SOUTHERN IMPLANTS

EXPANDING PROVEN CONCEPTS

CRANIO FACIAL Reconstruction

CAT-2036-02 (C344)

Dear Customers and Colleagues

Today, Dental Implants have become an indispensable part of Dental treatment options. With the globalization of medical infrastructures and higher standards of living, implant applications have rapidly become common.

Southern Implants has been a manufacturer and distributor of Dental Implants since 1987. Today, the Southern group is recognized as a leading bio-medical engineering entity, with major intellectual property and capabilities in implantable devices, arthroplasties, tissue regeneration, stem cells and cryoscience. The top-end professional users, who want more choices, have driven the product range expansion to enormous and exciting heights. Striving for excellence and meeting customer needs has lead to our wide product range characterized by numerous unique and innovative products which include:

- 3 interfaces: External hex, Internal morse taper/octagon, and Tri-nex.
- Many products optimized for primary stability and suited for immediate loading.
- The only angled-top tapered screw-form 12° and 24° Co-Axis implant.
- Implant lengths from 6mm to 20mm and diameters from 2.90mm to 10mm.
- A surface which continues to out-perform that which it is trialed against.
- Color-coded components for easy part recognition.
- 55° Zygomatic implant, optimized for load distribution.
- Compatibility with major brands, giving the patient more options.
- The MAX, wide diameter implant for molar teeth replacement.

Striving for excellence is synonymous with the search to improve. At Southern the development starts with computer simulation and Finite Element Modeling. This is followed by extensive laboratory trials and testing. Finally, clinical research has taken on a new dimension in our overall strategy where our preference is for independent RCTs.

Our sincere thanks to all specialists, dentists and technicians who give continual feedback, suggestions and input. The products here are our interpretation of your needs.

Yours sincerely

Graham Blackbeard
Managing Director
Southern Implants

Why Southern Implants?

Southern Implants was established in 1987 as a manufacturer and distributor of dental implants. At this time the science on a worldwide basis was still in it's infancy. Southern implants has been a pioneer in this field for the last 21 years and has contributed extensively to enhancements with respects to the osseointegration of implant devices, surgical techniques, patient education and options of treatment.

The company is focused on the top-end specialist sector of the implant market. The product range is constantly being expanded to incorporate the newest technologies and trends. Where many of our competitors are rationalizing their product range, Southern is offering more choices.

The implants are made from ASTM-F67-95 Grade 4 pure titanium, with a tensile strength of 550 MPa. The surface is enhanced with abrasion and chemical conditioning. The surface has been proven by way of extensive animal and clinical trials and has been in use for more than 15 years.

Southern Implants is not only the leading implant company in Southern Africa, but is a significant role player in the USA, the UK, Europe and Australasia. Manufacturing plants are situated in Irene, South Africa and Irvine, California. Each Plant produces 60 000 implants per annum.







Design & Layout by Ruan Pienaar

Content

www.southernimplants.com





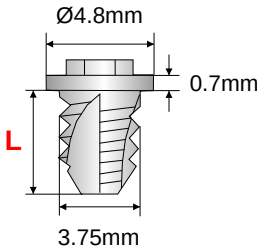


Instructions for Use

Extra Oral implants have a number of different indications for use, such as retaining cranio facial prosthesis' and bone conductor hearing aids. The general placement procedure is similar in most extra oral cases and therefore an example for an auricular prosthesis will be used.

The availability of bone as well as ideal placement for attachment of the prosthesis are considerations that need to be taken into account when dealing with extra oral implants. Case planning with the prosthesists making use of CT scans or other case planning devices, is highly recommended. At this stage the length of implant would be determined from the availability of bone.

IE Implant



Prepare the implant site by removing any remaining tissue or ligatures from the area. Make appropriate incisions and pull back the skin - exposing the implant site. The reduction of skin thickness is important to avoiding subsequent soft-tissue problems. Multiple authors have advocated subcutaneous skin reduction, fixed non-mobile skin and absence of hair sometimes requiring grafting of non hair-bearing skin to periosteum. The reduction of skin can take place at implant placement or abutment connection. This excision of a portion of dermal and subcutaneous tissue often includes removal of the adnexal structures, muscle, blood vessels and nerves. This is to aid in fixing the skin to the periosteum, to minimize mobility and remove glandular components.

Start the drilling process by using a dedicated round burr (Fig.1). The pilot hole is then created by using a slightly wider (Ø2.00mm) dedicated drill. (Fig. 2).

The final drill (Ø3.00mm) will then be used to prepare the site. Drilling is done at 1000 to 2000 rpm with copious irrigation (Fig.3).

The IE implant is self tapping by design, however, depending on the hardness of the bone, a tap can be used. Taps cut thread into bony walls of the prepared implant site, easing the placement of the implant in hard bone (Fig.4).

The site is now ready for an implant to be placed. Remove the implant from the sterile packaging tube either with a wrench or handpiece bit (I-CON-X) (Fig. 5A & 5B). Set the torque on the handpiece to 25Ncm. Place the implant with final position such that the platform of the implant is flush with the bone.

Remove the fixture mount and place the cover screw or temporary healing abutment (Fig. 6A & 6B). Cover the site (Fig. 7).

Material:

These Implants are machined from "Unalloyed Titanium for surgical implant application", ASTM F67-95 Grade 4. Although there are slight variations from one batch to another, a typical chemical composition is: Nitrogen 0.01%; Carbon 0.02%; Hydrogen 0.002%; Iron 0.07%; Oxygen 0.14%; balance Titanium, and has a tensile strength 550 Mpa. Such a material exceeds the chemical requirements of Grade 1, and has been classified as Grade 4 due to the superior strength (Grade 1 has a minimum strength of 240 Mpa).

The material chosen for these IE implants, makes them extremely tough and resistant to fatigue failure. The implants are surface enhanced to facilitate secure anchorage and to reduce the need for Hyperbaric Oxygen therapy.

Placement Technique

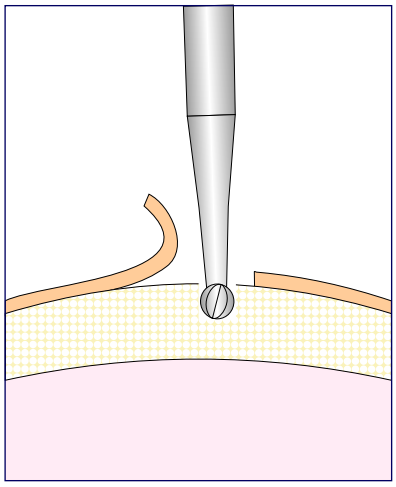


figure 1

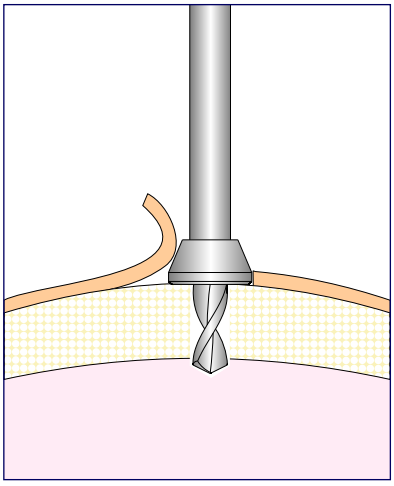


figure 2

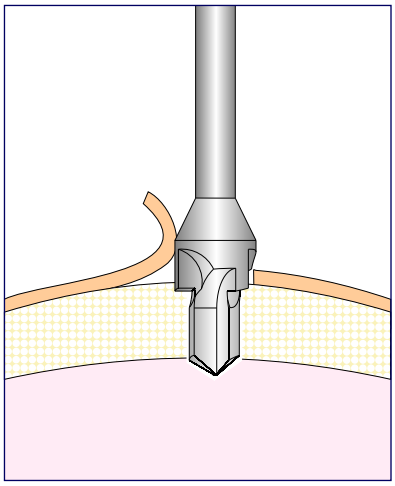


figure 3

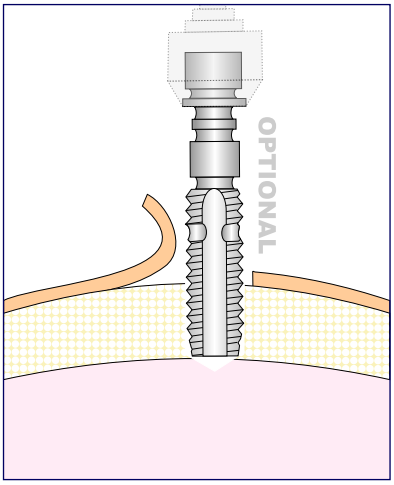


figure 4

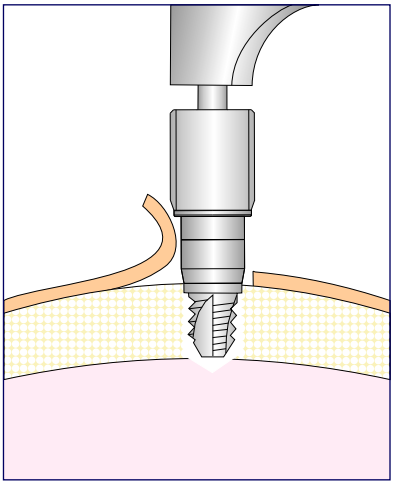


figure 5A

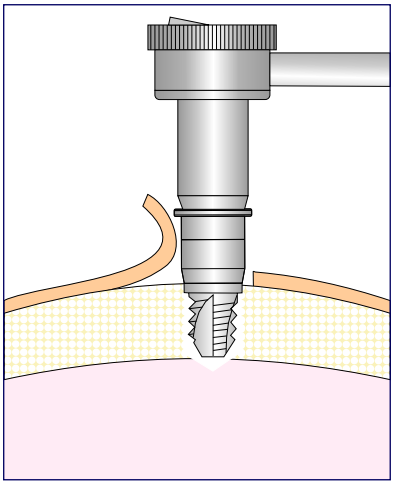


figure 5B

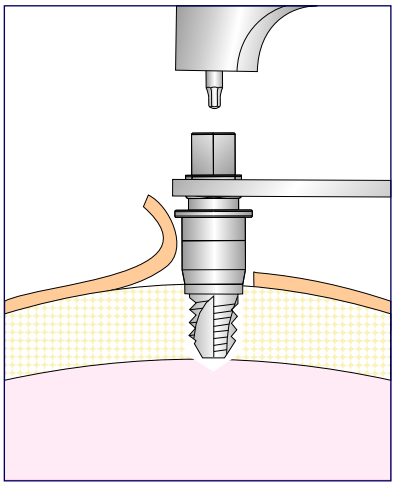


figure 6A

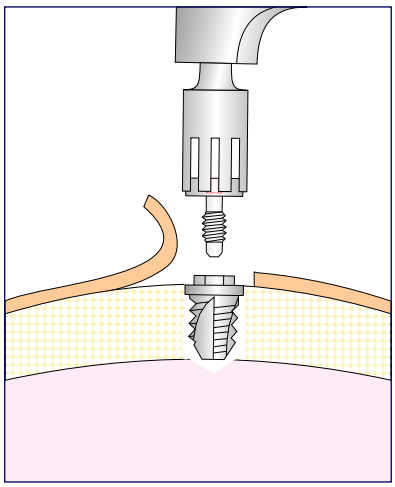


figure 6B

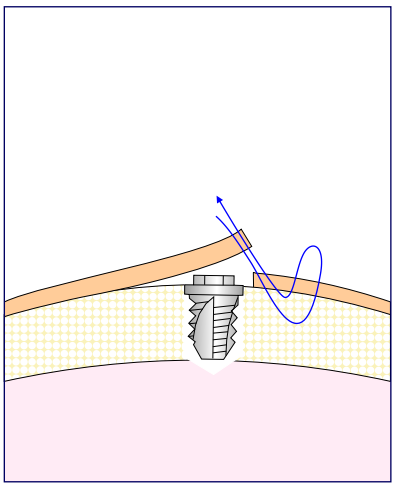
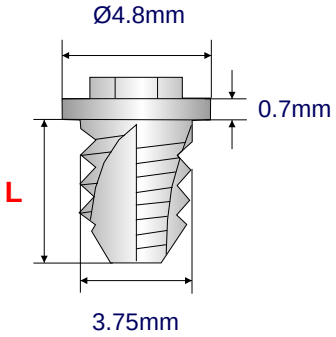


figure 7

IE Implant



IE Implants are pre-mounted and are available in lengths:

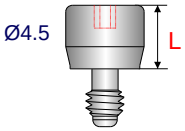
3mm	**code: IE3**
4mm	**code: IE4**
6mm	**code: IE6**

SC4 Cover Screw

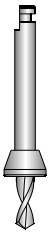
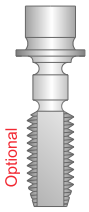
0.9 hex

TBE Healing Abutments

1.22 hex



IE Drilling Sequence

Round Burr	Dedicated Pilot Drill	Dedicated Final Drill	Tap
			
D-RB-MS	D-20E-03F D-20E-04F D-20E-06F	D-30E-03F D-30E-04F D-30E-06F	D-TAP-P10 (for thread cutting)

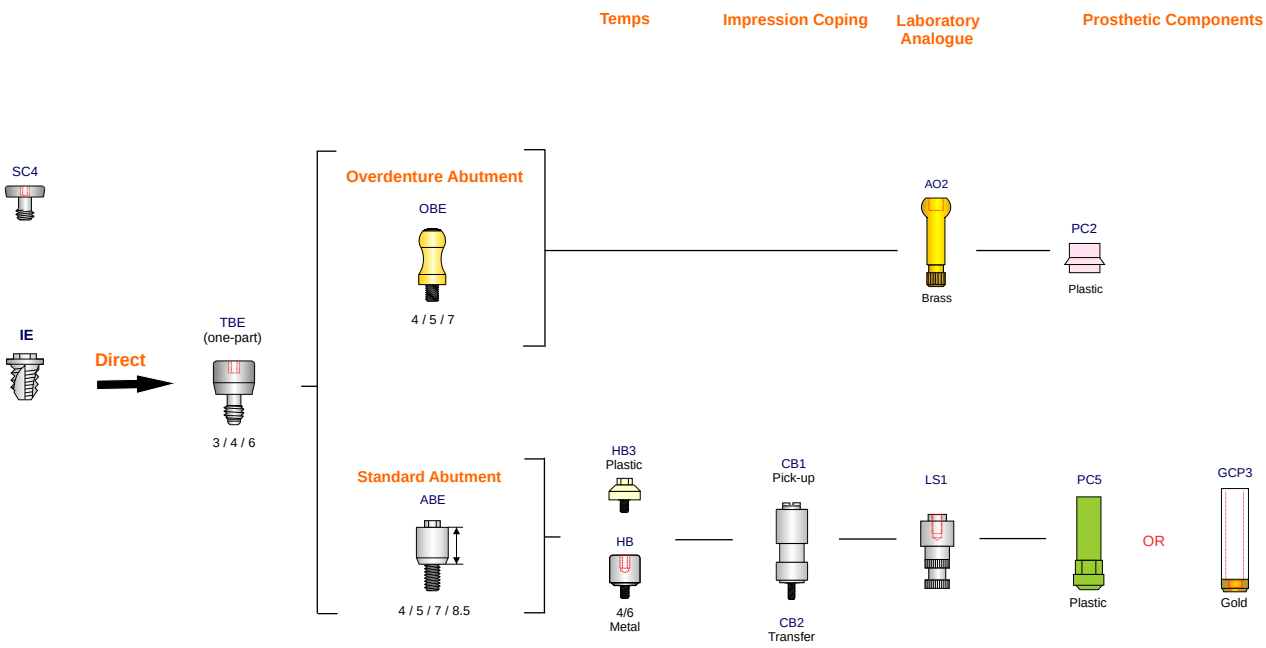
Hex Tool

I-HD-M

Abutment Driver

I-AD

Prosthetic Options: IE Implant



Southern Implants Series 1 Screws

GSS1 GSU1 GSH1 TSS1 TSU1 TSH1

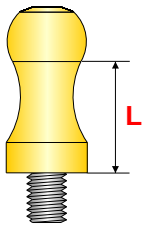
Series 1 Screws (M1.4)
10-15Ncm
Head Diameter 2.25mm

Ball Abutment for use with IE Implant - OBE

Application:

This component is used for clip-on prosthetic parts. The PC2 plastic clip must be incorporated into the prosthesis. Alternatively the Silicone prosthetic part can be made to adhere directly to this ball abutment

OBE Abutment

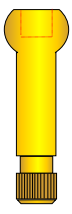
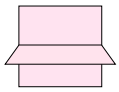
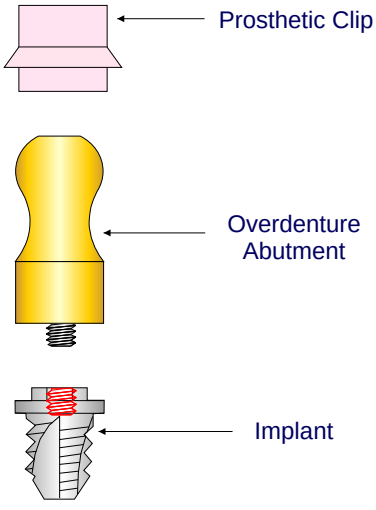


Placement:

The abutment is attached to the implant at second stage surgery upon removal of the SC4 cover screw or the TBE temporary abutment. Second stage surgery is commonly done by way of an incision over the implant, reflection of the skin, securing the abutment and then suturing the skin around the abutment. An alternative method is to punch a cylinder of skin out, above the implant. This is done using the handpiece-driven tissue cutter, I-TC1. Ensure that the hex engages the hex of the implant. Place the OBE abutment, tightening the screw to 20Ncm using the 1.22 Hexdriver (I-HD-M). To avoid inflamation of the tissue it is imperative that the skin is thinned down around the implant.

Prosthetic Reconstruction:

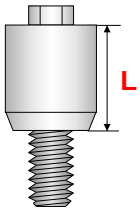
A rubber-based impression is taken of the region. The laboratory analogues are then inserted into the sockets created by the OBE's in the impression material. The model is then cast, incorporating the stem of the AO2.

AO2	PC2	I-HD-M	
			
Laboratory analogue, Brass	Prosthetic clip, Plastic	Hexdriver	

Transcutaneous Standard Abutment - ABE

Application:

ABE Abutment



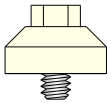
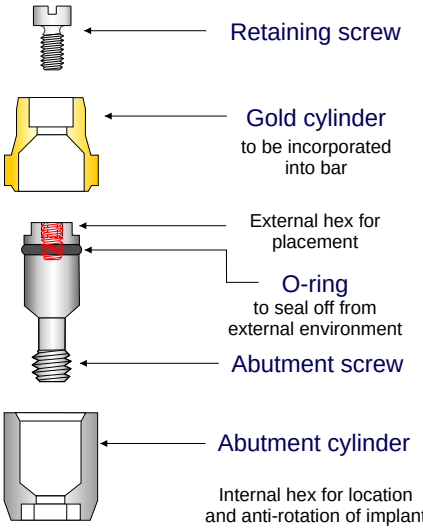
For retention of prosthetic parts, this standard abutment is most commonly used. A bar-type framework is constructed on top of the standard abutment, linking the implants to one another. These ABE abutments have transcutaneous heights, L, of 4 / 5.5 / 7 and 8.5mm.

Placement:

The standard abutment is connected to the implant at second stage surgery upon removal of the SC4 cover screw or TBE temporary abutment. Second stage surgery is commonly done by way of an incision over the implant, reflection of the skin, securing the abutment and then suturing the skin around the abutment. An alternative method is to punch a cylinder of skin out, above the implant. This is done using the handpiece driven tissue cutter, I-TC1. The standard abutment is secured using the abutment driver, I-AD. A Torque Wrench with a bit, I-WI-A, can also be used (tighten to 20 Ncm).

Prosthetic reconstruction:

After abutment placement, the head of the abutment can be protected and kept clean during healing by screwing the healing cap, HB3, into the top of the abutment using a I-AD abutment driver. A rubber-based impression is taken when healing is complete by removing the healing caps and replacing them with two-part CB1 impression copings. These impression copings require an impression tray with a “window” in order for the screw of the CB1 to be accessible. When the impression material has set, the CB1 screws are loosened completely and the impression can then be withdrawn. Abutment replicas (lab analogues) are then attached to the CB1’s in the impression and the model is cast. The gold cylinder, GCP3 or GCP4, is fitted to the model and the bar is waxed up onto the gold cylinder. The gold cylinder is then loosened from the model and invested with the wax bar for the cap-on technique. An alternative is to solder a gold bar to the gold cylinder on the model.

HB3	**I-AD**	
		
Healing cap, Plastic	Abutment driver	

Southern Implants' Enhanced Surface

The Southern enhanced surface is not a "coating", it is an abraided rough surface of Rutile Titanium. This is the same dense form of titanium common to "machined" surface implants. (the anodic oxidation surfaces are not Rutile Titanium; they are a mixture of anatase and amorphous titanium which are less dense and softer forms of titanium).

A. The first experimentation with this Southern Enhanced surface was in 1992. After extensive validation it was put into widespread clinical use in 1997. It is achieved by a subtractive process in which specifically sized and shaped, sharp cornered, Alumina particles (Al203) are blasted with decontaminated air onto the implant surface with controlled pressure, displacement and time. Every batch of A1203 particles are subject to SEM analysis to ensure consistent shape and size.

B. The particle size we use is supported by the work of Soskalne (Israel) and Wennerberg (Sweden) on the one hand and Ronald (Norway) on the other. Based on their research, greatest bone to titanium bond strength is obtained with abrasion particles greater that 75µm and less than 170µm.

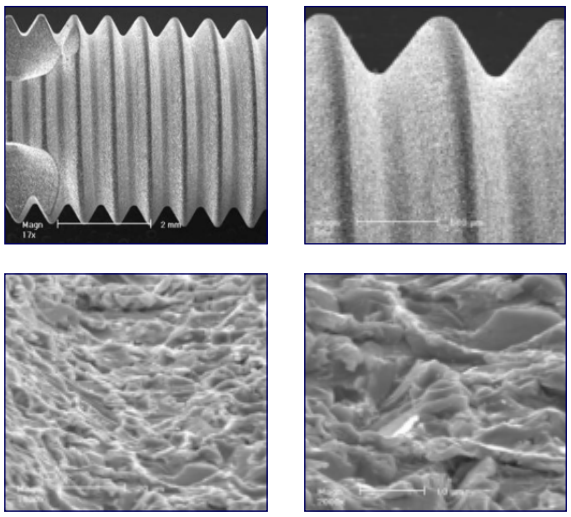
C. Szmukler-Moncler has analyzed and compared the popular implant surfaces in publications and a presentation at the AO, San Francisco 2004. He reports that the Southern Surface is remarkably consistent and free of contaminants whilst those that are acid etched or oxidized are shown to be highly variable. It is extremely difficult to control acid etching and oxidation in an industrial manufacturing process. This is one reason why Southern does not use acid etching or anodic oxidation.

D. There seems to be consensus in the literature that "moderately rough" surfaces have no great risks for the patient and are therefore safe to use. Moderately rough was defined by Albrektsson as S_a 1.0 to 2.0µm (applied Osseointegration Research Vol 5, 2006) and our surface has S_a = 1.43 in one published study and S_a = 1.55 on implants recently analyzed by Prof Ann Wennerberg in 2006.

Dr Mats Wikström, Chief of Clinics, Branemark Center, Goteborg, in 2007 concluded that the Southern surface is one of the three best documented moderately rough surfaces in the market.

Prof Alan Payne, Oral Implantology Research Group, University of Otago, is conducting Randomized Clinical Trials (RCTs) involving Southern Implants rough surface. 2008 signifies the 10 year follow-up. The 8 year and 5 year results are published in Cochrane Collaboration reports.

In conclusion, it is a well documented surface with a consistent manufacturing process and holds extremely low risk for the patient.



Publication

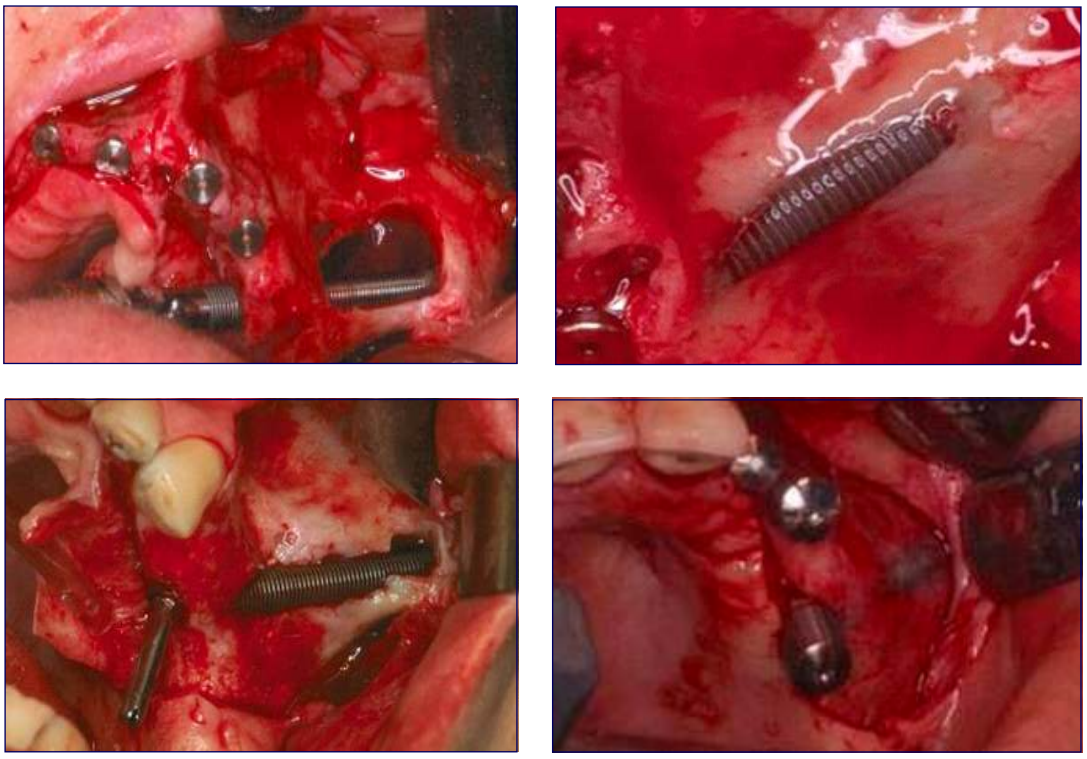
Rubén Davó, Chantal Malevez, Cristóbal López-Orellana,
Francisco Pastor-Beviá, Juliana Rojas

Sinus reactions to immediately loaded zygoma implants: a clinical and radiological study

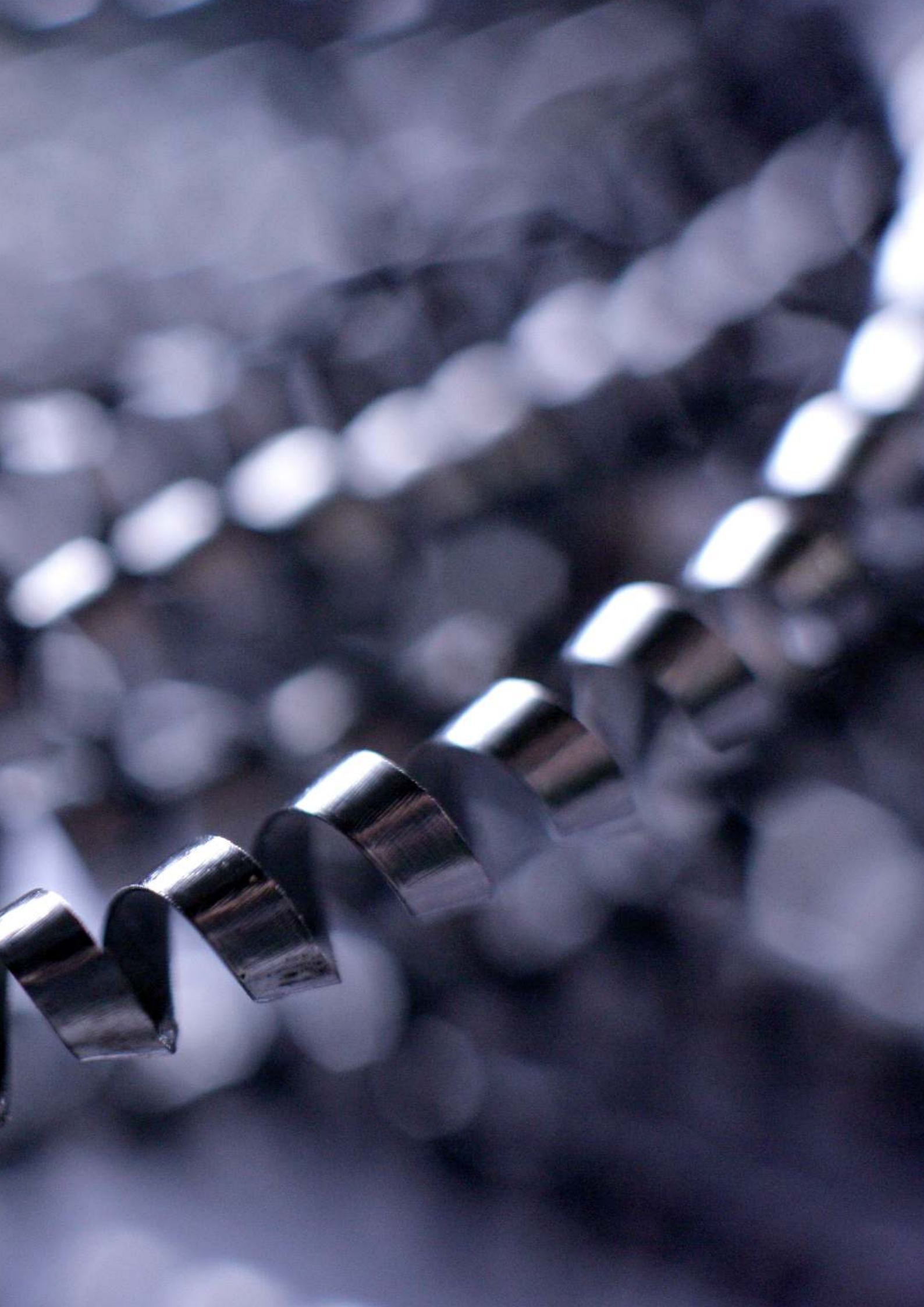
Aim: There are no published studies regarding sinus reactions to immediately loaded Zygomatic implants. The aim of this study was to evaluate the maxillary sinus in a cohort of patients by means of clinical criteria and computerised tomography performed before surgery and after Zygomatic implant placement (immediate function protocol).
Materials and Methods: A total of 36 patients with 71 immediate loaded Zygomatic implants were evaluated to find clinical criteria of maxillary sinus disturbance 13 to 42 months (average 21.9 months) after Zygomatic implant placement. A total of 44 implants had machined surface and 27 had a porous titanium oxide surface. 26 patients with 52 immediately loaded Zygomatic implants were evaluated by means of a CT scan of the paranasal sinuses, 3 to 20 months (average 10.5 months) after Zygomatic implant placement. All patients had no sinus symptoms before surgery and had a preoperative CT scan.
Results: No clinical signs or symptoms of sinusitis were found. Radiological opacity of the antrum was found in 2 sinuses (out of 26). In 8 of them, this was present in the preoperative CT scan.
Conclusions: Sinuses penetrated by Zygomatic implants seem to maintain a normal physiology. However, in approximately 15 to 20% of petients, early radiological findings without clinical symptoms were observed.

Eur J Oral Implantol 2008; 1(1):53-60

Preferred Positioning of Zygomatic Implants



Preferred position of Zygomatic implants is as shown here, with minimal penetration of the sinus and greater engagement of the sinus well. - Clinical photographs by courtesy of Prof D Howes and Dr. G Boyes-Varley.



Zygomatic & Oncology Implants

Introduction:

This manual is produced as an adjunct to the Southern Implants Zygomatic Course, and as an instruction sheet for use before and during placement of these Zygomatic implants. **It is not intended to be a guide for basic surgical techniques, as it is essential that practitioners using these implants are already experienced Maxillo-Facial or Cranio-Facial surgeons.**

Indications:

The main indications for the placement of Zygomatic implants are:

1. Patients who are fully edentulous in the maxilla, especially those with moderate to severe bone resorption.
2. Patients who have unilateral or bilateral posterior maxillary edentulism, & with moderate to severe bone loss.
3. Patients who have had ablative cancer surgery or who have suffered avulsive trauma to the middle third of the facial skeleton.

Pre-operative examination and treatment planning:

This must be done by the full team responsible for the complete treatment of the patient, usually a restorative Dentist or Prosthodontist in conjunction with a Maxillo-Facial or Cranio-Facial Surgeon. A full medical and dental history must be taken, with emphasis placed on the presence of soft tissue and hard tissue pathology and ensuring that the maxillary sinuses are clinically symptom-free. In addition, jaw relationships and resorption patterns must be noted.

Radiographic examination:

As with any implant patient, a radiographic assessment is essential. As far as the Zygomatic protocol is concerned, the main objectives are twofold:

1. To detect the presence of any pathology in the maxillary sinuses, bearing in mind that the thickness of the antral mucosa should not exceed 6mm.
2. To evaluate the volume of zygomatic bone available.

The following radiographic views should be taken as necessary:

1. Panoramic view - for detection of pathology changes within the maxilla as well as anatomical structures.
2. Occipitomental views to assess the extent of the maxillary sinus as well as the presence of sinus pathology.
3. Lateral cephalogram to assess jaw relationships.
4. CT scans. These must be in form of both axial cuts and reformatted images, as these give an excellent assessment of the maxillary sinuses. In the case of cancer and trauma surgery patients, 3D reconstructions are useful.
5. Intra oral x-rays. These are essential to supplement the other views in cases where partially edentulous posterior segments are being reconstructed.

Patient Preparation:

As zygomatic implants are generally placed under general anaesthetics, the standard protocol for patient preparation is adhered to. The part of the face above the zygomatic arch must be left uncovered when draping the patient or securing the endotrachael tube. Haemostasis is enhanced by the use of a suitable local anaesthetic infiltration in the entire operative area.

Operative Procedures

The Current Surgical Procedure is:

1. A crestal incision is made from just anterior to the maxillary tuberosity on one side to the same point on the other side. Three vertical releasing incisions are made in the second molar regions and the midline. These three incisions facilitate flap mobilization beyond the infraorbital margin. In unilateral cases, a hemimaxillary approach is used.

2. The buccal mucoperiosteal flaps are raised to expose the infraorbital nerve, the body of the zygoma and the zygomatic arch. A palatal flap is raised to expose the alveolar bone . The periosteum in the region of the upper molar teeth is incised to enhance flap mobility. A modified channel retractor is placed on the upper border of the zygomatic arch.

3. A window is cut on the lateral aspect of the maxillary antrum and the block of bone is removed. The lining of the sinus is reflected, attempting to keep it intact if possible.
NB: A perforation of the lining is not a major problem but thorough reflection of the lining is essential (fig. 1).

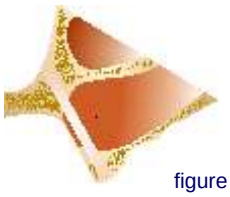


figure 1

4. The access cavity of the implant into the body of the zygoma is made through the antral window, and the tip of the placement device is positioned in the access cavity. This acts as a guide for the correct alignment of the implant on the alveolar ridge (fig. 2).


figure 2

5. The entrance point on the alveolus is made using a round bur. The penetration of the implant site is continued by means of a 2.9mm twist drill, a 3.4mm counterbore and a 3.4mm twist drill (fig. 3).

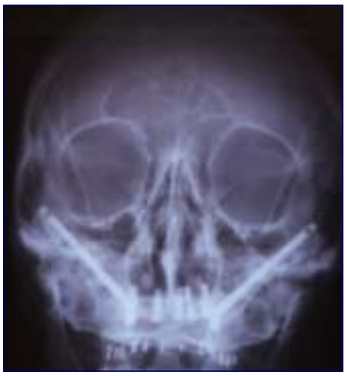

figure 3

6. The depth of the prepared implant site and the implant head angulation are gauged by the use of the angled depth indicator.

7. Before inserting the implant, ensure that the implant site is free of soft tissue remnants. Initial insertion of the implant is carried out using the machine connector to handpiece with the torque control set at 45Ncm at 15rpm.
During insertion:
   1. The implant must follow the prepared path of insertion.
   2. Soft tissue must not be caught up on the implant surface.
   3. Adequate coolant must be applied to both alveolar and zygomatic bone.
   4. The torque controller is set at 45Ncm. Once this level is reached, further insertion is achieved manually using the onion driver. When insertion is complete, rotate the implant head so that the hex is aligned correctly. The fixture mount is then removed and the cover screw placed by hand.

8. Suturing is carried out by the technique of choice using resorbable sutures. Thereafter a long-acting local anaesthetic solution is injected to control postoperative pain.

Postoperative Management



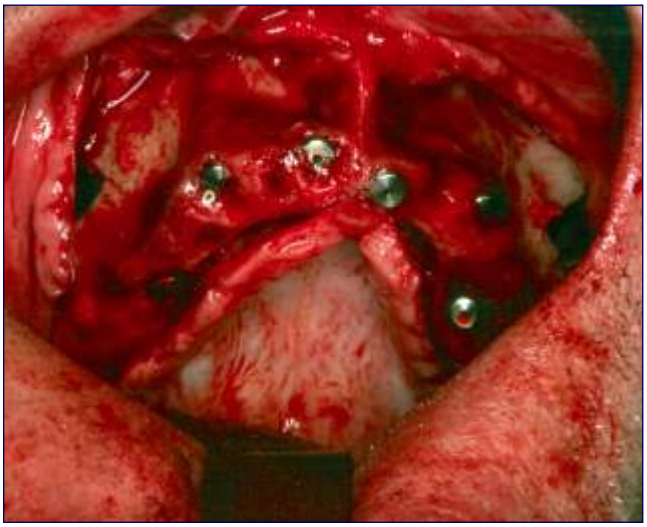
A further 8mg Decadron is given for 7 hours postoperatively. In addition, a course of oral antibiotics is given to the patient and a suitable analgesic regimen is prescribed. Occasionally a patient will complain of a feeling of congestion of the maxillary sinuses.In order to address this, a combination of nasal decongestant and cortisone nose drops is advised.

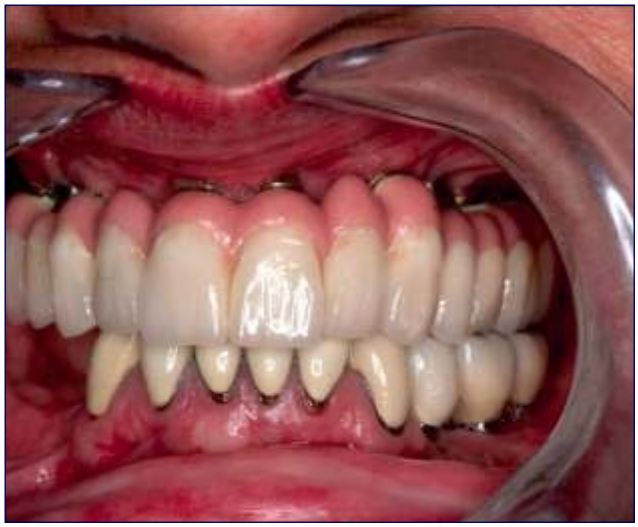
Patients may also complain of paraesthesia or anaesthesia in the distribution of the infraorbital nerve. This is transient and is due to stretching of the nerves during the operative procedure. These patients should therefore be counseled accordingly.

Modifications to the existing prosthesis will be necessary so that it can be worn during the integration phase. This should be carried out by the Prosthodontist or restorative Dentist.

Second Stage Surgery

It is common for these implants to be loaded immediately (same day or within a week of placement). However the well documented and conservative protocol, is exposure of implants performed 4 to 6 months after placement. This procedure may be carried out either under local or under general anaesthesia. It is recommended that impressions be taken at the time of implant exposure so that they can be splinted at the earliest opportunity. This is absolutely crucial in cases where bone grafting procedures have been performed. The surgical phase comprises exposure of the cover screws by means of a crestal incision and their replacement with temporary healing abutments. Suturing is then carried out according to the surgeons preference.

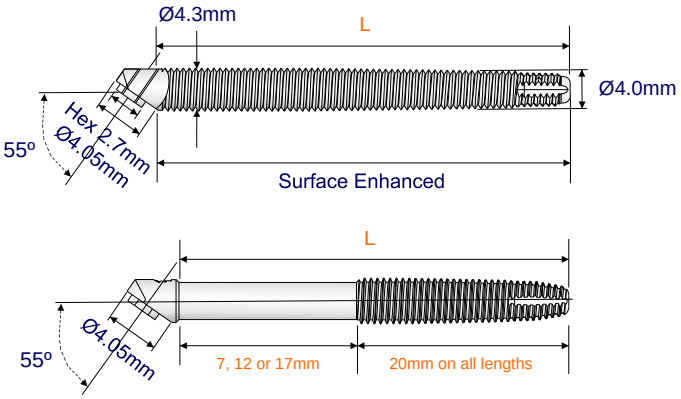




Non-integration of Implant

Should this occur, the implant should be removed. This is achieved by connecting a fixture mount and removing the implant by means of the onion driver. If any soft tissue is present in the implant site, this must be curetted out. In the unlikely event of the fracture of an implant, the coronal part is removed and the rest is left in site. Implants which have been removed due to non-integration may be replaced after a healing period of one year.

55° Zygomatic & Oncology Implants



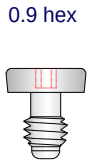
Zygomatic Implants are available in lengths:

35mm	**code: ZYG-55-35**
37.5mm	**code: ZYG-55-37.5**
40mm	**code: ZYG-55-40**
42.5mm	**code: ZYG-55-42.5**
45mm	**code: ZYG-55-45**
47.5mm	**code: ZYG-55-47.5**
50mm	**code: ZYG-55-50**
52.5mm	**code: ZYG-55-52.5**

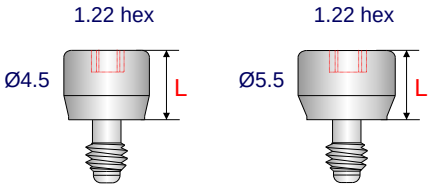
Oncology Implants are available in lengths:

27mm	**code: ONC-55-27**
32mm	**code: ONC-55-32**
37mm	**code: ONC-55-37**

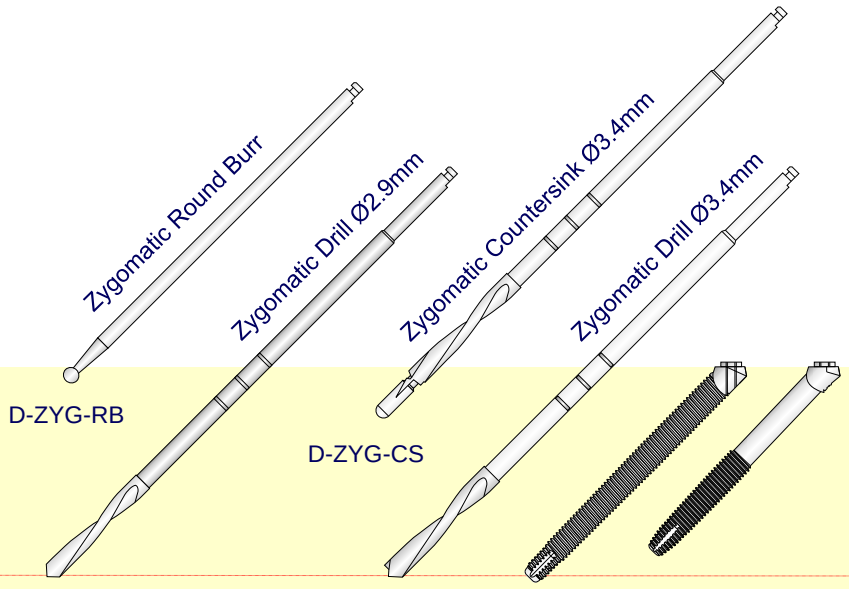
SCU2 Cover Screw



TB & WB Healing Abutments



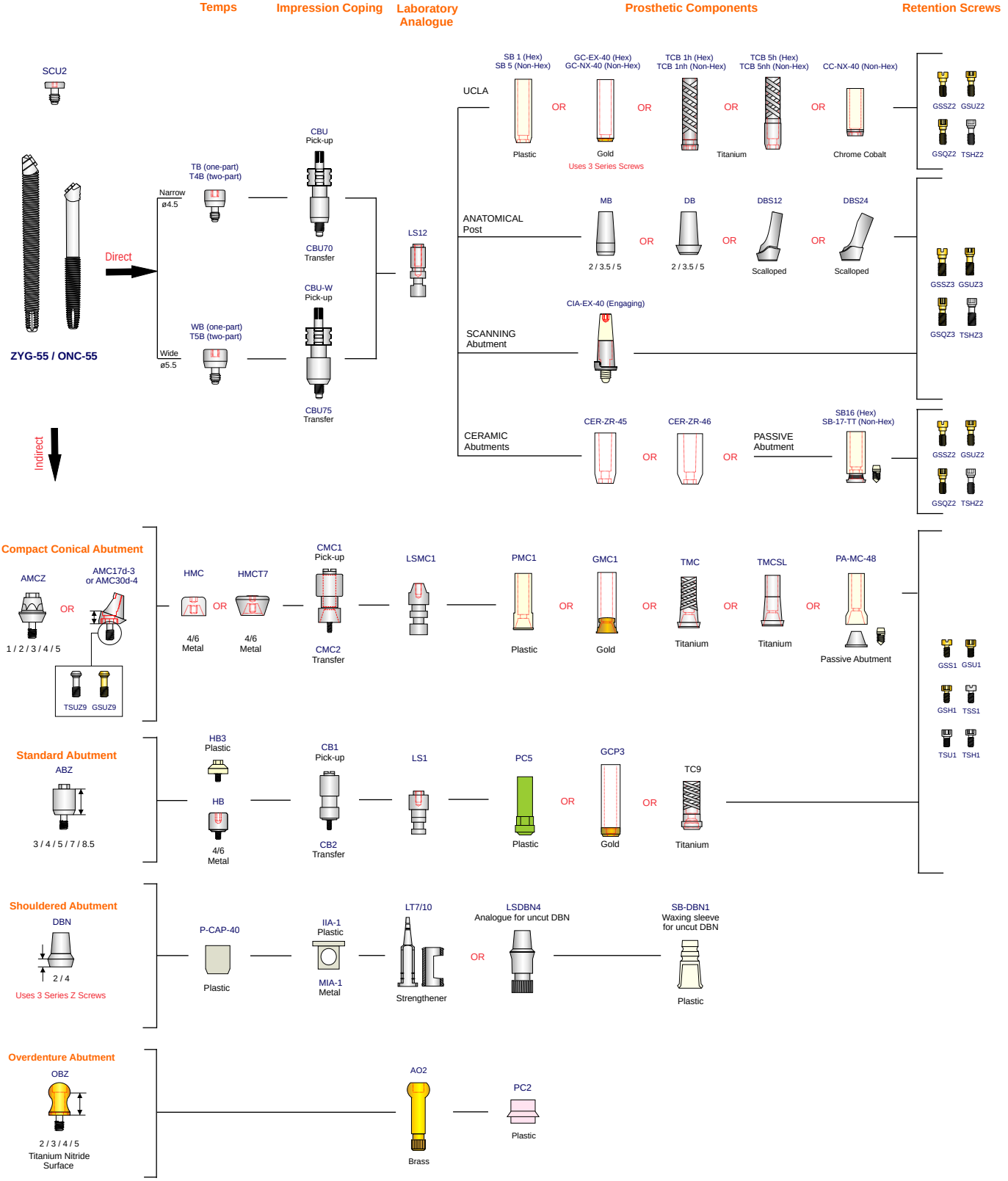
Zygomatic Drilling Sequence



DRILLING SEQUENCE:
Step1: Pilot Drill to full depth of implant
2: Countersink
3: Diameter 3.4mm Drill to full depth
4: Place Implant

Please note: Due to the nature of the long drills, a special surgical insert and 32:1 reduction handpiece is necessary for the placement of these implants.

Prosthetic Options: Zygomatic & Oncology Platform



A Protocol For Maxillary Reconstruction Following Gunshot And Oncology Resection

Howes, Dale G.*[1]; Boyes - Varley, John G.*[2]; Davidge - Pitts, Keith J*[3].; Brånemark, P- I*[4].; McAlpine, Alistair I*[5]

INTRODUCTION:

Tumour ablative surgery (Figs 1—2) and (gunshot) trauma (Figs 3—4) to the mid facial and maxillary complex involves structures integral to phonetics, deglutition and mastication which makes reconstruction both difficult and controversial. The surgery is complex and involves sealing of the oral cavity from the nasal cavity, re-establishment of the paranasal sinuses and restoration of the facial contour[1]. Apart from the psychological issues related to this surgery, the morbidity and quality of life compromise, the dental rehabilitation is also a massive functional and aesthetic consideration that should be considered when planning the proposed reconstruction[2].

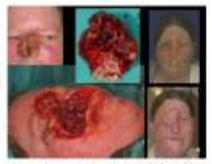


Fig 1: Nasal Squamous Cell CA

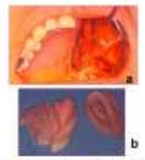


Fig 2: Maxillectomy Defect (a) & silicone obturator (b)

Several methods have been proposed for post surgical reconstruction[3] depending on the extent of the resultant bony and soft tissue defect. Effective obturation requires a working relationship between the surgical and prosthetic teams. The prosthetic design has evolved over decades[4] and now the advent of osseointegration has revolutionised facial reconstruction in these cases. This technology can mostly circumvent the need for vascularised osseomyocutaneous grafts or these grafts in combination with non vascularised free bone grafts. This enables the surgeon being able to inspect the resection cavity for recurrent disease. Some consider the visual inspection for recurrences may be superceded by interval radiographic assessment with the use of CT, MRI and PET scans. These investigations are costly and often unavailable to patients with recurrent disease, especially in a compromised health care system.

Fig 3: Gunshot Right maxilla

Fig 3: Gunshot anterior maxilla

They also cannot replace the accuracy of further biopsy and microscopic analysis prevented by flap surgery designed to obturate these defects.

This paper offers a protocol for surgical and prosthetic reconstruction, optimising a cost effective and predictable treatment outcome minimizing surgical reconstructive intervention and prosthetic complications.

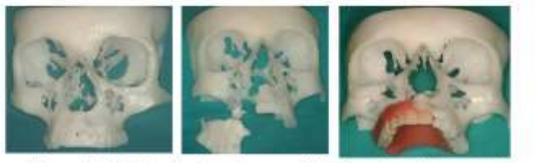
Materials and Methods

5 facial gunshot wounds and 20 maxillary oncology resections were rehabilitated over an 8 year period, using various applications of the Zygomatic implant concept. Patients were reconstructed prosthodontically using fixed-removable over dentures or fixed prostheses, with and without separate obturators. Evaluation quality of life complications and surgical and restorative visits was undertaken.

Reconstructive Protocol:

Reconstruction and implant placement for Oncology patients is planned at time of resection, while Gunshot patient reconstruction is undertaken after primary stabilization and healing:

Phase 1: Diagnosis and Planning
- Radiographic Views - Panoramic, Lateral cephalometric, Occipito-mental
- Surgical - Examination, Biopsy, Model Surgery
- Prosthodontic
  - Photography, Gnathostatic Models, Special trays
  - Stereolithography
- Psychological - Psychologist, Patient Support Group



Stereolithographic Model; Simulated surgery & Confirmation of obturator design

Reconstructive Protocol (Contd):

Phase 2:
- Tumour resection,
- Immediate implant placement
- primary Sectional Impression
- Temporary obturation.

Weber Furgusson Incision

Zygomatic Oncology Implants Placed

Post Operative Occipito—mental radiograph showing placement of implants and Prosthesis.

Zygomatic Oncology Implant. (Southern Implants Irene; South Africa)

Phase 3:
- Prosthodontic
- Laboratory planning

Phase 4: Wound evaluation and definitive impression
- Cofirmation of restorative Plan
- Jaw relation Record
- Splinting of Fixtures
- Definitive Impression

Phase 5: Prosthodontic Planning, Laboratory Fabrication of definitive super-structure and interim obturator

Phase 6:
- Wound inspection
- placement of definitive super-structure
- Placement of interim obturator
- Post-op evaluation of leakage and speech - using sinoscopy

Fixed Prosthesis placed

Removable Obturator

Obturator Placed

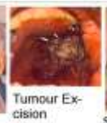
Post Operative panelipse

Phases 7 & 8: Definitive Obturation and Maintenance:

The temporary obturator is replaced after adequate healing and wound changes have stabilised, particularly with those patients who have undergone radiation therapy.

Strict professional and home care maintenance programmes are instituted.

Pre Op



Tumour Excision

Superstructure in situ

Definitive Obturator

5 yr Post Op

Protocol Evaluation:

20 Oncology Resections:
- 11 Squamous Cell Carcinoma (M=6/F=5)
- 1 Mucoepidermoid Carcinoma (F=1)
- 1 Ameloblastoma (M=1)
- 1 Chondrosarcoma (M=1)
- 1 Basal Cell Carcinoma (F=1)
- 2 Adenoid Cystic Carcinoma (M=1/F=1)
- 1 Infection (Actinomycosis) (F=1)
- 1 Odontogenic Keratocyst (M=1)
- 1 Osteoblastic Chondrosarcoma (M=1)

Table 1:

Loading Period	Zygomatic Implants (Gunshots in Brackets)		Conventional Implants (Gunshots in Brackets)		Total (Combined Zygomatic & Conventional Implants)	
	Implants	Patients	Implants	Patients	Implants	Patients
0-12 Months	15 (0)	6 (0)	19 (0)	6 (0)	34 (0)	6 (0)
13-36 Months	8 (4)	4 (2)	10 (6)	3 (2)	18 (10)	4 (2)
37-60 Months	10 (0)	5 (0)	29 (10)	7 (0)	39 (0)	7 (0)
61-96 Months	7 (3)	2 (3)	8 (0)	3 (3)	15 (13)	3 (3)
Total	**40 (7)**	**20 (5)**	**66 (16)**	**19 (5)**	**106 (23)**	**20 (5)**

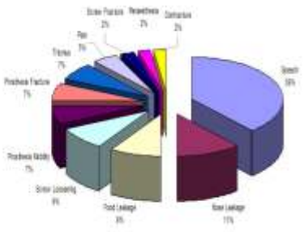
5 Gunshot Victims:
- 3 Hijack Victims (M/F =1/2) (Zimbabwe; Nigeria;RSA)
- 1 Defence Force (M) (Congo)
- 1 Self Inflicted (Failed Suicide) (M) (RSA)

These patients have been treated from 1997 to 2006, with 18 of the cases being rehabilitated with a fixed-removable prosthesis and two with fixed prostheses. The age of the patients ranged from 12 to 82 (mean age=56) 14 were male, 6 were female. The longest loading period is 8 years. A total of 129 implants have been placed (Table 1). All patients in this series were reconstructed with a combination of zygomatic and standard implants and either a fixed or fixed-removable prosthesis. ***Implant Survival:*** 3 extraoral implants placed into the outer table of the frontal sinus were lost in 1 *radiated* patient. No other mplants were lost. This represents a 96% conventional implant success and 100% Zygomatic Implant success using these protocols. ***Patient Mortality:*** Three of the twenty oncology patients (15%) died due to recurrent malignant disease during the first five years after surgical excision (2 patients with squamous cell carcinoma and 1 paediatric muco epidermoid carcinoma). All 3 patients had positive neck nodes and underwent subsequent radiation after surgery. One patient died due to a pulmonary embolus at home after discharge. No deaths were recorded in the gunshot sample. ***Radiation:*** Five patients underwent post resection radiation. These patients exhibited positive margins close to the resection margin and all underwent neck dissection.

Restorative Results and Complications:

Despite the loss of 3 standard implants, all initially placed superstructures were retained, one superstructure sectioned to accommodate fixture loss. Additional appointments for the management of complications were recorded. 44 such post-operative prosthetic "complication" visits were recorded. (Adjacent Table and figure). The majority of these complaints were to manage air, fluid and food escape around the prosthesis during speech and mastication. (59.1%)

Complications	Percentage Complications
Speech	38.6
Nose Leakage	11.4
Food Leakage	9.1
Screw Loosening	9.1
Prosthesis Mobility	6.8
Prosthesis Fracture	6.8
Trismus	6.8
Pain	4.5
Screw Fracture	2.3
Paraesthesia	2.3
Contracture	2.3



CONCLUSIONS

The protocols presented here for the treatment of maxillary defects after tumour ablation, can be integrated into the armamentarium for the rehabilitation of the maxilla and facial region. This provides the patient with an opportunity to undergo primary reconstruction in a more cost effective manner whilst still optimising function and aesthetics which also allows for regular and effective maintenance.

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2. Okay DJ, Genden E, Buchbinder D, Urken M: Prosthodontic guidelines for surgical reconstruction of the maxilla; a classification system of defects. J Prosthet Dent 86:352-363, 2001

3. Brown JS, Jones DC, Summerwill A, Rogers SN, Howell RA, Cawood JL, Vaughn ED: Vascularized iliac crest graft with internal oblique muscle for immediate reconstruction after maxillectomy. Br J Oral Maxillofac Surg 40: 183-190, 2002

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*[3] Morningside Mediclinic; Johannesburg; South Africa
*[4] Bauru; Brazil
*[1]; [2]P- I Brånemark Institute; South Africa

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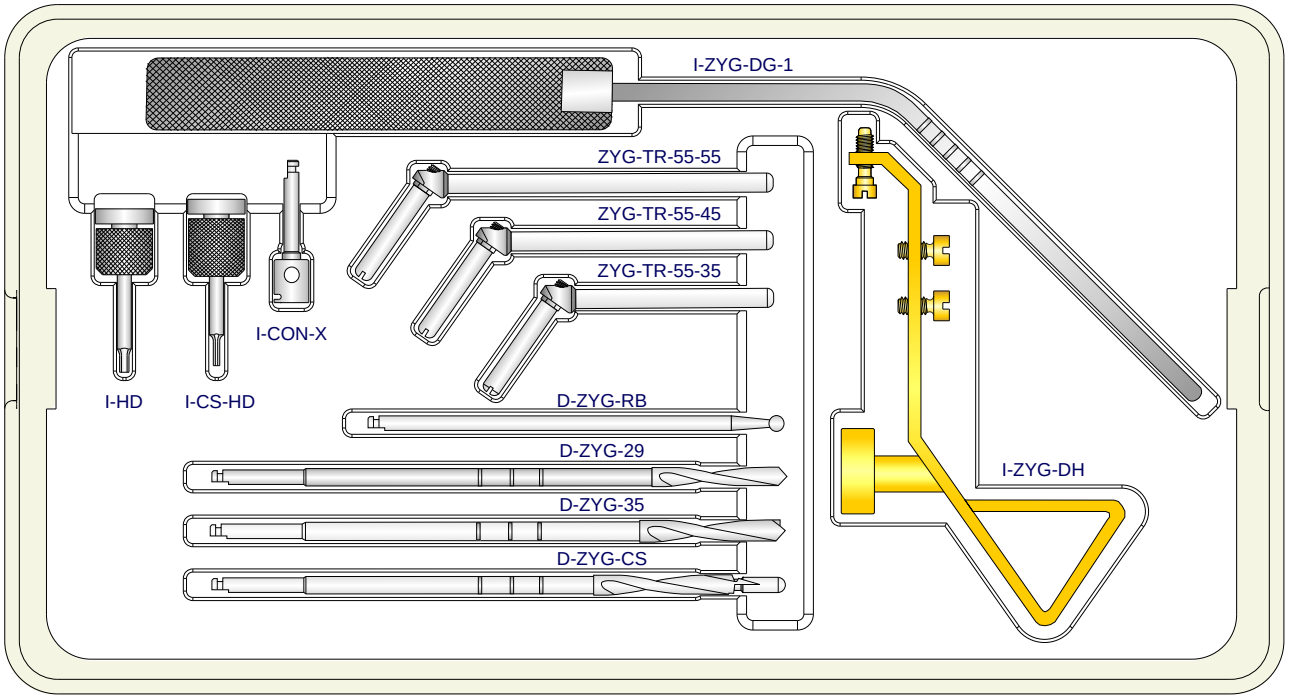
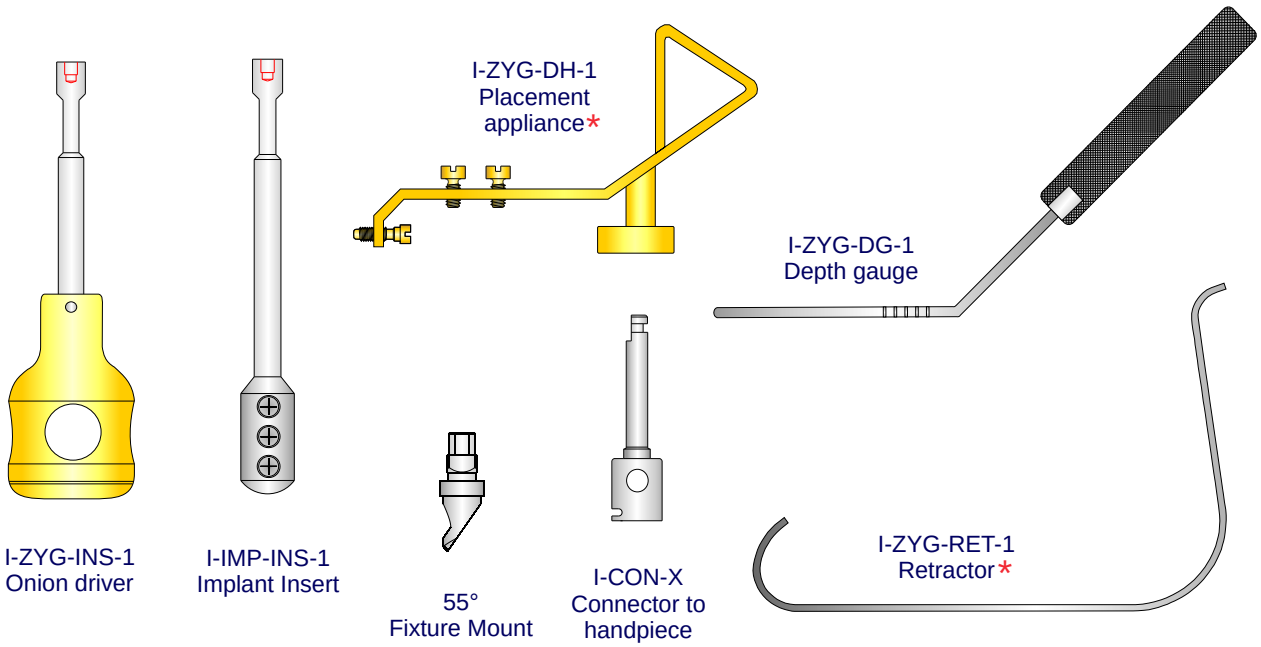
I-ZYG Zygomatic Tray



Zygomatic Instruments



* Additional Instruments: These are optional extras to assist with placement and can be manufactured on request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Annex II, Section 3 of the Directive 93/42/EEC

Complimentary Manuals & Instructions:

Externally Hexed Product Catalogue	CAT-2020
Tri-Nex Product Catalogue	CAT-2004
IT Product Catalogue	CAT-2005
Patient Information Brochure	CAT-2022
Patient Homecare Brochure	CAT-2023
Overdenture Information Brochure	CAT-2032
Zygomatic Information Brochure	CAT-2025
Instrument Catalogue	CAT-2006
Prosthetic & Laboratory Manual	CAT-2001
TMJ Prosthesis Catalogue	CAT-2018
Passive Abutments	CAT-1008
One Piece Implants	CAT-1083
Finger Implants Catalogue	CAT-2010
First & Secondary Stage Surgery Manual	CAT-2024
Instructions for use	PRO-6038

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The following symbols are used on our packaging labels and they indicate the following:

1: **“Use by”**

2: **“Batch code”** LOT

3: **“Do not reuse”**

4: **“Sterilization using Irradiation”** STERILE R

5: **“Caution”**

6: **“Consult instruction for use”**

7: **CE mark** CE


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