



Straumann® Zygomatic Implant System

## Patient Information

# STRAUMANN® ZYGOMATIC IMPLANT SYSTEM

## Name and model of the device

Straumann® Zygomatic Implant System

Straumann® Zygomatic Implants ZAGA™ Round		Straumann® Zygomatic Implants ZAGA™ Flat	
Length	Art.-No.	Length	Art.-No.
30.0 mm	CH-ZT-30.0	30.0 mm	CH-ZC-30.0
32.5 mm	CH-ZT-32.5	32.5 mm	CH-ZC-32.5
35.0 mm	CH-ZT-35.0	35.0 mm	CH-ZC-35.0
37.5 mm	CH-ZT-37.5	37.5 mm	CH-ZC-37.5
40.0 mm	CH-ZT-40.0	40.0 mm	CH-ZC-40.0
42.5 mm	CH-ZT-42.5	42.5 mm	CH-ZC-42.5
45.0 mm	CH-ZT-45.0	45.0 mm	CH-ZC-45.0
47.5 mm	CH-ZT-47.5	47.5 mm	CH-ZC-47.5
50.0 mm	CH-ZT-50.0	50.0 mm	CH-ZC-50.0
52.5 mm	CH-ZT-52.5	52.5 mm	CH-ZC-52.5
55.0 mm	CH-ZT-55.0	55.0 mm	CH-ZC-55.0
57.5 mm	CH-ZT-57.5	57.5 mm	CH-ZC-57.5
60.0 mm	CH-ZT-60.0	60.0 mm	CH-ZC-60.0

## Product description of Straumann Zygomatic Implants

The Straumann® Zygomatic Implant System is composed of a wide range of implants, related prosthetic components, instruments and accessories. The Straumann® Zygomatic Implants are available in 2 different designs, the ZAGA™ Round Implant and the ZAGA™ Flat Implant. 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, 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.

## Intended purpose of Straumann Zygomatic Implant System

The Zygomatic implants are intended to treat partially or fully edentulous patients with severely resorbed or absent maxillae for whom conventional implants are not an option as a means of fixing a permanent or removable dental or maxillofacial prosthesis.

## Intended performance of Straumann Zygomatic Implants

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. The expected device lifetime is 10 years. The lifetime of the implant may be shortened by overloading the prosthesis, chemotherapy or radiotherapy. Once an implant has integrated, the risk of failure is significantly lower. Regular check-ups and maintenance, assessing prosthesis for sustained fit are highly recommended.

## Changes in performance

It is the responsibility of the clinician to instruct the patient on all appropriate contraindications, side effects, and precautions as well as the need to seek the services of a trained dental professional if there are any changes in the performance of the implant (e.g., looseness of the prosthesis, infection or exudate around the implant, pain, or any other unusual symptoms that the patient has not been told to expect).

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## **Pain Management & looking after your Implants**

### **Medication**

Your surgeon will prescribe or recommend medication to assist in your pain management.

### **Diet**

Following surgery, protect the implants by not disturbing the wound.

Your surgeon will recommend a suitable diet, for example a soft diet for a few weeks. Good oral hygiene is essential to healing

### **Oral Hygiene**

Patients who have implants must commit themselves to a lifetime of stringent oral hygiene. This is to ensure that the gingival tissues surrounding the implant remain healthy, with no plaque accumulating around the implants, the prosthetic parts attached to them and around the teeth.

Follow the advice of your dental professional when it comes to regular checkups and professional teeth cleaning after your implant treatment. Ask your dental professional for personalised and detailed care instructions.

### **Undesirable side effects**

Potential side effects and temporary symptoms: pain, swelling, phonetic difficulties, gingival inflammation. More persistent symptoms: The risks and complications with implants include, but are not limited to: (1) allergic reaction(s) to implant and/or abutment material; (2) breakage of the implant and/or abutment; (3) loosening of the abutment screw and/or retaining screw; (4) infection requiring revision of the dental implant; (5) nerve damage that could cause permanent weakness, numbness, or pain; (6) histologic responses possibly involving macrophages and/or fibroblasts; (7) formation of fat emboli; (8) loosening of the implant requiring revision surgery; (9) perforation of the maxillary sinus; (10) perforation of the labial and lingual plates; and (11) bone loss possibly resulting in revision or removal.

### **Residual risks and warnings**

Responsibility for proper patient selection, adequate training, experience in the placement of Zygomatic 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.

Your compliance is crucial to ensure a successful and aesthetic outcome of the surgical procedure. Any serious incidents related to the use of the medical device should be reported to the manufacturer and to the Therapeutic Goods Administration.[www.tga.gov.au](http://www.tga.gov.au)

### **MR Safety**

These products have not been tested for MRI safety, however, an analysis and review of the literature has shown that the risks of scanning a Southern Implants implant system are not of concern under the following conditions:

- a static magnetic field of 1.5 Tesla and 3 Tesla.
- a magnetic field with a field gradient of 30T/M (3000G/cm).
- a whole body specific absorption rate (SAR) of 2W/kg, for 15 minutes of scanning.

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## Distributed by

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