



## i-Fix Implant

"i-Fix implants: Made in India for the World"

Dr. Mohammad Shahnawaz

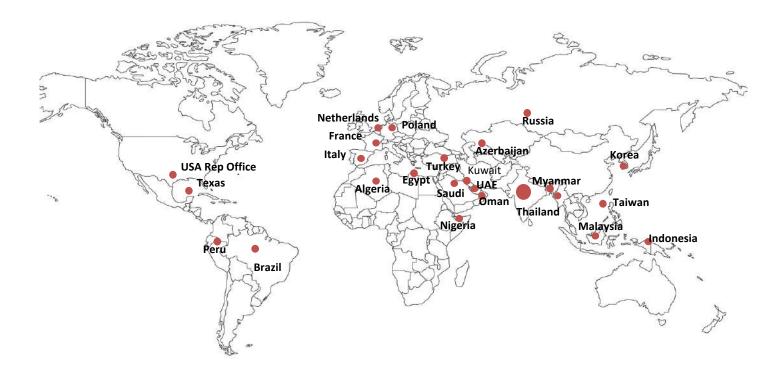


# Kamal Medtech Who we are?

## **Global Footprint**







## Unit 1 - Manufacturing Facilities at Yamuna Nagar -200Km north of Delhi





## Unit 2 - Casting & Machining Facilities at Yamuna Nagar





## Unit 3 - New Facility at IMT Faridabad, NCR Delhi





### Kamal Medical Devices Brands











### The Beginning.....

#### **Research Partners**



Indian Institute of Technology, Delhi

iFix Dental Implant has been Conceptualized, Designed & Developed by Indian Institute of Technology (IIT), Delhi in collaboration with Maulana Azad Institute of Dental Sciences (MAIDS), Delhi



Maulana Azad Institute of Dental Sciences New Delhi

iFix Dental Implant has been Clinically studied at Maulana Azad Institute of Dental Sciences, New Delhi





Council of Scientific and Industrial Research

Under the Patronage of Council of Scientific & Industrial Research (CSIR) - NMITLI Program



Manufacturers of high quality medical devices of global standards

#### Certifications: MDR 2017 & ISO 13485





#### FORM MD-9

[See sub-rule (1) rule 25]

Licence to Manufacture for Sale or for Distribution of Class C or Class D medical device

Licence Number: MFG/MD/2019/000057

 Mis KAMAL ENCON INDUSTRIES LIMITED, 56 INDUSTRIAL ESTATEYAMUNA NAGAR, — Haryana (india)-135001 Telephone No.: 1123351365 FAX: 1123721657 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at Mis KAMAL ENCON INDUSTRIES LIMITED, Plot No. 917, IMT Partidabad, Sector-69, Partidabad, Haryana (India) - 121001 Telephone No.: 11-23723158, 11-23351369 FAX: 11-23721657

- 2. Details of medical device(s) [Annexed]
- The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s); As per records maintain by the manufacturer
- 4. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

#### ANNEXURE

S.No.	Details Of Device(s)	
1	Generio Name-Dental Implants with Abutments & Prosthesis Model No.:NIL Intended Use-Dental Implants are intended for surgical placement in the upper or lower jaw to provide a means for prostheds attachment in single toofn restorations and in partially or fully edentifuous spans with muttiple single feeth utilizing delayed loading, or as a terminal or intermediary abutment for fixed or removate bridgework, and to retain overdentures. Class of medical device:Class C Material of construction:Tilanum Alloy, Th-6Al-4V Dimension(T any):Diameter (mm): 3.00, 3.50, 4.00, 4.50, 5.00 & 5.50 AND Length (mm): 7.50, 8.50 10.00, 11.50, 13.00 & 15.00 Sheriffle-50 months Sterile or Non sterile:Sherilized Brand Namel' Resistered under the Trade Marks Act, 1999:LFIX. MultiFix. SFix. CFIX	

Place: Date29-May-19 S ESWARA
REDDY Manual Central Licensing Authority

en th | evaluate | assess | certify | assessors of quality Certificate No. MD-QMS/91/R/2609 This is to certify that Kamal Encon Industries Ltd. Plot No. 917, Sector 68, IMT Faridabad - 121 001, Haryana, India has been found to conform to the requirements of Medical Devices - Quality Management System Standard ISO 13485:2016 This certificate is valid for the following scope: Design, Development, Manufacture and Sales of: (1) Interventional Cardiology Products: - Sirolhmus Euting Coronary Stent System - Everolimus Eluting Coronary Stent System (2) Dentat Implants and Prost heals Manufacture and Sales of Surgical Kits Initial Certification : 27/07/2019 Valid until : 26/07/2022 The authorizity of this document may be well than by writing to <u>perflorate marks to explorate come</u>, the sort of the control of control and the Control of leaving Au & orby: Zenith Quality Assessors Pvt. Ltd. 201, 48 Flor; Salaper, Vitarreger, Princ - 41 ft H. Interestre, Inde

### **CE CERTIFICATION**





#### EC Certificate No. 1434-MDD-344/2021

Full Quality Assurance System
Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies that the quality assurance system in the organization:

#### Kamal Encon Industries Limited Plot No. 917, Sector-68,IMT, Faridabad 121001, Haryana, INDIA

for the design, manufacture and final inspection of medical devices, class (Ib

#### Dental Implants & Prosthesis

The list of medical devices covered by this certificate is provided in the Annexes 1-13

complies with requirements of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 25.05.2021 to 27.05.2024

The date of issue of the Certificate: 25.05.2021

The date of the first issue of the Certificate: 25.05.2021

C E 1434

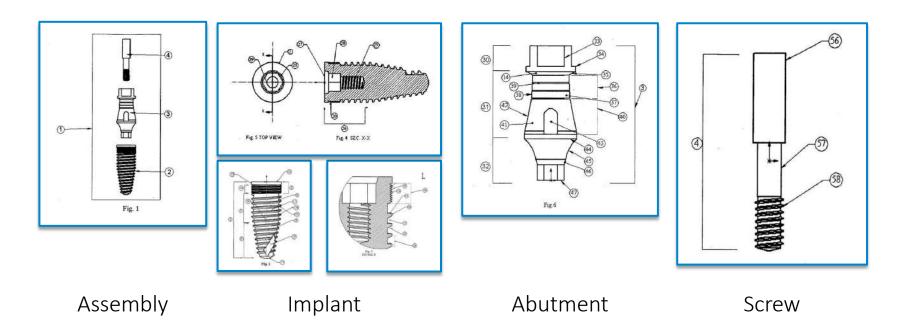
Issued under the Contract No. MD-80/200 Application No: 138/2020 Certificate bears the qualified signature. Warsaw, 25/05/2021 Module #2/3/4/5

Vice-President

## IIT Delhi Conceptual Design - led to Indian and US Patent



#### US Patent No. 9,833,300



## **GRADE 5 ELI**





Pro	Advantages		
Tensile strength	860 MPa minimum	Extremely high strength/ weight ratio	
Elongation	10%	Improved ductility and fracture toughness under static and dynamic loads	
Oxygen content	0.13% maximum		
Biocompanibility	Excellent	Direct structural and functional connection between bone and implant surface	

## Ti Grade 5 ELI

**Properties** 

Tensile strength

Elongation

Oxygen content

Biocomparibility

860 MPa minimum.

0.13% maximum

Excellent

10%

weight ratio

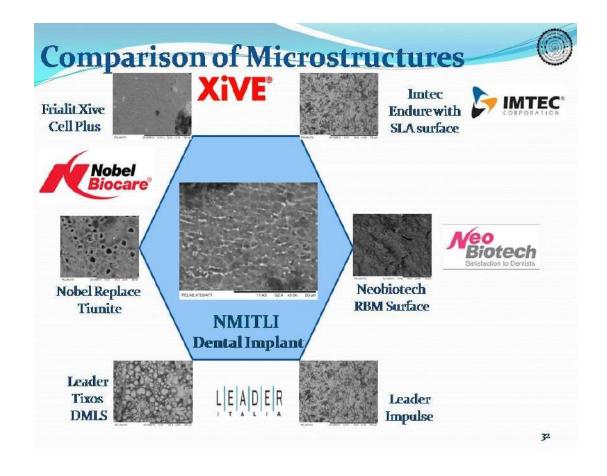




- Its properties of biocompatibility, corrosion resistance, high strength, and toughness make it especially suitable for implants and other medical devices.
- ELI is also referred to as Grade 23 Titanium and ASTM F136.
- Extremely high strengthy improved ductility and Direct structural and functional connection between bone and implant
- Ti6Al4V ELI contains reduced levels of oxygen, nitrogen, carbon and iron. ELI is short for "Extra Low Interstitials", and these lower interstitials provide improved ductility and better fracture toughness for the Ti6Al4V ELI material.

### A comparative study with commercially available Implants







#### SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH

(A unit of Shriram Scientific and Industrial Research Foundation)

An ISO - 9001:2008 Certified Institute

#### **TEST CERTIFICATE**

000358830

Issued to :

INDIAN INSTITUTE OF TECHNOLOGY, DELHI DEPT, OF MECHANICAL ENGINEERING HAUZ KHAS NEW DELHI - 110016 J.O.No. Reg.No. Date 502-111-1839 1370083 21-02-2015 GC-01 (REV-04)

Your Ref.No.

Kind Attn: DR NARESH BHATNAGAR, PROFESSOR & ASSO.

DEAN [R&D]

Sample Particulars :

Date

One sample of Dental Implant labelled as Lot No. 1 DT 17.01.2015 was received.

"The sampling was not carried out by Shriram Institute for Industrial Research. The sample details provided in test certificate are based on declaration by the party."

#### TEST RESULTS

S.No

TEST

RESULT

PROTOCOL

Sterility test

Sample complies with the test for sterility As per guidelines of USP-37

NOTE: Party asked for above test only.

\*\*\*\*\*\*

DOR: 06-02-15 DOC: 20-02-15

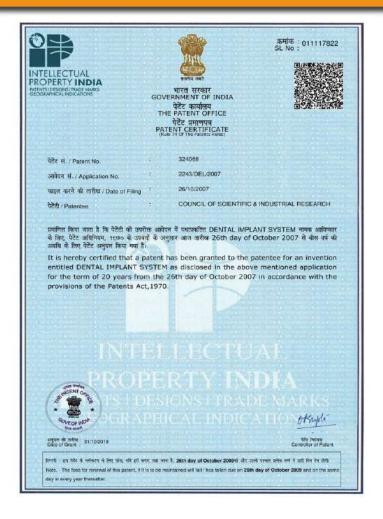






## Indian & US Patent







(Continued)

(10) Patent No.:

US 9,833,300 B2

Verma et al.			(45) Date of Patent:	Dec. 5, 2017
(54)	DENTAL	IMPLANT SYSTEM	(58) Field of Classification Searce	
(75)	Inventors:	Mahesh Verma, New Delhi (IN); Naresh Bhatnagar, New Delhi (IN);	CPC(Continued)	Ab1C 8/0048-8/00/8
		Abhinav Sood, New Delhi (IN);	(56) References Cit	ed
		Farukh Faraz, New Delhi (IN); Kshitij Sharma, New Delhi (IN);	U.S. PATENT DOCU	MENTS
		Gedela V. Rao, New Delhi (IN); Palani	5,588,838 A * 12/1996 Hansso	
	S. Kumar, New Delhi (IN); Shankar Iyer, Elizabeth, NJ (US)		6,149,432 A * 11/2000 Shaw e (Continued)	433/173 t al
(73)	Assignee:	Council of Scientific & Industrial	FOREIGN PATENT DO	CUMENTS
		Research, New Delhi (IN)		
(*)	Notice:	Subject to any disclaimer, the term of this	WO WO 03/030767 A 4/200 WO WO 2006/081239 A 8/200	
		patent is extended or adjusted under 35 U.S.C. 154(b) by 188 days.	WO WO 2007/022655 A 3/200	7
(21)	Appl. No.	: 12/739,654	OTHER PUBLICA	TIONS
(22)	PCT Filed		Eskitascioglu et al., "The influence of occlusal loading location on stresses transferred to implant-supported prostheses and supporting	
(86)	PCT No.:	PCT/IN2008/000700	bone: a three-dimensional finite element study," Feb. 2004, Journal of Prosthetic Dentistry, vol. 91, pp. 144-150.*	
	§ 371 (c)(	1),	Primary Examiner - Matthew Nels	on
	(2), (4) D	ate: Jan. 28, 2011	(74) Attorney, Agent, or Firm - Lo	cke Lord LLP; Daniel
(87)			J. Fiorello; Joshua L. Jones	
	PCT Pub.	Date: Apr. 30, 2009	(57) ABSTRACT	
(65)		Prior Publication Data	A screw type dental implant system (1), having a dental implant fixture (2), a multifunctional component (3) and an abutment screw (4). The screw shape dental implant fixture	
	US 2011/	0117522 A1 May 19, 2011	has an external surface having buttre	ss threads on the body
(30)	Foreign Application Priority Data		and micro threads at the collar. This combination provides the advantages of: improved biomechanics at the implant	
O	Oct. 26, 2007 (IN) 2243/DEL/2007		abutment interface, self-tapping natural minimizing the stresses at the crest	of the bone leading to
(51)	Int. Cl.		decrease resorption of crestal bone component serves the purposes of i	
	A61C 8/0	9 (2006.01)	sion analog and final abutment and	has a single prosthetic
(52)	U.S. Cl.	A61C 8/005 (2013.01); A61C 8/0022	platform so one component is cor	
	CFC	(2013.01): 461C 8/0025 (2013.01):	implant dimensions, which minimize for the implant system and allows	

(12) United States Patent

(Continued)

### Kamal Medtech Facility



Facility Area - 50000 Sqft State of the Art Clean Rooms 2017 & ISO 13485 High-tech QC Labs Controlled Area – 20000 Sqft
Compliant with MDR

World Class Mfg



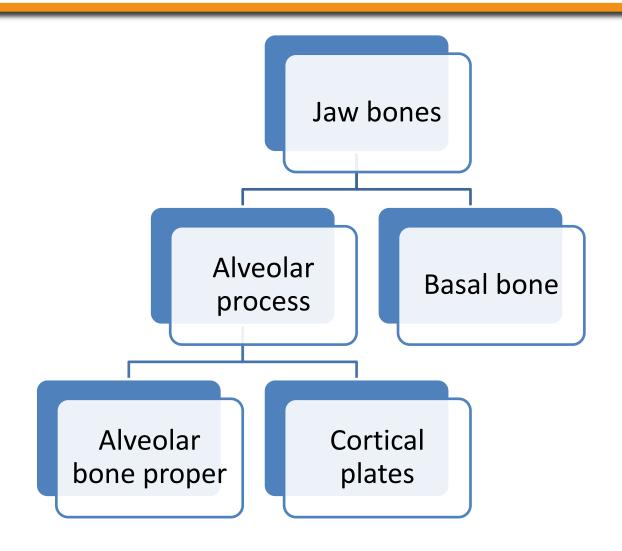




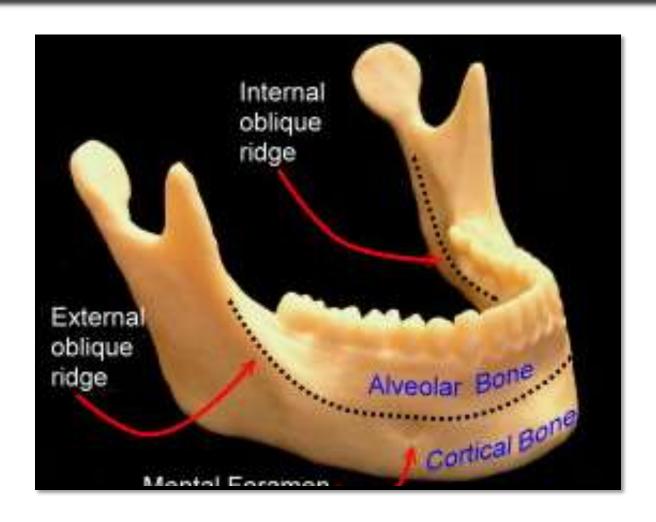


## **Basal Implants**









## Bicortical Implants



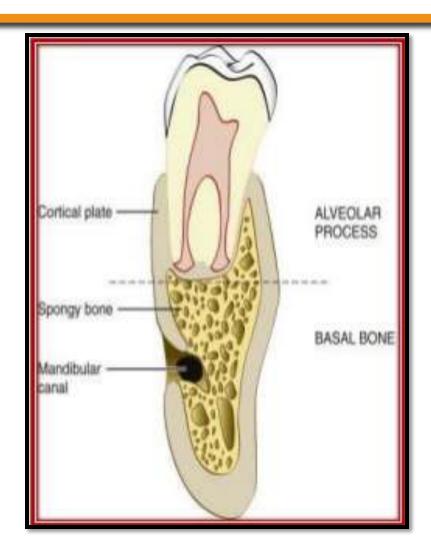
- Bicortical implants engage more than a single cortical plate when placing a dental implant.
- Typically, this is done with the cortical bone of the base of the mandible or the floor of the maxillary sinus or nasal cavity and the crestal cortical bone of the edentulous ridge.
- They depend on osseo-adaptation/mechanical retention
- Osseointegration completes after 20-24 months
- Basal bone is more stable with minimum changes in structure

## Compressive Implants

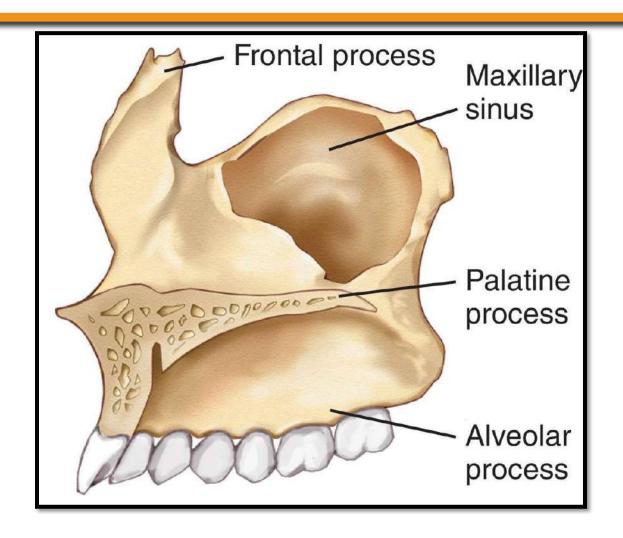


- Compressive implants are one-piece implant with compressive threads.
- The thread bearing portion is SLA treated.
- They are used for single and multiple restorations with immediate loading in the upper and lower jaws with adequate bone tissue.
- Implants can be placed by flap or flapless approach with subcrestal position of the implants.
- Implant placement is also possible immediately following tooth extraction, if sufficient bone tissue is available.

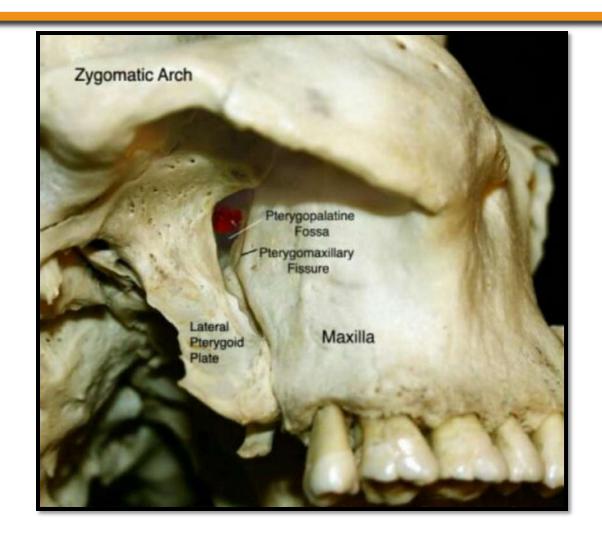








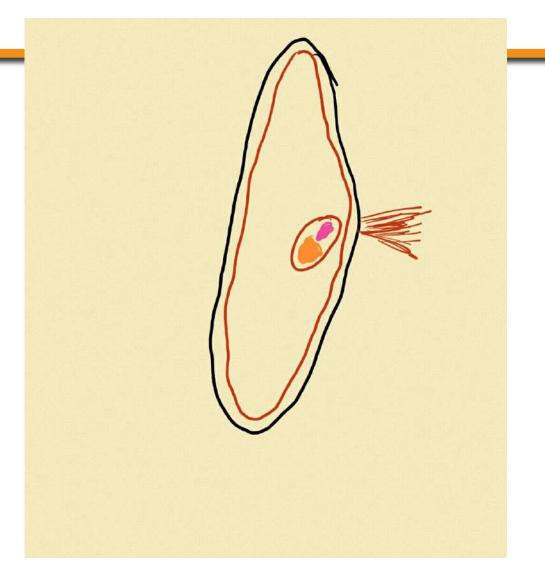












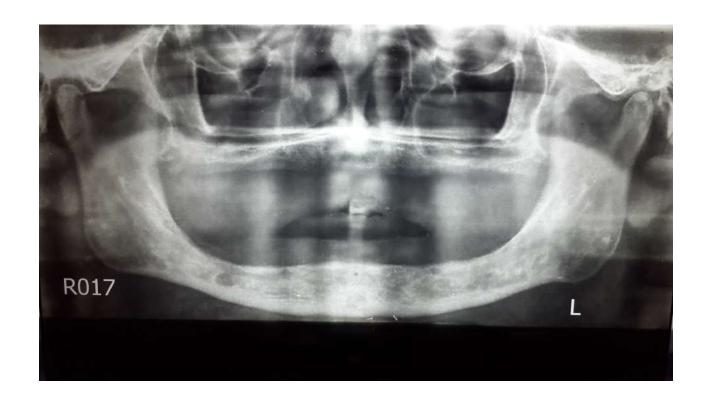




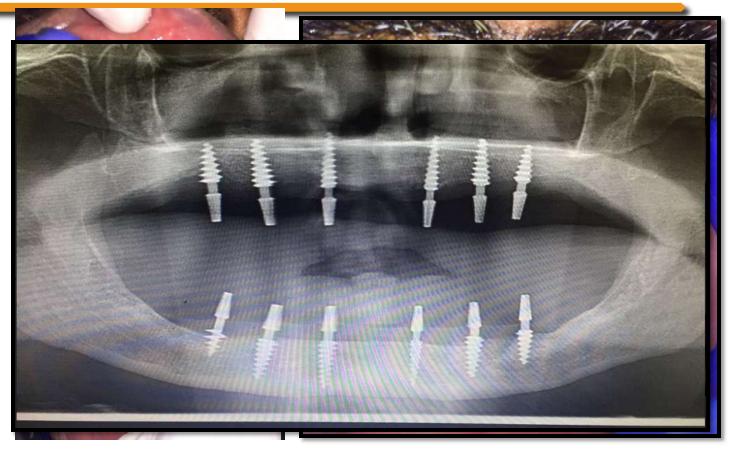




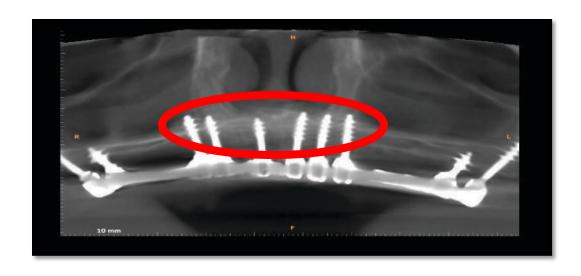








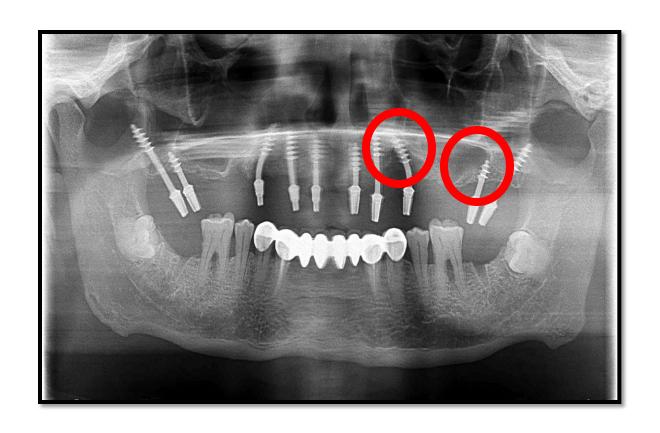
## NASAL CORTICAL ENGAGEMENT



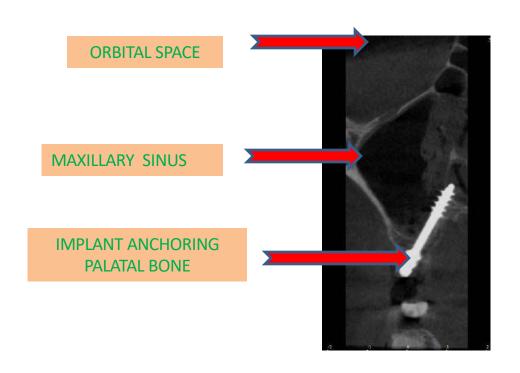
## SINUS FLOOR ENGAGEMENT FORERER SINCES



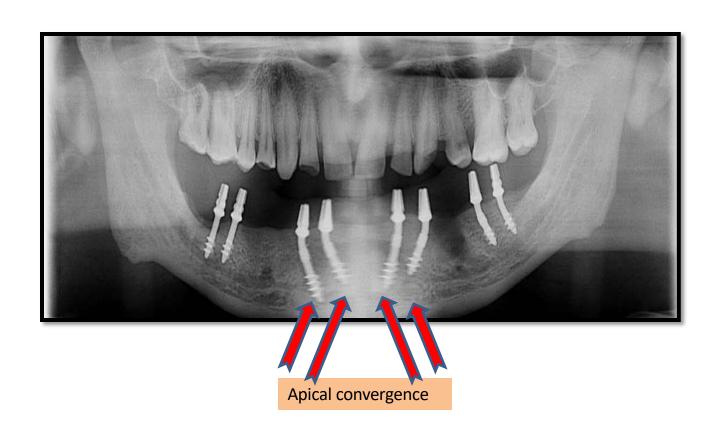
## SINUS SEPTA ENGAGEMENT 2-FIX



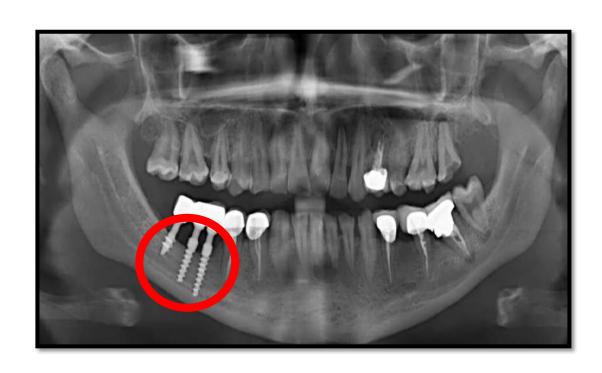
## ALVEOLAR PALATINE FIXATION FIXATION



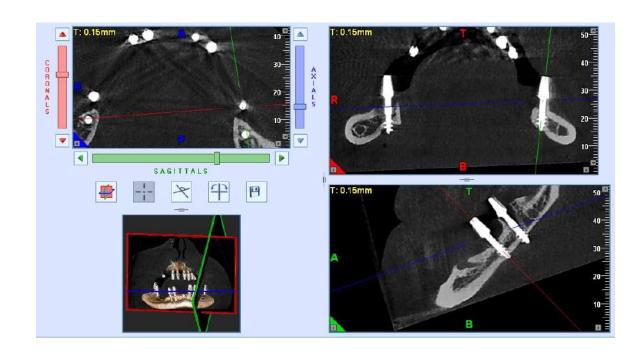
# APICALLY CONVERGING IMPLANTS EXTREMENTAL FORAMEN



## NERVE BYPASS – BUCCAL OR LINGUATIX

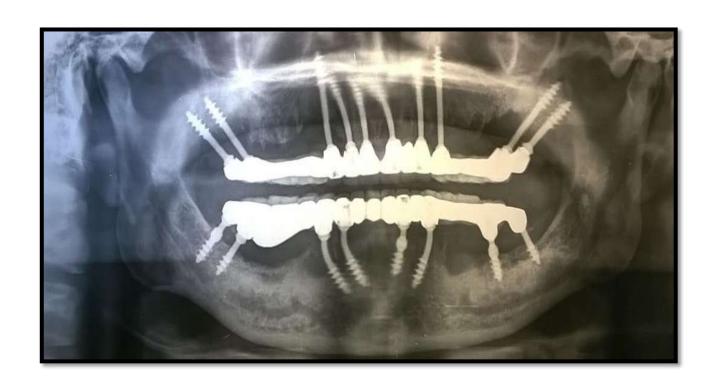


# LINGUAL CORTICAL ENGAGEMENTX



## PALATAL & BUCCAL CORTICAL 1-FIX ANCHORAGE ---

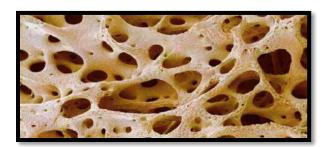




#### TRABECULAR/ CANCELLOUS BONE



- It's the meshwork of spongy/ porous tissue.
- Its organized in trabeculae oriented according to the direction of the physiological load.
- Active cellular process present.
- Formation & growth of new bone
- Attracts infectious cells also.

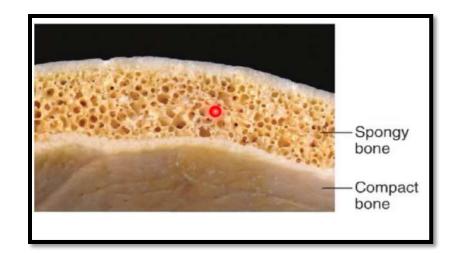




### **CORTICAL BONE**



- Dense tissue found at the surface.
- Mechanical load is borne along multiple axis.

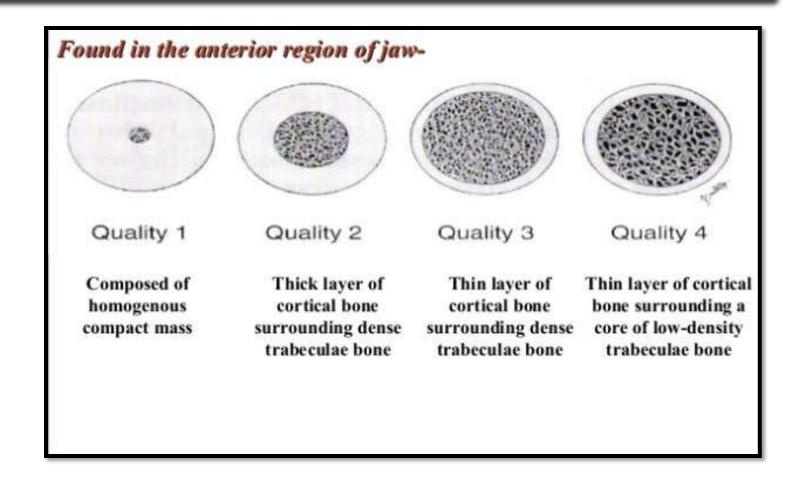


#### Think ....

- cortical bone as granite and
- cancellous bone as pumice.

## Types of bone depending upon cortical and cancellous bone ratio

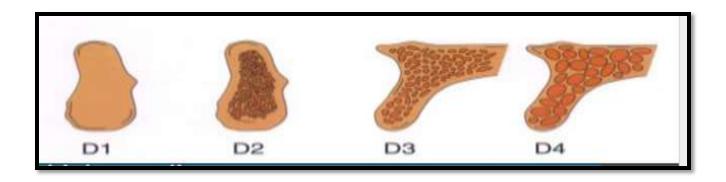




# Different types of bone in different locations



Bone density	Description	Anatomical location
D1	dense cortical	Anterior mandible
D2	porous cortical and coarse trabecular	Anterior mandible Posterior mandible Anterior maxilla
D3	porous cortical (thin) and fine trabecular	Anterior maxilla, Posterior maxilla Posterior mandible
D4	fine trabecular	posterior maxilla



## Cortical bone areas of Maxilla and Mandible 1-FIX



Maxilla	Mandible
<ul> <li>Maxillary tuberosity</li> <li>Pterygoid plate</li> <li>Wall &amp; floor of maxillary sinus</li> <li>Nasal wall and floor</li> <li>Medial nasal spine</li> <li>Buccal &amp; palatal cortical plate.</li> <li>Zygomatic process</li> </ul>	<ul> <li>Below or at linea oblique of mandible</li> <li>Buccal &amp; lingual cortical plate.</li> </ul>

## Single piece implants

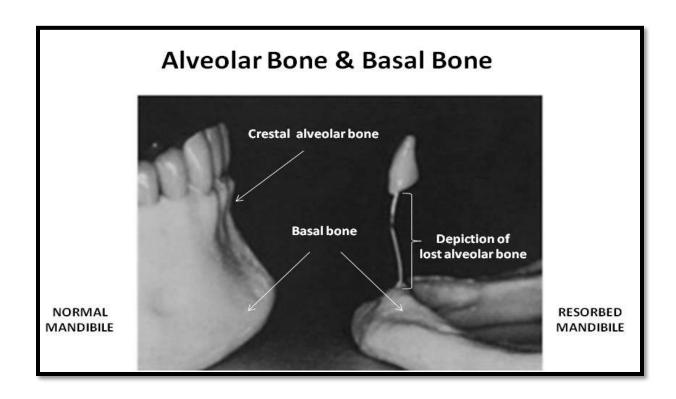




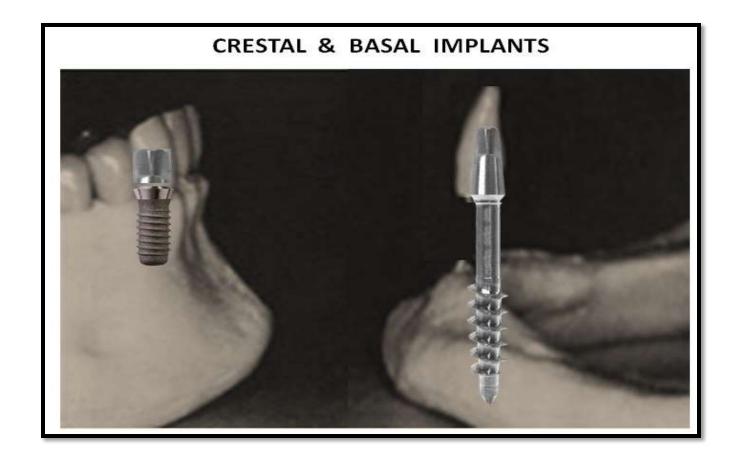


## What is Basal implant ...?









#### INDICATIONS FOR BASAL IMPLANTS



- Quick and simple procedures
- Immediate loading
- Economical
- Can be used in patients with poor bone quality and quantity
- Can be used in anatomically unfavorable situations
- Helps avoid sinus lifts and bone augmentation / grafting procedures
- Overcomes disadvantages of two piece implants

### CONTRAINDICATIONS



- Severely compromised medical conditions
- High risk of surgical failure
- High esthetic requirements
- Ti allergy

# REQUISITES FOR SUCCESSFUL IMMEDIATE LOADING



- High density bone at implant site
- Implant design that increases mechanical retention
- Rough implant surface to increase primary stability
- Bicortical implant placement for increase stability
- Avoidance or reduction of distal cantilevers
- Protected occlusal scheme against overloading









Single Piece Implants	Two – Three Piece Implants
implant and the abutment are fused	implant and the abutment are separate
Single sitting surgical procedure and very often flapless	complex surgical procedures , may involve grafting
less time consuming than that required for bridgework.	spread over 2 or 3 sittings in a period of 3-6 months
Immediate Loading	Delayed Loading
A wide range of sizes and designs are available suiting various bone types and measurements. The designs even help avoid bone augmentation and sinus lifts.	Limied sizes and designs
more cost effective in comparison with two/three piece implants	Expensive – with respect to the costs of the implants
Maintenance is very simple	more complex

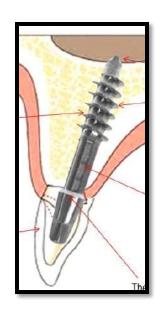
### Disadvantages



- Osseointegration takes a longer time
- Emergence profile is hard to achieve
- Aesthetics are compromised
- Only cement retained solutions are available
- Transfer of multi-implant impression is technique sensitive

### BI CORTICAL ENGAGEMENT

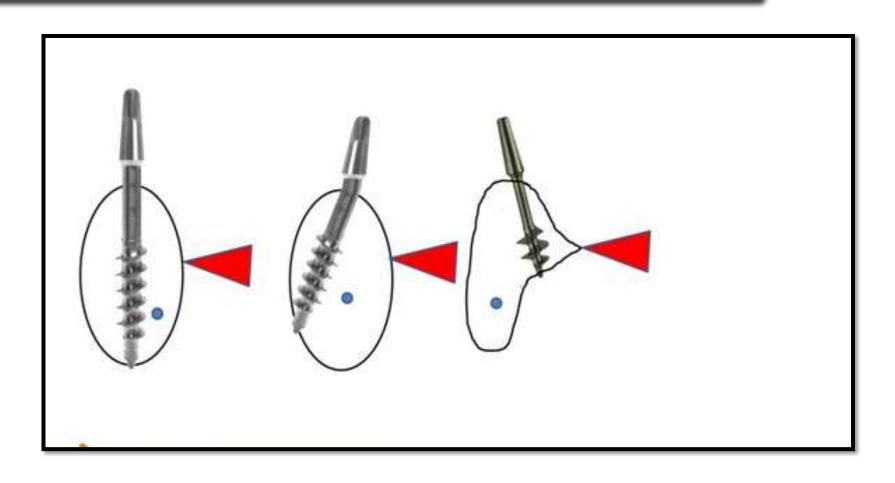




- Maxillary tuberosity
- Ptyerygoid plate
- ➤ Wall & floor of maxillary sinus
- Nasal wall and floor
- Medial nasal spine
- Buccal & palatal cortical plate.
- Zygomatic process
- > Below or at linea oblique of mandible

### BI-CORTICAL ENGAGEMENT IN MANDIBLE

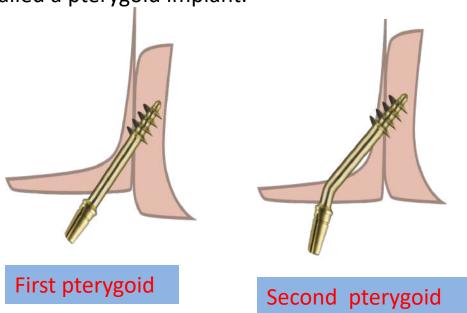




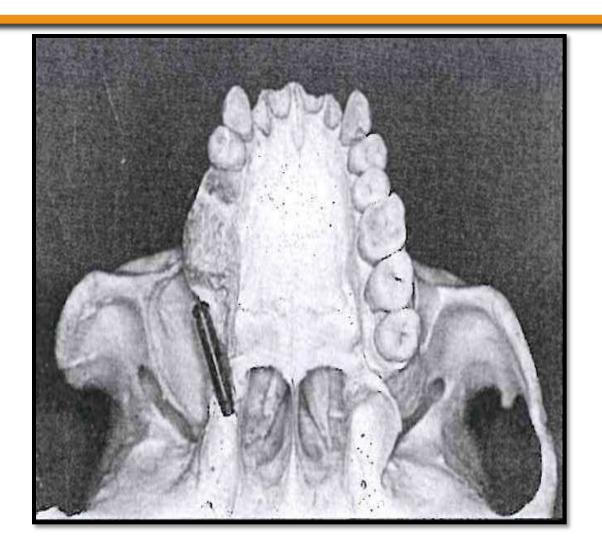
### PTERYGOID IMPLANTS



 An implant engaging the pterygoid apophysis and thus taking distal support and avoiding successfully the cantilever situation is called a pterygoid implant.



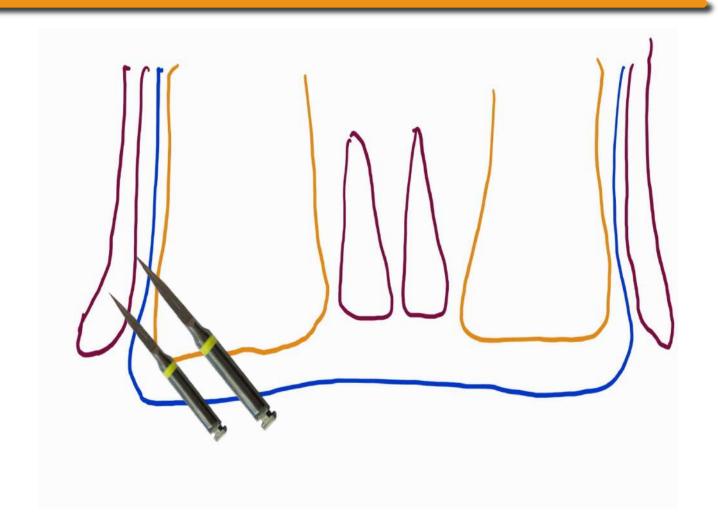








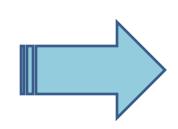




# WHICH IMPLANT IN WHICH REGION...? FOR MAXILLA

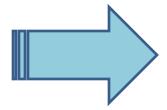


- CLEAN SOCKET
- > HEALTHY BONE
- NO INFECTION
- CLEAN EDENTULOUS SPACE





- ➤ INFECTED SOCKET
- POOR BONE
- IMMEDIATE EXTRACTION
- ➤ IN IMPLANT REJECTED CASES





#### i-Fix One



- Implant surface is polished for protection from bacteria when placed in infected sockets
- Bicortical engagement
- Immediate loading
- Can be placed in extraction sockets
- Grade V ELI Ti
- Bendable



### **Indications**



- Full mouth rehabilitation
- Graftless solution
- Thin ridge situation
- Bicortical engagement

	A	В	C	D	E	F	6	н
3.6x8	1	4.5	3.5	1.5	3.1			1.6
3.6x10	1	6	4	1.5	3.1			1.6
3.6x12	1	6	6	1.5	3.1			1.6
3.6x14	1	9	5	1.5	3.1			1.6
3.6x17	1	9	8	1.5	3.1	3	2.5	1.6
3.6x20	1	9	11	1.5	3.1	3	2.5	1.6
3.6x23	1	9	14	1.5	3.1	3	2.5	1.6
3.6x26	1	9	17	1.5	3.1	3	2.5	1.6

A - Tip Length

B - Thread Length

C - Shaft Length

D - Apical Core Diameter

E - Apical Major Diameter

F - Collar Length

6 - Collar Diameter

H - Pich

#### PROSTHETIC OPTIONS







Impression Coping

i-Fix One Analog

BurnOut Cap

#### PRODUCT CODE

		Brand Name: i-Fix One										
		Length (in mm)										
Diameter (mm)	8	8 10 12 14 17 20 23										
3.6	10360800	10360100	10360120	10360140	10360170	10360200	10360230	10360260				



### i-Fix C1



- SLA surface on threads
- Excellent primary stability
- Condensation of soft cancellous bone
- Minimum osteotomy required
- Excellent for narrow ridges
- Immediate loading
- Grade V ELI Ti



#### **Indications**



- Immediate Prosthetic loading
- Elimination of screw loosening
- Reduces cost & time

#### INDICATIONS

- ✓ Immediate Prosthetic Loading
- ✓ Elimination of screw loosening
- ✓ Reduces cost & time

			C	D	400	F	6	. H	10.00	1
3510	0.65	10	10	2	1.8	0.9	3.5	2.56	1.55	0.5
3512	0.65	12	8	2	1.8	0.8	3.5	2.46	1.55	0.5
3514	0.65	14	7	2	1.8	0.8	3.5	2.46	1.55	0.5
3516	0.65	16	6	2	1.8	0.8	3.5	2.46	1.55	0.5
4008	0.7	8	13.5	2	2.2	1.2	4	2.95	1.55	0.5
4010	0.7	10	13	2	0.8	0.8	4	2.95	1.55	0.5
4012	0.7	12	11	2	1.8	0.8	4	2.95	1.55	0.5
4014	0.7	14	9	2	1.8	0.8	4	2.95	1.55	0.5
4016	0.7	16	8	2	1.8	0.8	4	2.95	1.55	0.5
4508	0.75	8	12.5	2.3	2.8	1.4	4.5	3.05	1.55	0.7
4510	0.75	10	13	2.3	2.3	0.9	4.5	3.05	1.55	0.7
4512	0.75	12	10.5	2.3	2.3	0.9	4.5	3.05	1.55	0.7
4514	0.75	14	9	2.3	2.3	0.9	4.5	3.05	1.55	0.7
5008	0.85	8	14	2.3	3.2	1.8	5	3.55	1.55	0.7
5010	0.85	10	14.5	2.3	2.6	1.2	5	3.55	1.55	0.7
5012	0.85	12	12	2.3	2.6	1.2	5	3.55	1.55	0.7
5014	0.85	14	11	2.3	2.3	0.9	5	3.55	1.55	0.7
5508	0.95	8	18	2.5	3.2	1.8	5.5	4.04	1.55	0.7
5510	0.95	10	18	2.5	2.5	1.1	5.5	4.04	1.55	0.7
5512	0.95	12	15	2.5	2.5	1.1	5.5	4.04	1.55	0.7



B - Thread Length

C - Total Angle

D - Shaft Diameter

E - Apical Diameter

F - Apical Core Diameter

6 - Implant Crestal Diameter

H - Implant Crestal Core Diameter

1 - Pitch

J - Thread Depth

#### PROSTHETIC OPTIONS







Impression Coping

I-Fix C1 Analog

BurnOut Cap

#### PRODUCT CODE

			Branc	Name: i-Fix	Cl						
		Length (in mm )									
Diameter (mm)	8	10	12	14	16	18	20				
3.5	IC350800	IC350100	IC350120	IC350140	IC350160	IC350180	IC350200				
4	IC400800	IC400100	IC400120	IC400140	IC400160	IC400180	IC400200				
4.5	IC450800	IC450100	IC450120	IC450140	IC450160	X	X				
5	IC500800	IC500100	IC500120	IC500120	X	X	X				
5.5	IC550800	10550100	IC550120	IC550140	X	X	X				



## WHY IMPLANTS HAS TO BE PLACED LIKE THIS..??

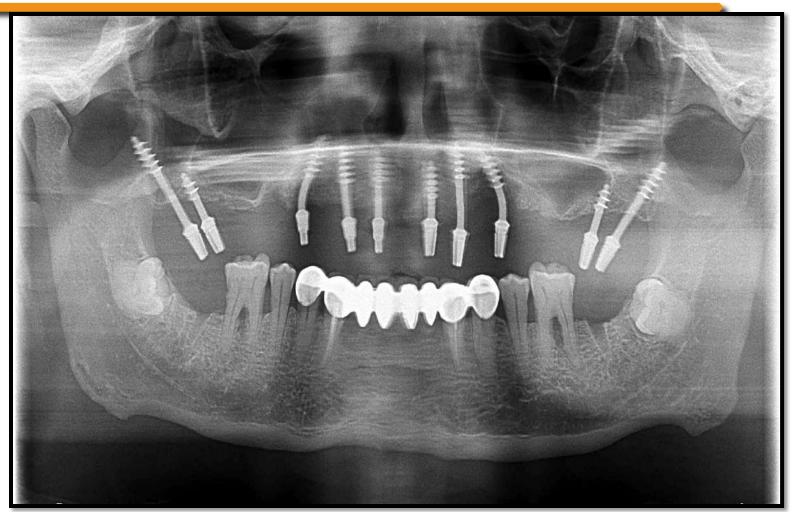


Strategic implantology is all about to place implant in good bone with bicortical engagement with good primary stability and long-term retainability....











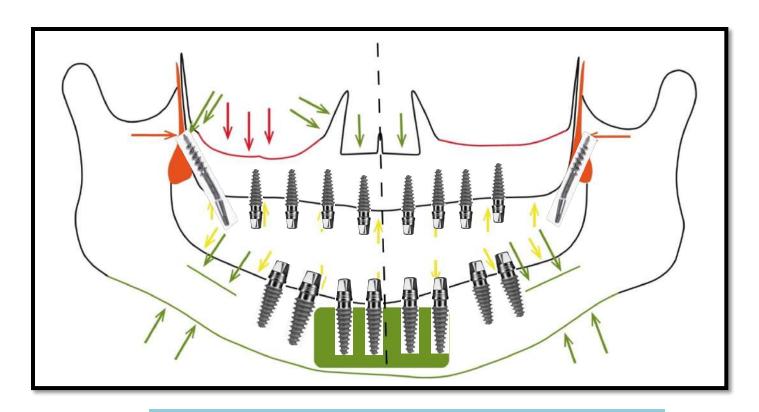








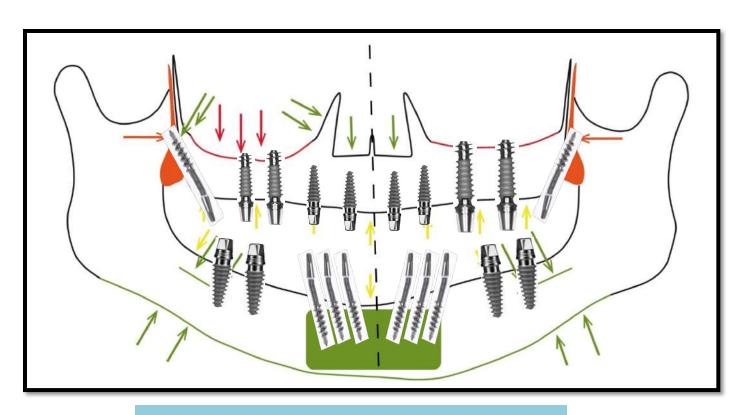
#### WHICH IMPLANT IN WHICH REGION...?



NON INFECTED CASE WITH GOOD AND HEALTHY RIDGE



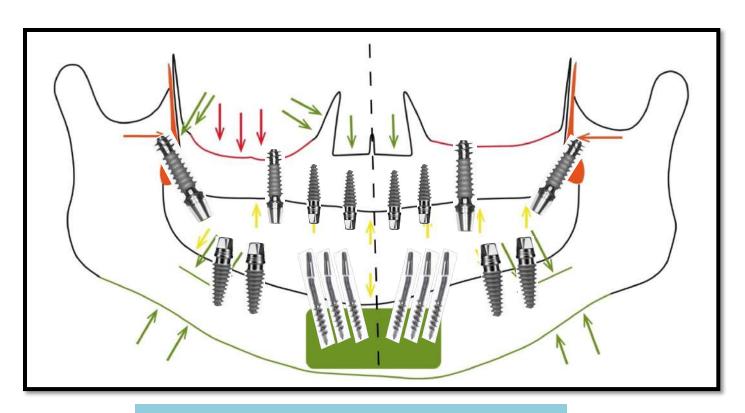
#### WHICH IMPLANT IN WHICH REGION ...?



NON INFECTED CASE WITH IMPROPER RIDGE



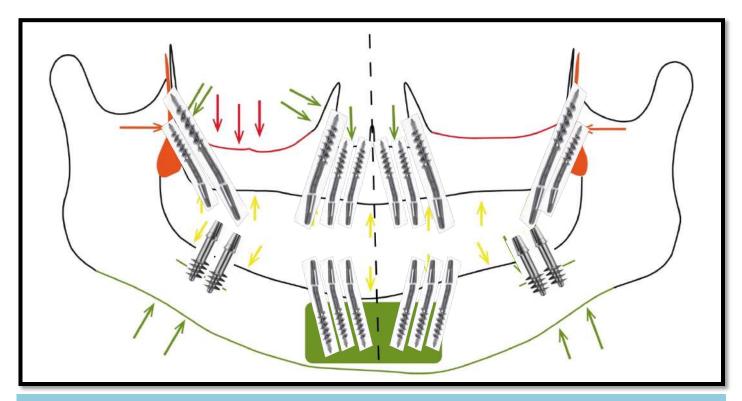
#### WHICH IMPLANT IN WHICH REGION ...?



NON INFECTED CASE WITH IMPROPER RIDGE



#### WHICH IMPLANT IN WHICH REGION ...?



INFECTED CASE WITH ATROPHIC RIDGE, DIABETIC AND POOR PROGNOSIS

# SURGICAL PROTOCOL BEFORE PLACEMENT OF IMPLANTS



- Full mouth scaling has to be done 24 to 48 hours before surgery.
- Antibiotics 5 days course along with mouth wash has to be started 24 hours before surgery.

# SURGICAL PROTOCOL ON THE DAY OF IMPLANTS



- Infected tooth has to be extracted completely and should be curetted completely with gauge till all the granulation tissue is removed.
- Use betadine gargle to clean the sockets
- Avoid over drilling and use proper irrigant to avoid over heating

#### POST SURGICAL CARE



- Check for good clearance of implant abutment from the opposing tooth or implants.
- Hybrid denture impressions has to be started on the same day after surgery and has to be delivered with in 3 days.
- Ask patient to continue the medication for three to five days



#### COMPLICATIONS

Paresthesia

Dysthesia

Analgesia

Anesthesia

Bleeding

Sublingual hematoma

Airway obstruction



#### MANAGEMENT

Wait till 3 months

Nerve regenerating agents

Homeopathic

Micro - neurosurgeon

Bi digital pressure

Drainage

Maxillofacial help



#### **PRECAUTION**

Block - contraindicated

Keep finger – feel the perforation , don't dip

Preserve lingual mucosa

Lingual anastomosis, lateral lingual channels

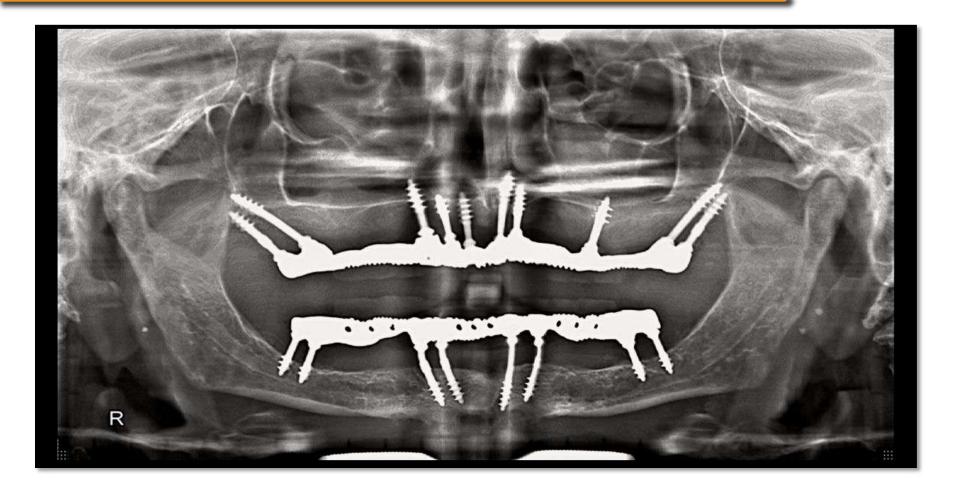
Reflect flap when in doubt

**CBCT** 

After pathfinder use twist drill

Make good friendship with maxillofacial surgeons









# By rigid metal framework 2-FIX











#### **OCCLUSION**

















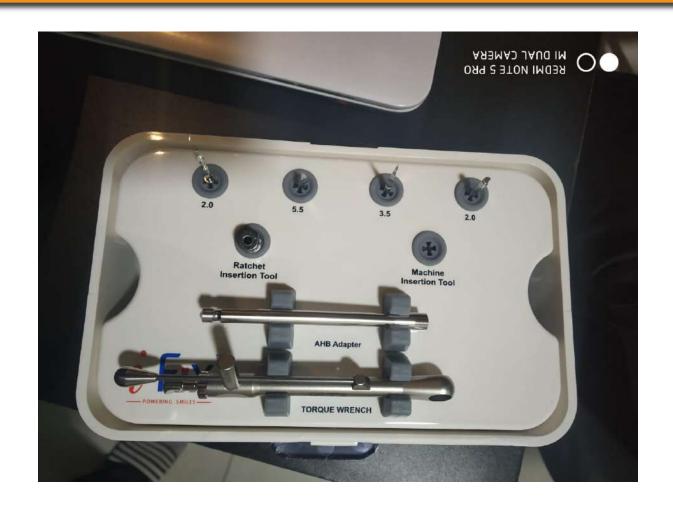












### Pilot drill





### 2.0mm Drill





### 3.5mm





### 5.5 mm





## AHB Adaptor





## Hand Grip





#### CIX driver





### Torque wrench







## Thank you