IFU Patent™ Symbionic Tooth

Patent

SYMBIONIC TOOTH

Disclaimer

The products referenced herein are part of a comprehensive treatment concept and may only be used in combination with the corresponding original products according to the instructions and recommendations of ZV3 – Zircon Vision GmbH. The use of external products in combination with ZV3 – Zircon Vision GmbH products without recommendation invalidates the warranty and voids any other express or implied obligations of ZV3 – Zircon Vision GmbH. It is the responsibility of the user of the ZV3 – Zircon Vision GmbH products to determine whether the product is suitable for a particular patient under the given conditions. ZV3 – Zircon Vision GmbH assumes no liability, express or implied, for any direct, indirect, punitive or other damages arising from or in connection with errors of professional judgment or practice in the use of ZV3 – Zircon Vision GmbH products. The user is also obliged to keep himself regularly informed about the latest developments regarding the ZV3 – Zircon Vision GmbH products and their application. In case of doubt, ZV3 – Zircon Vision GmbH should be contacted. As the use of the products is under the control of the user, the user assumes responsibility. ZV3 – Zircon Vision GmbH does not accept any liability for damages resulting from the use of the product.

Product description

Patent™ Symbionic Tooth System is an integral system of transgingival endosseous dental implantable devices with the associated prosthetic components and instruments. Patent™ Symbionic Teeth are available as one-piece (with integrated abutment) or two-piece dental devices both with a rough endosseous surface that is sandblasted. Patent™ Symbionic Teeth can be used for immediate or delayed insertion after extraction or loss of natural teeth. For the restoration of single and/or multiple teeth (up to 3 units), the Patent™ Symbionic Teeth can be placed with immediate loading if good primary stability is achieved and adequate occlusal contact with the antagonists is present to restore chewing ability. Single crowns, bridges, partial or full dentures are used for the prosthetic restoration of the implantable device, which are connected to the Patent™ Symbionic Tooth via the corresponding glass fiber post.

Patent™ prosthetic components consist of glass fiber reinforced polymer abutments for prosthetic restoration on Patent™ two-piece Symbionic Teeth of various types, endosseous diameters, lengths and platforms. They are available in a variety of shapes and sizes for optimal adaption to the individual patient situation. They are cemented onto Patent™ two-piece Symbionic Teeth.

Intended Use

Patent™ Symbionic Teeth and Patent™ Glass Fiber Posts were developed for use in maxillary and mandibular implant surgery to affic single crowns or bridges of up to three parts and therefore reestablish the patient's chewing function.

Intended Users

Patent™ Symbionic Teeth should only be implanted by dentists or oral and maxillofacial surgeons who are trained in implantology and who have received appropriate training in the clinical application of the Patent™ Symbionic Tooth System. The reprocessing is to be carried out by qualified personnel only.

Patient Population

Patent™ Symbionic Teeth can be used on patients who are adult (18 and older) and who have all the existing teeth erupted through the gingiva.

Indications

Patent™ Symbionic Teeth are indicated for the functional and aesthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients.

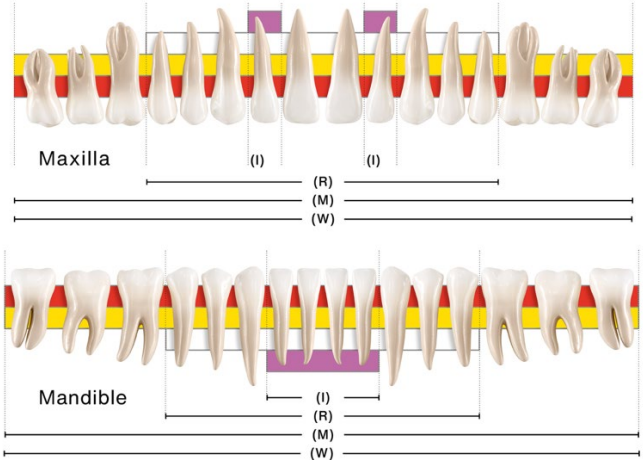
See indications:

Care Profile

Shoulder Size SZ		Wide (W)		Medium (M)		Regular (R)	Micro (I)
		8.2 mm x 6.2 mm		6.2 mm		5.2 mm	3.5 mm
Endosseous Diameter ED		5.0 mm	4.5 mm	5.0 mm	4.5 mm	4.1 mm	3.5 mm
Endosseous Length EL	7.0 mm	-	-	SMCCL.5007	SMCCL.4507	SRCCS.4107	-
	9.0 mm	SWCCL.5009	SWCCL.4509	SMCCL.5009	SMCCL.4509	SRCCS.4109	SIECS.3509
	11.0 mm	SWCCL.5011	SWCCL.4511	SMCCL.5011	SMCCL.4511	SRCCS.4111	SIECS.3511
	13.0 mm	SWCCL.5013	SWCCL.4513	SMCCL.5013	SMCCL.4513	SRCCS.4113	SIECS.3513

Performance Profile

Shoulder Size SZ		Wide (W)		Medium (M)		Regular (R)
		8.2 mm x 6.2 mm		6.2 mm		5.2 mm
Endosseous Diameter ED		5.0 mm	4.5 mm	5.0 mm	4.5 mm	4.1 mm
Endosseous Length EL	7.0 mm	-	-	SMCPL.5007	SMCPL.4507	SRCPS.4107
	9.0 mm	SWCPL.5009	SWCPL.4509	SMCPL.5009	SMCPL.4509	SRCPS.4109
	11.0 mm	SWCPL.5011	SWCPL.4511	SMCPL.5011	SMCPL.4511	SRCPS.4111
	13.0 mm	SWCPL.5013	SWCPL.4513	SMCPL.5013	SMCPL.4513	SRCPS.4113



For the treatment of single and/or multiple teeth (up to three units), Patent™ Symbionic Teeth can be placed with immediate loading if good primary stability is achieved.

Patent™ Glass Fiber Posts are used as prosthetic retention elements for Patent™ Symbionic Teeth. They serve as a load-bearing support structure in the functional and aesthetic oral rehabilitation of edentulous or partially edentulous patients.

Contraindication

Pregnancy, previously irradiated bone, diabetes, anticoagulant treatment, hemodynamic problems, bruxism/parafunctional habits, poor bone anatomy, heavy smoking habit, uncontrolled periodontitis, malocclusion, temporomandibular joint problems, oral cavity diseases, inadequate oral care, inadequate quality or quantity of bone, existing roots, chronic or acute bone inflammation that has not yet healed at the site where a Patent™ Symbionic Tooth is to be placed, localized disease of the gums, possible pathologies on the neighboring teeth or allergies or hypersensitivity to chemical components of the materials used: Patent™ BIOXIDE-S (Y-TZP Zirconia).

The patient must not have any local or systemic disease. She or he must have normal healing ability, have sufficient healthy bones and practice good oral hygiene.

Complications and side effects

The clinical outcome of dental treatment is influenced by various variables. The following potential residual risks and side effects are associated with these products. These may require additional treatment at the dentist's practice:

Bone damage, loss of the Patent™ Symbionic Tooth , loss of prosthetic components, recall to the dental practice, sinus membrane perforation, nerve damage with the possible consequence of chronic pain, local pain, irritation/inflammation, other toxicity reactions, hypersensitivity reactions/ allergic reactions, swallowing/aspiration of small parts during the surgical/prosthetic procedure, gum injuries, surgical explantation of the device, longer than

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expected wound healing/recovery, problems with biting/chewing/speaking, paresthesia, dysesthesia, hyperplasia

Swelling, local inflammation, bruising, resorption of the upper/lower jaw ridge, systemic or local infection (including peri-implantitis, periodontitis, gingivitis, fistula), minor bleeding

Note: Immediately after Patent™ Symbionic Teeth have been inserted, activities involving strenuous physical exertion should be avoided.

Warnings

Patients may swallow or inhale prosthetic components. During intraoral handling, all components must be secured against aspiration. Aspiration of components may result in infection or unforeseen injury to the patient.

Failure to follow the practices and procedures described in this manual may result in any or all of the following complications: inhalation or ingestion of a component and subsequent treatment.

When preparing the osteotomy and inserting the Patent™ Symbionic Tooth, attention must be paid to the canal of the alveolar nerve. Nerve damage can result in anesthesia, paresthesia or dysesthesia.

To avoid bone necrosis or Patent™ Symbionic Tooth damage, do not exceed recommended insertion torques and speeds.

Patent™ Symbionic Teeth may only be restored with Patent™ Glass Fiber Posts that are compatible with Patent™ Symbionic Teeth.

Damaged products must not be repaired by the user.

Materials

The following table provides information on the materials used for Patent™ Symbionic Teeth:

Product group	Material
Patent™ Symbionic Teeth	Patent™ BIOXIDE-S (Y-TZP Zirconia)

Magnetic Resonance Imaging (MRI) safety information:

These products are fabricated from a material which is not affected by exposure to MRI energy and is MR Safe.

General Caution

One hundred percent treatment success cannot be guaranteed. In particular, non-observance of the product's indications for use and the surgical/handling procedure(s) may result in failure.

Treatments involving means Patent™ Symbionic Teeth may lead to biologic or mechanical failures including fatigue fracture of Patent™ Symbionic Teeth. Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful Patent™ Symbionic Teeth treatment.

Patent™ Symbionic Teeth must only be used with compatible Patent™ Medical instruments and components. Use of instruments or components that are not intended to be used in combination with Patent™ Symbionic Teeth can lead to product failure, damage to tissue, or unsatisfactory esthetic results.

Always choose the Patent™ Symbionic Tooth with the largest possible diameter that is adequately supported by the local bone (thickness and quality), in the given interdental space, and by the anticipated chewing forces. In areas with comparatively high loads, the correct alignment of the Patent™ Symbionic Tooth is particularly important.

When replacing a single tooth, the crown must be in slight infraocclusion to compensate for the elasticity of the periodontal ligament. It is important to avoid later occlusion so that the Patent™ Symbionic Tooth is not subjected to excessive radial load, which can cause the Patent™ Symbionic Tooth to become damaged or break. The dentist and dental technician must have extensive experience with all-ceramic prostheses. Patent™ Symbionic Teeth must not be connected to natural teeth, and the connection between two devices must not be larger than a tooth gap. The cement used must be suitable for zirconium oxide.

Patent™ Symbionic Teeth must not be used after the expiration date printed on the packaging (shelf life: 4 years).

Patent™ Symbionic Teeth must not be clinically reprocessed or resterilized. Cleaning, disinfection, and sterilization can compromise essential material and design features and lead to functional failure.

When using a new device/treatment method for the first time, working with a colleague who is experienced with the new device/ treatment method may help avoid possible complications.

Patent Medical has a global network of mentors available for this purpose.

It is especially important to achieve proper stress distribution through adaptation and fitting of the crown or bridge, by adjusting the occlusion to the opposing jaw. In addition, avoid excessive transverse loading forces, particularly in immediate loading cases.

Reading and understanding these instructions for use is not sufficient to be able to use the Patent™ Symbionic Tooth System. Patent™ Symbionic Teeth may only be used by dentists, doctors or surgeons who have completed the training to Patent™ Symbionic Tooth System and have extensive experience in jaw surgery, periodontal treatment, surgery and prosthetics. The assessment of the qualifications in this regard is the responsibility of the sole sales person Patent Medical AG or the approved manufacturer ZV3 - Zircon Vision GmbH. For more information, see our website at https://www.mypatent.com/de/event

Patent™ Symbionic Teeth

Patent™ Symbionic Teeth are delivered sterile and for single use. They must not be cleaned, disinfected and sterilized. The manufacturer does not accept any responsibility for processing of devices initially delivered sterile, regardless of who carries out processing or by what method.

The tamper-proof packaging system protects the sterilized device from outside influences and, if the device is stored correctly, ensures sterility up to the expiration date. When removing the device from the protective packaging and sterile barrier system, the rules of asepsis must be observed. The sterile barrier system must not be opened until immediately prior to insertion of the Patent™ Symbionic Tooth. ZV3 - Zircon Vision GmbH is only liable for Patent™ Symbionic Teeth which were inserted immediately after being taken out of the original packaging. Check sterile packaging of the devices for damage before opening. Devices with a damaged packaging system must not be used. It is recommended to have a replacement to hand.

The manufacturer does not accept any responsibility for re-sterilized devices initially delivered sterile, regardless of who carries out re-sterilization or by what method. A previously used or non-sterile symbionic teeth must not be used under any circumstances. If the original packaging is damaged, the contents will not be taken back by the manufacturer.

Patent™ Glass Fiber Post:

The Patent™ Glass Fiber Posts are delivered non-sterile must be cleaned and disinfected prior to intra-oral use. Prior to processing, remove the packaging system from the product.
The following procedure for cleaning and disinfection is recommended:
The product must be cleaned and disinfected manually with ethanol 70%.

Unpacking

Open the folding box. Pull off the outer lid and lay the inner blister with the Patent™ Symbionic Tooth ready for the operation. Use sterile gloves for opening the inner blister, upturn the glass tube and press the Patent™ Symbionic Tooth into the tube with the index finger, then take the tube out of the packaging and put it on the tray in the position corresponding to the tooth.

Please do not place the Patent™ Symbionic Tooth on an operation cloth during handling, cotton fibers may stick onto the rough surface. If needed, the Patent™ Symbionic Tooth can be stored temporarily into its glass tube.

Handling procedure

Before Surgery

Careful psychological and physiological evaluation followed by clinical and radiological examination must be performed on the patient prior to surgery to determine the suitability of the patient for treatment.

Special attention must be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft-tissue or the osseointegration process (e.g. cigarette smoking, poor oral hygiene, uncontrolled diabetes, oro-facial radiotherapy, steroid therapy, infections in the neighboring bone). Special caution is advised for patients who receive bisphosphonate therapy.

In general, Patent™ Symbionic Tooth placement and prosthetic design must accommodate individual patient conditions. In case of bruxism, other parafunctional habits or unfavorable jaw relationships, reappraisal of the treatment option may be considered.

The device has not been evaluated in pediatric/adolescent patients and is not recommended for use in children. Routine treatment is not recommended until the end of the juvenile jaw bone growth phase has been properly documented.

Pre-operative hard tissue or soft tissue deficits may yield a compromised aesthetic result or unfavorable Patent™ Symbionic Tooth angulations.

In order to assess the psychological and physical status of the patient, a thorough clinical and radiological examination must be carried out before the procedure.

Preoperative deficits of the bone or soft tissue can lead to poor aesthetic or an unfavorable Patent™ Symbionic Tooth orientation.

Before the surgical procedure, inform patients about the generally applicable precautions, rules of behavior and possible complications and side effects.

Even if the materials used have been used in the medical device industry and for fixed tooth replacement systems for years and are generally biocompatible, allergic reactions to the materials used may occur.

Preoperative planning

The Patent™ Symbionic Tooth diameter, Patent™ Symbionic Tooth type, position and

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number of Patent™ Symbionic Teeth should always take into account the individual intraoral anatomy.

Note: Treatment planning requires a thorough clinical diagnosis of the oral cavity, which may include the following: e.g. aesthetics, quality and quantity of the bone, occlusion, anatomy and pathologies of the neighboring teeth. For this purpose, additional examinations such as the following can be conducted: X-rays, CT or DVT photos, working models or a diagnostic wax-up

Procedure

For treatment recommendations see the detailed step-by-step description:

At Surgery

Care and maintenance of sterile instruments are crucial for a successful treatment. Sterilized instruments not only safeguard your patients and staff against infection but are also essential for the outcome of the total treatment. Because of the small sizes of the devices, care must be taken that they are not swallowed or aspirated by the patient. It is appropriate to use specific supporting tools to prevent aspiration of loose parts (e.g. gauze, dental dam, or throat shield).

After Patent™ Symbionic Tooth placement, the surgeon's evaluation of bone quality and primary stability will determine when Patent™ Symbionic Teeth may be loaded. Lack of adequate quantity and/or quality of remaining bone, infection and generalized diseases may be potential causes for failure of osseointegration both immediately after surgery, or after osseointegration is initially achieved.

Bending moments: Forces that cause bending moments are known to be the most unfavorable, as they can potentially jeopardize the long-term stability of a Patent™ Symbionic Tooth- supported restoration. In order to decrease bending moments, the distribution of forces should be optimized by cross-arch stabilization, minimizing distal cantilevers, having a balanced occlusion as well as decreased cuspidal inclination of the prosthetic teeth.

Osteotomy preparation:

Bone damages caused by overheating prevents a Patent™ Symbionic Tooth from osseointegration. Excessive rises in temperature must therefore be minimized by following the guidelines for the use of Patent™ Symbionic Tooth System drills and instruments regarding drilling speeds, intermittent drilling and adequate cooling.

Insertion of the Symbionic Tooth:

Patent™ Symbionic Teeth can be placed either manually with the ratchet or with the aid of the handpiece. A maximum speed of 15 rpm and a maximum torque of 35 Ncm are recommended.

Once the Patent™ Symbionic Tooth is placed, in order to protect its connection during the healing phase, it is recommended to use a temporary obturation material.

Note: Should the Patent™ Symbionic Tooth have insufficient primary stability after insertion, the Patent™ Symbionic Tooth must be removed, and the procedure repeated once the wound has healed.

Warning: Drills are sharp instruments. Handle with care. During drilling procedures bone quality should be considered. Patent™ Symbionic Teeth Drilling Protocol presents the recommended drill sequences based on bone quality to ensure optimal primary stability when applying immediate function. The recommended drill sequences are based on bone quality.

After Surgery

To ensure a successful long term-treatment outcome, it is advised to provide comprehensive regular patient follow-up after treatment and to inform the patient about appropriate oral hygiene.

Healing Phase

Post-operative controlling of overload and oral hygiene measures are important for unimpaired osseointegration. The Patent™ Symbionic Tooth must be able to heal unimpeded. Attention must be paid to mouth care. Within the scope of their indications, Patent™ Symbionic Teeth are suitable for immediate and early restorations of single missing teeth and edentulous or partially edentulous jaws. Good primary stability and an appropriate occlusal load are essential.

A radiographic check is recommended after a healing phase before starting the prosthetic restoration.

Note: If the bone quality is poor, the bone is regenerating or a Patent™ Symbionic Tooth is inserted immediately after a tooth extraction, the healing time can be longer and lead to extra risks regarding the possible early loss of the Patent™ Symbionic Tooth.

Use and handling of Patent™ Glass Fiber Posts

Patent™ Glass Fiber Post are provided in a separate packaging as Universal GFP and Straight GFP.

Patent™ Universal or Straight Glass Fiber Posts can be prepared either chairside or in the lab by the dental technician. Patent™ Glass Fiber Posts must be cemented to the corresponding Patent™ Symbionic Teeth with a MDP type cement (e.g. RelyX™ Unicem from 3M ESPE). To prepare Patent™ Glass Fiber Posts use a diamond bur at high speed and with water cooling. If the Patent™ Glass Fiber Post is prepared chairside, the impression is taken on the post as if it would be a prepared natural tooth. In case Patent™ Glass Fiber Post is prepared in the lab, the impression is taken directly on the Patent™ Symbionic Tooth connection. To make a coping or crown, follow the standard procedures according to the material manufacturer's instructions.

Caution:

Any type of synthetic material, composite, or synthetic material out of which a temporary prosthesis should be made sticks to the glass fiber reinforced post. If there is a contact between a temporary prosthesis and the glass post and core, a separator (e.g. Vaseline) must be used. After the temporary prosthesis has been removed, the glass fiber post must be cleaned with ethanol 70% and can be processed further. Once restored, Patent™ Glass Fiber Posts must be completely covered by the crown. Under no circumstances should a part of Patent™ Glass Fiber Posts be permanently exposed to human tissue.

Note:

For any reason a cemented Patent™ Glass Fiber Post has to be removed, use if a 1mm diameter diamond bur in a red contra-angle hand piece with a large amount of cooling and intermittent grinding.

Disposal

Disposal should be handled in an environmentally sustainable manner according to local regulations. Hazardous waste from contaminated devices or sharps should be disposed of in appropriate containers which meet specific technical requirements.

Validity

Upon publication of this document, all previous versions are superseded.

Performance Requirements and Limitations:

To achieve the desired performance, the Patent™ Symbionic Tooth System must only be used with the products described in this Instructions for Use.

Availability

Individual components of the Patent™ Symbionic Tooth System are not available in all countries.

Storage

Store the Patent™ Symbionic Teeth under normal environmental conditions. Patent™ Symbionic Teeth should be left in the packaging and not opened or removed from the package until just prior to use. There are no specific transportation conditions.

Notes

The lifetime warranty for Patent™ is available online at www.zircon-medical.com

Any problems that arise in connection with the product should be reported to Zircon Medical Management AG with reference to the corresponding product. Serious incidents must also be reported to the local organization or Patent Medical AG and, as required by law and regulatory authorities, to the competent authorities.

Please report any serious incident that has occurred in connection with the medical device in an EU country to the manufacturer and the competent authority in your country. The contact details can be found on the European Commission website (https://health.ec.europa.eu/medical-devices-sector/new-regulations/contacts_en).

The Summary Safety and Clinical Performance Report (SSCP) can be found at https://ec.europa.eu/tools/eudamed, quoting the relevant Basic UDI-DI (see Table 1). Until the database is fully operational, the SSCP will be provided by ZV3 – Zircon Vision GmbH. Please submit a request via the website https://www.mypatent.com/de/sscp.

Table 1: Basic UDI-DI

Product group	Basic UDI-DI
Patent™ Symbionic Tooth one-piece	426235568 OPIMPLANT U2
Patent™ Symbionic Tooth two-piece	426235568 TPIMPLANT XM
Patent™ Glass Fiber Post	426235568 GFT HE

Symbols Glossary

The following symbols may be present on the device labeling or in information accompanying the device. Refer to the device labeling or accompanying information for the applicable symbols.

Manufacturer

Manufacturing date

Country of manufacture (Germany)

Batch code

Catalogue number

Medical device

Unique device identifier

Caution

Non-sterile

Observe instructions for use

Consult instruction for use

Use-by date

Quantity

Do not resterilize

Sterilized using steam or dry heat

Double sterile barrier system

Do not use if package is damaged and consult instructions for use

Keep dry

Keep away from sunlight

Do not re-use

MR Safe

Rx only

Prescription device

CE 0483

Core Diameter

Connection Size

Endosseous Diameter

Endosseous Length

Endosseous Profile

Ferrule Heigth

Post Diameter

Post Height

Shoulder Design

Shank Length

Shoulder Size

Table Diameter

Transmucosal Height

Thread Length

Thread Pitch

Care Profile

Performance Profile

Connection

Universal GFP

Straight GFP

Straight GFP

Manufacturer and Distributor Information:

Distributor
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