and lower jaws, anterior and posterior regions
- Limited vertical bone volume

The ATID is a standard cylindrical implant suitable for all bone types but especially recommended for bone types I & II. The short 6 mm implants are ideal for cases with limited bone height.

ATID Clinical Advantages

Clinical advantages of implant design:

- Classic cylindrical implant
- Easy insertion and better control during placement
- Excellent for type I & II bone
- Suitable for use with limited bone volume, especially in the mandible
- Reduces pressure on the bone

Improved Internal Hex

Design Features:
- Extremely precise internal hex
- One platform for all diameters

Advantages:
- Perfect implant-abutment connection
- Simple restoration process

Coronal Part

Design Features:
- Micro rings*
- Bone platform shifting
- Rough surface to the top

Advantages:
- Greater surface area
- Less crestal resorption
- Better load distribution
- Decreased crestal stress

Implant Body and Core

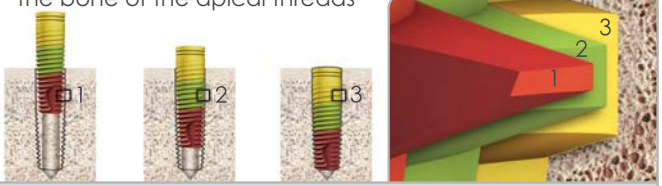
Design Features:
- Straight body
- Straight core

Advantages:
- Minimal pressure on hard bone

Implant Threads

Design Features:
- Double thread design 2X1.2mm
- Variable threads design:
  Coronal – thick square threads
  Middle – thinner square threads
  Apical – V threads

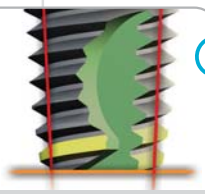
The coronal threads condense the bone of the apical threads



Advantages:
- Easy insertion
- Bone condensing property
- Self drilling
- Self tapping

Apical Part

Design Features:
- Sharp threads
- Apical blades
- Straight apical border
- Cutting taper



Advantages:
- Self tapping
- Self drilling
- Easy insertion
- Helps prevent damage to anatomical structures

* The number of micro rings may vary between different implant diameters and/or lengths.

Ideal for very hard bone

Though suitable for all bone types, the combined features of the ATID make it the ideal implant for very hard bone. Due to its cylindrical body shape, the ATID applies minimal pressure on very hard bone, thus helping to prevent hard bone necrosis. The ATID's cutting taper and sharp apical threads facilitate a simple and easy implant insertion process.


Fig. 1


Fig. 2


Fig. 3


Fig. 4

Extra short implants for cases with limited bone volume

The ATID features two extra short 6 mm implants in ⌀ 5mm and ⌀ 6 mm.

- Ideal for use in cases with very limited bone volume
- Ideal for avoiding damage to anatomical structures

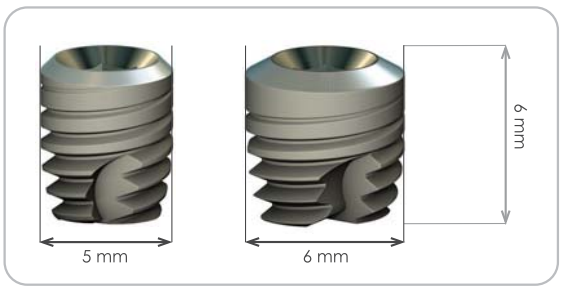
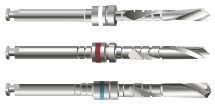
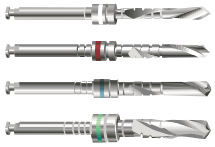
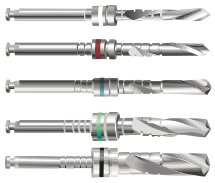
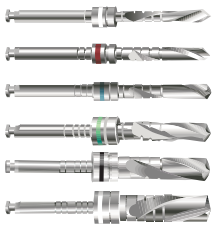
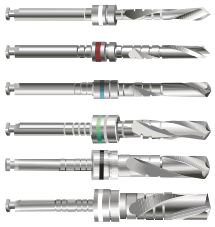


Fig. 5

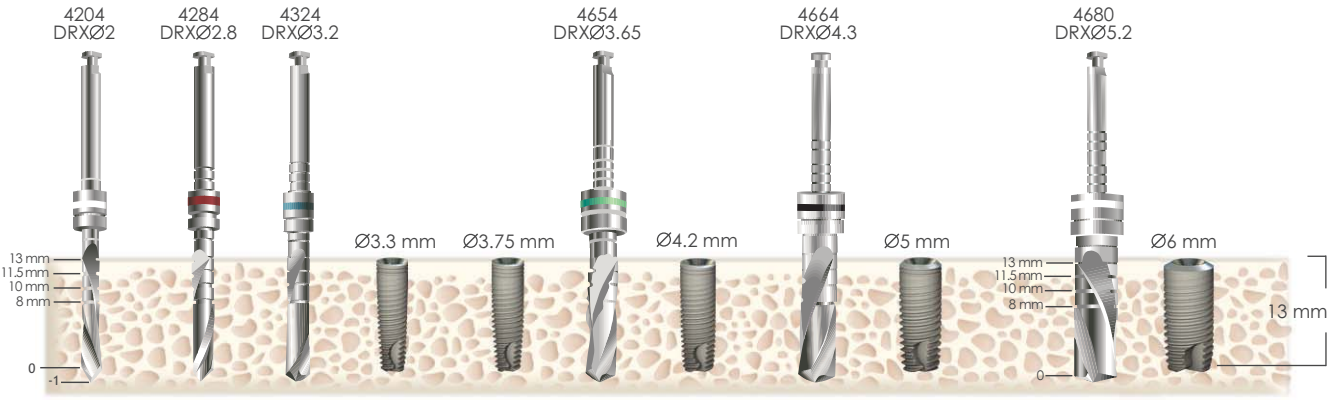
Example of a short ATID implant used near the Mandibular nerve with limited bone height.


Fig. 6

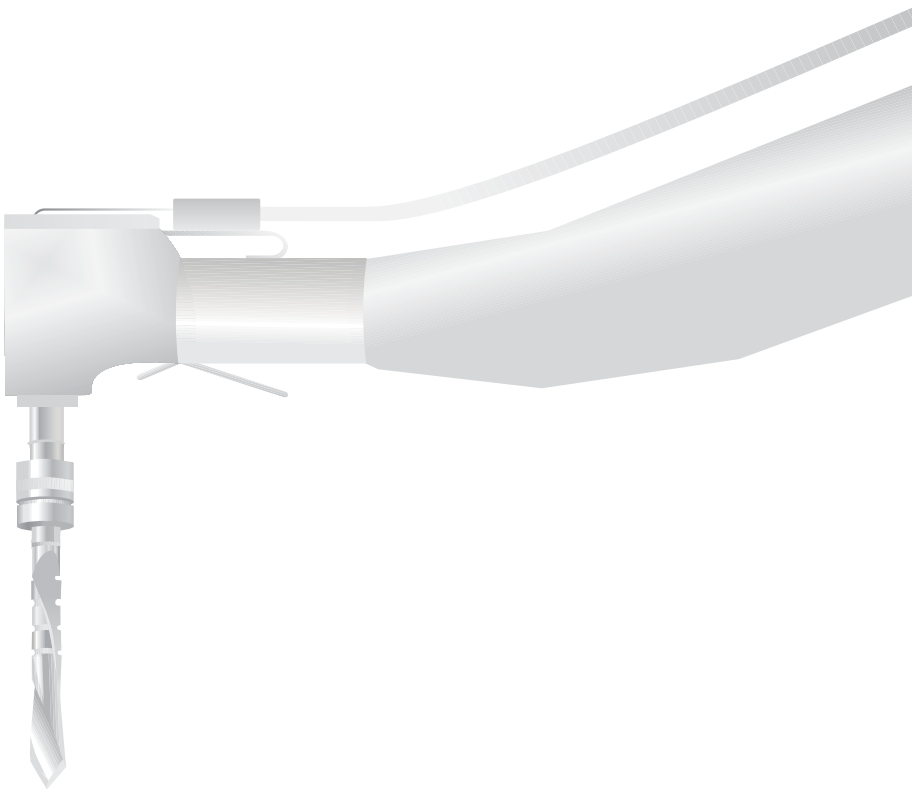
ATID Drilling Sequences for All Bone Types

	Type IV	Type II, III	Type I	
ATID Ø 3.3 mm	Ø 2 mm	Ø 2 mm Ø 2.8 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm	
ATID Ø 3.75 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm Ø 3.65 mm	
ATID Ø 4.2 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm Ø 3.65 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm Ø 3.65 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm Ø 3.65 mm Ø 4.3 mm	
ATID Ø 5 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm Ø 3.65 mm Ø 4.3 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm Ø 3.65 mm Ø 4.3 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm Ø 3.65 mm Ø 4.3 mm Ø 5.2 mm	
ATID Ø 6 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm Ø 3.65 mm Ø 4.3 mm Ø 5.2 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm Ø 3.65 mm Ø 4.3 mm Ø 5.2 mm	Ø 2 mm Ø 2.8 mm Ø 3.2 mm Ø 3.65 mm Ø 4.3 mm Ø 5.2 mm	

The marked drills are used only to penetrate the cortex.
They are not to be used for drilling to the final depth.



Surgical Protocol



Surgical Protocol

Surgical Stages - Examination, Planning and Treatment

Carry out the examination and treatment plan as usual.

1. Patient information:

- The patient should be informed before any treatment as to the expected results of the pre-operative examination.
- Explanation should be provided as to the intended treatment, including expected outcomes and risks involved.
- Patients should indicate their acceptance of treatment by signing an appropriate consent form.
- Care should be taken that general contraindication of patient's medical status precludes surgical treatment, mental psychosis, alcohol and all listed information noted in the instructions for use.

The pre-operative examination includes a general evaluation of the patient's health, clinical and radiographic examination (CT scan is recommended in most cases).

Special attention should be given to soft and hard tissues, dental history, restorative status and occlusion. In complex cases accurate details can be obtained by CT data.

Radiographic examination provides evaluation on anatomy, pathology, quantity and quality of bone. Usually a panoramic X-Ray is used for the initial evaluation and then a CT Scan for the advanced planning .

In the majority of cases the implant's special abilities reduce the need for an additional surgical procedure of bone augmentation prior to the implant placement session, even in compromised situations. The implant can be stabilized in very small bone volume and bone augmentation can be carried out in the same session.

2. Bone quality

Traditionally, dense and compact bone provides good initial stabilization for the installed implant while cancellous bone provides reduced retention and therefore more bone to implant contact necessary for achieving high enough initial stabilization. The bone quality usually dictates the sequence of drilling, and when the bone is very soft fewer drills should be used in order to achieve greater primary stability. Usually the softest bone (type IV) is in the posterior maxilla while the hardest bone (type 1) is in the anterior mandible. Most implant failures occur in type IV bone and that is why it is very important to achieve greater primary stability. Primary stability is achieved by the special implant design of the SPI and DFI and ARRP implants.

Bone Type II
Very hard bone

Fig. 2A

Bone Type II
Hard bone

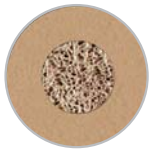


Fig. 2B

Bone Type III
Soft bone

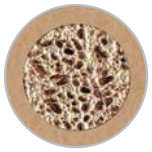


Fig. 2C

Bone Type IV
Very soft bone

Fig. 2D

3. Vertical bone quantity

The amount of bone available for implant retention differs from site to site. Regular implants require sufficient quantity (a few millimeters) of good quality bone for minimal retention to achieve immediate stabilization and a successful result. In all situations where the initial stabilization is questionable it is necessary to augment the bone volume prior to implant insertion. This calls for an additional surgical procedure and a prolonged process. The unique design of the Alpha-Bio Tec implants allows them to achieve enough primary stability even in very small quantities of bone. This allows bone volume augmentation simultaneously with implant insertion, if needed. It is very important to maintain a safety zone from anatomical structures such as the mandibular canal.

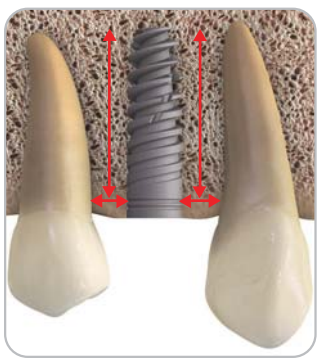


Fig. 3A

4. Horizontal bone quality

It is recommended to have at least 1.5 mm of bone surrounding the implant especially buccaly and lingually. It is recommended to leave at least 3 mm of bone between two implants. Only a CT Scan can give us the correct data of the ridge width. In cases of less than 1.5 mm surrounding the implant, bone augmentation procedure is needed especially in the esthetic zone. In very narrow ridges it is recommended to take advantage of the narrow ARRP implants in order to avoid bone augmentation procedures or to do bone augmentation simultaneously with the implantation instead of a two stage procedure.

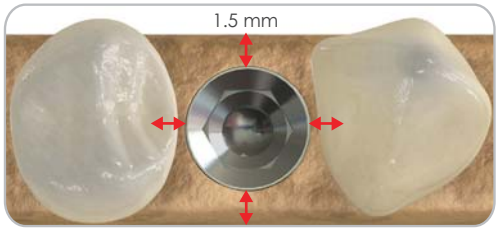


Fig 4A

5. Implant selection

When selecting the implant, the following factors need to be taken into account:

Implant length is chosen according to the measurements of the ridge vertical length on the CT Scan. A safety zone of at least 2 mm from anatomical structures such as the mandibular canal should be maintained.

Implant diameter is chosen according to the measurements of the ridge width on the CT Scan. You must take into consideration at least 1.5 mm of bone all around the implant otherwise bone augmentation will be required.

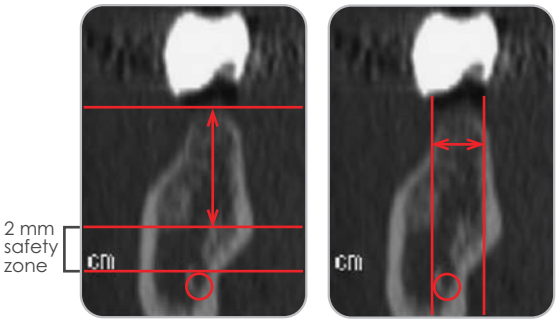


Fig 5A Fig 5B

6. Pre-operative handling

6.1 The clinician's understanding and familiarity with the Alpha-Bio Tec system will ensure efficient and accurate installation.
6.2 The patient should be treated periodontally prior to implant placement. The implant surgery should be done only after initial preparation of the patient.
6.3 Premedication is given based on individual indications and according to literature updates. Non allergic patient may be given 2g of amoxicillin one hour before implant placement prophilactically and 500mg TID post treatment for one week.
6.4 Proper room sterilization and surgical instruments preparation should be carried out prior to the procedure.
6.5 Patient should be draped with sterile operating sheets covering the body and head.
6.6 Local anesthesia is given in desired areas. Additional anesthesia can be given during surgery when needed.
6.7 Mouth rinsing should be carried out with 0.2% chlorhexidine solution for 1 minute.

7. Preparation of the implant site:

7.1 Perform incisions to expose the surgical field.
7.2 Elevate the mucoperiosteal flaps.
7.3 Reshape alveolar ridge if necessary.
7.4 Mark the bone with a guide drill. You can use a guide drill of your choice such as a round bar or a sharp pointed guide drill. Mark drilling speed should not exceed 1,500 rpm and should be performed under ample irrigation.
7.5 To check angulation, depth and parallelism use parallel/depth guide PDG 4080 (Fig 7A, 7B) or PDGS 4081 or implant depth probe IDG 4100 (Fig 7C).
For correct preparation for future abutment placement use the Paraguide system - TPG 0°, TPG 15° or TPG 25° (Fig 7D).


Fig 7D

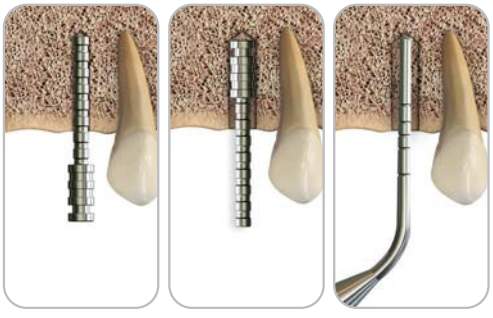


Fig 7A Fig 7B Fig 7C

8. Drilling

Implant site is prepared in a sequential procedure using drills of increasing diameter with depth indication lines that give a reading of the desired drilling depth. Drills should be replaced when their cutting efficiency is reduced. All preparation of bone tissue must be carried out under ample irrigation with saline solution and using an intermittent drilling technique.

Drill selection

The surgical drills are available in sequential diameters and in two lengths. Two types of drills are available:

- Internal irrigation drills made of surgical titanium. These drills are to be used with internal and external irrigation. A Teflon ring in the irrigation canal facilitates friction free insertion of the irrigation tab.
- External irrigation drills made of stainless steel are to be used with external irrigation only.
  All drills are color and groove coded for easy identification during surgery.
  Drills are groove marked for lengths as shown below.

Nominal length marks are measured from the beginning of the parallel walls. The length does not include the triangular shaped cutting edge. Actual osteotomy length is approximately 1mm longer. It is important to bring into consideration the additional length in situations of close proximity to anatomical structures such as the mandibular nerve canal or sinus floor. Optional surgical drills with flat heads are also available for such situations.
For a selection of Alpha-Bio Tec drills, see pages 42-46.

Surgical Drills - Internal Irrigation

Fig 8A

Surgical Drills - External Irrigation

Fig 8B

Drilling sequence

The drilling protocol is adapted to the implant diameter and bone quality at the site. The instructed drilling steps are suggested for dense/cortical bone.
In softer bone fewer steps may be performed. In soft bone, 2 mm or 2.8 mm drills are often enough for all implant sizes.
For the recommended drilling sequence for each implant, please refer to pages 15, 21, 27.
In very hard cortical bone it may be necessary to drill with the next size drill only for the thickness of the cortical layer. For bone types 3, you can skip the last drilling step. When the bone is very soft, skip the last two drilling steps.
Due to the Spiral SPI special design it is possible to insert the implant into a prepared site of a much lower diameter than usual, thus allowing preservation of precious bone tissue and allowing the special incremental bone condensation feature of the implant to take effect. The resulting retention and stability are much higher without using bone condensing accessories such as osteotomes.

It should be noted, however, that in case of high resistance to insertion (50 Ncm), such as in a site with a substantial cortical bone layer, additional steps may be necessary, though usually just to penetrate the cortex.

If you a feel strong resistance at any point during implant insertion, rotate the implant counterclockwise 2-3 rounds and continue inserting the implant.

Step-by-Step Clinical Procedure

For 3.75 mm internal hex family implants

Illustration shows the drill sequence for SPI internal 3.75X13mm in medium bone. For the rest of the diameters, as well as drill protocol in various bone densities, please refer to the sequence table on pages 15, 21, 27.

1. Marking drill

Mark the designated drilling spot with a marking drill.
When using the flapless technique, punch the soft tissue before using the marking drill.


Fig 1A


Fig 1B

2. Twist Drill 2 mm

Drill to the appropriate depth using the 2 mm Twist Drill.
When using a flapless technique add the soft tissue thickness to the drilling depth.
High speed (Max. 2000 rpm)


Fig 2A


Fig 2B

3. Direction indicator

- Check orientation using a 2 mm direction indicator
- If applicable, take a radiograph to verify correct direction
- When placing multiple implants, proceed to the next implant site before continuing to the next drilling sequence


Fig 3A


Fig 3B

4. Twist Drill 2.8 mm

Continue site preparation using a 2.8 mm twist drill
High speed (Max. 2000 rpm)


Fig 4A


Fig 4B

Step-by-Step Clinical Procedure

For all 3.75 mm internal hex family

5. Twist Drill 3.2 mm

Continue site preparation using a 3.2 mm twist drill

High speed (Max. 2000 rpm)

Fig 5A

Fig 5B

6. Direction indicator 3 mm

Check orientation using a 3 mm direction indicator.

Fig 6A

Fig 6B

7. Determine implant length

Use a depth probe to verify that the desired depth has been achieved.

Fig 7A

Fig 7B

8. Packaging

All implants are delivered in sterile double packaging. The transparent outer blister houses a vial that includes the pre-mounted implant and a cover screw. The vial's end is labeled with the implant type and diameter and color coded for implant length. A sticky label displays all pertinent information regarding the implant. Two labels are supplied in the package. Open the blister package and place the vial on the sterile working area.

Package - International

Fig 8A

Package - Israel

Fig 8B

Fig 8C

Step-by-Step Clinical Procedure

For all 3.75 mm internal hex family

9. Implant insertion tools

Torque wrench

Fig 9A

Surgical screwdriver

Fig 9B

Surgical unit

Fig 9C

Implant drivers 2.5 mm (ITD) - to be used with the torque wrench or surgical screwdriver

Fig 9D

Contra-angle motor hex driver - to be used with the surgical unit

Fig 9E

10. The FID (Fast Implant Delivery)

The FID (Fast Implant Delivery) is a unique multi functional implant mount supplied with all internal hex implants. It is attached to the implant by friction on one end and has external (6.35 mm) and internal (2.5 mm) hex mounts on the other end.

The FID delivery system was especially designed to simplify the implantation process. It enables a simple, manual removal of the implant from the vial, followed by a direct placement of the implant in the surgical field.

In addition to the recommended manual insertion, the hex connectors offer the option of using ratchets, surgical screwdrivers and extension parts.

Fig 10A

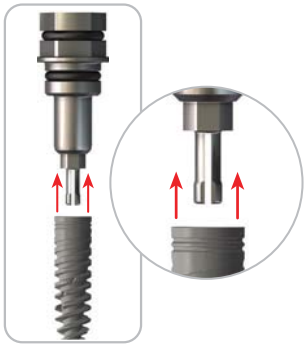


Fig 10B

11. Removing the implant from the vial:

You can choose to remove the implant from the vial in one of 3 ways:

A. Removing implant from vial by hand (Fig 11A):

- Gently loosen the FID sealing the vial by rotating it.
- Slowly pull the implant out of the vial.

Fig 11A

B. Removing implant from vial using a wrench (Fig 11B):

- Connect the wrench to the FID sealing the vial.
- Gently loosen the FID by rotating it with the wrench.
- Slowly pull the implant out of the vial.

Fig 11B

C. Removing implant from vial using a surgical screwdriver (Fig 11C):

- Connect the surgical screwdriver to the FID sealing the vial.
- Gently loosen the FID by rotating it with the screwdriver
- Slowly pull the implant out of the vial.

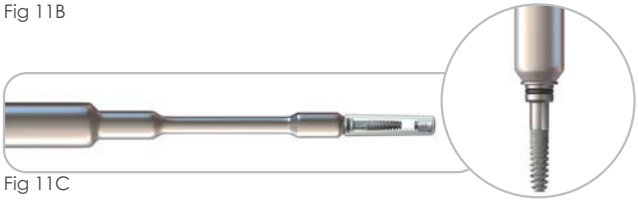


Fig 11C

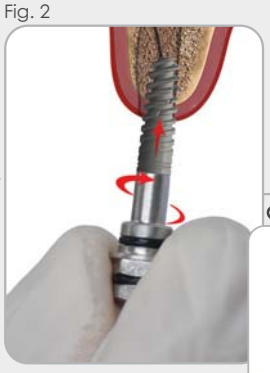
12. Implant Insertion

- It is recommended to pull the implant out of the vial manually and to start implant insertion manually using the FID until you feel a resistance and the implant stops. It is possible to use a manual torque wrench, a surgical screwdriver or a surgical unit for this stage.
- Once the implant has stopped, remove the FID by simply pulling it out manually.
- Continue inserting the implant as specified below.
- Avoid contact between the implant and other oral tissue or saliva.

Fig. 1

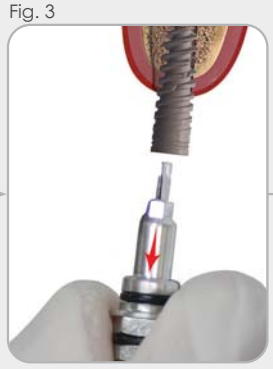
Remove the implant from the vial as explained on page 35.

Fig. 2



Insert the implant until you feel a resistance.

Fig. 3



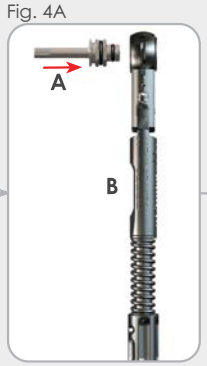
Remove the FID by pulling it out manually.

Caution! With any insertion tool used, avoid over tightening of the implant. Over tightening may compromise the integrity of internal connection and over compress the surrounding bone, compromising osseointegration. It is recommended to place the implants using a torque lower than 60 Ncm.

Step-by-Step Clinical Procedure - Implant Insertion

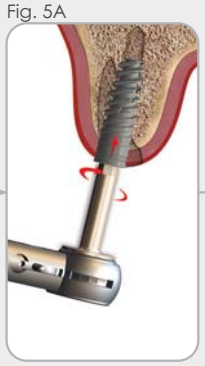
Using a torque wrench

Fig. 4A



Connect the implant driver (A) to the manual wrench driver (B).

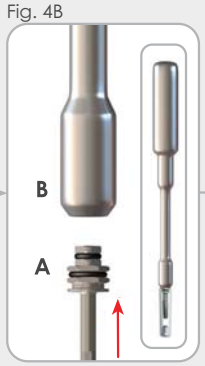
Fig. 5A



Place the driver into the implant and continue inserting the implant to the final depth.

Using the surgical driver

Fig. 4B

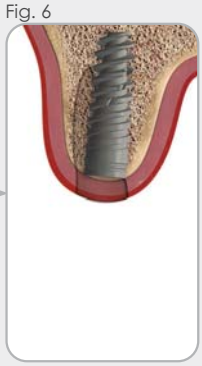


Connect the implant driver (A) to the surgical driver (B).

Fig. 5B

Place the driver into the implant and continue inserting the implant to the final depth.

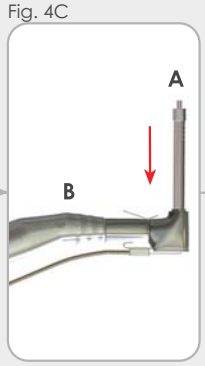
Fig. 6



Final implant placement - for maximum esthetic results align the implant to the level of the buccal bone or 0.5-1 mm below.

Using a drilling unit

Fig. 4C



Connect the implant driver (A) to the handpiece (B).

Fig. 5C

Place the driver into the implant and continue inserting the implant to the final depth using low speed (25 Ncm). The drilling unit may be set to the max 50 Ncm insertion torque.

13. Cover screw installation

Remove cover screw from vial

Fig. 13A

Remove cover screw from holder using manual driver 1.25 mm

Fig. 13B

Insert cover screw into implant using hex driver 1.25 mm

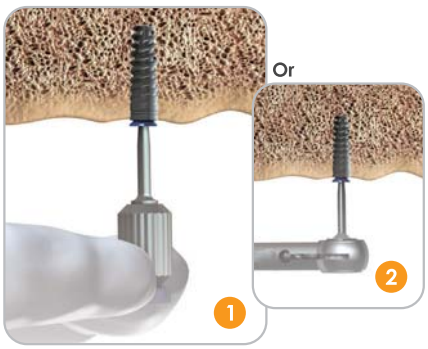


Fig. 13C

Close the flap above the cover screw

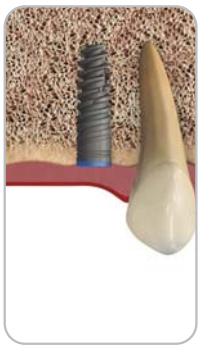


Fig. 13D

14. One-stage surgery

When stabilization is adequate and a one stage protocol is desired a transmucosal healing abutment should be placed using the hexagonal 1.25 mm driver.

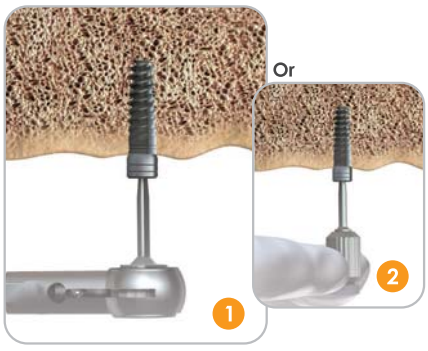


Fig. 14A

Fig. 14B

15. Immediate loading

The Alpha-Bio Tec Internal Hex Implant (SPI, DFI, ATID) are indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Use 30 Ncm to close the abutment screw.

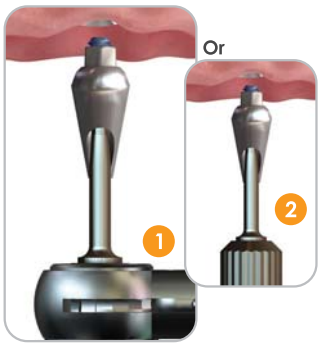


Fig. 15A

Fig. 15B

Fig. 15C

Fig. 15D

Special Surgical Protocols

Immediate Implantation

The particular lead angle of the deep and sharp threads of the SPI implants and their osteotomlike condensing action enables non traumatic insertion and excellent retention that is sufficient for stabilization of the implant. Bone augmentation can be immediately followed as indicated – all in the same session.

Closed and Open Sinus Floor Elevation

The unique design of the SPI and DFI implants allows insertion into a small drill hole and gradual condensation in all dimensions throughout the entire length of the implant. The excellent primary stability that is achieved with the Alpha-Bio Tec implants is very important especially in the area of the posterior maxilla (type 4 bone) combined with closed or open sinus floor elevation (reduced vertical ridge).

Immediate Implantation – Aesthetic Zone

Achieving aesthetic results in the anterior maxilla is very difficult and considered highly unpredictable. The buccal bone plate is usually very thin and is often missing altogether, whereas maintaining bone height and soft tissue architecture requires at least 1.5 mm of bone thickness buccal to the implant.
Regular implants tend to slide into low resistance areas at the bottom of the socket and in order to achieve the desired results bone augmentation must be performed prior to implant placement. Sometimes more than one session of bone augmentation is required for sustained results. The unique design of the tapered Alpha-Bio Tec implants enables them to reach very good primary stability even in extraction sockets with reduced horizontal width. This enables the desired bone augmentation together with implant placement in a one stage procedure .

Surgical Instrumentation

Kit Box Cat.No 4610

Mini Organizer Kit Cat.No 4611

One Kit for all Systems

Surgical instrument kit for one stage and two stage procedures.
Includes spare holders for extras.

Surgical Kit

Alpha-Bio Tec provides dentists with all the necessary tools for successful surgical procedures, from the basic surgical kit to advanced therapy tools.

Surgical kit

- The numbers in white on the Kit Box are catalog numbers
- Instruments are sold separately

Surgical Instrumentation - Surgical Drills

Surgical Drills - Internal Irrigation

The surgical drills are available in sequential diameters and in two lengths. The drills are made of surgical titanium and are to be used with internal irrigation. A Teflon ring in the irrigation canal facilitates friction free insertion of the irrigation tab. All drills are color and groove coded for easy identification during surgery.
Drills are groove marked for lengths as shown below.
Important - an additional 0.8-1.0 mm must be added to the length of the drill to account for the angled cutting tip.

Drills (titanium)						
Cat.no	4200	4280	4320	4650	4660	4680
Code	DR2	DR2.8	DR3.2	DR3.65	DR4.3	DR5.2
Diameter	2.0 mm	2.8 mm	3.2 mm	3.65 mm	4.3 mm	5.2 mm
Color & marks	○ I	● I	● III	● IIII	● IIIII	○ II

Short Drills (titanium)						
Cat.no	4202	4282	4322	4652	4662	4682
Code	DR2 SH	DR2.8 SH	DR3.2 SH	DR3.65 SH	DR4.3 SH	DR5.2 SH
Diameter	2.0 mm	2.8 mm	3.2 mm	3.65 mm	4.3 mm	5.2 mm
Color & marks	○ I	● I	● III	● IIII	● IIIII	○ II

Surgical Instrumentation - Surgical Drills

Surgical Drills - External Irrigation

The surgical drills are available in sequential diameters and in two lengths.
The drills are made of stainless steel and are to be used with external irrigation.

Drills (stainless steel)						
Cat.no	4204	4284	4324	4654	4664	4684
Code	DRX2.0	DRX2.8	DRX3.2	DRX3.65	DRX4.3	DRX5.2
Diameter	2.0 mm	2.8 mm	3.2 mm	3.65 mm	4.3 mm	5.2 mm
Color & marks	○ I	● II	● III	● IIII	● IIIII	○ IIIIII

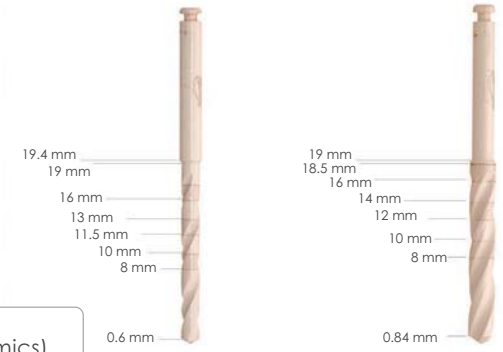
Short Drills (stainless steel)						
Cat.no	4205	4285	4325	4655	4665	4685
Code	HDRX2	HDRX2.8	HDRX3.2	HDRX3.65	HDRX4.3	HDRX5.2
Diameter	2.0 mm	2.8 mm	3.2 mm	3.65 mm	4.3 mm	5.2 mm
Color & marks	○ I	● II	● III	● IIII	● IIIII	○ IIIIII

Ceramic Drills

The innovative ceramic pilot drills are made of high efficiency ceramics featuring an excellent cutting performance. The Ceramic Drills offer the possibility of working without metal, thus offering a biocompatible and antiallergenic operation.
The multifunctional ceramic pilot drills are ideally suited for initial preparation of the implant site axis and depth. The drills feature high initial sharpness and optimal cutting efficiency, thus achieving an effective material reduction.
The special twist drill blade geometry ensures smooth and precise surgery.
The lasered depth markings intervals offer precise and safe control of the penetration depth.

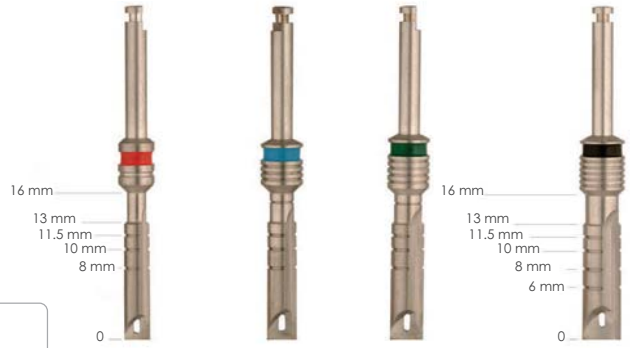
Advantages at a glance:

- Biocompatible
- Free of metal
- Corrosion-free
- S-shaped tip transversing blade for easy penetration
- Stepped blade shoulder for low bone friction
- Large chip spaces for optimal chip removal
- Lasered depth marks in intervals of 2 mm, beginning at 8 mm from the tip.



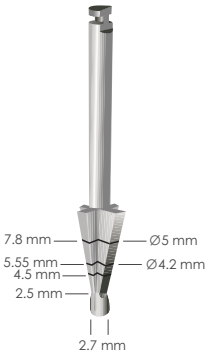
Ceramic Drills (zircon - dioxide ceramics)		
Cat.no	4209-DRC2	4289-DRC2.8
Diameter	2.0 mm	2.8 mm

Surgical Instrumentation - Surgical Drills



Straight Drills (titanium)				
Cat.no	4281-DRS2.8	4321-DRS3.2	4651-DRS3.65	4661-DRS4.3
Diameter	2.8 mm	3.2 mm	3.65 mm	4.3 mm

Straight drills are intended for closed sinus lift or for drilling close to anatomic structures.



Countersink (stainless steel)	
Cat.no	4672
Diameter	2.7-5.9 mm

Used to widen the bone.

Narrow Drill (stainless steel)	
Cat.no	4671-DRX1.5
Diameter	1.5 mm

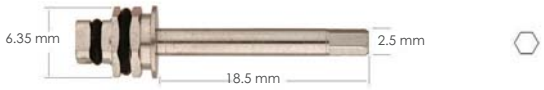
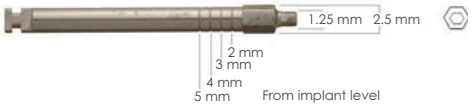
Drill Extention (stainless steel)	
Code	DX
Cat.no	4240

Extends drill by 17.5 mm

Surgical Instrumentation - Surgical Accessories

Implant Insertion Tools 2.5 mm (ITD) (stainless steel)

Used for placing threaded implants with internal hex 2.5 mm.
Fits hexagonal 6.35 mm (1/4 in) or square head 4 mm.

	Cat.no
	4151-ITD 2.5*
	4152-ITD 2.5 S*
Contra angle – motor mount hex driver 	4161-IT 1.25/2.5 M

Hex Driver 1.25 mm (0.050 inch) HTD (stainless steel)

for all types of cover screws, healing abutments and prosthetic pieces.
Fits hexagonal head 6.35 mm (1/4 in) or square head 4 mm

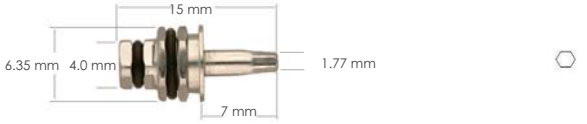
	Cat.no
	4055-HTD 1.25*
	4056-HTD 1.25 S*

Hand Hexagonal Screw Driver 1.25 mm (stainless steel)

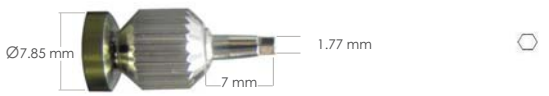
	4052-HHS 1.25
	4053-HHSS 1.25
Contra angle – motor mount hex driver 	4165-HT 1.25 M

Hex Drivers 1.77 mm (stainless steel) Used for TCT, TSA abutment system

Fits hexagonal head 6.35 mm (1/4 in) or square head 4 mm

	4077-HTD 1.77M*

Hand Hexagonal Screw Driver 1.77 mm (stainless steel)

	4177-HHSS 1.77
Contra angle – motor mount hex driver 	4167-HT 1.77M

* Fits hexagonal ⎔ 6.35 mmd (1/4 in) or square □ 4 mm ratchet

Surgical Instrumentation - Surgical Accessories

Ratchet Wrench (stainless steel) for 6.35 mm (1/4in) hexagonal head.

Cat.no

4011-RAT**

Universal Torque/Ratchet (stainless steel) allows the clinician to accurately apply the recommended preload torque for surgery and prosthetics.

4572-URT** 0-45Ncm

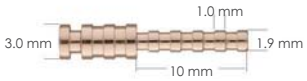
Universal Square Head Adaptor (stainless steel)

4012-USH

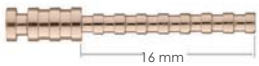
Surgical Screwdriver (stainless steel) for 6.35 mm (1/4in) hexagonal head.

4220-SDH

Parallel/Depth Guide (titanium)
for accurate measurement of x-ray distortion. Each step is 1 mm.



4081-PDGS



4080-PDG

Parallel Guide
used for precise spacing and parallel placement of implant.

4082-PG

IDG Implant Depth Probe (stainless steel)

4100-IDG

Its gently rounded apex simplifies depth measurments and provides easy, tactile examination of bone preparation and sinus membrane.

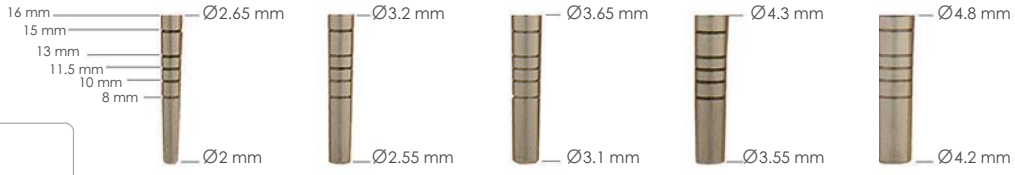
Osteotomes

Use for implant placement, sinus elevation, ridge expansion and site preparation.
The tapered walls laterally compress bone Stoppers for drills or osteotomes.

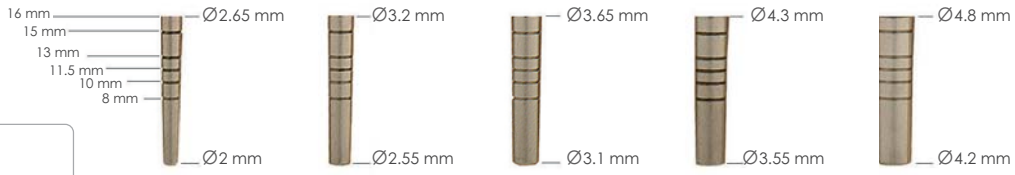
Straight Osteotomes (stainless steel)
5 piece cat.no 4260 - OST set

Angled Osteotomes (stainless steel)
5 piece cat.no 4261 - OST set

Osteotomes organizer kit
cat.no 4262



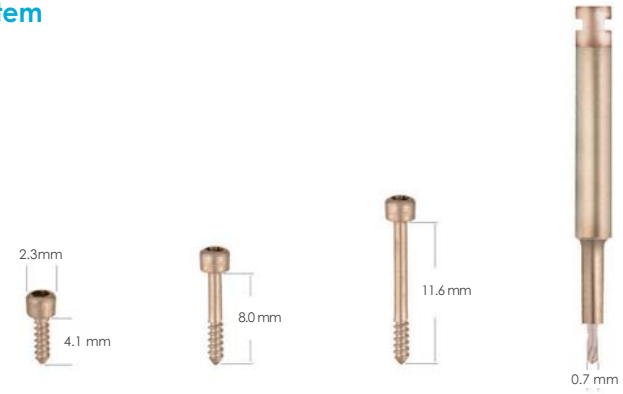
Straight Osteotomes (stainless steel)					
Code	4260/1	4260/2	4260/3	4260/4	4260/5
Diameter	2 - 2.65 mm	2.55 - 3.2 mm	3.1 - 3.65 mm	3.55 - 4.3 mm	4.2 - 4.8 mm



Angled Osteotomes (stainless steel)					
Code	4261/1	4261/2	4261/3	4261/4	4261/5
Diameter	2 - 2.65 mm	2.55 - 3.2 mm	3.1 - 3.65 mm	3.55 - 4.3 mm	4.2 - 4.8 mm

Surgical Instrumentation - Advanced Therapy

Membrane and Bone Fixation System



Screw Fixation 1.2 mmd				
Cot. no	3010	3030	3031	3040
Code	SFM	SFS	SFSL	DRM
	titanium			stainless steel

Use Hex Driver HTD 1.25 mm (0.050in).

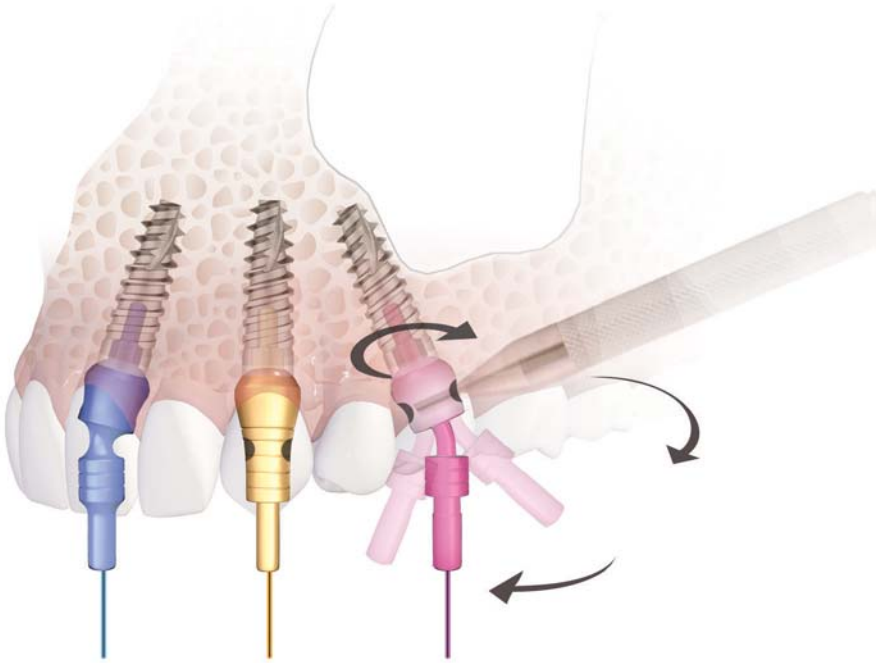
Trephine Burs (stainless steel)		
Cat.no	4940-DRT4	4950-DRT5
Diameter	4 mm	5 mm

For harvesting bone and implant removal.

Disposable Sterile Mini Surgical Kit	Cat.no
Patient cover (45*75 cm) Surface working cover (45*75 cm) Light handle cover Hand piece cover Sterilized by E.T.O	4641

Surgical Instrumentation - Paraguide System

Paraguide System for Implant Parallelism



Paraguide helps you achieve parallelism, esthetics and function quickly and easily.

An implant should be placed between cortical plates in the available bone, oriented and parallel to other implants, abutments and or teeth.

Protocol

The implant is placed at the alveolar crest level. Insert the specific Paraguide (0°, 15°, 25°) into the implant. Screw the implant into the bone with the help of the Paraguide Abutment and the rotation tool (RT), until the Paraguide Abutment is parallel to other abutments.

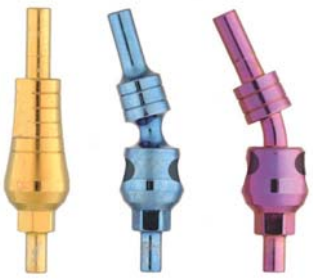
Tip

In order to ensure use of the same angle abutment (TLA 0°, TLA 15°, TLA 25°) for the rehabilitation make sure to record the angle of the Paraguide Abutment used for each implant.

In the case of a single abutment insert the Paraguide and rotate it to the angle which orients it to adjacent teeth.

Use Abutments

TLA, TLA 15°, TLA 25°



Internal Hex Paraguide (titanium)			
Code	TPG 0	TPG 15	TPG 25
Cat.no	5230-0	5230-15	5230-25
titanium			

Rotation Tool	
Code	RT
Cat.no	4290
stainless steel	

Items sold separately or as a 3-piece set.
Set Cat. no - 5230.

Appendices

Instructions of Use for Alpha-Bio Tec Implant System

1. Product description

The Alpha-Bio Tec implant system includes different types and sizes of dental implants made of grade 5 titanium and undergo a unique surface treatment. At the end of the process, the implants are sterilized by gamma radiation. The implantation is performed by surgery that includes opening a flap, drilling and inserting the implant into the jawbone.

2. Product purpose

Alpha-Bio Tec implants are used for rehabilitating completely or partially edentulous patients. The rehabilitation on the implants includes a number of options: single crown, a number of connected crowns and partial or full dentures that are connected to Alpha-Bio Tec implants using abutments.

3. Indications

Quantity and quality of bone that are suitable for performing implants are an essential condition. This data is gathered during the planning stage by making appropriate radiographs (panoramic and computer tomography) of the implantation site. Anatomic areas near the implantation site such as: blood vessels, nerves, maxillary sinus and nasal cavity must be identified in order to prevent their damage. The performance of surgical procedures is subject to the patient's systemic condition.

4. Recommendations

It is advised not to overload 3 mm and 3.3 mm implants.
It is recommended to place Arrow Press implants using a force lower than 60 Ncm.

5. Contraindications

Patients who take steroid based, anticonvulsant and anticoagulant drugs. Patients receiving radiotherapy, chemotherapy or any other immunosuppressive treatment or who have been administered radiotherapy in the last 5 years. Metabolic bone disorders, uncontrolled bleeding disorders such as: hemophilia, thrombocytopenia, granulocytopenia. Degenerative diseases, osteoradionecrosis, renal failure, organ transplant recipients, AIDS, malignant diseases, diseases that compromise the immune system, unbalanced diabetes mellitus, psychotic diseases, hypersensitivity to one of the components of the implant in general and titanium in particular, pregnancy, inability of the patient to maintain reasonable oral hygiene, lack of patient cooperation, use of alcohol, narcotics and uncontrolled endocrine diseases.
Any systemic condition that is unbalanced and therefore precludes surgical procedures. Lack of appropriate experience or training of the attending dentist.

6. Relative contraindications

Previously irradiated bone, treatment with anticoagulant drugs or bisphosphonates, bruxism, parafunctional habits, untreated and/or uncontrolled periodontal disease, temporomandibular joint disease, various pathologies of the oral mucosa.

7. Post-operation instructions for patients

Avoid actions that subject the body to physical stress after implantation. Eat only cold, soft food and take antibiotics, oral rinses and analgesics as instructed by the attending dentist. Do not spit or brush your teeth at the day of implantation. It is advisable to place an ice pack intermittently on the external area of the implantation on the day of the operation.

8. Short term post-operation adverse effects

Pain, swelling, infection, bleeding, hemorrhages.

9. Short term complications and risks

Nerve damage causing temporary or permanent loss of sensation of the lower lip and/or tongue, damage to blood vessels (may cause life threatening bleeding), perforation to nasal cavity and/or maxillary sinus and local and systemic infection.

10. Long term complications and risks

Chronic pain, lack of sensation in the lip or tongue, local or systemic infection, perforation to the sinus, rupture of nasal cavity, damage to adjacent teeth, fracture of implant, fracture of restoration, fracture of bone, esthetic disorders and infectious endocarditis.

11. Warnings!

An error in patient evaluation, in pre-treatment diagnosis and in the treatment plan resulting from inexperience or lack of inappropriate training of the attending dentist may endanger the health of the patient and cause severe, irreversible and even life threatening damage. Therefore, implantation must not be performed without appropriate training of the implanting dentist at a recognized institute!
The implant is designed to be used once. Do not sterilize!
The implant is sterile unless its package is open or damaged!
Performing implantations may require prophylactic antibiotics!
Alpha-Bio Tec devices are intended for practitioners only.

12. Prosthetic parts, healing caps and fixation screws

Abutments, healing caps and fixation screws for bone augmentation are provided in a non-sterile condition. Before use, sterilize in an autoclave, subject to the manufacturer's instructions, at a temperature of 121°c for 40 minutes and then dry for another 30 minutes.

13. Shipment and maintenance

Implants and cover screws have been cleaned and sterilized by gamma radiation and are ready for use.
Open the implant and cover screw case onto a sterile surface and use titanium tools only.

Limited warranty

In the case of failure of an implant, Alpha-Bio Tec will replace/provide another implant in exchange free of charge, in accordance with the following conditions:

- Filling in a report form supplied by Alpha-Bio Tec and attaching a radiogram taken before and after the implantation.
- Submitting the report no later than 6 months from the beginning of the event, with the failed implant.

This is the full scope of the warranty for implantation provided by Alpha-Bio Tec that lists the sole remedies related to implantation.

STERILE R	Sterilized using irradiation
	Do not re-use
	Caution: Consult accompanying documents
	Expiry date
LOT	Batch No.
CE 0483	CE marking
Rx only	To be used by practitioners only

Instrument Cleaning Instructions

Internal and external irrigation drills & drills extension

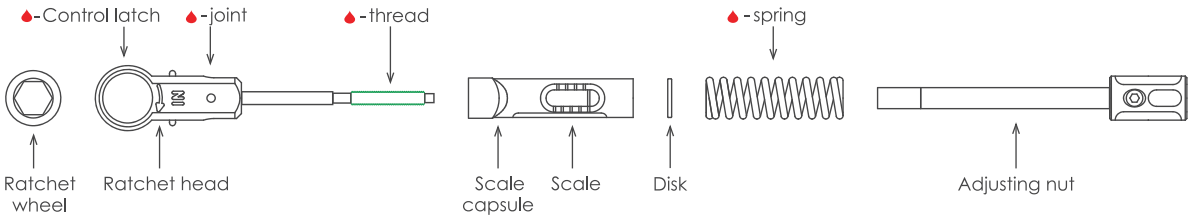
- Meticulously eliminate all the post-operative residues (blood, bone etc.) on the drills. After using drills with internal irrigation make sure to eliminate residues inside the drill.
- Avoid, as much as possible, shocks and contacts with other drills or instruments (damaging of the quality surface and / or cutting power)
- Do not clean the implant drills with other tools made of different materials in the same ultrasonic box.
- Use suitable cleaning solutions. Follow the manufacturer instructions of use.
- Rinse, and then dry the drills immediately after the cleaning process (preferably use distilled water to rinse). Thorough drying is necessary.
- Store the drills in a clean and dry place.
- Sterilize using a steam autoclave according to autoclave manufacturer recommendations.

Instruments and motor mount for contra angle

- Meticulously eliminate all the post-operative residues (blood, bone etc.) on the instrument.
- Use suitable cleaning solutions. Follow the manufacturer instructions of use.
- Rinse, and then dry the instruments immediately after the cleaning process (preferably use distilled water to rinse). Thorough drying is necessary.
- Store the instruments in a clean and dry place.
- Sterilize using a steam autoclave according to autoclave manufacturer recommendations.

Manual torque wrench

- After use, take the ratchet apart (does not require tools).
- Preclean the individual pieces with a soft brush under running water. Avoid the drying of remains of blood and other adhesion.
- Lay the precleaned pieces in disinfection and cleansing fluid for rotating dental instruments. Please follow the manufacturing instructions for the cleansing agent.
- Dry the individual parts.
- Slightly moist the areas marked in the drawings with special care-oil for contra angles.
- Re-assemble the ratchet.
- For the Universal Torque Ratchet – store in a relaxed position (setting about 10Ncm).
- Sterilize using a steam autoclave according to autoclave manufacturer recommendations.



Healing caps, abutments and screw, screw fixation

- Abutments, healing caps and fixation screws for bone augmentation are provided in a non-sterile condition.
- Before use, sterilize in an autoclave, subject to the manufacturer's instructions, at a temperature of 121°c for 40 minutes and then dry for another 30 minutes.

Implant Catalog Numbers

SPI - Spiral Implant

	8 mm	10 mm	11.5 mm	13 mm	16 mm
SPI Ø 3.3 mm	1308	1300	1301	1303	1306
SPI Ø 3.75 mm	1358	1350	1351	1353	1356
SPI Ø 4.2 mm	1338	1330	1331	1333	1336
SPI Ø 5 mm	1348	1340	1341	1343	1346
SPI Ø 6 mm	1368	1360	1361	1363	—

DFI - Dual Fit Implant

	8 mm	10 mm	11.5 mm	13 mm	16 mm
DFI Ø 3.3 mm	1288	1280	1281	1283	1286
DFI Ø 3.75 mm	1268	1260	1261	1263	1266
DFI Ø 4.2 mm	1278	1270	1271	1273	1276
DFI Ø 5 mm	1298	1290	1291	1293	1296

ATID - Standard Implant

	6 mm	8 mm	10 mm	11.5 mm	13 mm	16 mm
ATID Ø 3.3 mm	—	1418	1410	1411	1413	1416
ATID Ø 3.75 mm	—	1428	1420	1421	1423	1426
ATID Ø 4.2 mm	—	1438	1430	1431	1433	1436
ATID Ø 5 mm	1446	1448	1440	1441	1443	—
ATID Ø 6 mm	1456	1458	1450	1451	1453	—


AlphaBio TEC

Our warranty - Your peace of mind

Alpha-Bio Tec's high quality products meet strict international standards. This is why we can provide you with a **Lifetime Warranty** for our wide range of implants.
In any case of a defect in the product, implant rejection, fracture or contamination of the product, subject to filing a complaint report, Alpha-Bio Tec shall replace the defective merchandise.

Warranty: Alpha-Bio Tec warrants that all products will be free of defects in materials and/or workmanship. This warranty applies to the original purchaser only. There are no warranties, express or implied, except this warranty, which is given in lieu of any other warranties, express or implied, including any implied warranty of fitness for a particular purpose.

Important - Read instructions before use.
A complaint report is available at Alpha-Bio Tec's customer service and will be sent upon demand.

Alpha-Bio Tec Warranty

Alpha-Bio Tec continually strives to update and improve its products; hence we reserve the right to modify designs, products and/or techniques when we feel it is warranted. We also reserve the right to change prices, policies and terms without prior notice.
Warranty: Alpha-Bio Tec makes no warranty, expressed or implied, except that all products will be free of defects in materials and/or workmanship. This warranty applies to the original purchaser. In the event of a product defect, please notify Alpha-Bio Tec in writing prior to returning the product.

Alpha-Bio Tec will then, at its discretion, repair, replace or issue a credit for defective merchandise.
The purchaser assumes all risk and liabilities from the use of these products, whether used separately or in conjunction with products not of Alpha-Bio Tec's manufacture.

Alpha-Bio Tec strongly recommends completion of post-graduate implant education and adherence to all technical procedures and instructions.
Federal law permits the sale of these products to licensed physicians and dental practitioners only. Products in this catalog may be protected by more than one patent.

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Alpha-Bio Tec's products are CE-approved and cleared for marketing in the USA. Alpha-Bio Tec complies with: ISO 13485:2003 under the Canadian Medical Devices Conformity Assessment System, ISO 9001:2000 and Council Directive 93/42/EEC.

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