straumann

BASIC INFORMATION

Straumann® Zygomatic Implant System

Technical Information

ABOUT THIS GUIDE

This surgical and prosthetic procedure describes the steps required for implantation and restoration of the Straumann® Zygomatic Implant System. The Straumann® Zygomatic Implant System is recommended for use only by clinicians with advanced surgical skills. It is assumed that the user is familiar with placing Zygomatic implants. Not all detailed information will be found in this guide.
Reference to existing Straumann procedure manuals will be made throughout this document.

NOTE:

Not all products shown are available in all markets.

CONTENTS

1. THE STRAUMANN® ZYGOMATIC IMPLANT SYSTEM

The Straumann® Zygomatic Implant System is composed of a wide range of implants, the related prosthetic components, instruments and accessories.

The Straumann® Zygomatic Implants are available in two different designs:

Straumann® Zygomatic Implant, ZAGA™ Flat

Straumann® Zygomatic Implant, ZAGA™ Round

They are designed to provide immediate support for a fixed overdenture in edentulous and partially edentulous patients suffering from severe atrophy of the maxilla. Straumann® Zygomatic Implants are extra-long to enable bone anchorage in the Zygomatic bone and have a 55° head angle. They are made from biocompatible, commercially pure, UFG (ultrafine-grained) grade 4 titanium (ASTM F67 and ISO 5832-2, UTS ≥ 900MPa) and are available in a wide range of lengths, from 30 to 60 mm to address the variety of patient anatomies and bone deficits. The distal threaded region of the implants has a roughened surface for bone anchorage, while the mesial surface and the apex have a smooth machined surface. The implants are supplied pre-mounted on a fixture mount. Straumann® Zygomatic Implants are appropriate for immediate loading when sufficient primary stability is achieved and with appropriate occlusal loading.

When a traditional Zygomatic procedure is performed (one Zygomatic implant placed in each Zygomatic bone), Straumann® Zygomatic Implants are usually used in the maxilla in conjunction with at least two regular implants suitable for immediate loading (such as Straumann® BLX).

Bilateral Zygomatic procedure with four regular implants

To obtain additional information on indications and contraindications related to Straumann® Zygomatic Implants, please refer to the corresponding instructions for use at: www.southernimplants.com/IFU.

1.1 PORTFOLIO OVERVIEW

Straumann® Zygomatic Implant System product range

Straumann® Zygomatic Implants, ZAGA™ Flat	Straumann® Zygomatic Implants, ZAGA™ Round
	

Implant length (mm)

	30	32.5	35	37.5	40	42.5	45	47.5	50	52.5	55	57.5	60
ZAGA™ Round	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
ZAGA™ Flat	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Surgical components

				
Needle Drill	Round Burr for Zygomatic	Multi-use Twist Drills for Zygomatic (silver)*	Twist Drill, Disposable	Side-cut Burr
026.0054	D-ZYG-RB	D-ZYG-CH-29 D-ZYG-CH-29S D-ZYG-CH-27 D-ZYG-CH-27S	D-35T-M15	CH-D-CM

* Single-use Twist Drills for Zygomatic are available (Ø 2.9 mm D-ZYG-29, D-ZYG-29S and Ø 2.7 mm D-ZYG-27, D-ZY-27S).
All other drills can be used multiple times, recommended to a maximum of 10 times, or upon surgeon's criteria.

Prosthetic components

							
Screw-retained Abutments for Zygomatic Implants	Protective caps	Copings	Burn-out copings	Impression components and analogs	Lab auxiliaries	Replacement Screw	Cover Screw for Zygomatic Implants
CH-SRA-1.5 CH-SRA-2.5 CH-SRA-3.5 CH-SRA-4.5	024.4323-04 024.4324-04 024.4325-04 024.0020-04	024.0024 023.4754 023.0028 023.4752 023.4755	023.4758 023.0032	025.0050 025.0012 025.0014 025.0001 025.0008	025.0005 025.0006 025.0052	023.4763	CH-CS

1.2 INDICATIONS FOR USE

Straumann® Zygomatic Implants are intended to be implanted in the upper jaw arch to provide support for fixed dental prostheses in patients with partially or fully edentulous maxillae. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading. This implant system is not intended, nor should it be used in conjunction with an angled abutment. These implants are not intended for single unit loading.

1.2.1 Contraindications

Do not use in patients:

- who are medically unfit for oral surgical procedures;
- who are allergic or have hypersensitivity to pure titanium or titanium alloy (Ti-6Al-4V), gold, palladium, platinum or iridium;
- with inadequate bone volume or quality for Zygomatic or conventional implants;
- where adequate numbers of implants can not be placed to achieve full functional support for a prosthesis;
- who have undergone irradiation of maxillary bone;
- who are under the age of 18, have poor bone quality, blood disorders, infected implant site, vascular impairment, uncontrolled diabetes, drug or alcohol abuse, chronic high dose steroid therapy, anti-coagulant therapy, metabolic bone disease, radiotherapy treatment and sinus pathology.

1.2.2 Cautions

For the safe and effective use of dental implants it is strongly recommended that specialized training be undertaken, including hands-on training to learn proper technique, biomechanical requirements and radiographic evaluations.

Products must be secured against aspiration when handled intraorally. Aspiration of products may lead to infection or physical injury.

Responsibility for proper patient selection, adequate training, experience in the placement of implants, and providing appropriate information for informed consent rests with the practitioner. Improper technique can result in implant failure, damage to nerves/vessels and/or loss of supporting bone.

Implant failure increases when implants are placed in irradiated bone as radiotherapy can result in progressive fibrosis of vessels and soft tissue, leading to diminished healing capacity. Additionally, use of Zygomatic Implants in bone tissue which has been irradiated as part of cancer therapy may result in the following:

- Delayed or failed osseointegration of implants due to reduced bone vascularity, clinically expressed as osteoradionecrosis
- Tissue dehiscence and osteoradionecrosis
- Implant failure and loss
- Implant treatment of irradiated patients is dependent upon issues such as timing in relation to radiation therapy, anatomic site chosen for implant placement and radiation dosage at that site and consequent risk of osteoradionecrosis.

New and experienced implant users should undergo training before using a new system or attempting a new treatment method.

Take special care when treating patients who have local or systemic factors that could affect the healing of the bone and soft tissue (i.e. poor oral hygiene, uncontrolled diabetes, steroid therapy, smokers, infection in the nearby bone and patients who have undergone orofacial radiotherapy).

Thorough screening of prospective implant candidates must be performed including:
- A comprehensive medical and dental history.
- Visual and radiological examination to determine adequate bone dimensions, anatomical landmarks, occlusal conditions, periodontal status, and adequacy of bone.

Bruxism and unfavorable jaw relations must be taken into account.

Proper pre-operative planning with a well organized team approach involving well-trained surgeons, restorative dentists and lab technicians is essential for successful implant treatment.

Minimizing the trauma to the host tissue increases the potential for successful osseointegration.

Electro-surgery should not be attempted around metal implants, as they are conductive.

1.2.3 Precaution to maintain the sterility of the implant

1. Care must be taken to maintain the sterility of the implant by following the correct procedure when opening the packaging and handling the implant.
2. The outer cardboard box and the outside of the inner plastic tray-lid are not sterile; do not touch the outside with sterile gloves, and do not place the box or inner plastic tray-lid in the sterile field.
3. The packaging for the implant contains a stainless-steel clip that supports the implant and fixture mount, keeping the implant from contact with the container.
4. Inside the box, the sealed inner plastic tray-lid is sterile only on the **inside**. The sealed tray-lid is to be opened by an assistant (with nonsterile gloves): remove the lid and do not touch the sterile implant.
5. Maintain the sterility of the implant, after opening the tray and removing the implant, until placement in the surgical site.

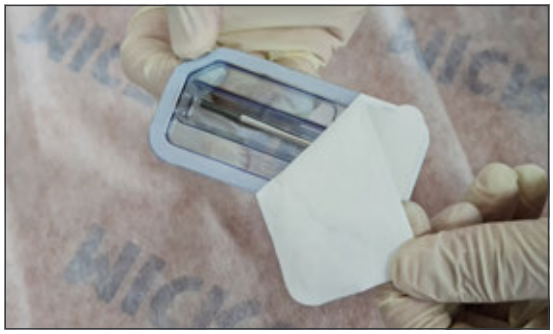
1.2.4 Recommendations for implant preparation for insertion:

1. Place the implant package in the non-sterile field.

2. With non-sterile gloves open the outer box by breaking the protective seal.

3. Remove the inner plastic tray.

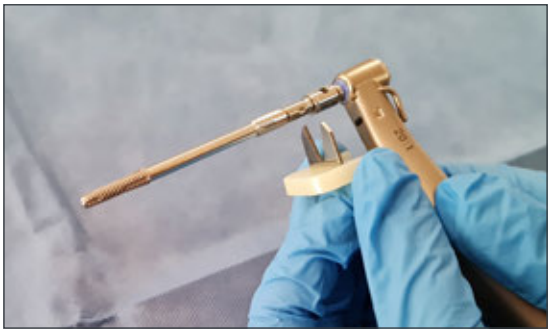
4. Peel the Tyvek seal back from the plastic tray.



5. The assistant presents the open tray to the surgeon. Without touching the outside of the tray, the surgeon removes the implant holder with sterile gloves.

6. The surgeon engages the Connector to Handpiece (I-CON-X) onto the fixture mount.

7. Using an upward force, the implant is removed from the carrier.



8. A visual control confirms that the implant is now ready for placement.

1.2.5 During surgery

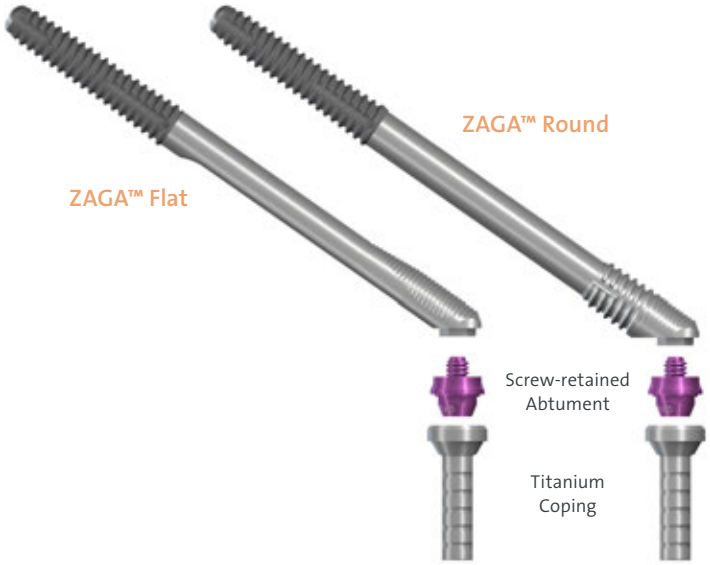
Care must be taken that parts are not swallowed or aspirated during any of the procedures; thus rubber-dam application is recommended when appropriate.
Care must be taken to apply the correct tightening torque to prosthetic components.

1.2.6 Post-surgery

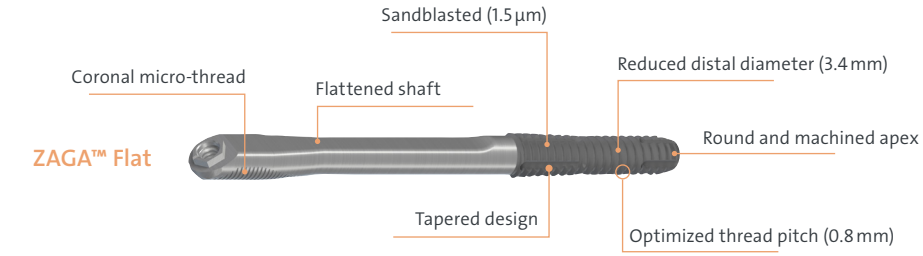
Regular patient follow-up and proper oral hygiene are essential for favorable long-term results.

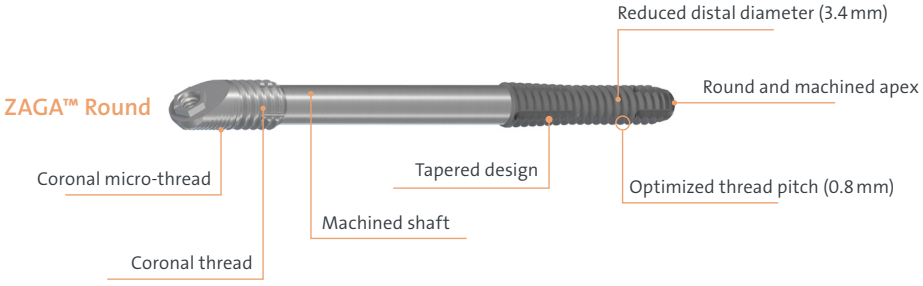
1.3 STRAUMANN® ZYGOMATIC IMPLANT SYSTEM AT A GLANCE

Straumann® Zygomatic Implants have unique designs and a straight forward prosthetic concept that provide versatile treatment options. This helps clinicians to tailor the solution to patients with various anatomy types and bone deficits.



Straumann® Zygomatic Implants are designed with a unique combination of features for anatomical structures.

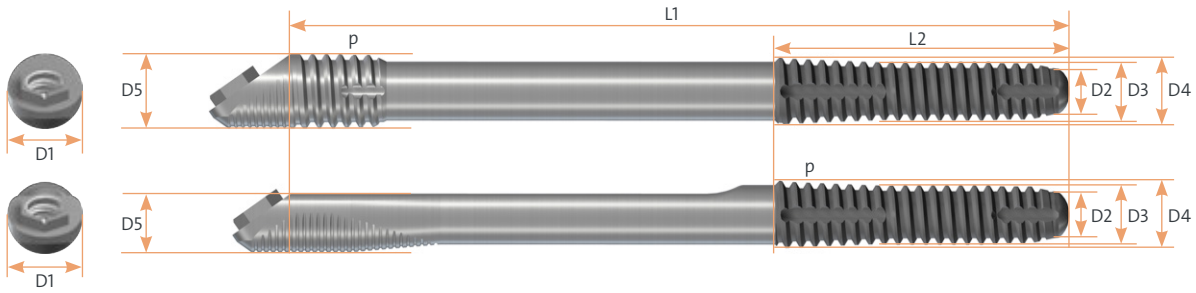




1.4 DIMENSIONS AND RANGE

1.4.1 Implants

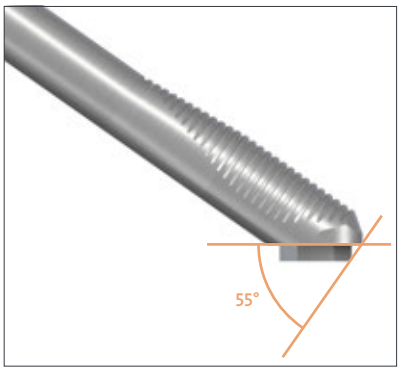
Straumann® Zygomatic Implant ZAGA™ Round and ZAGA™ Flat are available in a variety of lengths.



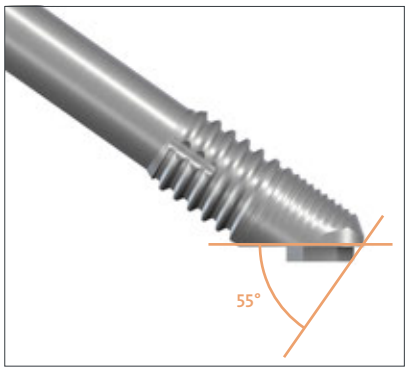
	Coronal Ø (D1)	Apical Ø (D2)	Distal Ø (D3)	Distal Ø (D4)	Distal Ø (D5)	Thread length (L2)	Thread pitch (p)	Implant length (L1) (mm)												
								30	32.5	35	37.5	40	42.5	45	47.5	50	52.5	55	57.5	60
ZAGA™ Round	4.3	2.6	3.4	3.9	4.3	17	0.8	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
ZAGA™ Flat					3.35			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Straumann® Zygomatic Implant ZAGA™ Round and ZAGA™ Flat implant dimensions and range.

Straumann® Zygomatic Implant, ZAGA™ Flat



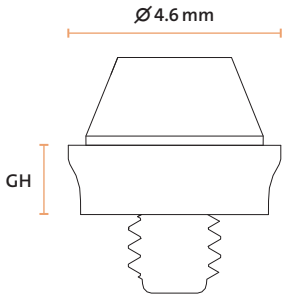
Straumann® Zygomatic Implant, ZAGA™ Round



Straumann® Zygomatic Implant ZAGA™ Flat and Round have a 55° platform

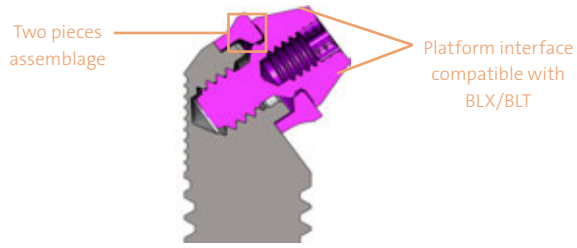
1.4.2 Screw-retained Abutments

Straumann® Screw-retained Abutments for Straumann® Zygomatic Implants (CH-SRA-1.5, CH-SRA-2.5, CH-SRA-3.5 or CH-SRA-4.5) are straight and have been developed to ensure compatibility with Straumann® Bone Level prosthetics for fixed overdenture (for a complete list, see chapter 5 – Product reference list). These abutments are available in different gingival heights.



GH = gingiva height
Ø = diameter

Gingiva height (mm)



The Screw-Retained Abument consist of assemblage of two-pieces, which should not be disassembled.

The platform interface design of the Screw-Retained Abutment ensures compatibility with the Straumann BLX and BLT Implant systems prosthetic portfolio.

1.5	2.5	3.5	4.5
✓	✓	✓	✓

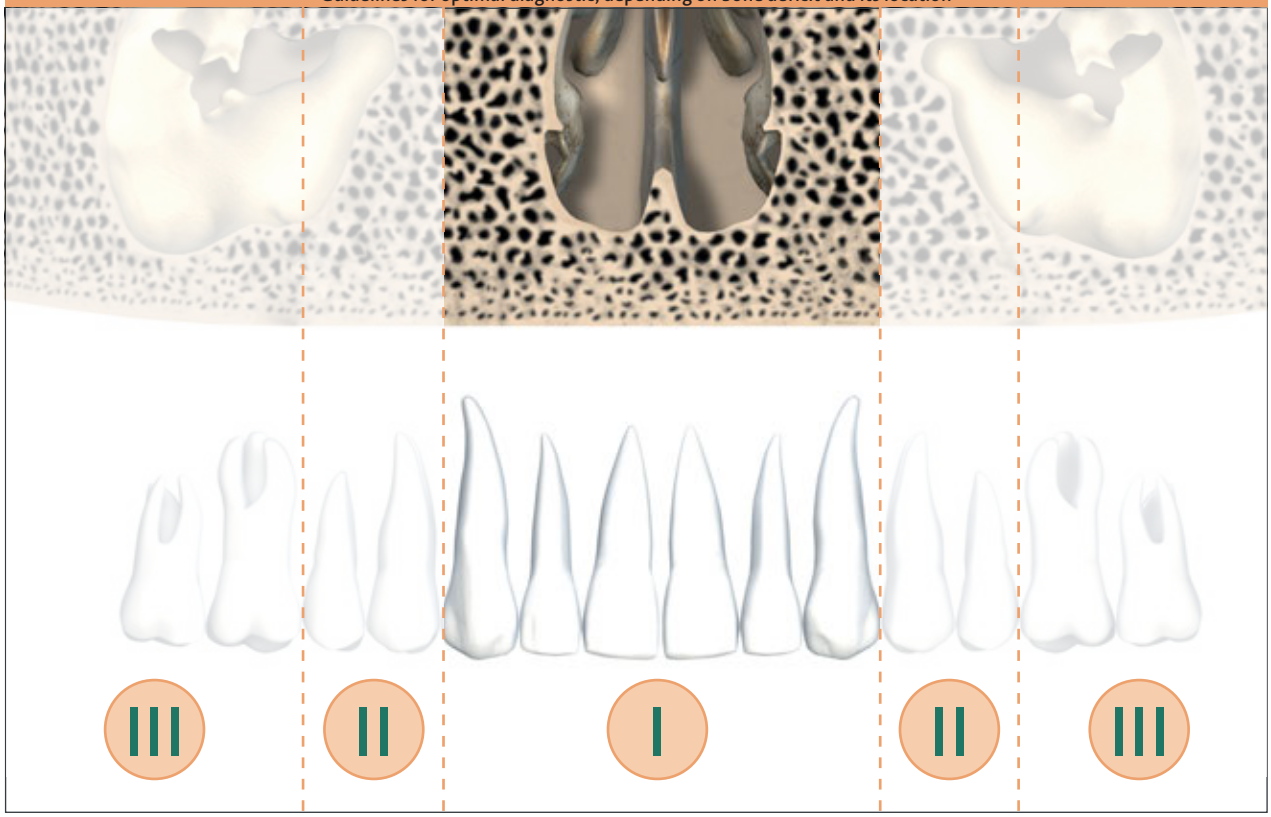
All dimensions are in mm

Straumann® Zygomatic Implant ZAGA™ Round with Screw-retained Abutment for Zygomatic Implants mounted

2. ANATOMICAL CONSIDERATIONS

2.1 CLASSIFICATION OF AN EDENTULOUS JAW (BEDROSSIAN ET AL. 2008)

Guidelines for optimal diagnostic, depending on bone deficit and its location



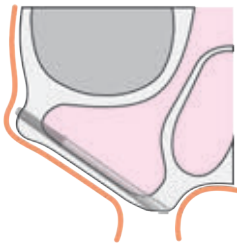
Guidelines for optimal implant surgical approach	
Bone Present for Implants	**Posterior surgical approach**
Zone I, II, III	Traditional implants
Zone I, II	Inclined implants, posterior implants Traditional anterior implants
Zone I only	Zygomatic implants or sinus-inlay grafting followed by implants Traditional anterior implants
Insufficient bone in any zone	4 Zygomatic implants or Brånemark horseshoe graft followed by traditional implants

Bedrossian et al. Implant Restoration of Edentulous Maxilla. Oral Maxillofac Surg 2008.

2.2 ZAGA™ CLASSIFICATION

Currently, different protocols are used by various centers around the world to place Zygomatic implants. The classic technique for Zygomatic placement involved cutting a sinus window and placing the implant through the sinus. The sinus-slot technique and exteriorized technique have since been developed, with the implant placed through the sinus wall and outside the sinus wall respectively. It has been suggested that the choice of technique should consider the ridge crest concavity and sinus anatomy (Aparicio et al. 2012). The ZAGA™ approach classifies the anatomy into different types to determine the appropriate technique for Zygomatic placement (Aparicio et al. 2022).

Anatomically, patients vary with regard to the concavity of the lateral wall of the sinus and the zygoma in relation to the ridge crest. Classification of Zygomatic implants according to Aparicio presents the five different types based on the concavity of the maxillary wall. In each type, the implant is placed at the crest inferiorly and at the zygoma superiorly. A portion of the body of the implant may not be encased in the maxillary wall, meaning that, in some clinical situations it lies on the exterior of the lateral wall of the sinus.

ZAGA™ type 0	ZAGA™ type I	ZAGA™ type II	ZAGA™ type III	ZAGA™ type IV
				
The anterior maxillary wall is very flat. The implant head is located on the alveolar crest. The implant body has an intrasinus path. The implant comes in contact with the bone at the alveolar crest and zygoma, and sometimes at the internal side of the sinus wall.	The anterior maxillary wall is slightly concave. The implant head is located on the alveolar crest. The drill has performed the osteotomy slightly through the wall. Most of the implant body has an intrasinus path. The implant comes in contact with the bone at the alveolar crest, lateral sinus wall, and Zygomatic bone.	The anterior maxillary wall is concave. The implant head is located on the alveolar crest. The drill has performed the osteotomy through the wall. The implant can be seen through the wall and most of the body has an extrasinus path. The implant comes in contact with the bone at the alveolar crest, lateral sinus wall, and Zygomatic bone.	The anterior maxillary wall is very concave. The implant head is located on the alveolar crest. Most of the body has an anterior extrasinus path. The middle part of the implant body is not touching the most concave part of the wall. The implant contacts the bone in the coronal alveolar and apical Zygomatic bone.	The maxilla and alveolar bone show extreme vertical and horizontal atrophy. The implant head is located buccally of the alveolar crest. The drill has arrived at the apical Zygomatic entrance following a path outside the sinus wall.

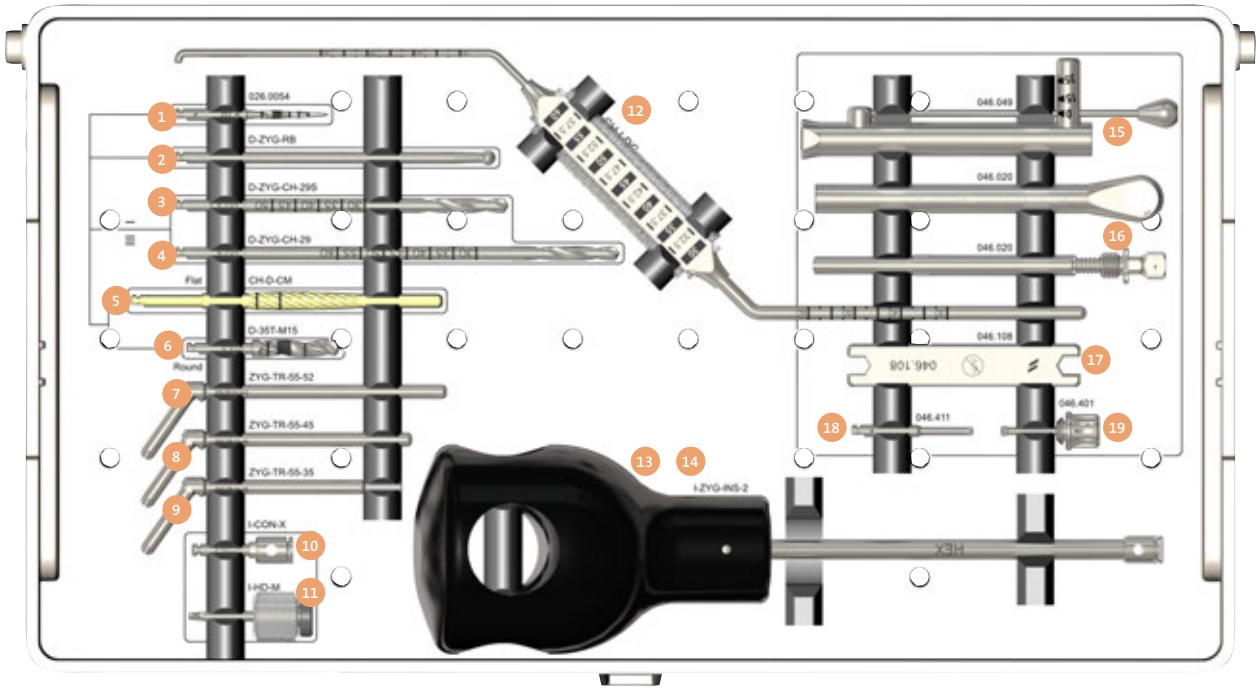
3. SURGICAL PROCEDURE

The workflow for the surgical procedure for the Straumann® Zygomatic Implant System involves three steps:

- Preoperative planning, common to both ZAGA™ Round and ZAGA™ Flat versions
- Implant osteotomy preparation
- Implant insertion.

3.1 INSTRUMENTS

Straumann® Zygomatic Surgical Tray has been designed to provide surgeons with all necessary instruments for the placement of Straumann® Zygomatic Implant, ZAGA™ Flat and Straumann® Zygomatic Implant, ZAGA™ Round Implants.



No.	Image	Article	Art. No.
1		Needle Drill, short, Ø1.6 mm, L 33 mm, stainless steel	026.0054
2		Round Burr for Zygomatic, Ø2.9 mm	D-ZYG-RB
3		Multi-use Twist Drill for Zygomatic, Short, Ø2.9 mm	D-ZYG-CH-29S
4		Multi-use Twist Drill for Zygomatic, Ø2.9 mm	D-ZYG-CH-29
5		Instrument, Side-cut Burr, Ø2.8 - Ø3.9 mm	CH-D-CM
6		Twist Drill, Disposable, Ø3.5 x 15 mm	D-35T-M15
7		Instrument, Try-In Implant, Zygomatic 55° x 52.5 mm	ZYG-TR-55-52
8		Instrument, Try-In Implant, Zygomatic 55° x 45 mm	ZYG-TR-55-45
9		Instrument, Try-In Implant, Zygomatic 55° x 35 mm	ZYG-TR-55-35
10		Instrument, Connector to Handpiece	I-CON-X
11		Instrument, 1.22 mm Hex Driver, Medium	I-HD-M

No.	Image	Article	Art. No.
12		Instrument, Zygomatic Z Depth Gauge	CH-I-DG
13		Instrument, Zygomatic Implant Inserter, Hex	I-ZYG-INS-2
14		Small Implant Inserter: with a slimmer handle	I-IMP-INS-2
15		Torque Control Device for Ratchet, stainless steel	046.049
16		Ratchet, incl. Service Instrument	046.119
17		Service instrument for Ratchet, L 50 mm, stainless steel	046.108
18		SCS Screwdriver short, for handpiece adapter, length 26 mm, stainless steel	046.411
19		SCS Screwdriver, for Ratchet, short, L 21 mm, stainless steel	046.401

3.1.1 Drills

Straumann® Zygomatic Twist Drills are available in two different lengths:

- Short: for placement of implants up to 50 mm (ref. D-ZYG-CH-29S, D-ZYG-CH-27S)
- Long: for placement of longer implants (ref. D-ZYG-CH-29, D-ZYG-CH-27)

Multi-use variants are available in both lengths.

Multi-use drill

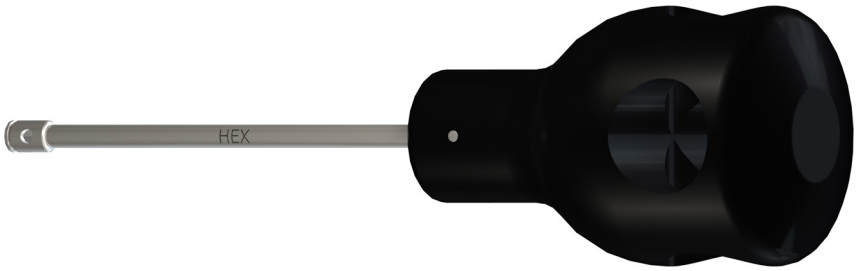
Straumann® Zygomatic Multi-use Twist Drills are for limited use. Bone quality affects wear on the drill. In case you feel excessive cutting resistance, the use of a new drill should be considered. Be aware that reusing drills may cause bone necrosis due to thermal injury. The recommended number of use of the multi-use drill is 10 times. The recommended drill speed, during their use described in the following pages, is 1000-1500 rpm.

3.1.2 Implant Inserter

The Implant Inserter is available in two versions:

- Standard: with a large handle (I-ZYG-INS-2)
- Optional: small with a slimmer handle (I-IMP-INS-2)

Zygomatic Implant Inserter (Standard)



Optional: Implant Inserter (Small)

3.2 PREOPERATIVE PLANNING

A full medical and dental history must be taken, with a focus on any soft and or hard tissue pathology. The patient must have clinically symptom-free sinuses and no lesion/defects in the surrounding bone or soft tissue. It is recommended that a CT scan and/or CBCT analysis be performed as part of the planning process in order to:

- detect any pathology in the maxillary sinuses,
- determine bone volume and condition,
- determine jaw relations.

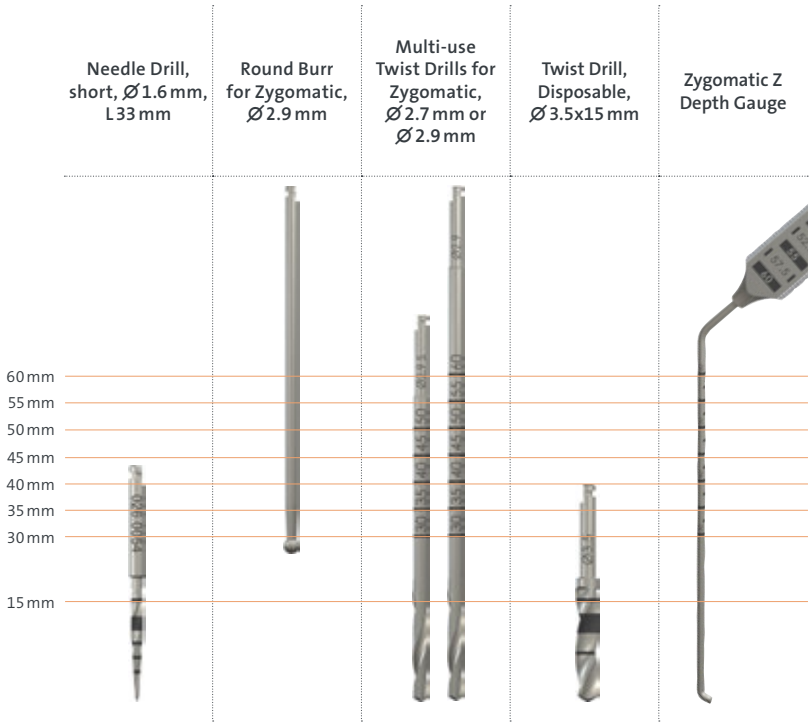
Zygomatic implants are recommended for the posterior (pre-molar/molar) region, with one Zygomatic implant on each side and at least two regular dental implants in the anterior region to support a fixed restoration. Alternatively, two Zygomatic implants can be placed on each side, without regular dental implants.

3.3 SURGICAL PROCEDURE FOR STRAUMANN® ZYGOMATIC IMPLANT ZAGA™ ROUND

The Straumann® Zygomatic Implant ZAGA™ Round has a circular section able to fit/seal an adequate osteotomy.

3.3.1 Drilling sequence overview

The Straumann® Zygomatic Drills have depth marks at 5 mm intervals. The multi-use drills are delivered sterile.

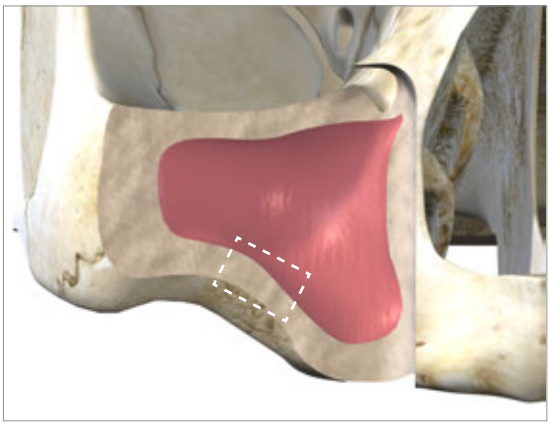


Needle Drill, short, Ø 1.6 mm, L 33 mm	Round Burr for Zygomatic, Ø 2.9 mm	Multi-use Twist Drills for Zygomatic, Ø 2.7 mm or Ø 2.9 mm	Twist Drill, Disposable, Ø 3.5x15 mm	Zygomatic Z Depth Gauge
026.0054	D-ZYG-RB	D-ZYG-CH-27 D-ZYG-CH-27S D-ZYG-CH-29 D-ZYG-CH-29S	D-35T-M15	CH-I-DG

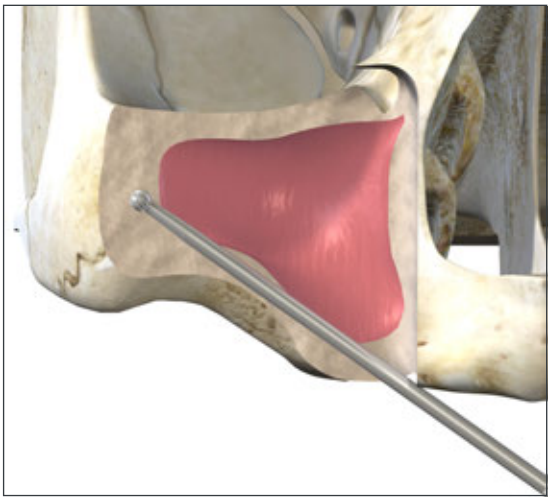
Note: Ø 2.7 mm and Ø 2.9 mm single use Twist drills, short and long, are available as spare part, upon surgeons preference (D-ZYG-27S, D-ZYG-27, D-ZYG-29S, D-ZYG-29)

3.3.2 Detailed surgical sequence

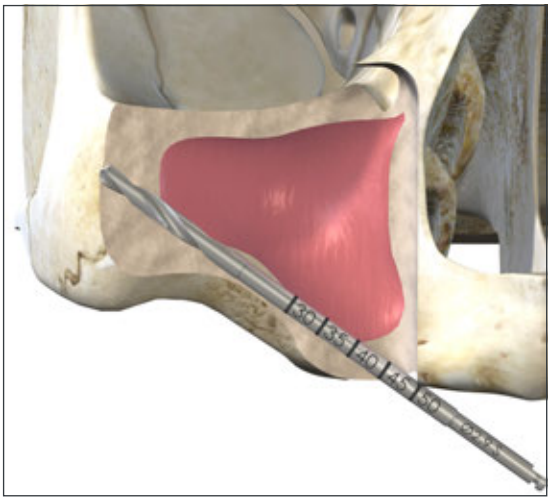
A crestal incision is made from anterior to the maxillary tuberosity on one side to the same point on the other side. Three vertical releasing incisions are made in the second molar region and the midline. These three incisions facilitate flap mobilization beyond the infraorbital margin. In unilateral cases a hemi-maxillary approach is used. 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 channel retractor is placed on the upper border of the Zygomatic arch.



A small sinus window is cut on the lateral aspect of the maxillary sinus and the block of the bone is removed. The lining of the sinus is reflected, attempting to keep it intact if possible. Thorough reflection of the lining is essential.

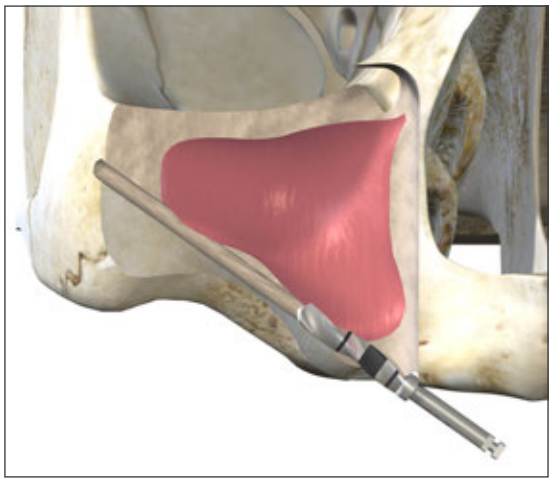


The entry point for the osteotomy is located in the first pre-molar-first molar region on the maxillary crest. The Round Burr (D-ZYG-RB) or the Needle Drill (026.0054) is used initially to prepare the implant entry point. Following the posterior maxillary wall, the Round Burr (D-ZYG-RB) continues to the cavity seen through the sinus window at a speed between 1000 and 1500 rpm and bore a shallow entry into the base of the zygoma bone, allowing for the stabilization of the ∅ 2.9 mm drill.

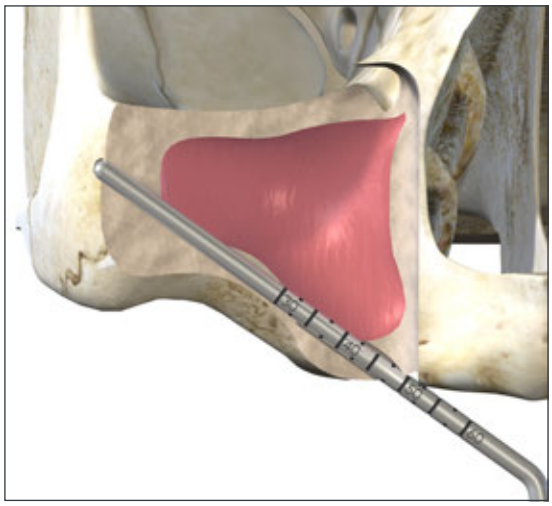


The Multi-use Twist Drill for Zygomatic ∅ 2.9 mm (D-ZYG-CH-29/ D-ZYG-CH-29S for multi-use drills) follows the path established by the Round Burr (D-ZYG-RB). The ∅ 2.9 mm drill is positively seated into the shallow osteotomy created by the Round Burr (D-ZYG-RB).

The drill travels through the zygoma bone at a speed between 1000 and 1500 rpm and exits its buccal cortical plate below the fronto-Zygomatic notch.
(A direct visualization of the apical portion of the drill through the lateral wall of the zygoma bone is beneficial to ensure the trajectory of the drill is not in the orbit.)



In cases of dense maxillary crestal bone, the ∅ 3.5 mm D-35T-M15 drill is used to enlarge the osteotomy at the alveolar ridge at a speed between 1000 and 1500 rpm.
Note: Do not use this drill in soft bone.



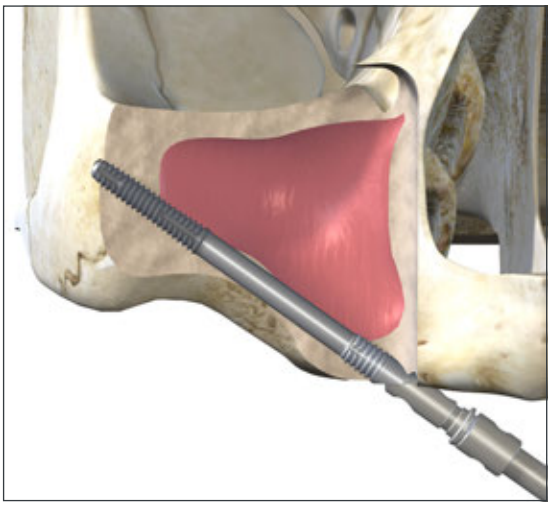
The depth of the prepared implant site is assessed with the Zygomatic Z Depth Gauge (CH-I-DG).

After the osteotomy is completed having its most apical part located in the external cortical bone aspect of the Zygomatic bone reaching a trans-cortical position just under the periosteum, the Zygomatic Z Depth Gauge (CH-I-DG) is inserted.
The apical end of the Zygomatic Z Depth Gauge (CH-I-DG) shall be positioned at the most apical point of the osteotomy, which should not pass the lateral cortex of the zygoma bone.

A positioning control is conducted by fingertip palpation through the skin. If a fingertip-palpation is not possible, use the hook-end of the Zygomatic Z Depth Gauge (CH-I-DG) to measure the correct length of the implant.

Then, the length of the Zygomatic implant can be read by the markings at the coronal part of the Zygomatic Z Depth Gauge (CH-I-DG) exactly at the level where its body emerges out of the alveolar/palatal bone.

The implant length is then chosen accordingly. After deciding on the implant length, the best corresponding Try-In Implant (ZYG-TR-55-52 for length 52.5 mm, ZYG-TR-55-45 for length 45 mm or ZYG-TR-55-35 for length 35 mm) is inserted into the implant bed to simulate and predict the future implant-abutment connection position. The most cervical part of the Try-In Implant's body is placed flush with the palatal aspect of the alveolar ridge, the 55° angulated part of the Try-In Implant being given an orientation in the mouth mimicking the position of the future screw-retained abutment.



Insert the Connector to Handpiece (I-CON-X) in the handpiece. Remove the implant from its sterile casing and using Hex Driver (I-HD-M), check the fixture mount screw to ensure it is tight. Connect the fixture mount to the Connector to Handpiece (I-CON-X). Once it is connected, remove the implant from its holder by rotating it and gently lifting it out of the clip.

Recommendations preceding implant insertion:

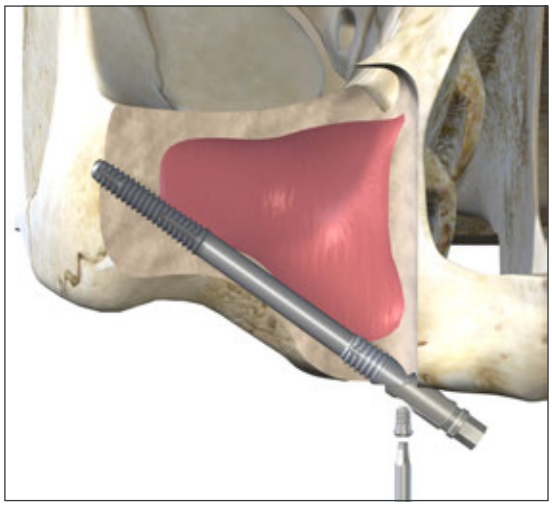
- Before inserting the implant, ensure that the implant site is free of soft tissue remnants. Any soft tissue that may have been picked up on the implant threads while moving through the bone structures (alveolar ridge, maxillary sinus) must be cleared off before the implant enters the Zygomatic placement site.
- Avoid applying bending moments to the fixture mount while inserting the implant.
- Check the fixture mount screw for loosening periodically and re-tighten if necessary, with the Hex Driver (I-HD-M).

The Connector to Handpiece (I-CON-X) is used for the initial insertion of the implant, which can be conducted also with the Ratchet (046.119) and Torque Control Device (046.049) positioned and stabilized at the implant coronal end by help of the Connection (I-WI-SH), upon surgeons preference. In both cases a 15 rpm will be selected reaching 50 Ncm max. Guide the Straumann® ZAGA™ Round Implant straight through the prepared path of insertion. Start rotating it when the apex reaches the Zygomatic bone. When the handpiece torques out and/or the ratchet reaches out its torque limit, switch to the Implant Inserter (I-ZYG-INS-2/I-IMP-INS-2).

General Recommendation:

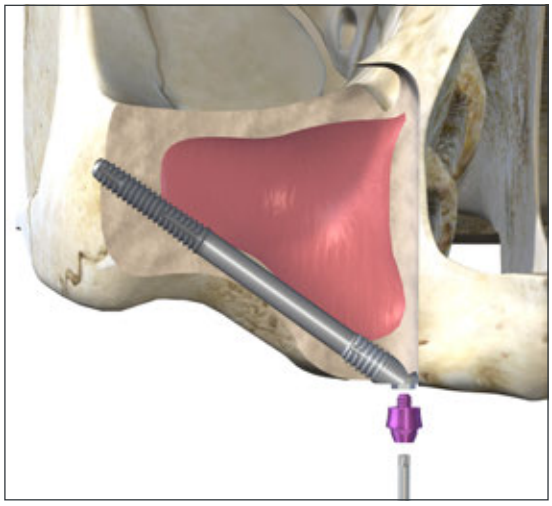
To assess the orientation of the implant head, connect the Hex Driver (I-HD-M) to the fixture mount screw. The Hex Driver has to be parallel to the sagittal plane.

Note: One revolution of the implant results in 0.8 mm axial movement. Insertion is complete when the head is in the correct prosthetic position and angle.



To ensure proper orientation of the 55 degree implant, connect the fixture mount Hex Driver (I-HD-M) to the fixture mount screw. The screwdriver has to be perpendicular to the alveolar ridge. The fixture mount screw is then loosened with the Hex Driver (I-HD-M) and the fixture mount is removed.

Note: Each rotation of the implant will result in a 0.8 mm apical movement of the implant.



In case of immediate loading a Screw-retained Abutment (CH-SRA-1.5, CH-SRA-2.5, CH-SRA-3.5 or CH-SRA-4.5) with an appropriate gingival height is secured to the zygoma implant with the SCS Screwdriver (046.401/046.411).

The Screw-retained Abutment (CH-SRA-1.5, CH-SRA-2.5, CH-SRA-3.5 or CH-SRA-4.5) has to be tightened to 35 Ncm using the the Ratchet (046.119) and Torque Control Device (046.049) or a Handpiece.

In case of delayed loading a Zygomatic Cover Screw (CH-CS) is placed, the wound sutured and the denture relined if delayed loading was planned or lack of adequate insertion torque was evident. The cover screws are placed to secure the internal connection of the implant. The Cover Screw (CH-CS) has to be tightened manually with the Hex Driver (I-CS-HD) up to max. 15 Ncm.

Prior to suturing, and in some cases in preparation for the conversion of the patient's denture, protective cap(s) with adapted gingival height (024.4323, 024.4324, 024.4325 or 024.0020-04) are secured to the screw-retained abutments.

Suturing is then carried out according to the surgeon's preference.

3.4 SURGICAL PROCEDURE FOR STRAUMANN® ZYGOMATIC IMPLANT ZAGA™ FLAT

Straumann® Zygomatic Implant ZAGA™ Flat has a semi-circumference section.

3.4.1 Specific features of the Straumann® Zygomatic Implant ZAGA™ Flat

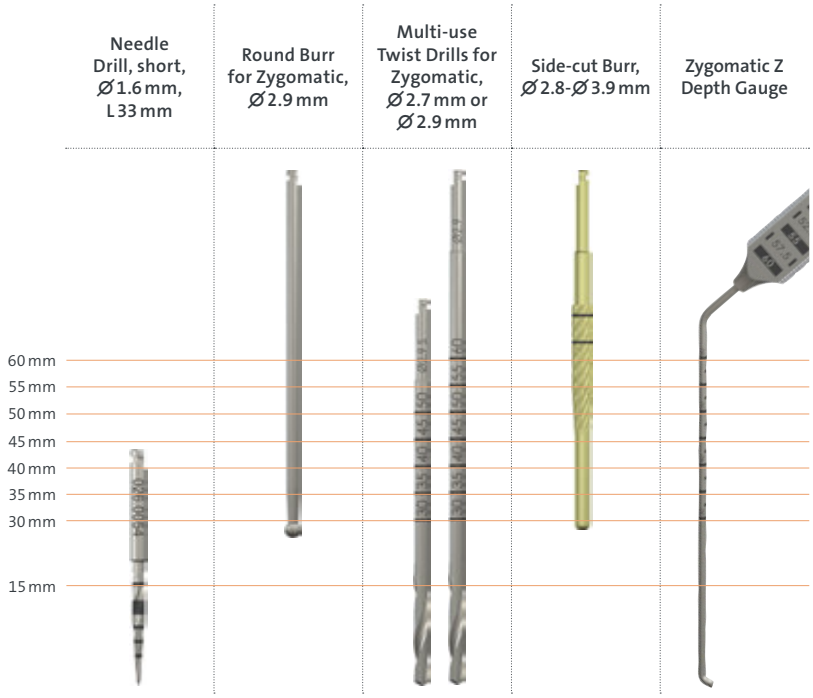
The Straumann® Zygomatic Implant ZAGA™ Flat design has a semi-circumference section. It is specifically designed to overcome situations were a circular/tunnel osteotomy cannot be performed. In other words, since the Straumann® Zygomatic Implant ZAGA™ Flat design has a semi-circumference section, it cannot fully cover a circular osteotomy. It is at the surgeon's discretion whether to use a flat or round implant design, based on the residual bone at the crestal/ sinus floor level.

Maxillary anatomies with advanced atrophy may involve a residual amount of pristine alveolar bone that is not suitable for a circular implant osteotomy, while still maintaining sinus integrity at floor level.

Use of the unique Straumann® Zygomatic Implant ZAGA™ Flat Implant features allows the surgeon to opt for an open channel-type osteotomy in the shape of a semi-circumference section. Placement of the implant flat side towards the maxillary facial side is recommended. This implant position is intended to decrease soft tissue vascular compression produced by implants placed exterior to the maxillary wall.

3.4.2 Drilling sequence overview

The Straumann® Zygomatic drills have depth marks at 1 mm intervals. The multi-use drills are delivered sterile.

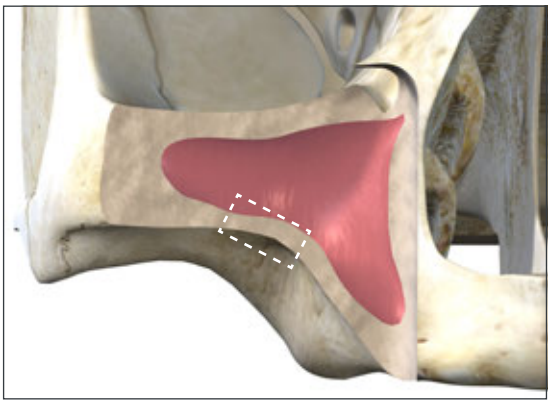


026.0054	D-ZYG-RB	D-ZYG-CH-27 D-ZYG-CH-27S D-ZYG-CH-29 D-ZYG-CH-29S	CH-D-CM	CH-I-DG

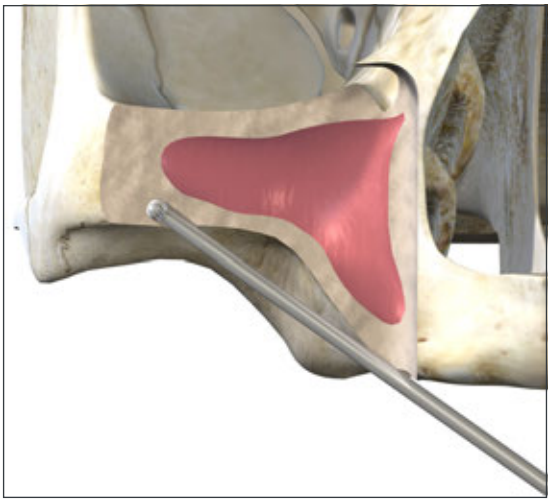
Note: Ø 2.7 mm and Ø 2.9 mm single use Twist drills, short and long, are available as spare part, upon surgeons preference (D-ZYG-27S, D-ZYG-27, D-ZYG-CH-29S, D-ZYG-CH-29)

3.4.3 Detailed surgical sequence

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 region and the midline. These three incisions facilitate flap mobilization beyond the infraorbital margin. In unilateral cases a hemi-maxillary approach is used. 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 channel retractor is placed on the upper border of the Zygomatic arch.

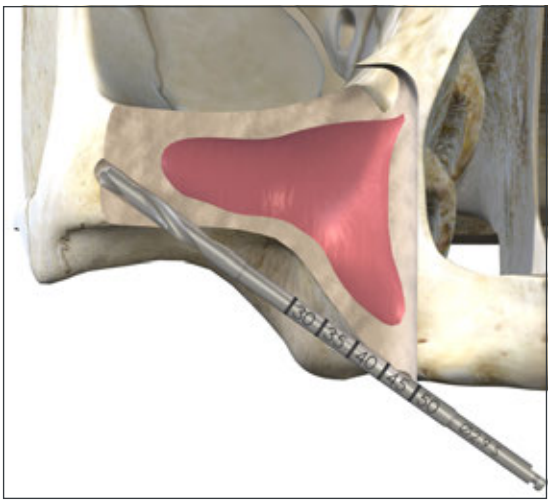


A small sinus window is cut on the lateral aspect of the maxillary sinus and the block of the bone is removed. The lining of the sinus is reflected, attempting to keep it intact if possible. Thorough reflection of the lining is essential.

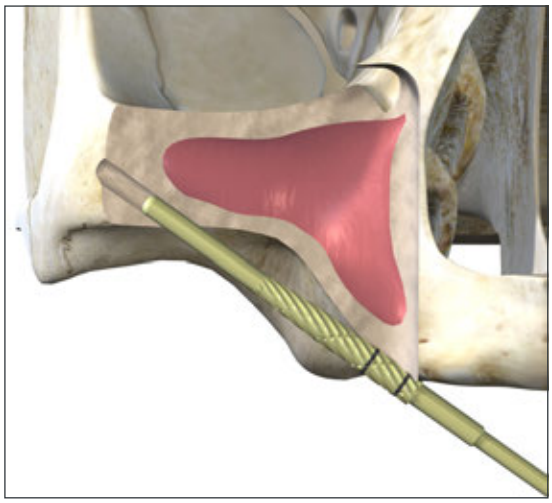


The entry point for the osteotomy is located in the first pre-molar area on the maxillary crest and following the posterior maxillary wall.

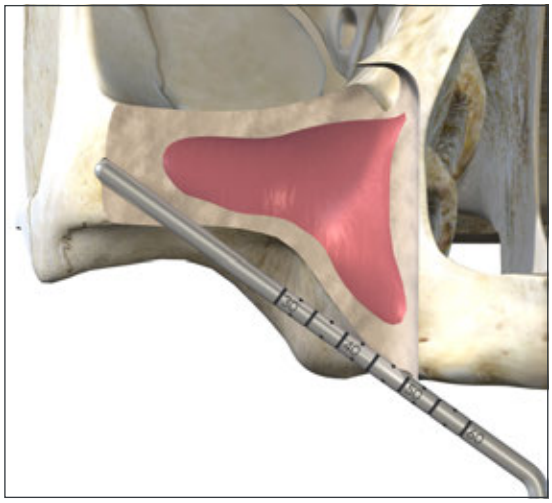
The entry at the alveolar ridge is drilled using a Round Burr (D-ZYG-RB) or the Needle Drill (026.0054), at a speed between 1000 and 1500 rpm, which are used to establish the trajectory of the implant by making an indentation at the base of the zygoma bone.



The implant site is prepared with the ∅ 2.9 mm Twist Drill (D-ZYG-CH-29/D-ZYG-CH-29S for multi-use drills), at a speed between 1000 and 1500 rpm, and seated within the indentation created by the Round Burr (D-ZG-RB) and continued into the zygoma.



If necessary, use the Side-cut Burr (CH-D-CM) at a speed of 800 rpm to create and/or enlarge the groove between the maxillary alveolar crest and the lateral wall of the resorbed sinus. The implant shall be placed with the buccal face sitting flush with the alveolar bone outer surface.



The depth of the prepared implant site is assessed with the Zygomatic Z Depth Gauge (CH-I-DG).

After the osteotomy is completed having its most apical part located in the external cortical bone aspect of the Zygomatic bone reaching a trans-cortical position just under the periosteum, the Zygomatic Z Depth Gauge (CH-I-DG) is inserted.

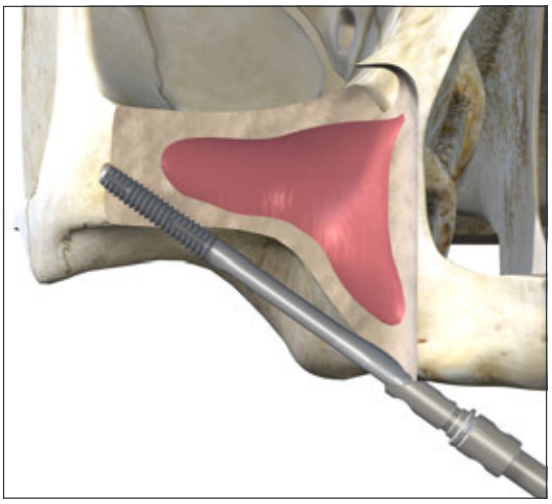
The apical end of the Zygomatic Z Depth Gauge (CH-I-DG) shall be positioned at the most apical point of the osteotomy. The apical position of the Zygomatic Z Depth Gauge (CH-I-DG) should not pass the lateral cortex of the zygoma bone.

A positioning control is conducted by fingertip palpation through the skin. If a fingertip-palpation is not possible, use the hook-end of the Zygomatic Z Depth Gauge (CH-I-DG) to measure the correct length of the implant.

Then, the length of the Zygomatic implant can be read by the markings at the coronal part of the Zygomatic Z Depth Gauge (CH-I-DG) exactly at the level where its body emerges out of the alveolar/palatal bone.

The implant length is then chosen accordingly. After deciding on the implant length, the best corresponding Try-In Implant (ZYG-TR-55-52 for length 52.5 mm, ZYG-TR-55-45 for length 45 mm or ZYG-TR-55-35 for length 35 mm) is inserted into the implant bed to simulate and predict the future implant-abutment connection position. The most cervical part of the Try-In Implant's body is placed flush with the palatal aspect of the alveolar ridge, the 55° angulated part of the Try-In Implant being given an orientation in the mouth mimicking the position of the future screw-retained abutment.

Insert the Connector to Handpiece (I-CON-X) in the handpiece. Remove the implant from its sterile casing and using Hex Driver (I-HD-M), check the fixture mount screw to ensure it is tight. Connect the fixture mount to the Connector to Handpiece (I-CON-X). Once it is connected, remove the implant from its holder by rotating it and gently lifting it out of the clip.



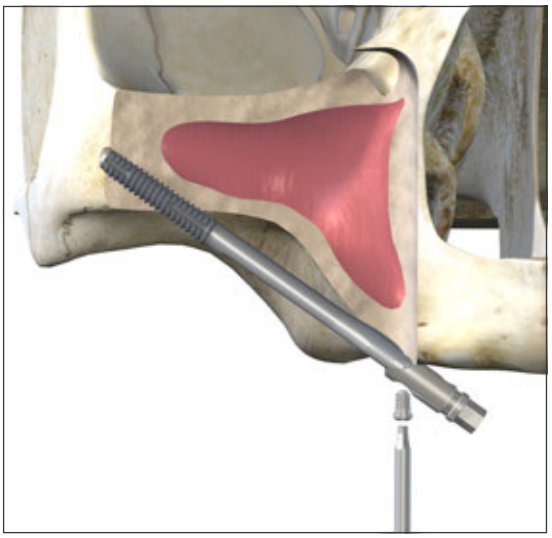
Recommendations preceding implant insertion:

- Before inserting the implant, ensure that the implant site is free of soft tissue remnants. Any soft tissue that may have been picked up on the implant threads while moving through the bone structures (alveolar ridge, maxillary sinus) must be cleared off before the implant enters the Zygomatic placement site. In particular debridement of the sinus with sterile water or saline is essential.
- Avoid applying bending moments to the fixture mount while inserting the implant.
- Check the fixture mount screw for loosening periodically and re-tighten if necessary, with the Hex Driver (I-HD-M).

The Connector to Handpiece (I-CON-X) is used for the initial insertion of the implant, which can be conducted also with the Ratchet (046.119) and Torque Control Device (046.049) positioned and stabilized at the implant coronal end by help of the Connection (I-WI-SH), upon surgeons preference. In both cases a 15 rpm will be selected reaching 50 Ncm max. Guide the Straumann® ZAGA™ Flat Implant straight through the prepared path of insertion. Start rotating it when the apex reaches the Zygomatic bone. When the handpiece torques out and/or the ratchet reaches out its torque limit, switch to the Implant Inserter (I-ZYG-INS-2/I-IMP-INS-2).

The implant must follow the prepared path of insertion. Any soft tissue that may have been picked up on the implant threads while moving through the alveolus and sinus must be cleared off before the implant enters the Zygomatic placement site.

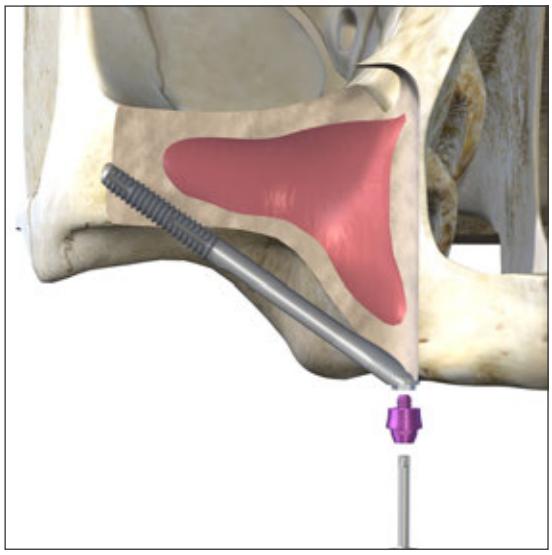
General Recommendation:
It is recommended to perform entry and exit trajectories in order to prevent excessive bone compression.



To assess the orientation of the implant head, connect the Hex Driver (I-HD-M) to the fixture mount screw. The screwdriver has to be parallel to the sagittal plane.

Note that one revolution of the implant results in 0.8 mm axial movement. Insertion is complete when the head is in the correct prosthetic position and angle.
To ensure proper orientation of the 55 degree implant, connect the Hex Driver (I-HD-M) to the fixture mount screw. The screwdriver has to be perpendicular to the alveolar ridge. The fixture mount screw is then loosened with the Hex Driver (I-HD-M) and the fixture mount is removed.

Note: Each rotation of the implant will result in a 0.8 mm apical movement of the implant.

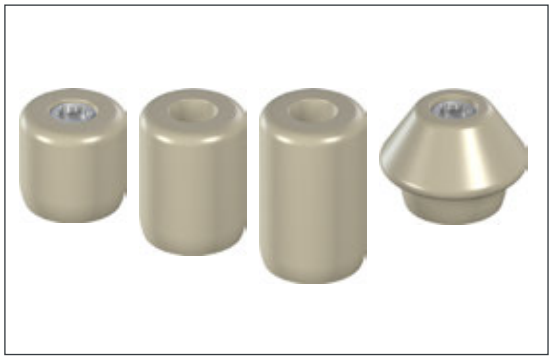


In case of immediate loading a Screw-retained Abutment (CH-SRA-1.5, CH-SRA-2.5, CH-SRA-3.5 or CH-SRA-4.5) with an appropriate gingival height is secured to the zygoma implant with the SCS Screwdriver (046.401/046.411).

When fully seated the Screw-retained Abutment (CH-SRA-1.5, CH-SRA-2.5, CH-SRA-3.5 or CH-SRA-4.5) is tightened to 35 Ncm using Ratchet (046.119) and Torque Control Device (046.049) or a handpiece.

In case of delayed loading a Zygomatic Cover Screw (CH-CS) is placed, the wound sutured and the denture relined if delayed loading was planned or lack of adequate insertion torque was evident.

The cover screws are placed to secure the internal connection of the implant. The Cover Screw (CH-CS) has to be tightened manually with the Hex Driver (I-CS-HD) up to max. 15 Ncm.



Prior to suturing, and in preparation for the conversion of the patient's denture, protective cap(s) with adapted gingival height (024.4323, 024.4324, 024.4325 or 024.0020-04) are secured to the screw-retained abutments. The protective caps would protect the screw-retained abutment.

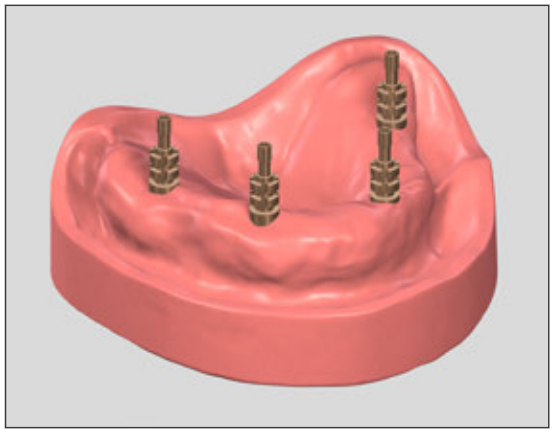
Suturing is then carried out according to the surgeon's preference.

Warning:
It is very important to be aware of and avoid damage to vital structures such as nerves, veins and arteries. Injuries to vital anatomical structures may cause serious complications such as injury to the eye, nerve damage and excessive bleeding.

It is essential to protect the infraorbital nerve. Failure to identify actual measurements relative to the radiographic data could lead to complications.

4. PROSTHETIC PROCEDURE

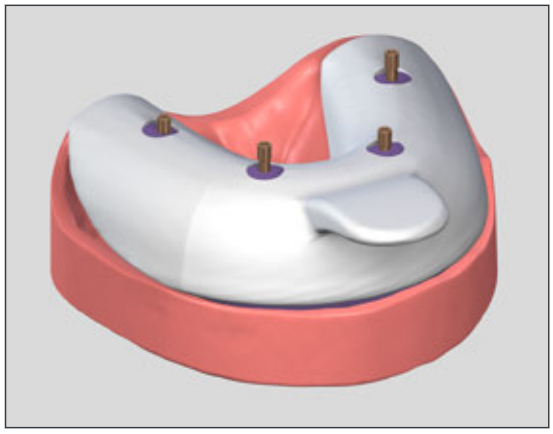
The final restoration of the Straumann® Zygomatic Implants must be performed at the abutment level. Thus, to ensure proper fit of the temporary and final restoration, Straumann® Zygomatic Implant System offers only an indirect prosthetic workflow.



Note: With the Straumann® Zygomatic Implant System, impression is taken at the abutment level

Open-tray impression

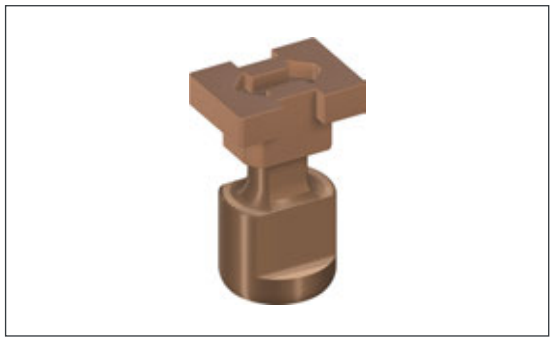
- Make sure the abutments are torqued down with 35 Ncm.
- Place the open-tray impression posts onto the abutments and fix them with the screw.
- Ensure correct positioning of the impression posts on the abutments.
- Use the impression components with the non-engaging feature.



- Take the impression using an elastomeric impression material.
- Forward the impression and all corresponding impression components to the dental lab.

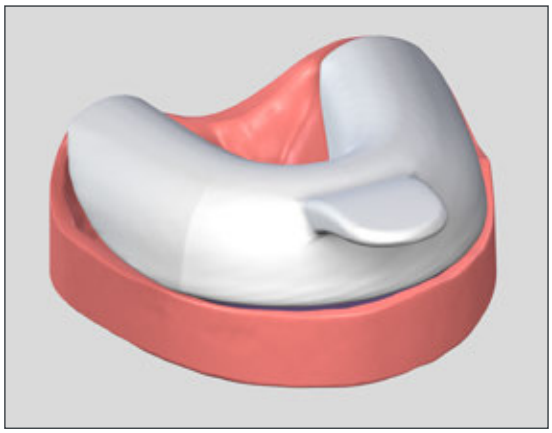
Caution: Unscrew the open-tray impression posts from implants/abutments before releasing the impression material from the patient/model.

Note: An open-tray impression procedure requires a custom-made tray with perforations. Impression posts are intended for single use only to ensure optimal fit and precise impression taking for each patient.

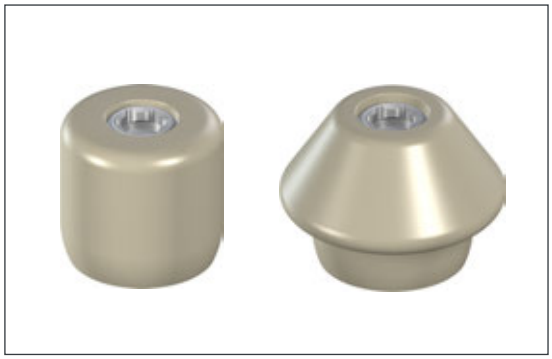


Closed-tray impression

- Make sure the abutments are torqued down with 35 Ncm.
- Place the closed-tray impression posts onto the abutments and fix them with the screw.
- Ensure correct positioning of the impression posts on the abutments.
- Position the positioning cap onto the impression post.



Take the impression using an elastomeric impression material. Forward the impression and all corresponding impression components to the dental lab.



Temporary restoration

Using protective caps

Mount the protective caps on the abutments and hand-tighten the screws with the SCS Screwdriver.

Note: Do not keep protective caps in the patient's mouth for longer than 180 days.

Protective caps are available in different shapes and heights, to be chosen according to the patient's anatomical situation and desired outcome.

Temporary restoration

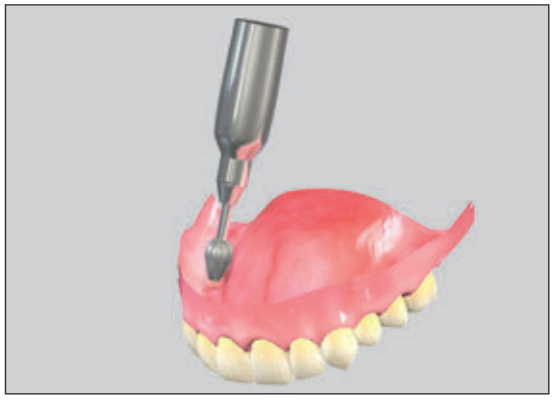
Using temporary TAN copings or titanium copings

In this case, the preparation of an immediate provisional in the dental lab is shown.

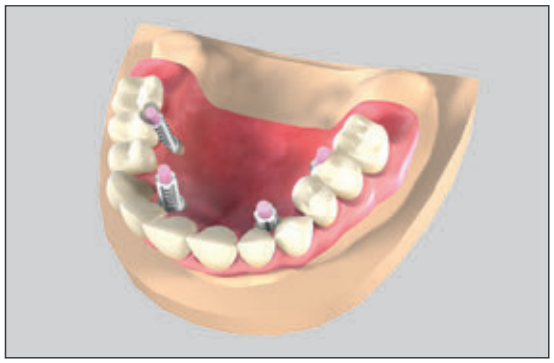
Based on dental impression, prepare the master cast using standard procedure. Based on the impression and bite registration, prepare the provisional denture. For the surgical procedure, prepare a duplicate of the provisional in clear acrylic material.

Temporary TAN or titanium copings will represent the implant position and angulation in the acrylic guide.

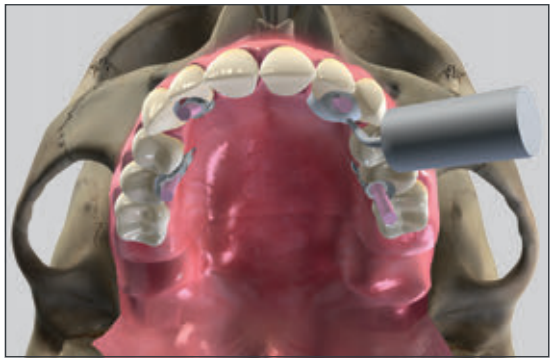
Note: For more detailed information on the surgical procedure, please see the *Straumann® Pro Arch, Basic Information* (702166/en).



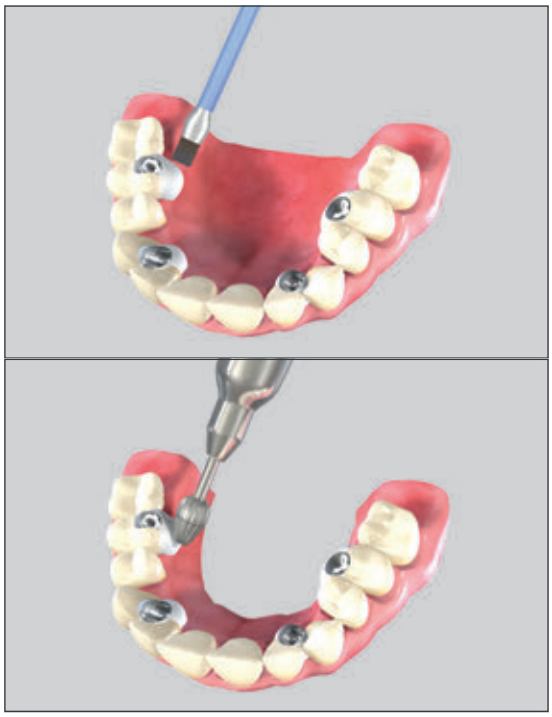
In the dental lab, prepare holes in the temporary denture according to the number of copings. Consider sufficient space for resin material.



Check if there is sufficient space for the copings.



In the patient's mouth, connect the copings with the temporary prosthesis using resin material and transfer to the dental lab to finalize.



In the dental lab, finalize and polish the temporary restoration.

Note: Use the polishing aids to protect the abutment configuration from resin ingress.

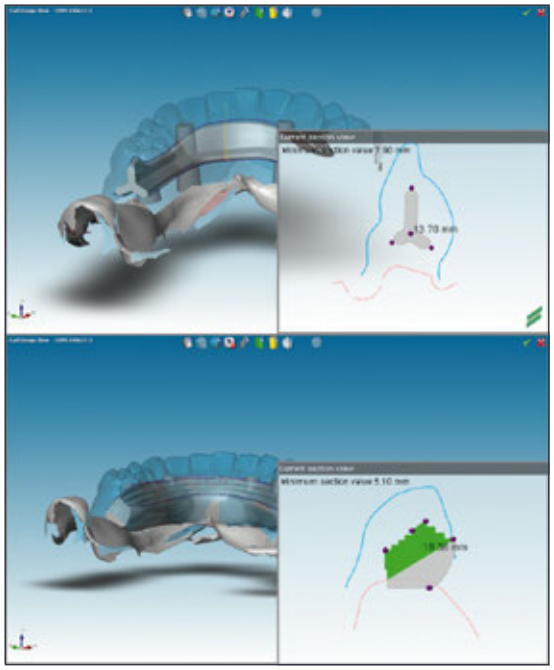
Final restoration: Screw-retained – CADCAM option

Fabricate the master cast using standard procedure (for instructions see chapter 6. Impression taking from *Straumann® Bone Level Prosthetic Procedures, Basic Information* (702061/en)).

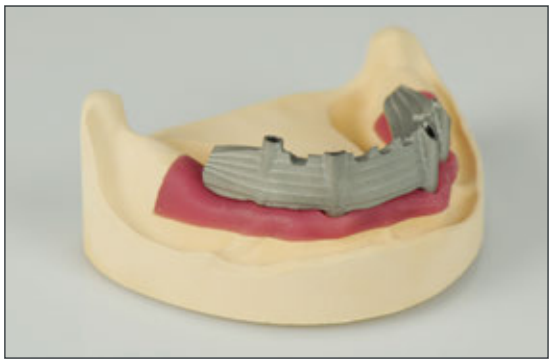
In order to transfer the impression data into the CARES® software, use abutment-level scanbodies for the screw-retained abutments.

Hand-tighten the scanbodies onto the analogs in the dental model.

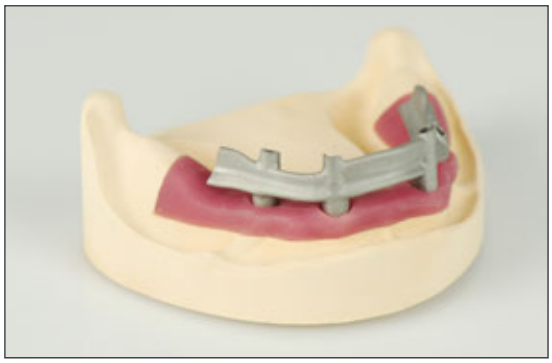
Place the dental model in the scanner and follow the scanning instructions.



Design the framework for screw-retained restorations in the software as needed. Transfer the final design to the milling facility.



Example of a Straumann® CARES® Advanced Fixed Bar on four implants

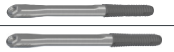
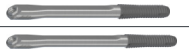
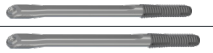


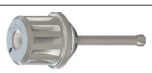
Example of a Straumann® CARES® Basic Fixed Bar on four implants

Straumann® CARES® Advanced Fixed Bar
Veneer and finalize the custom-milled superstructure.

Straumann® CARES® Basic Fixed Bar

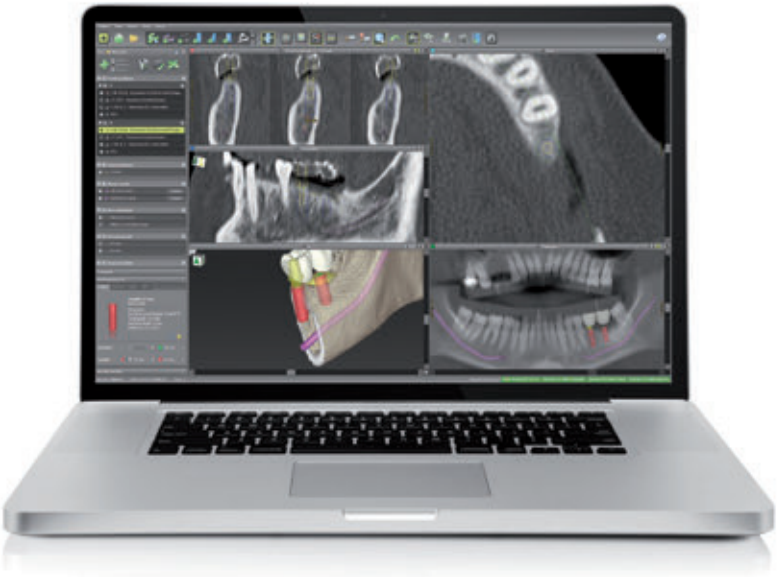
5. PRODUCT REFERENCE LIST

Art. No.	Image	Product
CH-ZT-30.0		Straumann® Zygomatic Implant, ZAGA™ Round, Ø 4.3 mm, L 30 mm, Ti
CH-ZT-32.5		Straumann® Zygomatic Implant, ZAGA™ Round, Ø 4.3 mm, L 32.5 mm, Ti
CH-ZT-35.0		Straumann® Zygomatic Implant, ZAGA™ Round, Ø 4.3 mm, L 35 mm, Ti
CH-ZT-37.5		Straumann® Zygomatic Implant, ZAGA™ Round, Ø 4.3 mm, L 37.5 mm, Ti
CH-ZT-40.0		Straumann® Zygomatic Implant, ZAGA™ Round, Ø 4.3 mm, L 40 mm, Ti
CH-ZT-42.5		Straumann® Zygomatic Implant, ZAGA™ Round, Ø 4.3 mm, L 42.5 mm, Ti
CH-ZT-45.0		Straumann® Zygomatic Implant, ZAGA™ Round, Ø 4.3 mm, L 45 mm, Ti
CH-ZT-47.5		Straumann® Zygomatic Implant, ZAGA™ Round, Ø 4.3 mm, L 47.5 mm, Ti
CH-ZT-50.0		Straumann® Zygomatic Implant, ZAGA™ Round, Ø 4.3 mm, L 50 mm, Ti
CH-ZT-52.5		Straumann® Zygomatic Implant, ZAGA™ Round, Ø 4.3 mm, L 52.5 mm, Ti
CH-ZT-55.0		Straumann® Zygomatic Implant, ZAGA™ Round, Ø 4.3 mm, L 55 mm, Ti
CH-ZT-57.5		Straumann® Zygomatic Implant, ZAGA™ Round, Ø 4.3 mm, L 57,5 mm, Ti
CH-ZT-60.0		Straumann® Zygomatic Implant, ZAGA™ Round, Ø 4.3 mm, L 60 mm, Ti
CH-ZC-30.0		Straumann® Zygomatic Implant, ZAGA™ Flat, Ø 4.3 mm, L 30 mm, Ti
CH-ZC-32.5		Straumann® Zygomatic Implant, ZAGA™ Flat, Ø 4.3 mm, L 32.5 mm, Ti
CH-ZC-35.0		Straumann® Zygomatic Implant, ZAGA™ Flat, Ø 4.3 mm, L 35 mm, Ti
CH-ZC-37.5		Straumann® Zygomatic Implant, ZAGA™ Flat, Ø 4.3 mm, L 37.5 mm, Ti
CH-ZC-40.0		Straumann® Zygomatic Implant, ZAGA™ Flat, Ø 4.3 mm, L 40 mm, Ti
CH-ZC-42.5		Straumann® Zygomatic Implant, ZAGA™ Flat, Ø 4.3 mm, L 42.5 mm, Ti
CH-ZC-45.0		Straumann® Zygomatic Implant, ZAGA™ Flat, Ø 4.3 mm, L 45 mm, Ti
CH-ZC-47.5		Straumann® Zygomatic Implant, ZAGA™ Flat, Ø 4.3 mm, L 47.5 mm, Ti
CH-ZC-50.0		Straumann® Zygomatic Implant, ZAGA™ Flat, Ø 4.3 mm, L 50 mm, Ti
CH-ZC-52.5		Straumann® Zygomatic Implant, ZAGA™ Flat, Ø 4.3 mm, L 52.5 mm, Ti
CH-ZC-55.0		Straumann® Zygomatic Implant, ZAGA™ Flat, Ø 4.3 mm, L 55 mm, Ti
CH-ZC-57.5		Straumann® Zygomatic Implant, ZAGA™ Flat, Ø 4.3 mm, L 57.5 mm, Ti
CH-ZC-60.0		Straumann® Zygomatic Implant, ZAGA™ Flat, Ø 4.3 mm, L 60 mm, Ti
CH-CS		Straumann® Zygomatic Cover Screw for Zygomatic Implants, Ti
CH-SRA-1.5		Screw-retained Abutment for Zygomatic Implants, for Ø 4 mm Ex Hex, straight 0°, Ø 4.6 mm, GH 1.5 mm, Ti
CH-SRA-2.5		Screw-retained Abutment for Zygomatic Implants, for Ø 4 mm Ex Hex, straight 0°, Ø 4.6 mm, GH 2.5 mm, Ti
CH-SRA-3.5		Screw-retained Abutment for Zygomatic Implants, for Ø 4 mm Ex Hex, straight 0°, Ø 4.6 mm, GH 3.5 mm, Ti
CH-SRA-4.5		Screw-retained Abutment for Zygomatic Implants, for Ø 4 mm Ex Hex, straight 0°, Ø 4.6 mm, GH 4.5 mm, Ti
024.4323-04		Protective Cap for Screw-retained Abutment, Ø 4.6 mm, H 5.1 mm, PEEK/TAN
024.4324-04		Protective Cap for Screw-retained Abutment, Ø 4.6 mm, H 6.6 mm, PEEK/TAN
024.4325-04		Protective Cap for Screw-retained Abutment, Ø 4.6 mm, H 8.1 mm, PEEK/TAN
024.0020-04		Protective Cap for Screw-retained Abutment, Ø 4.6 mm, H 4.5 mm, wide, PEEK/TAN
025.0012		Impression Post for open tray for Screw-retained Abutment, abutment level, Ø 4.6 mm, non-engaging, TAN
025.0014		Impression Post for closed tray for Screw-retained Abutment, abutment level, Ø 4.6 mm, non-engaging, TAN/POM
025.0001		CARES® Mono Scanbody for Screw-retained Abutment, abutment level, Ø 4.6 mm, PEEK/TAN
025.0008		Repositionable Analog, for Screw-retained Abutment, Ø 4.6 mm, stainless steel
025.0050		Analog for Screw-retained Abutment, edentulous, straight 0°, Ø 4.6 mm, TAN
024.0024		Temporary Coping for Screw-retained Abutment, Bridge, Ø 4.6 mm, TAN
023.4751		Coping for Screw-retained Abutment, Bridge, Ø 4.6 mm, TAN
023.4754		Coping for Screw-retained Abutment, Bridge, Ø 4.6 mm, Ceramicor®/POM
023.4758		Burn-out Coping for Screw-retained Abutment, Bridge/Bar, including screw, Ø 4.6 mm, POM/TAN
023.0028		Variobase® for Bridge/Bar Cylindrical Coping H 4 mm, for Ø 4.6 mm Screw-retained Abutment, incl. screw & CA3, TAN/POM
023.0032		Burn-out Coping for Variobase® for Bridge/Bar Cylindrical, Coping Screw-retained Abutment Ø 4.6 mm, POM
023.4752		Coping for Screw-retained Abutment, Ti, Bar, Ø 4.6 mm

Art. No.	Image	Product
023.4755		Coping for Screw-retained Abutment, Bar, Ø 4.6 mm, Ceramicor®
023.4763		Occlusal screw, TAN, for coping, screw-retained abutment
025.0005		Polishing Aid, for Screw-retained Abutment, Ø 4.6 mm, TAN
025.0006		Lab Processing Screw, for Screw-retained Abutment, L 20 mm, stainless steel
025.0052		Lab Processing Screw, for Screw-retained Abutment, L 10 mm, stainless steel
026.0054		Needle Drill, short, Ø 1.6 mm, L 33 mm, stainless steel
D-ZYG-RB		Round Burr for Zygomatic, Ø 2.9 mm, stainless steel
D-ZYG-29S		Twist Drill for Zygomatic, Short, Ø 2.9 mm, Ti
D-ZYG-29		Twist Drill for Zygomatic, Ø 2.9 mm, Ti
D-ZYG-27		Twist Drill for Zygomatic, Ø 2.7 mm, Ti
D-ZYG-27S		Twist Drill for Zygomatic, Short, Ø 2.7 mm, Ti
D-ZYG-CH-27		Multi-use Twist Drill for Zygomatic, Ø 2.7 mm, stainless steel
D-ZYG-CH-27S		Multi-use Twist Drill for Zygomatic, Short, Ø 2.7 mm, stainless steel
D-ZYG-CH-29S		Multi-use Twist Drill for Zygomatic, Short, Ø 2.9 mm, stainless steel
D-ZYG-CH-29		Multi-use Twist Drill for Zygomatic, Ø 2.9 mm, stainless steel
CH-D-CM		Instrument, Side-cut Burr, Ø 2.8 - Ø 3.9 mm, Ti
D-35T-M15		Twist Drill, Disposable, Ø 3.5 x 15 mm, stainless steel
I-ZYG-INS-2		Instrument, Zygomatic Implant Inserter, Hex
I-IMP-INS-2		Instrument, Implant Inserter, Hex
CH-I-DG		Instrument, Zygomatic Z Depth Gauge
046.108		Service Instrument for Ratchet, L 50 mm, stainless steel
046.119		Ratchet, including service instrument, L 84 mm, stainless steel
046.049		Torque Control Device for Ratchet, L 82 mm, stainless steel
ZYG-TR-55-35		Instrument, Try-In Implant, Zygomatic 55° x 35 mm
ZYG-TR-55-45		Instrument, Try-In Implant, Zygomatic 55° x 45 mm
ZYG-TR-55-52		Instrument, Try-In Implant, Zygomatic 55° x 52.5 mm
I-CON-X		Instrument, Connector to Handpiece
I-HD-M		Instrument, 1.22 mm Hex Driver, Medium
046.401		SCS Screwdriver, for Ratchet, short, L 21 mm, stainless steel
046.411		SCS Screwdriver short, for Handpiece Adapter, length 26 mm, stainless steel
CH-I-ZYG		ZAGA™ Surgical Cassette
I-WI-SH		Connection to the Ratchet (046.119) and the Torque Controled Device (046.049)
I-CS-HD		Instrument, 0.9 mm Hex Driver

6. DIGITAL PLANNING WITH CODIAGNOSTIX®

This 3D diagnostics and implant planning software is designed for the image-guided surgical planning of dental implants, including Straumann® Zygomatic Implants, which are included in the digital library of the system. Working with the software is based on a patient's medical image data such as a CT (Computed Tomography) and DVT (Digital Volume Tomography) that is processed by coDiagnostiX®. Planning is performed calculating several views (such as virtual OPG or a 3-dimensional reconstruction of the image dataset) and the analysis of the image data and the virtual replacement of implants, abutments and drilling sleeves. Digital planning, guided surgery and guided implant placement with the SP Guided Adapter are available.



For further information, please refer to the coDiagnostiX® Manual.

6.1 DWOS SYNERGY WORKFLOW

DWOS Synergy provides real-time communication between the implant planning software (coDiagnostiX®) and the lab software (i.e. Straumann® CARES® Visual) and improves implant planning by allowing the relationship between the proposed implant position and the proposed restoration to be visualized.

7. FURTHER INFORMATION

For more detailed information on the instructions for use, please consult the following IFU documents available at: https://southernimplants.com/media-center/EIFU-library/

- Straumann® ZAGA™ Zygomatic Implants – CAT-8049
- Straumann® ZAGA™ Cylindrical Twist Drills – CAT-8053
- Straumann® ZAGA™ Screw-Retained Abutments – CAT-8047
- Straumann® ZAGA™ Side Cut Burr – CAT-8048

For information on the Instrument Tray, including applicable cleaning and Sterilization procedures:

- Southern Implants® Instrument tray – CAT-8003

For the Screw Retained Abutment broken screw removal, please consult the “Broken screw removal protocol” at CAT-1132 Broken Screw Removal protocol.
More information is available at:
https://southernimplants.com/media-center/screw-information/

For more information on the care and maintenance of Straumann® surgical and prosthetic intruments, please consult:

- *Straumann® Surgical and Prosthetic Instruments, Care and Maintenance (702000/en)*

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