

## Instructions for use: sterile ceramic dental implants - Patent™ standard line

### 1. System description

Patent™ standard line implant consist of 1-part and 2-part implants as well as the related prosthetic parts for the 2-part version. Patent™ standard implants are made of Y-TZP zirconia. The thread with three chambers for bone chippings which is inserted into the bone is at one end and the integrated abutment is at the other end of the 1-part implant. The other end of the 2-part implant is the drill hole in an integrated partial abutment, in which the post and core is bonded. The thread has a surface on which the tetragonal structures caused by sintering are retained in its original form, as the implant is not sintered until it has been completely processed, rather than the other way around. Implants are certified according to European guidelines (Guideline 93/42/EEC, Appendix II, classification IIb). Essentially, the implant is a substitute for a natural root, although one should be mindful that an implant cannot be a 100% fully adequate replacement for a natural tooth. An implant has no periodontal membrane and patients should also be informed of this. Our ceramic has a 4-point modulus of rupture, which is more than twice as high as the 4-point modulus of rupture for dental titanium. In the case of overload, titanium bends, and therefore gives out. However, although ceramic gives out later than titanium due to its high stability, and hardly bends at all, it can break. Both ceramic and titanium implants are suitable for a normal chewing load, but not for chewing loads which can occur with bruxers and/or clenchers, or for accidental biting on very hard objects. In these cases, natural teeth are also in danger of breaking, but implants more so, as there is no periodontal membrane to act as an absorber, as is the case with a natural tooth.

Patent™ standard implants were developed for use in surgery on the bone of the maxillary and mandibular arch to affix single crowns or bridges of up to three parts and therefore reestablish the patient's chewing function. Cantilever pontics are not permitted. Reading and understanding these instructions for use is not enough to be able to use Patent™ standard implants. To use Patent™ standard implants we recommend training by an expert with experience of this system. Implants may only be inserted by dentists, doctors or surgeons who have completed Patent™ standard implant training and who have advanced experience of maxillary surgery, periodontal treatment, implantology and implant prosthodontics. The assessment of eligibility in this regard lies with the distributor Zircon Medical Management AG or the manufacturer ZV3 – Zircon Vision GmbH. This is particularly important because the surgical implantation technique differs from the one used for titanium implants and ceramic is a material which is significantly different from metal and specific handling is therefore essential.

### 2. General handling

Patent™ standard implants are sterile and double-packed and must be stored carefully in the unopened protective packaging. Before unpacking the implant, the entire packaging should be checked for damage. If the lid or blisters are damaged, the sterility of the implant is no longer guaranteed. You should only open the blisters immediately before use. Damaged implants or implants which have already been used may not be reused.

### 3. Handling of sterile packaging

Open the folding box. The stickers can be taken off for the purposes of tracing and stuck on an index card, for example. Pull off the outer lid and lay the inner blister with the implant ready for the operation. After opening the inner blister (sterile gloves!), upturn the glass vial and press the implant into the vial with the index finger, then take the vial out of the packaging and put it on the tray in the position corresponding to the tooth. You may also watch the instruction video. Please do not place the implant on an operation cloth during handling, cotton fibers may stick onto the rough surface. If you wish to put down the implant, put it back into its glass vial. ZV3 - Zircon Vision GmbH is only liable for implants which were implanted immediately after being taken out of the original packaging. Non-sterile implants are strictly to be disposed of.

#### Warning!

Implants which have fallen on a hard surface can get tiny cracks. Furthermore, avoid excessive grinding on ceramic implants, as this may lead to tiny cracks which can result in fractures.

### 4. Packaging and sterility

The implant is double packed in blisters sealed with Tyvek film and these in turn are packed in a folding box. As is the case with similar blister packaging, sterility can be assumed to be guaranteed for 4 years.

### 5. Documentation

The stickers serve to identify the implant for doctor and patients. Next to the lot numbers, the type number of the implant is given under Ref. If the user does not store this documentation, it will not be possible to trace back the implant.

### 6. Indications

The patient should not have any local or systemic illnesses; he/she should have a normal ability to heal, possess enough healthy bone and practice good oral hygiene. Implants with a diameter of 4,1mm are only indicated for premolars in the upper and lower jaw and lateral incisors in the upper jaw.

### 7. Contraindications

- Relative contraindications: pregnancy, bone previously irradiated, diabetes, anticoagulant treatment, haemodynamic problems, teeth-grinding at night, parafunctional habits, poor bone anatomy, heavy smoking habit, uncontrolled periodontitis, malocclusion, TMJ problems, diseases in the oral cavity, insufficient mouth care. - Local contraindications: insufficient quality or quantity of the bone, retained roots, chronic or acute bone inflammations which have not healed in the position where an implant is to be inserted, localized disease of the gums, and any pathologies in the neighboring teeth.

#### Note:

Dental implants were developed for surgical implantation in the maxilla and mandible in order to fix single crowns or three-part bridges to replace missing or damaged teeth. There are different types of implants, with different design, dimensions and indications. The surface with its certain roughness mainly consists of tetragonal crystal structures which lead to osseointegration when combined with sufficient primary stability.

### 8. Notes concerning operation techniques and basics for treatment planning

Treatment planning requires thorough clinical diagnostics of the oral cavity, which may include the following, for example: 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-ray, CT or DVT photos, working models or a diagnostic wax up. The dentist or surgeon should determine which implant type and implant length are the best in each case, considering the implant notes and treatment planning. A radiological and surgical guide is helpful to ensure that the implant is inserted in the exact position at the precise angle. Failures in treatment planning may lead to the loss of the implant.

### 9. Operation

Surgical standard procedures for dental implants must be adhered to, e.g. drill speed (800RPM), tap speed (35RPM), pressure and cooling and taking care that drills and taps are sharp. The timely replacement of rotating instruments which do not cut perfectly is very important. The main goal during implantation is to achieve the primary stability of the implant. The implant bed should be prepared in such a way that the implant can be positioned so that the edge of the implant crown is iso-gingival, and the thread is inserted into the bone to approx. 2.0 mm. After the implant bed has been prepared, the implant must be inserted in it manually or mechanically by means of a dedicated insertion instrument. Here it must be taken into account that the concave sides of the implant shoulders are correctly aligned in the buccal-lingual position as planned. The abutment side of the implant must not be able to touch the antagonists during the healing phase, not even when the patient is lying down at night, in order to avoid premature pressure and hence the loss of the implant. Should the implant have insufficient primary stability after implantation, the implant must be removed, and the procedure repeated once the wound has healed.

## 10. Important directions concerning Patent™ standard line implants

Crowns can be produced as usual. Good occlusion and articulation are necessary. The crown must be in slight infra-occlusion in case of single tooth replacement to compensate for the elasticity of the periodontal membrane. It is important to avoid lateral occlusion so that the implant does not have to bear an excessive radial load, which can lead to the implant becoming damaged or broken. The dentist and lab technician should have extensive experience of prosthetics made completely of ceramic. Patent™ standard implants should not be connected to natural teeth and the connection between two implants must be no greater than the gap of one tooth. The cement used must be suitable for zirconium dioxide.

Please observe the following when using Patent™ standard line implants:

### a. The correct choice of implant is extremely important

The chances of the operation being a success are essentially determined by the choice of the right implant (model and size). The size and form of the human bone limit the size and form of the implant. However, this also limits the load-carrying ability. Compared to natural teeth, undersized implants are not suitable for unlimited chewing loads. The load should be limited to the normal functional load. Implants are not suitable for disproportionate loads, which can occur with bruxers and clenchers. Loads which are out of the ordinary, particularly those caused by impact, can lead to fractures of the implant.

### b. The correct handling of Patent™ standard implants is extremely important

Under no circumstances must the implant be hit by hard objects during the operation or later during the prosthetic treatment. Nor may a temporary crown be removed using pneumatics or shock inducing devices. Only the instruments assigned for the task may be used to insert the implant. When screwing in the implants you should avoid axis deviations with the handpiece to force an implant in a direction not compatible with the drilled hole, as this can lead to the implant being subject to great force. If this is not adhered to, it can cause damage to the structure of the ceramic and indiscernible damage to the material, which can lead to the implant fracture later on. Insertion torques should be limited to 32 Ncm. If an implant cannot be inserted at this force, a thread should be cut with a tap accordingly. After 2-part Patent™ standard implants have been plugged in, an A-silicone impression material is used as temporary protection against food debris becoming impacted in the clover-leaf hole. In our courses we teach the precise procedure for dealing with this.

### c. No implant may be re-used or re-sterilized in place

Even if the implant does not look damaged, there is likely to be internal material fatigue. Implants which have become non-sterile may not be sterilized again either, as this could lead to hairline cracks. We expressly point out that only brand-new implants in the original packaging are to be used.

### d. Post-operative care is also very important

Post-operative controlling of overload and oral hygiene measures are important for unimpaired osseointegration. During the healing phase there must be no contact with temporary prosthetics, removable prosthetics, electric or manual toothbrushes under any circumstances. The implant must be able to heal unimpeded.

## 11. Duration of wound healing

The duration of osseointegration depends very much on the individual and on the treatment. During the healing time it is especially important to pay attention to mouth care and non-contact implant healing period. During the healing time the implant must not be subjected to lateral pressure, as this can lead to micro-movement and therefore to the loss of the implant. If the bone quality is poor, the bone is regenerating or an implant 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 implant. The implant can be controlled with the help of X-rays after osseointegration to discover a possible risk of losing an implant. Patent™ standard implants must not be loaded by any temporary *removable* prosthetics before osseointegration. Every type of temporary prosthesis in case of direct loading must be bonded using the appropriate cement. During the healing phase in case of direct loading the temporary prosthesis must lie outside the occlusion and articulation. Direct loading may lead to more early loss compared with non-direct loading procedures.

## 12. Glass fiber reinforced post and core (GFS)

An unprocessed glass fiber post is delivered together with the Patent™ standard 2-part implant and is fit checked in the factory. Keep this post together with this implant and do not mix up the posts with those for other implants. When storing, write the name of the patient and the tooth position on the outer packaging. We aim for a fit as exact as possible with very little free rotation in the implant. With universal posts this fit would show much more free rotation. If a post is lost and you reorder a post, please provide the lot number of the implant.














The glass fiber reinforced post and core can be prepared by a dental technician (recommended). In this case, when taking an impression, make sure that the impression material (recommended: Impregum Penta Soft or Duo Soft) has hardened completely before you remove it from the patient's mouth, otherwise you will deform the tri-channel internal connection in the impression and the dental technician will have problems fitting the glass fiber post into the model. The glass fiber reinforced post and core should be cemented with Unicem 2 Automix order no. 56846 in line with the instructions for use from 3M Espe, in the same way as a glass fiber post is cemented into a natural tooth.

Caution: The post / implant fit is exact, which means that any air bubbles which become trapped when inserting the post can be compressed. If you release the post too early, it may rise slightly, which can lead to crowns not fitting.

**Warning:** 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 and core. If there is temporary contact between a temporary prosthesis and the glass fiber reinforced post and core, a separator (e.g. Vaseline) MUST be used. After the temporary prosthesis has been removed, the glass fiber reinforced post and core is cleaned with alcohol and can be treated further. The glass fiber reinforced post and core should be completely covered by the crown. Under no circumstances should a part of the glass fiber reinforced post and core be permanently exposed to saliva.

If for any reason the post has to be removed, use a 1mm spiral drill first, after this use a red diamond round head cylinder max. Ø1.2mm L ca. 8mm in the red contra-angle hand piece with a large amount of cooling and intermittent grinding. Avoid heat developing, as you would when preparing a root canal for a natural tooth. This cannot be mediated in instructions for use, but you can learn this in our courses. Before you take this measure, it is imperative for you to contact us in order to avoid implant damage.

## 13. Symbols

	USE BEFORE: DATE (YEAR-MONTH)		STERILISATION WITH STEAM OR DRY HEAT
 eIFU indicator	"Consult instructions for use" for an electronic instruction for use (eIFU)		DO NOT STERILISE AGAIN
	DO NOT USE CONTENTS OF DAMAGED PACKAGING		DO NOT RE-USE
	LOT DESCRIPTION	CE0483	CE MARK NO. 0483
	ORDER NUMBER		KEEP DRY
	GENERAL WARNING		PROTECT FROM SUNLIGHT
	MEDICAL DEVICE		Manufacturer

## 14. Contact

### Distributor

Zircon Medical Management AG  
 Churerstrasse 66  
 8852 Altendorf  
 Switzerland  
 T +41 (0)78 859 73 33  
 info@zircon-medical.com  
 www.zircon-medical.com  
 ifu.zircon-medical.com

 CE0483  
 ZV3 - Zircon Vision GmbH  
 Hans-Urmiller-Ring 46c  
 D-82515 Wolfratshausen  
 Germany