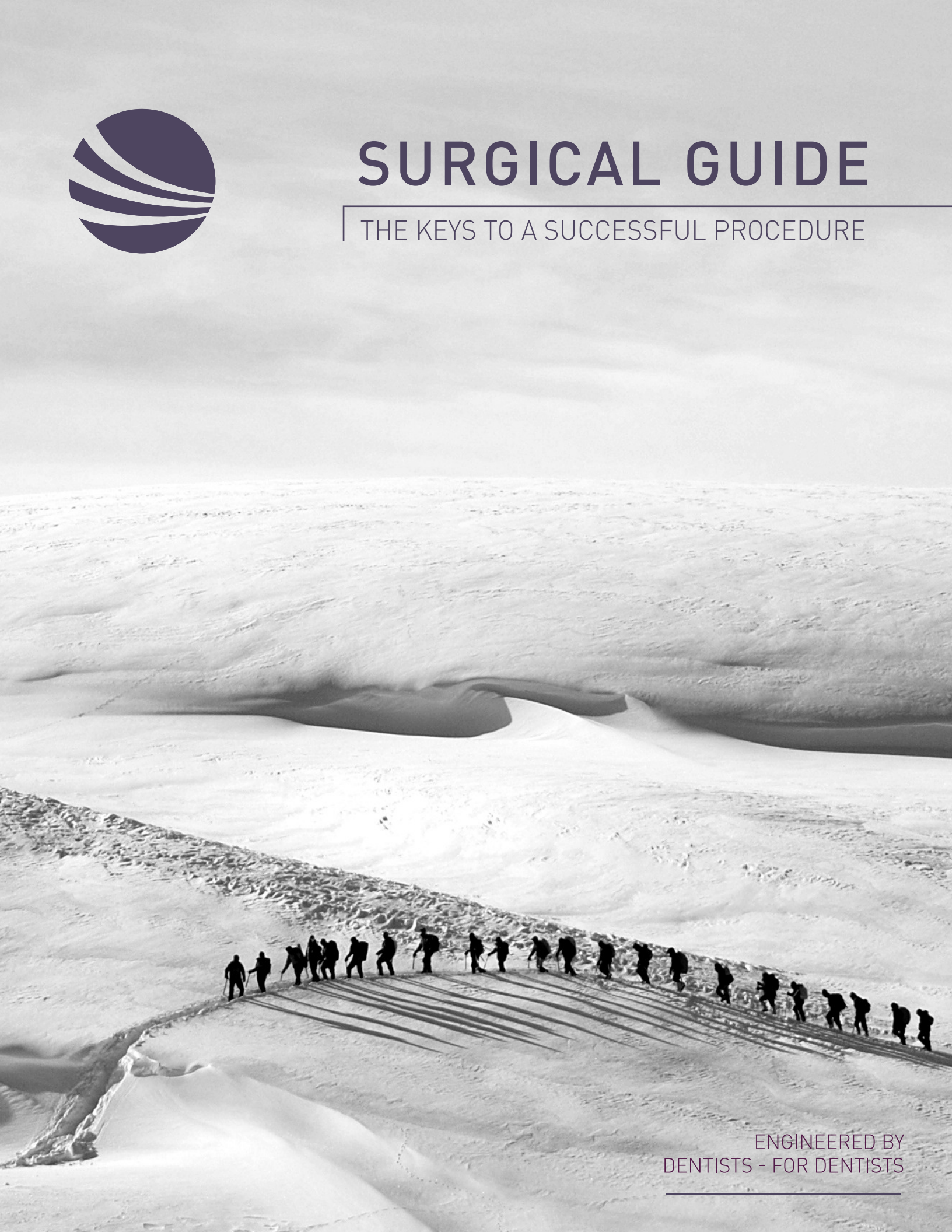
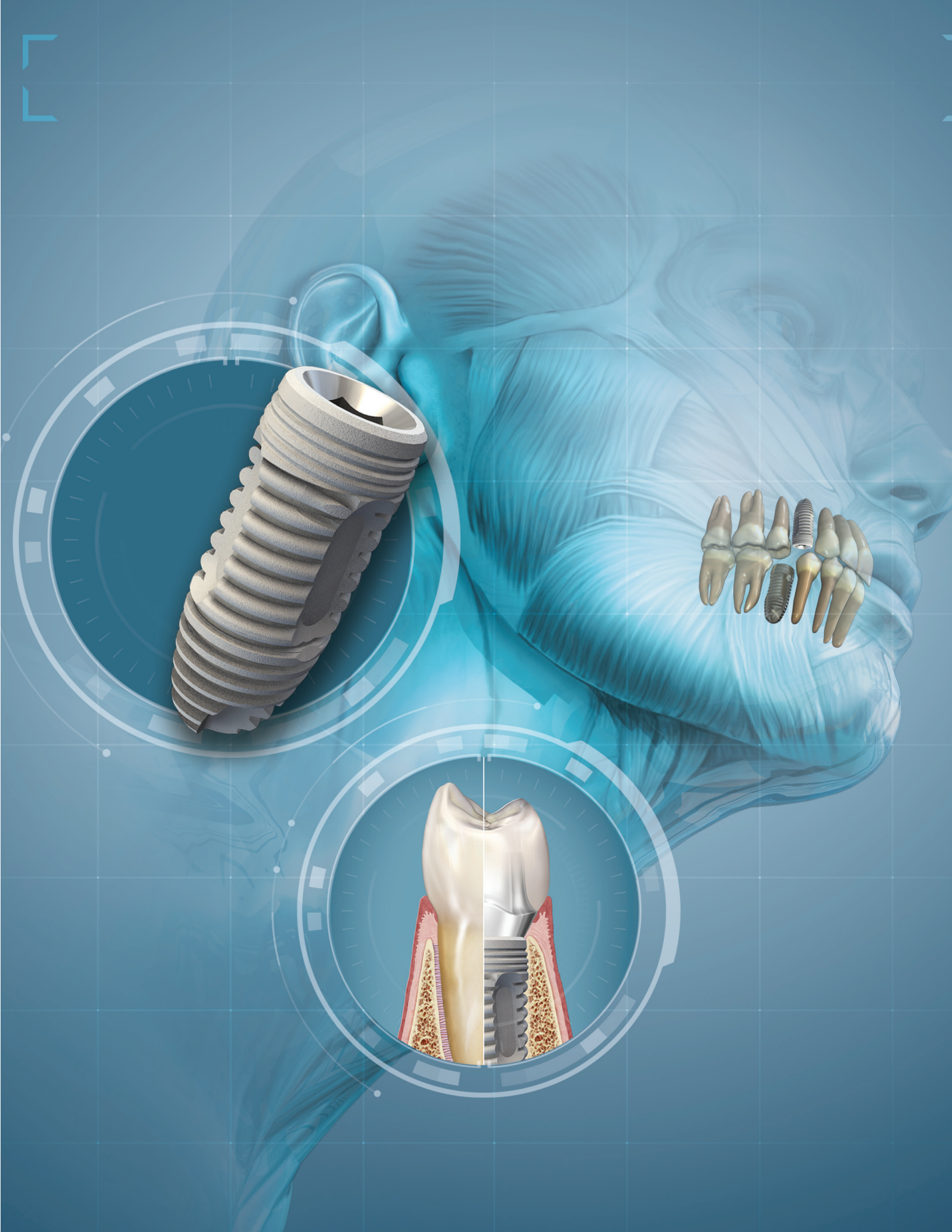
SURGICAL GUIDE

THE KEYS TO A SUCCESSFUL PROCEDURE



ENGINEERED BY
DENTISTS - FOR DENTISTS



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Introduction

Device Description

The SpiralTech implant system is a comprehensive product line that includes implants, corresponding abutments, and cover screws. SpiralTech dental implants are grade 5 titanium (Ti 6Al-4V ELI, conforms to ASTM F136) implants that come in 2 different surface treatments - SLA and RBM.

SpiralTech dental implants come in four product lines with three based on their thread designs. The ESi has sharp, square, and rounded threads. The Ultimate implant also has sharp threads. The Premium implant features square and sharper threads in a more conventional design. The implants have diameters ranging from 3.0 mm to 6.0 mm, and the lengths from 8mm to 15 mm. ESi and Ultimate are intended to be used for immediate loading. The fourth implant type is the Solo One Piece, which comes with an abutment and cannot be used with low mechanical stability cases. Abutments are available in various types including straight, shoulder, angulated, ball attachments, multi-unit, temporary and healing. All abutments come in both hex and conical connections. Temporary abutments come in PEEK and zirconia. Healing abutments come in titanium alloy and zirconia. Abutments come in titanium alloy and as a titanium base with zirconia abutment. Ball attachments and multi-units are titanium alloy. No SpiralTech abutments are intended to be modified.

Indications For Use

The SpiralTech Dental Implants are endosseous implants intended to be surgically placed in the upper or lower jaw arches to provide support for prosthetic devices. The implants are designed to restore a patient's esthetics and chewing function. SpiralTech implants are intended for single or multiple unit restorations on splinted or non-splinted applications. The implants ESi and Ultimate are intended for immediate loading when good primary stability is achieved and with appropriate occlusive loading. These implants [along with Premium and Solo One Piece] can also be used for loading after a conventional healing period.

Solo One Piece 3.0 and 3.3 implants, Ultimate (conical) 3.0 implants, and ESi (conical) 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible. Mandibular central and lateral incisors must be splinted if using two or more 3.0 and/or 3.3 implants adjacent to one another.

*Federal law restricts this device to sale by or on the orders of a dentist or physician. These devices are only to be used by trained professionals.

Initial Appointments

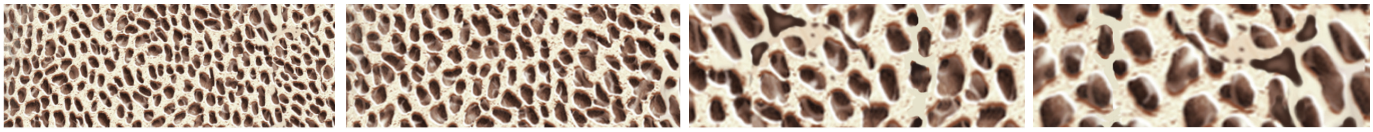
- Medical and Dental History
- Dental Evaluation and X-ray Examinations
- Diagnostic Casts
- Preliminary Discussion of Treatment Alternatives
- Decision to Proceed with Treatment
- Initial Treatment Plan, Case Presentation, and Alternatives
- Clinical/Laboratory Procedure Prior to Additional Diagnostic Records
- Extra Office Diagnostic Orders Setup, Computed Tomography Scans, Tests for Medical Evaluation, Consultation, and Team Members
- Diagnostic Wax-up of Final Results on Duplicate Diagnostic Casts
- Final Treatment Plan and Alternatives
- Medical Laboratory Tests Evaluated
- Prescriptions and Postoperative Instructions
- Consent Forms and Request for Treatment Forms
- Pictures of Existing Condition

Treatment Planning

- Diagnose patient with radiograph. Take Aliginate Impression and Study Model to take record of upper and lower jaw.
- Diagnosis of the needed reconstructed area:
    a. Location of the missing teeth
    b. Bone Type
    c. Bone Width
    d. Bone Height (from Sinus floor or Inferior Alveolar Nerve to Crestal area of the bone)
    e. Decide on immediate or non-immediate loading and follow the chart, make sure to distance your implant 1.5mm away from Alveolar Nerve or Sinus Floor
    f. 3.5mm implants should be placed 0.5mm below crestal level of the bone
    g. All implants should leave a minimum of 1.5mm for both buccal and lingual bone thickness
    h. Allow 1.5 distance between root and implant, and 3.0mm distance between two implants

Presurgical Restorative Appointment

- Carries Removal, Extractions, Temporary Teeth
- Periodontal Treatment, Endodontic Therapy, Orthodontics
- Occlusal Vertical Dimension
- Occlusal Plane Correction, Treatment Prosthesis, Recontour Existing Teeth, Enamoplasty
- Transitional Prosthetics (Removal or Fixed) or Diagnostic Try-In; Tissue Conditioning
- Impression for Surgical Guide Template (If Oral Condition Altered from Initial Diagnostic Cast)



Type I (Dense)

Type II
Dense trabecular bone

Type III
Trabecular bone

Type IV (Soft)
Low-density trabecular bone

Implant Design

- Help with Diagnosis
  - a. Crown Lengthening
  - b. Occlusal Plane
  - c. Hopeless Teeth
- Evaluate the Psychologic Profile of the Patient
- Denture before Implant Surgery
- Improve Soft Tissues before Final Impression for Implant Overdentures
- Postoperative to Implant Surgery
- Evaluate Occlusal Vertical Dimension
- Evaluate Temporomandibular Joint Dysfunction
- Improve Implant Position Related to Final Tooth Position
- Evaluate Esthetics before Surgery
- Evaluate Hygienic Contours of Fixed Restorations
- Determine whether Removable Restoration is Required for Maxillary Lip Support (RP versus FP)
- Protect Bone Graft or Implants During Healing
- Patient's Financial and Compliance Management
- Progressive Bone Loading
- Phonetics and Esthetics for Full Arch Implant-Fixed Prosthetics on Complete Edentulous Patients

ESi

Bone Type I, II, III, IV
Immediate and
Non-Immediate Loading

Premium

Bone Type I, II, III, IV
Non-Immediate Loading

Ultimate

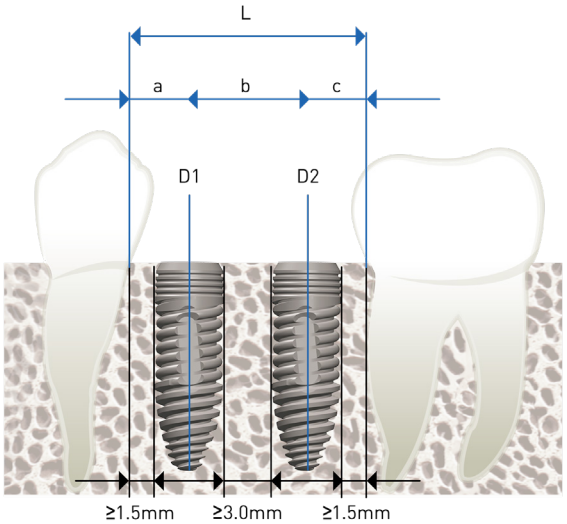
Bone Type II, III, IV
Immediate and
Non-Immediate Loading

Mesiodistal Implant Position

The point of reference for measuring mesiodistal distances is always the implant shoulder, as it is the widest part of the implant. Note that all distances given in this flyer are rounded off to the 0.5mm. The following basic rules must be applied:

Rule 1: The distance to the adjacent tooth at bone level:
A minimal distance of 1.5mm from the implant shoulder to the adjacent tooth at bone level (mesial and distal) is required.

Rule 2: Distance to the adjacent implants at bone level:
A minimal distance of 3.0mm between two adjacent implant shoulders (mesiodistal) is required.



Implant Diameter D1 (mm)	Implant Diameter D2 (mm)	a min (mm)	b min (mm)	c min (mm)	L min (mm)
3.0	3.0	3.0	6.0	3.0	12.0
3.0	3.5	3.0	6.3	3.3	12.6
3.5	3.5	3.3	6.6	3.3	13.2
3.5	4.3	3.3	7	3.7	14
4.3	4.3	3.7	7.4	3.7	14.8
4.3	5.0	3.7	7.7	4	15.4
5.0	5.0	4	8	4	16
5.0	6.0	4	8.5	4.5	17
6.0	6.0	4.5	9	4.5	18

ESi Implant *with Standard Hex or Conical Hex Connection*

The Essential Spectrum Implant (ESi) has been pantented. The ESi implant is versatile and can be used in most clinical situations. Placement is intuitive and fast. Great for beginning and experienced surgeons alike.

Ø3.00

Length (mm)	HEX Catalog No.	CONICAL Catalog No.
10.0	-	ESiC30010
11.5	-	ESiC30011
13.0	-	ESiC30013
15.0	-	ESiC30015

Ø3.50

Length (mm)	HEX Catalog No.	CONICAL Catalog No.
8.0	ESi35008	ESiC35008
10.0	ESi35010	ESiC35010
11.5	ESi35011	ESiC35011
13.0	ESi35013	ESiC35013
15.0	ESi35015	ESiC35015

Ø4.30

Length (mm)	HEX Catalog No.	CONICAL Catalog No.
6.0*	ESi43006	ESiC43006
8.0	ESi43008	ESiC43008
10.0	ESi43010	ESiC43010
11.5	ESi43011	ESiC43011
13.0	ESi43013	ESiC43013
15.0	ESi43015	ESiC43015

Ø5.00

Length (mm)	HEX Catalog No.	CONICAL Catalog No.
6.0*	ESi50006	ESiC50006
8.0	ESi50008	ESiC50008
10.0	ESi50010	ESiC50010
11.5	ESi50011	ESiC50011
13.0	ESi50013	ESiC50013
15.0	ESi50015	ESiC50015

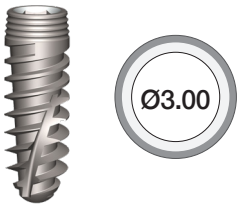
Ø6.00

Length (mm)	HEX Catalog No.	CONICAL Catalog No.
6.0*	ESi60006	ESiC60006
8.0	ESi60008	ESiC60008
10.0	ESi60010	ESiC60010
11.5	ESi60011	ESiC60011
13.0	ESi60013	ESiC60013
15.0	ESi60015	ESiC60015

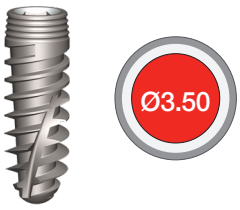
*Call for more information.

Ultimate Implant *with Standard Hex or Conical Hex Connection*

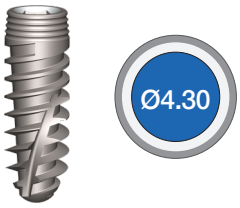
The Ultimate Implant is designed for initial stability, even in soft bone. It is a suitable implant for immediate placement and / or immediate loading. Due to its design, it can be slightly adjusted to reposition implant during the surgery.



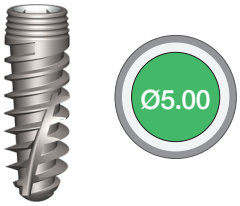
Length (mm)	HEX Catalog No.	CONICAL Catalog No.
10.0	-	ULC30010
11.5	-	ULC30011
13.0	-	ULC30013
15.0	-	ULC30015



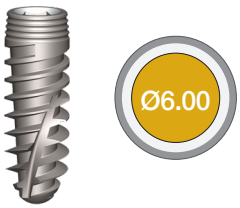
Length (mm)	HEX Catalog No.	CONICAL Catalog No.
8.0	UL35008	ULC35008
10.0	UL35010	ULC35010
11.5	UL35011	ULC35011
13.0	UL35013	ULC35013
15.0	UL35015	ULC35015



Length (mm)	HEX Catalog No.	CONICAL Catalog No.
6.0*	UL43006	ULC43006
8.0	UL43008	ULC43008
10.0	UL43010	ULC43010
11.5	UL43011	ULC43011
13.0	UL43013	ULC43013
15.0	UL43015	ULC43015



Length (mm)	HEX Catalog No.	CONICAL Catalog No.
6.0*	UL50006	ULC50006
8.0	UL50008	ULC50008
10.0	UL50010	ULC50010
11.5	UL50011	ULC50011
13.0	UL50013	ULC50013
15.0	UL50015	ULC50015

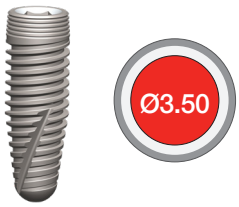


Length (mm)	HEX Catalog No.	CONICAL Catalog No.
6.0*	UL60006	ULC60006
8.0	UL60008	ULC60008
10.0	UL60010	ULC60010
11.5	UL60011	ULC60011
13.0	UL60013	ULC60013
15.0	UL60015	ULC60015

*Call for more information.

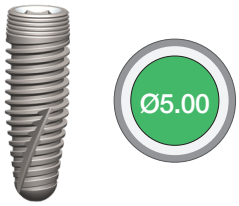
Premium Implant *with Standard Hex or Conical Hex Connection*

The Premium Implant is a conventionally designed implant. While it can be used in all clinical situations, its conservative threads are best suited for healed ridges. All implants are provided with the corresponding cover screw and average-size healing abutment.



Length (mm)	HEX Catalog No.	CONICAL Catalog No.
8.0	PR35008	PRC35008
10.0	PR35010	PRC35010
11.5	PR35011	PRC35011
13.0	PR35013	PRC35013
15.0	PR35015	PRC35015

Length (mm)	HEX Catalog No.	CONICAL Catalog No.
6.0*	PR43006	PRC43006
8.0	PR43008	PRC43008
10.0	PR43010	PRC43010
11.5	PR43011	PRC43011
13.0	PR43013	PRC43013
15.0	PR43015	PRC43015



Length (mm)	HEX Catalog No.	CONICAL Catalog No.
6.0*	PR50006	PRC50006
8.0	PR50008	PRC50008
10.0	PR50010	PRC50010
11.5	PR50011	PRC50011
13.0	PR50013	PRC50013
15.0	PR50015	PRC50015

Length (mm)	HEX Catalog No.	CONICAL Catalog No.
6.0*	PR60006	PRC60006
8.0	PR60008	PRC60008
10.0	PR60010	PRC60010
11.5	PR60011	PRC60011
13.0	PR60013	PRC60013
15.0	PR60015	PRC60015

*Call for more information.

Temporary Healing Abutments

Available in various heights and diameters; healing abutments are used to sculpt soft tissues in preparation for placement of the final restoration.
They can be used in the one-stage or two-stage surgical approach
All flat zirconia abutments have a 5mm height above the margin.*

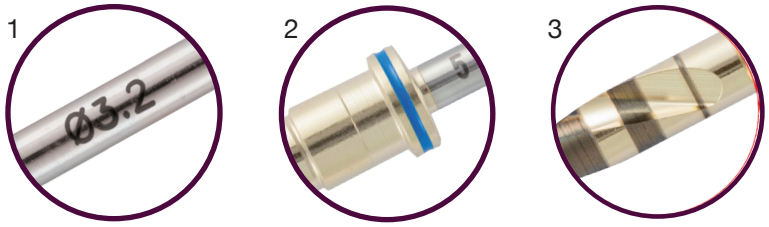
Design	Diameter (mm)	Facial Height (mm)	Hex Catalog No.	NP Conical Catalog No.	RP Conical Catalog No.	Slim Conical Catalog No.
Healing Cap, slim	3.5	2	-	-	-	HACSP352
		3	-	-	-	HACSP353
		4	-	-	-	HACSP354
		5	-	-	-	HACSP355
		6	-	-	-	HACSP356
Healing Cap, narrow	3.8	2	HAH382	HACNP382	HACRP382	-
		3	HAH383	HACNP383	HACRP383	-
		4	HAH384	HACNP384	HACRP384	-
		5	HAH385	HACNP385	HACRP385	-
		6	HAH386	HACNP386	HACRP386	-
Healing Cap, medium	4.5	2	HAH452	HACNP452	HACRP452	-
		3	HAH453	HACNP453	HACRP453	-
		4	HAH454	HACNP454	HACRP454	-
		5	HAH455	HACNP455	HACRP455	-
		6	HAH456	HACNP456	HACRP456	-
Healing Cap, wide	5.5	2	HAH552	-	HACRP552	-
		3	HAH553	-	HACRP553	-
		4	HAH554	-	HACRP554	-
		5	HAH555	-	HACRP555	-
		6	HAH556	-	HACRP556	-
	6.0	2	HAH602	-	HACRP602	-
		3	HAH603	-	HACRP603	-
		4	HAH604	-	HACRP604	-
		5	HAH605	-	HACRP605	-
		6	HAH606	-	HACRP606	-
Zirconia Healing Cap*	3.5	2	-	-	-	ZHCSP352
		3	-	-	-	ZHCSP353
		4	-	-	-	ZHCSP354
		5	-	-	-	ZHCSP355
		6	-	-	-	ZHCSP356
	3.8	2	ZHCH382	ZHCNP383	ZHCRP383	-
		3	ZHCH383	ZHCNP384	ZHCRP384	-
		4	ZHCH384	ZHCNP385	ZHCRP385	-
		6	ZHCH386	ZHCNP386	ZHCRP386	-
	4.3	3	ZHCH433	ZHCNP433	ZHCRP433	-
		4	ZHCH434	ZHCNP434	ZHCRP434	-
	5.5	3	ZHCH553	-	ZHCRP553	-
		4	ZHCH554	-	ZHCRP554	-

*Call for more information.

ESi / Premium Surgical Drills

Drill speed: 850-950 RPM | **Torque:** 35-40 Ncm

1. Laser identification
2. Color coding
3. Depth laser marking



Drill No.	1	2	3	4	5	6	7	8
ESi/Premium	1.2/2.0	2.0/2.8	2.8/3.1	3.1/3.4	3.4/3.9	3.9/4.4	4.4/4.8	4.8/5.8
Catalog No.	ESiPR1	ESiPR2	ESiPR3	ESiPR4	ESiPR5	ESiPR6	ESiPR7	ESiPR8

Drill Sequences ESi/Premium Drills Kit

Diameter ø	IV, III Soft Bone	II Medium Bone	I Hard Bone
3.0	1	1	1 - 2
3.5	1 - 3	1 - 3, 4*	1- 4
4.3	1 - 4	1 - 4, 5*	1 - 5 (CS)
5.0	1 - 5, 6*	1 - 6	1 - 6, 7* (CS)
6.0	1 - 7	1 - 7, 8*	1 - 8 (CS)

***IMPORTANT**: All asterisks indicate 1/2 - 2/3 drill length insertion

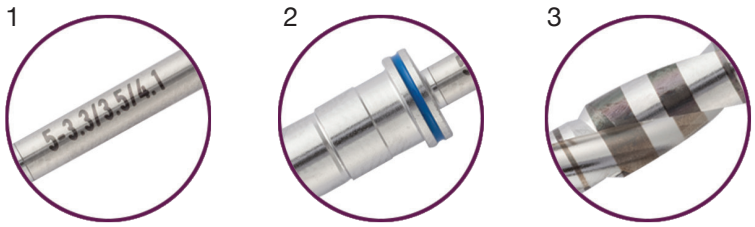
CS Countersink Option

Tool	Countersink	Countersink	1/2 Round	1.5 Spade
Corresponding Implant Ø	3.5-4.3	5.0-6.0	-	-
Catalog No.	CURS354	CURS456	05RD	SPADE15

Ultimate Surgical Drills

Drill speed: 850-950 RPM | **Torque:** 35-40 Ncm

1. Laser identification
2. Color coding
3. Depth laser marking



Drill No.	1	2	3	4	5	6	7	8
Ultimate	1.2/1.8/2.4	1.8/2.4/2.8	2.4/2.8/3.1	2.8/3.1/3.3	3.3/3.5/4.1	3.5/4.1/4.7	4.1/4.7/5.2	4.7/5.2/5.8
Catalog No.	DUAL1	DUAL2	DUAL3	DUAL4	DUAL5	DUAL6	DUAL7	DUAL8

Drill Sequences

Diameter ø	IV, III Soft Bone	II Medium Bone	I Hard Bone
3.0	1	1	1-2
3.5	1-2	1-3	1-4
4.3	1-4	1-5	1-5 (CS)
5.0	1-5	1-6	1-6 (CS)
6.0	1-6	1-7	1-8 (CS)

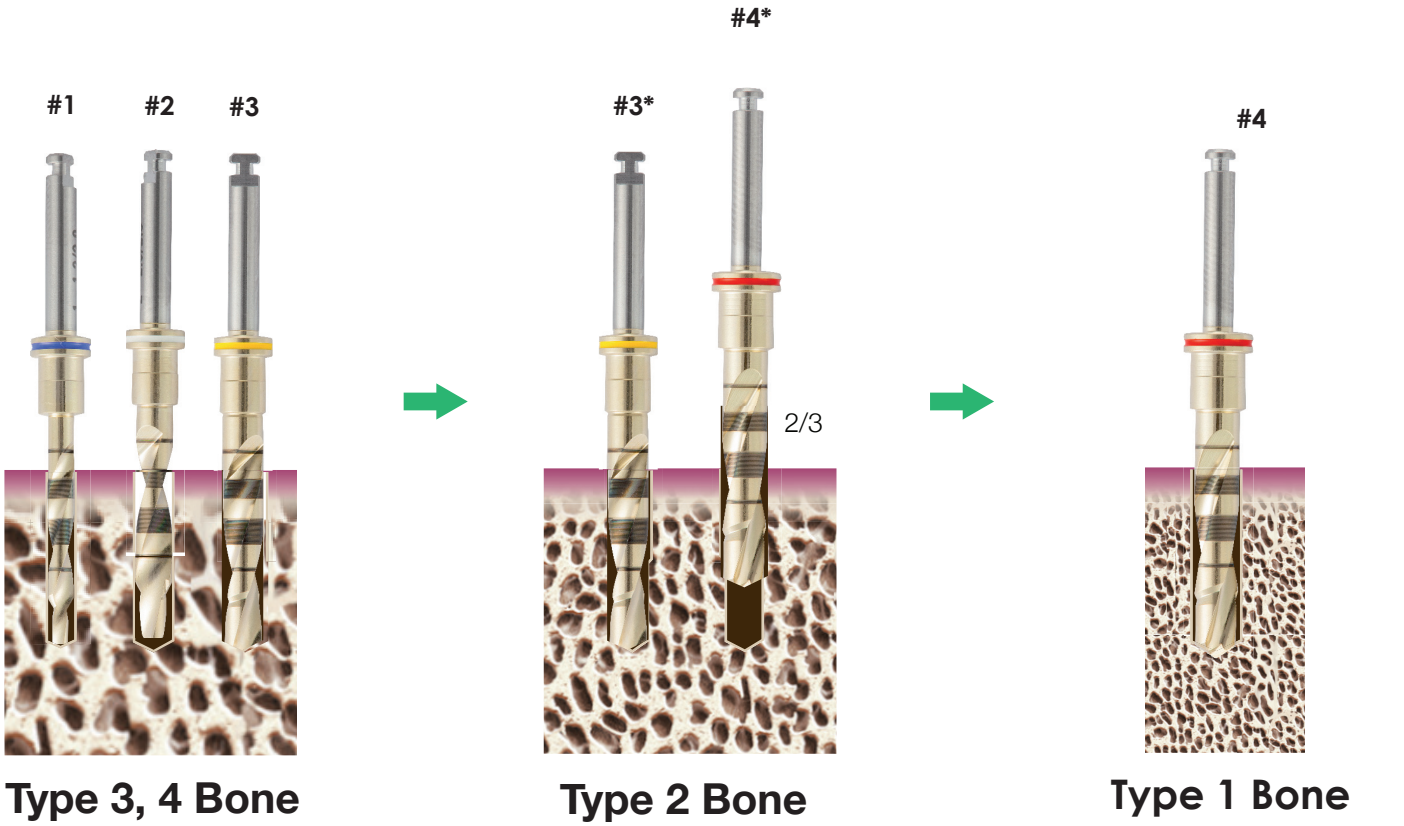
Ultimate Drills Kit
CATALOG NO.
SKU

Tool	Countersink	Countersink	1/2 Round	1.5 Spade
Corresponding Implant Ø	3.5-4.3	5.0-6.0	-	-
Catalog No.	CURS354	CURS456	05RD	SPADE15

ESi / Premium Drill Sequence

Drill speed: 850-950 RPM
Torque: 35-40 Ncm
Important: Do not go above 45 NCM, if you did, please reverse to an 1/8 - 1/4 of a turn.

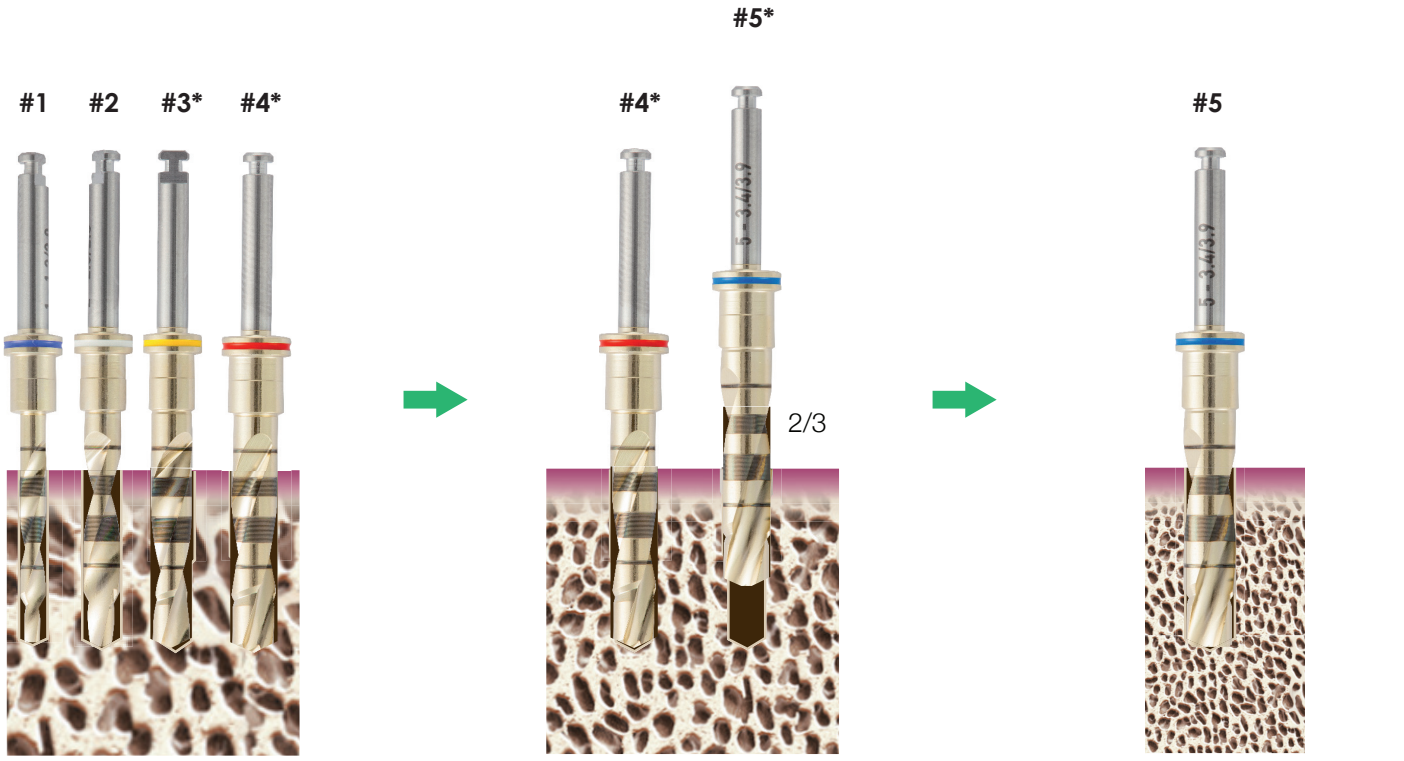
ø 3.5 Hex or NP High Stability Drill Sequence



Type 3, 4 Bone | **Type 2 Bone** | **Type 1 Bone**

*1/3 Implant Length Drilling

ø 4.3 Hex or RP



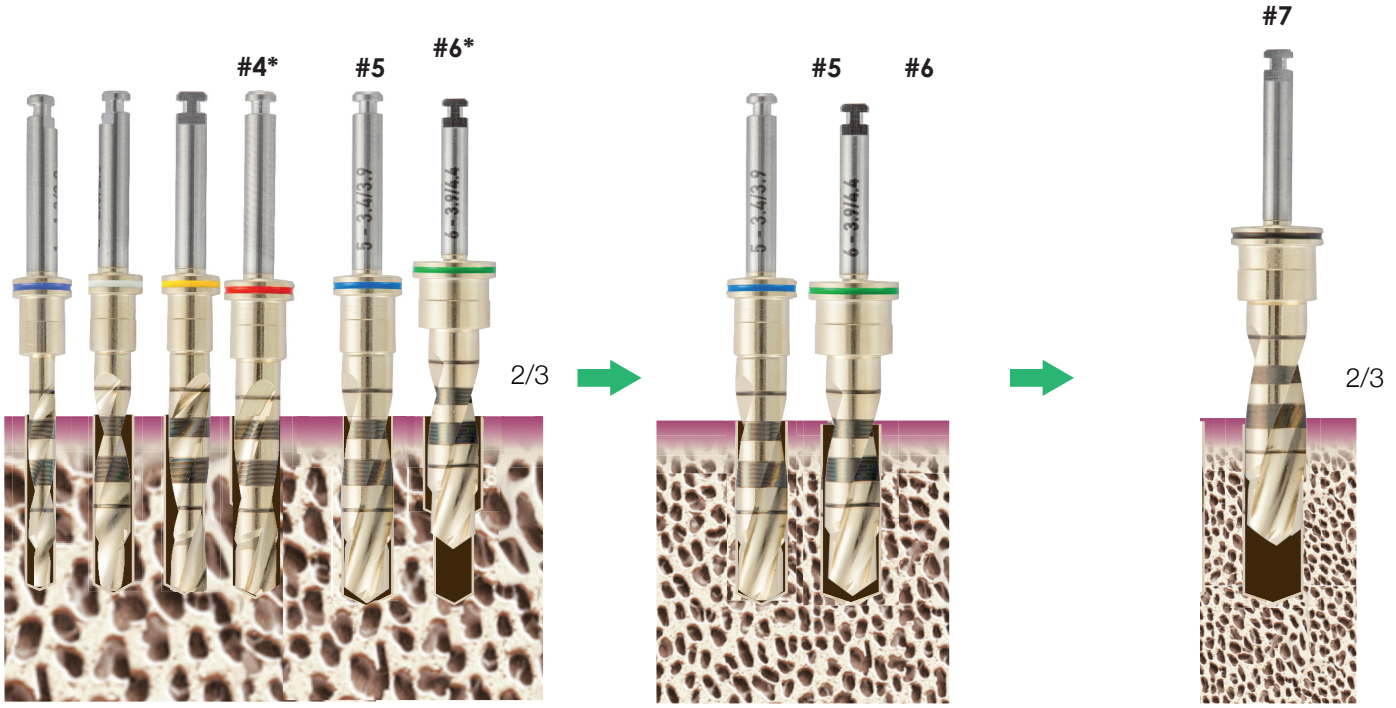
Type 3, 4 Bone | **Type 2 Bone** | **Type 1 Bone**

*1/3 Implant Length Drilling

ESi / Premium Drill Sequence

Drill speed: 850-950 RPM
Torque: 35-40 Ncm

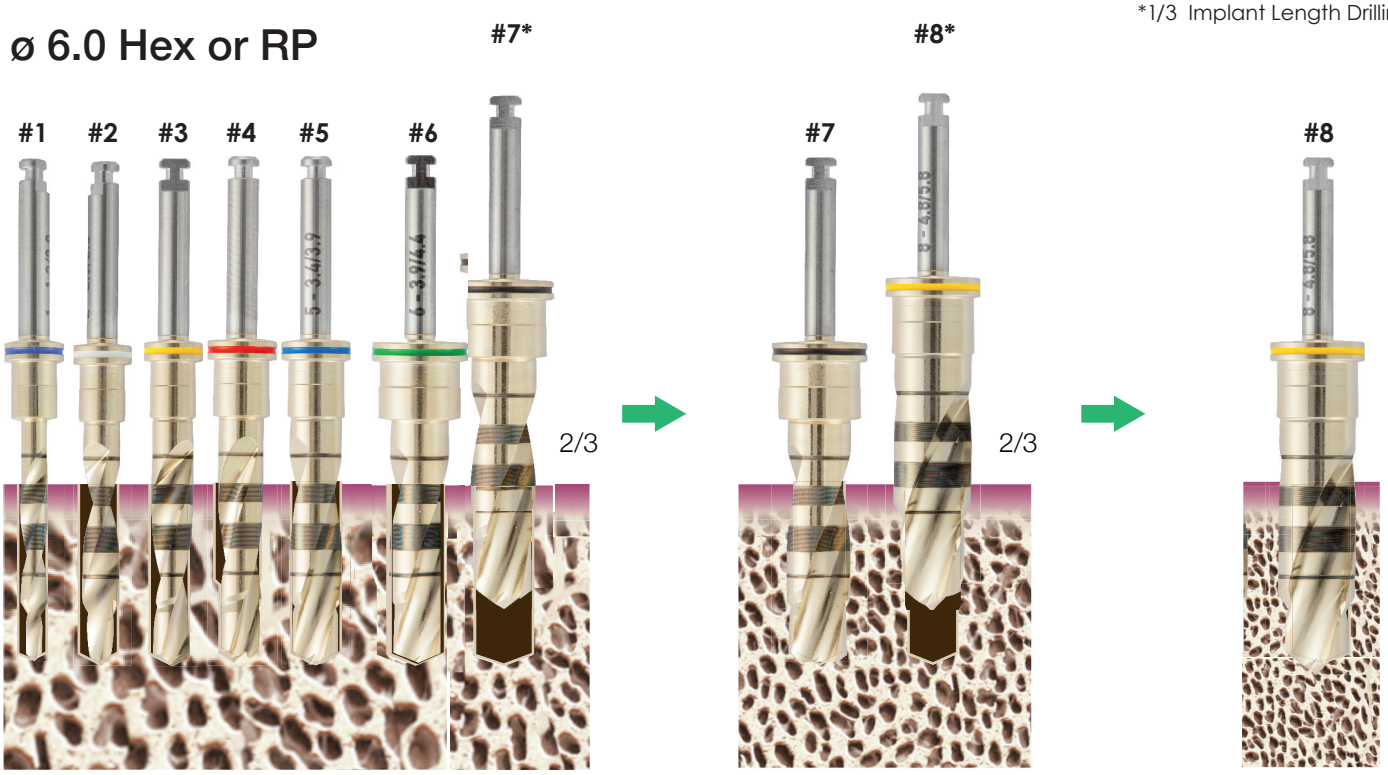
ø 5.0 Hex or RP



Type 3 & 4 Bone | **Type 2 Bone** | **Type 1 Bone**

*1/3 Implant Length Drilling

ø 6.0 Hex or RP



Type 3 & 4 Bone | **Type 2 Bone** | **Type 1 Bone**

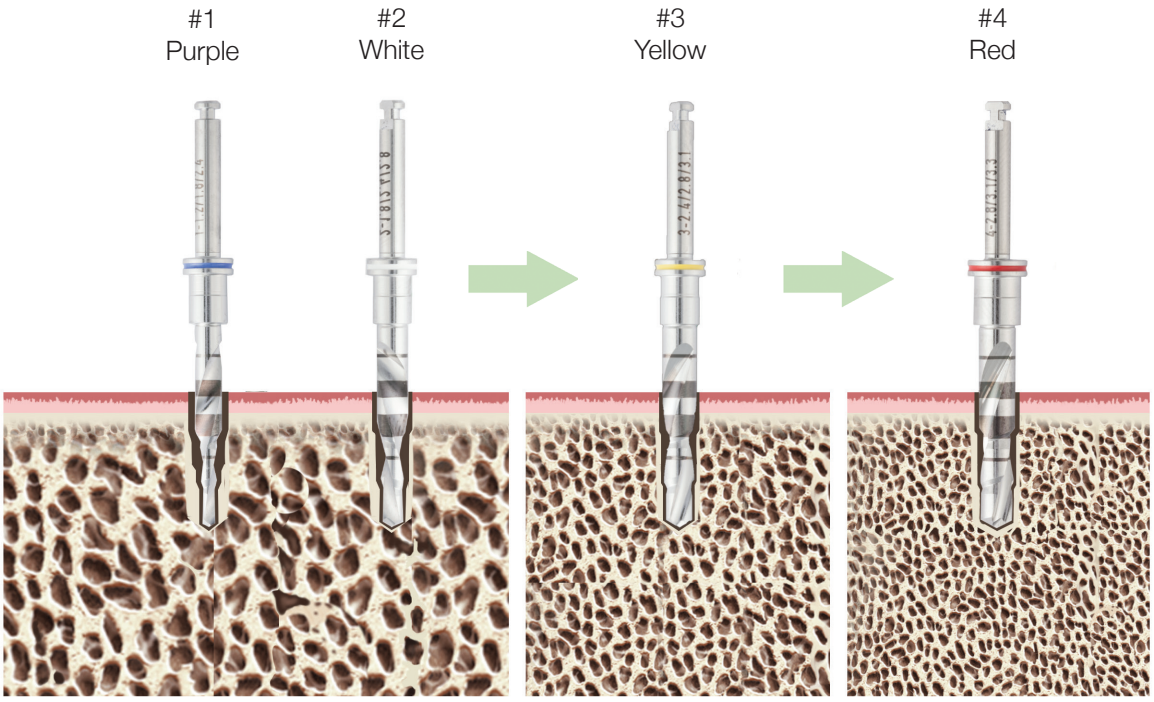
*1/3 Implant Length Drilling

NOTE: Make sure you are at least 1.5mm away from Inferior Alveolar Nerve or Sinus Floor

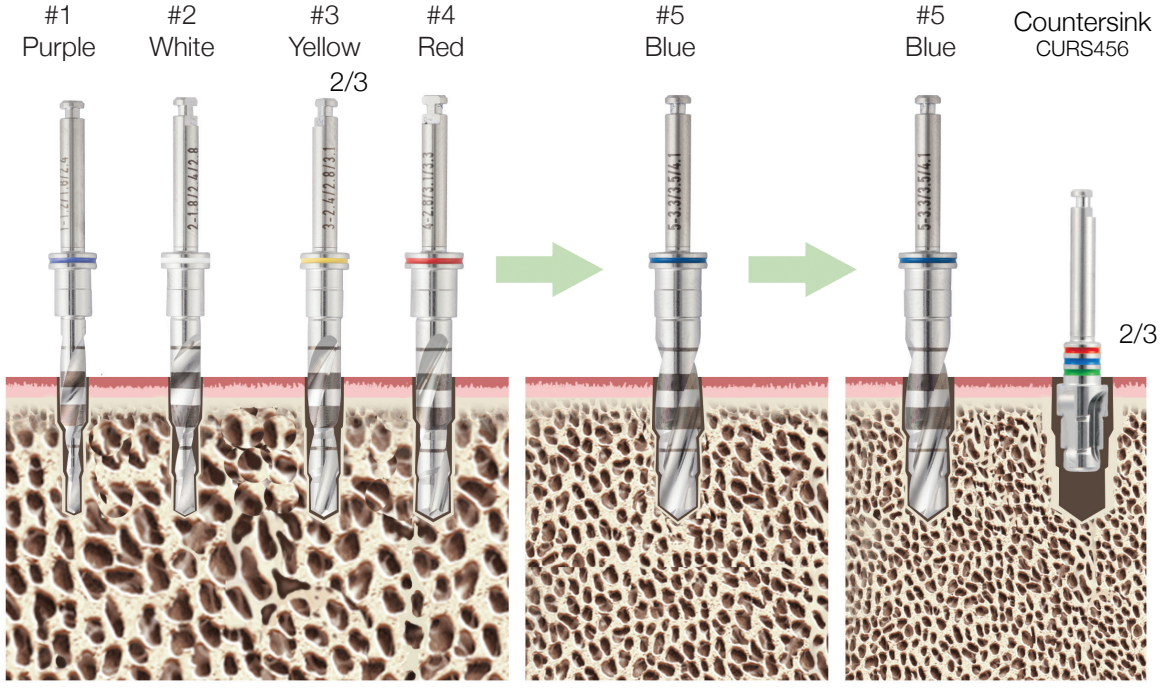
Ultimate Drill Sequence

Drill speed: 850-950 RPM
Torque: 35-40 Ncm

ø 3.5 Hex or NP



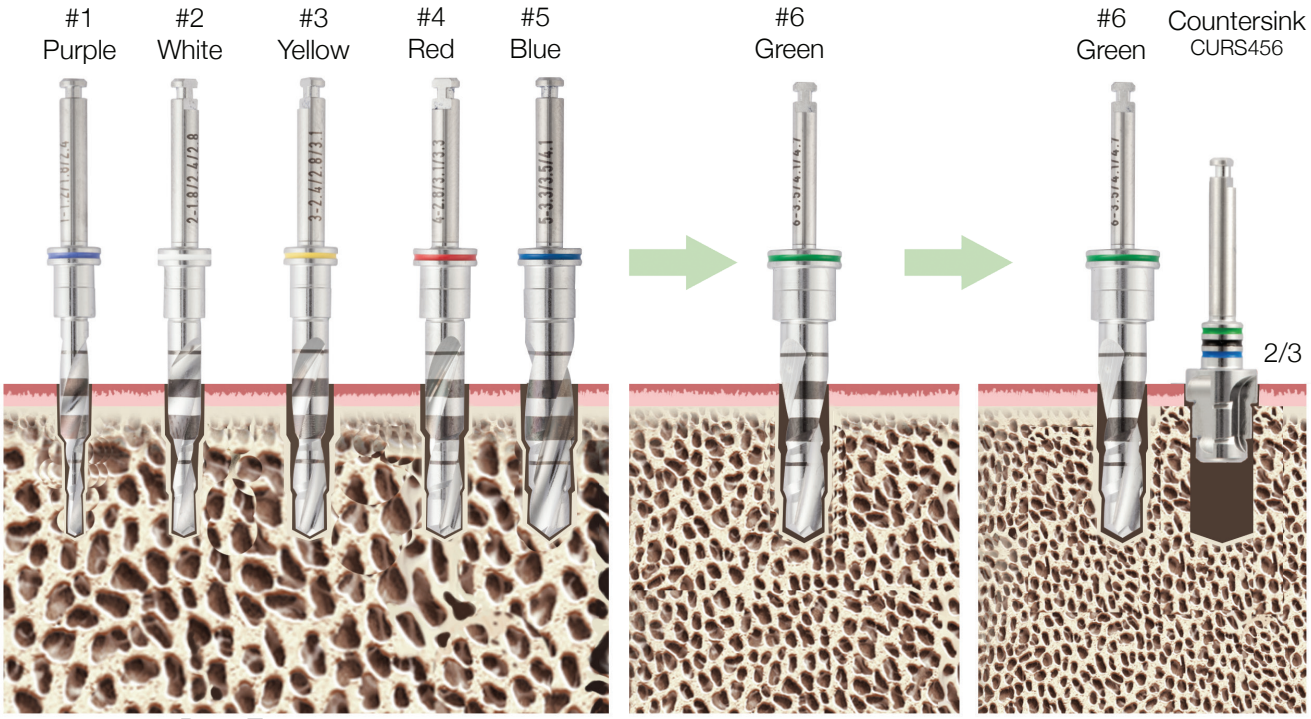
ø 4.3 Hex or RP



Ultimate Drill Sequence

Drill speed: 850-950 RPM
Torque: 35-40 Ncm

ø 5.0 Hex or RP

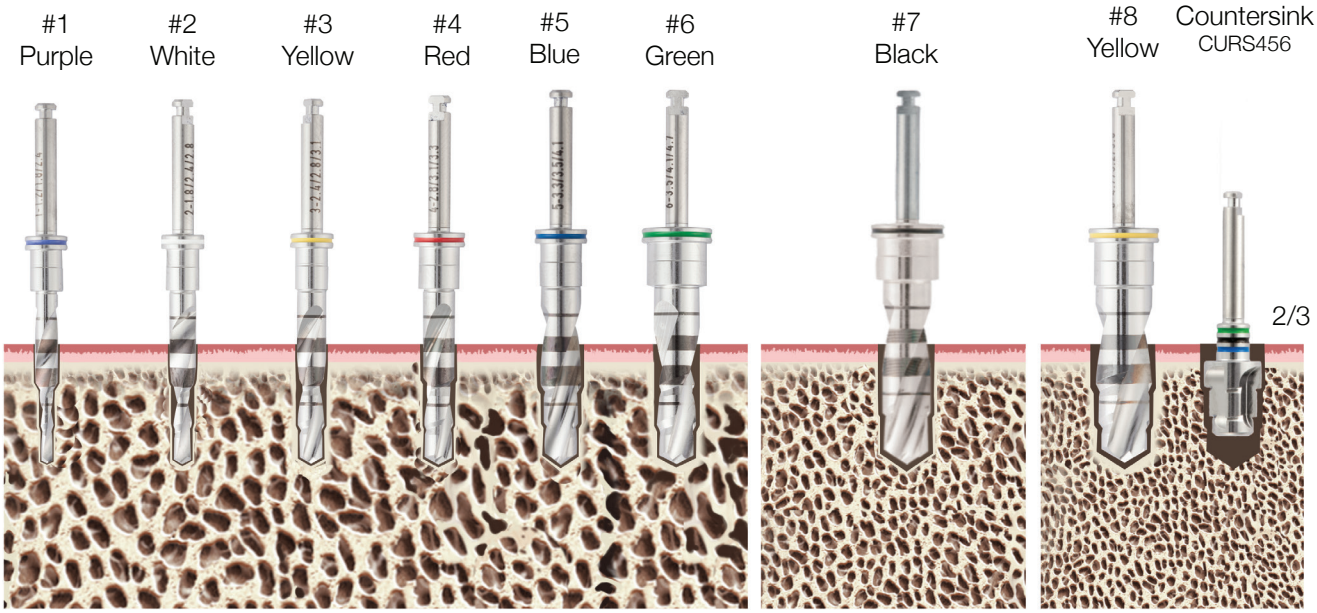


Bone Type
IV, III
Soft Bone

Bone Type
II
Medium Bone

Bone Type
I
Hard Bone

ø 6.0 Hex or RP



Bone Type
IV, III
Soft Bone

Bone Type
II
Medium Bone

Bone Type
I
Hard Bone

NOTE: Make sure you are at least 1.5mm away from Inferior Alveolar Nerve or Sinus Floor

Drill Stoppers

Drill Stoppers Kit
CATALOG NO.
DSK

Length	L8	L10	11.5	L13
Drills	1, 2, 3	1, 2, 3	1, 2, 3	1, 2, 3
Implant Ø	3.5mm	3.5mm	3.5mm	3.5mm
Drills	4, 5	4, 5	4, 5	4, 5
Implant Ø	4.3mm	4.3mm	4.3mm	4.3mm
Drills	6, 7, 8	6, 7, 8	6, 7, 8	6, 7, 8
Implant Ø	5.0mm, 6.0mm	5.0mm, 6.0mm	5.0mm, 6.0mm	5.0mm, 6.0mm

Implant Length	8	10	11.5	13
Drill #	1,2,3	1,2,3	1,2,3	1,2,3
Stop ø mm	4.5	4.5	4.5	4.5
Implant ø mm	3.5	3.5	3.5	3.5
Stopper length mm	14.3	12.3	10.8	9.3
Laser mark	Red Red	Red Blue	Red Green	Red Yellow
Catalog No.	RRS800	RBS100	RGS115	RYS130

Implant Length	8	10	11.5	13
Drill #	4,5	4,5	4,5	4,5
Stop ø mm	5.3	5.3	5.3	5.3
Implant ø mm	4.3	4.3	4.3	4.3
Stopper length mm	14.3	12.3	10.8	9.3
Laser mark	Blue Red	Blue Blue	Blue Green	Blue Yellow
Catalog No.	BRS800	BBS100	BGS115	BYS130

Implant Length	8	10	11.5	13
Drill #	6,7,8	6,7,8	6,7,8	6,7,8
Stop ø mm	7.2	7.2	7.2	7.2
Implant ø mm	5.0,6.0	5.0,6.0	5.0,6.0	5.0,6.0
Stopper length mm	14.3	12.3	10.8	9.3
Laser mark	Green Red	Green Blue	Green Green	Green Yellow
Catalog No.	GRS800	GBS100	GGS115	GYS113

Surgical Tools

MOTOR MOUNTS

Product	Implant Motor Mount Hex .050/1.25	Implant Motor Mount Hex	Implant Motor Mount Conical NP	Implant Motor Mount Conical RP	Drill Extender	Tissue Punch	Depth Pin
Size	1.25mm	2.42mm	2.25mm	2.65mm	-	Ø 3.0x4.0mm	-
Length	22/28mm	22/28mm	22/28mm	22/28mm	26mm	Ø 4.0x5.0mm	-
Catalog .No	**MMH122 MMH128**	**MMH222 MMH228**	**MMCNP222 MMCNP228**	**MMCRP222 MMCRP228**	**DE26**	**TPU30/40 TPU40/50**	**DDM115**

RATCHET MOUNTS

Product	Ratchet Abutment Screw Driver Hex	Ratchet Implant Driver Hex	Ratchet Implant Driver Conical NP	Ratchet Implant Driver Conical RP
Size	1.25mm	2.42mm	2.25mm	2.65mm
Length	7mm/15mm	13mm	13mm	13mm
Catalog .No	**HXD107 HXD115**	**HXD213**	**CDNP213**	**CDRP213**

OTHER TOOLS

Ratchet

WR

Torque Ratchet

TWR

Hand Wrench Hex

0.25mm

TWRCHT

Screw Driver

1.25mm 10/15mm

HND10 HND15

Instructions for Surgical Procedure .....

The following are instructions for usage of straight or angled abutment.

PLEASE READ THIS MANUAL THOROUGHLY BEFORE STARTING

2.1 Opening the Implant Package

STEP 1 Open the blister package (Fig 1.0) and remove the outer plastic tube. The blister ensures the sterility of your SpiralTech implant. DO NOT open the blister until immediately prior to implant placement.

STEP 2 Snap off the outer tube colored cap (Fig 2.0).

STEP 3 Obtain the inner titanium barrel or the plastic tube. All SpiralTech implants are packed in double packaging for protection and sterility (Fig 3.0).

Fig 1.0

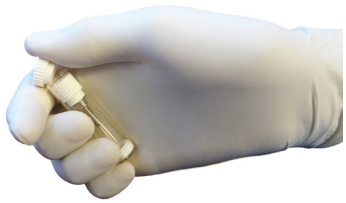


Fig 2.0

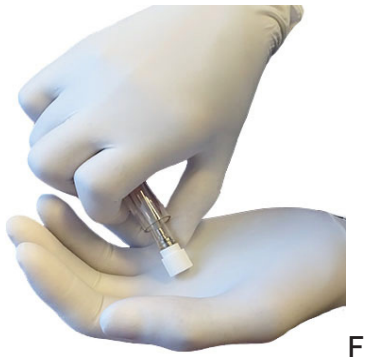


Fig 3.0

IMPORTANT

To maintain sterile conditions, SpiralTech implants SHOULD NOT BE taken out of the inner vial until ready to be placed into a prepared implant bed site.

2.2. Method of Placement

After the gingiva has been opened and the implant bone bed site has been prepared with successive drilling steps (refer to pages 10-13), proceed:

Instruction For Use: Plastic Tube With Carrier Option

a. Remove implant with carrier from the inner plastic tube and snap away white cover. (Fig 8.0)

b. Place implant with carrier into prepped osteotomy and manually rotate clockwise until stability is developed.

Two Options For Final Implant Positioning -

Ratchet Option

1a. Place ratchet (set at 35 NF) with ratchet mount in implant and rotate clockwise (Fig 5.0)

IMPORTANT

While rotating ratchet clockwise, apply vertical pressure with your other hand to activate the knife-edged apical threads of the implant to allow smooth penetration

1b. Remove carrier by pulling up and out.

1b. Remove carrier by pulling up and out (Fig 5.0)

1a. Place ratchet (set at 45 NF) with ratchet mount in implant and rotate clockwise (Fig 5.0)

IMPORTANT

While rotating ratchet clockwise, apply vertical pressure with your other hand to activate the knife-edged apical threads of the implant to allow smooth penetration

1b. Remove carrier by pulling up and out (Fig 6.0)

Handpiece Driver Option -

2. Use of handpiece (Fig 7.0). Set the motor to 50RPM and 45NF and activate motor until the implant reaches 0.5mm subcrestal level.

IMPORTANT

While rotating ratchet clockwise, apply vertical pressure with your other hand to activate the knife-edged apical threads of the implant to allow smooth penetration

PLEASE NOTE:

That above 80Ncm the implant carrier will deform to protect from bone fracture. Your SpiralTech implant carrier tip has been specifically designed to release the implant with minimal "pull off" pressure.

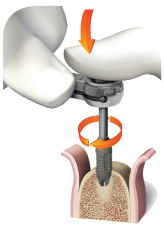


Fig 5.0

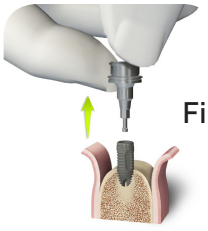


Fig 6.0

Fig 7.0

Instructions For Use: Titanium Tube Packaging

a. Gently remove the white plastic cap from the titanium barrel (Fig 8.0).

CAUTION: The cover screw is stored in either the white cap or the base of the titanium barrel

b. Set motor to 50RPM and 35NF

c. Place the implant motor mount into the handpiece and use it to remove the implant from the barrel. Confirm that the motor mount is engaged into the implant (Fig 9.0).

d. Place implant in osteotomy area at 35NF and rotate implant into its position (Fig 7.0). position implant into osteotomy prepped area, IMPORTANT make sure to apply vertical pressure to activate the knife-edged thread of the implant for smooth penetration.

e. You can rotate the last few turns by using the ratchet and the ratchet mount at 35NF. It is recommended to rotate the implant until it is 0.5mm below crestal height (Fig 5.0).

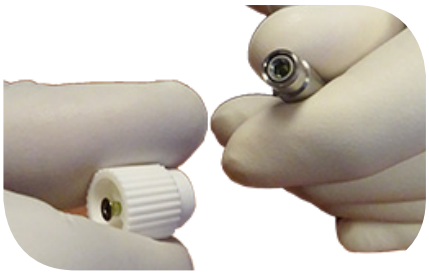


Fig 8.0

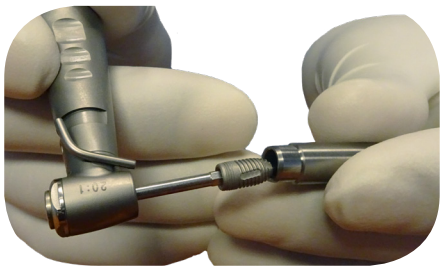


Fig 9.0

IMPORTANT

3.5mm implants should be placed 0.5mm below crestal level of the bone. All implants should leave a minimum of 1.5mm for both buccal and lingual bone thickness. Allow 1.5mm distance between root and implant, and 3.0mm distance between two implants.

2.3. Soft Tissue Management Enclosure

After implantation, the implant is closed, hand-tightened—with an SpiralTech cover screw, healing cap or healing abutment to protect the implant. The surgeon can choose between:

OPTION 1 Submucosal Healing **OPTION 2** Transmucosal Healing

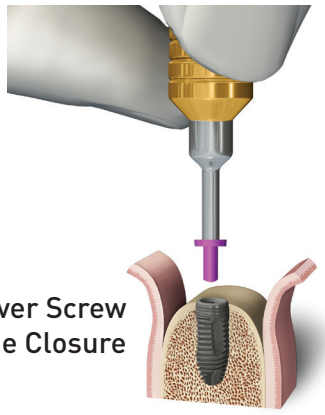
The surgeon has all options available for soft tissue management made possible through a set of secondary healing components.

OPTION 1 Submucosal Healing (Primary Closure)

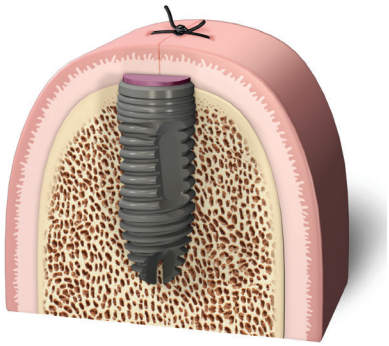
a. Irrigate the area, confirm gingival crest are parallel to each other, permitting primary closure.
b. Place cover screws and sutures. Note that Submucosal Healing is suggested in esthetic indications and for implantations with simultaneous guided bone restoration (GBR) or membrane technique.
c. A second surgical procedure is required for uncovering the implant and insertion of the desired secondary component.

PLEASE NOTE:

Bone level cover screws are delivered sterile and ready to use. All other SpiralTech cover screws are delivered non-sterile and MUST BE STERILIZED prior to use.



Cover Screw with Tissue Closure



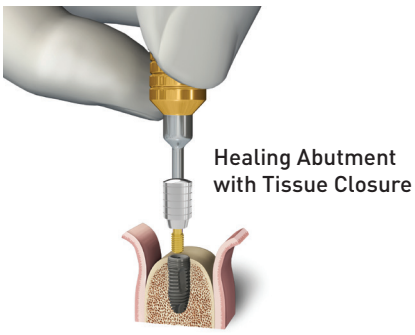
PLEASE NOTE:

When the floor of the bone cavity is reached, there is a palpable increase in resistance. Avoid vertical position corrections using reverse (counter-clockwise) rotations. This can cause loosening of the transfer part and may lead to a decrease in primary stability.

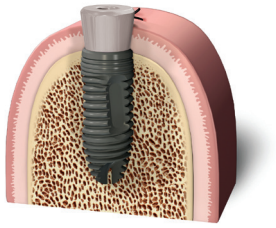
OPTION 2 Transmucosal Healing

a. The non-epithelialized side of the flap should be approximated to the implant neck. Irrigate over and place healing abutment. Prepare gingiva crest to be semi-circular on each side in order of closure around healing abutment.
b. If necessary, this step must be combined with a gingivectomy. The wound margins are closed with atraumatic suture material, and the sutures must not be tied too tightly.
c. One relieving suture is placed on either side of the closure healing cap so that the wound margins are approximated without tension.

- Use of non-absorbable suture material is recommended. (e.g. Polyamide or Teflon)
- The sutures are removed after 7 to 10 days. A postoperative X-ray is recommended.



Healing Abutment with Tissue Closure

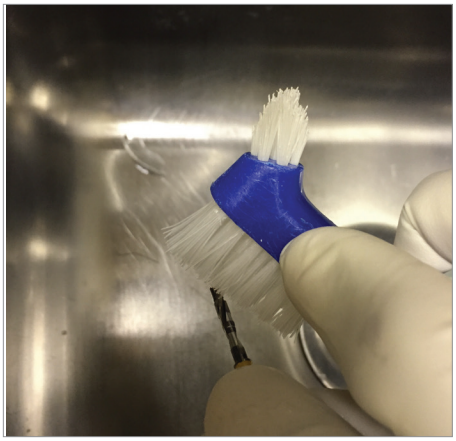


CAUTION:

Insertion torque should not exceed 30Ncm. To prevent bone compression, perform a correct implant bed preparation. (As shown in pages 10 to 13) When reaching final drilling sequence and placement of implant in bone, use torque force; if you pass this range please evaluation depth and diameter of bone preparation and correct accordingly. SpiralTech implant carrier is designed to avoid higher torque than 65Ncm, should you cross that threshold it will not continue to turn the implant into the bone and carrier will collapse and the hex will strip and turn freely.

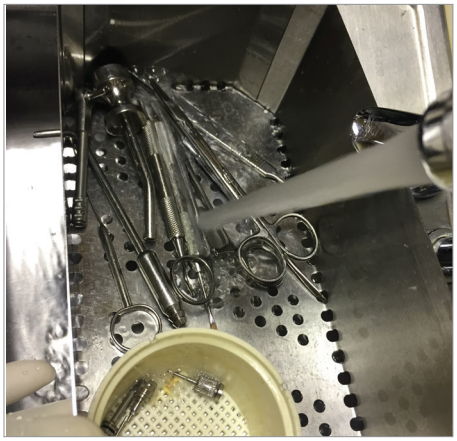
Sterilization Parameters

1. **PEEK and Titanium Abutments**
   a. Sterilize the instruments by applying a gravity displacement process (according to [ISO 13060/ISO 17665]) under consideration of the respective country requirements.
   b. Autoclave (gravity displacement), at a temperature of 132° C (270° F).
   c. Full cycle time: 15 min.
   d. Drying time: minimum 15 min.
2. **Zirconia Abutments**
   a. Steam sterilization: 135° C (275° F).
   b. Full cycle time: 10 min.
   c. Drying time: minimum 30 min.
3. **Drills**
   a. Steam sterilization (gravity): 134° C (273° F)
   b. Full cycle time: 4 min.
   c. Drying time: minimum 10 min.



Check for debris blood clots or other particles on surgical instruments and drill bits. Then scrub instruments with a brush.

Place all surgical instruments and drill bits in ultra sonic.



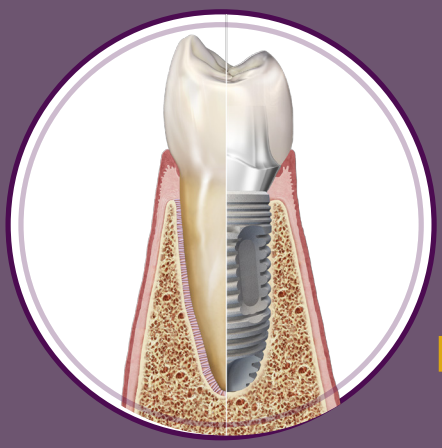
Rinse all instruments with water and place in surgical container.

Place container in surgical container and place box in sterilzation bag.

Place surgical box and follow the table recommendation.

HEX CONNECTION

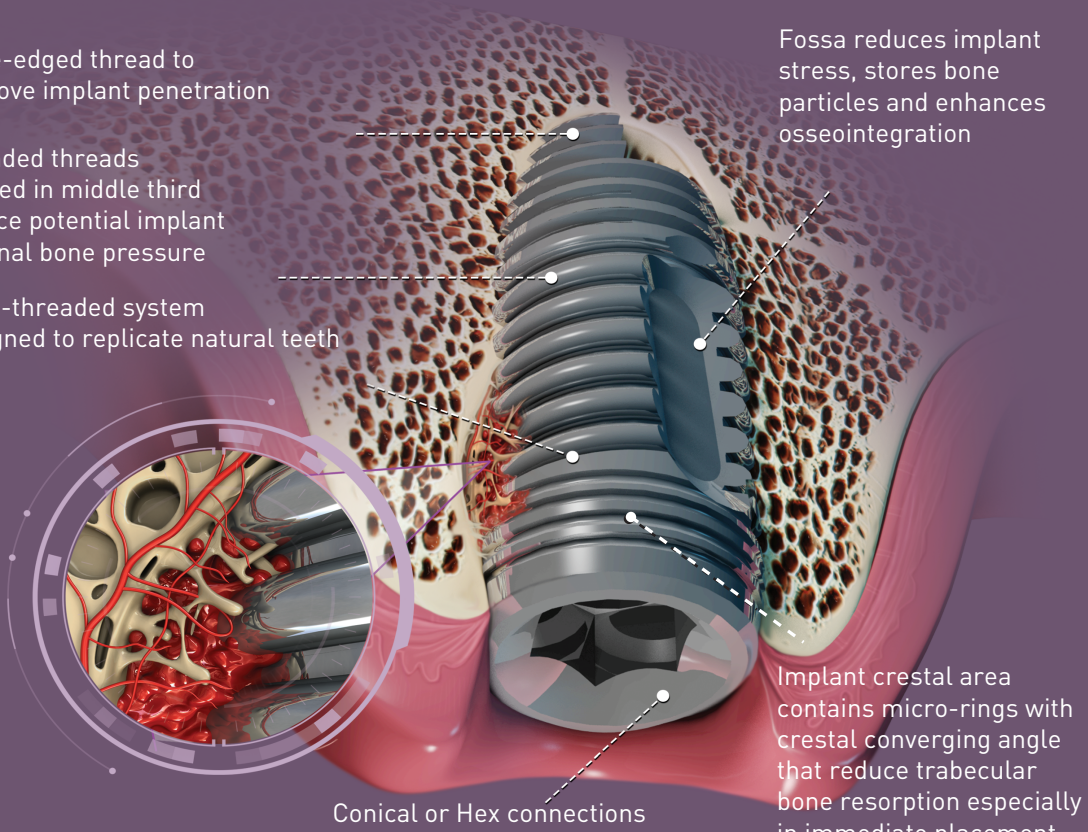
CONICAL CONNECTION



ESi Implant maintains root formation

ONE OF OUR SUPERIOR PRODUCTS, ESi IMPLANT

U.S. Patent No. 9,387,027 B2




SpiralTech
875 N MICHIGAN AVE. | SUITE 3100
CHICAGO, IL, 60611
312.440.7777
INFO@SPIRALTECH.COM