INSTRUCTIONS FOR USE ZERAMEX® IMPLANTS

ZERAMEX®

1. Disclaimer of liability
ZERAMEX® implants are part of an overall concept and may only be used in combination with the appropriate original components and instruments and in compliance with the manufacturer's instructions. The use of non-compliant parts might impair the function of the implants and of the abutments and consequently result in implant failure. Sole responsibility for correct application is assumed by the user and is beyond control of Dentalpoint AG. Dentalpoint AG does not assume any responsibility and liability for damages caused by misuse.

2. Description
ZERAMEX® implants are available in different lengths specified in the current product lists.
Diameter: The shoulder and enossal diameter is separately indicated on the package.
Length: The length of ZERAMEX® implants specified on the package equals the enossal length of the implant.
Material: ZERAMEX® implants are made of biocompatible zirconia / zirconium dioxide.
Surface: ZERAMEX® implants are equipped with ZERAFIL™ surface (sandblasted and acid etched)

3. Indications for use
The ZERAMEX® Dental Implant System is intended to be surgically placed in the bone of the upper and lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore aesthetics and chewing function. The ZERAMEX® Dental Implant System can be used for single or multiple unit restorations. The ZERAMEX® implants are intended for delayed loading. The ZERAMEX® implants are specially indicated for patients with metal allergies/ intolerances and chronic illness due to metal allergies/intolerances. The ZERAMEX® P6 (Ø3.3 mm SN) implant may only be used in the anterior teeth in the lower jaw and lateral incisor in the upper jaw. The ZERAMEX® T (Ø 3.5 mm) implant may only be used in the anterior teeth in the lower jaw and lateral incisor in the upper jaw.

4. Contraindications
Implantation is contraindicated in patients with the following conditions:
- Poor bone quality, i.e. if a stable fit of the implant (primary stability) cannot be assured, even with bone grafts
- Patients with osteoporosis currently undergoing course of bisphosphonates
- Patients under the age of 15
- Smoking
- Poorly motivated, non-cooperative patients who cannot or will not comply with oral hygiene directions and post-operative restrictions, including patients with certain mental diseases
- Active infection
- Intractable periodontitis and untreated severe periodontal disease
- Heart diseases affecting the valves, recent infarcts, severe cardiac insufficiency, cardiomy-opathy
- Severe immunodeficiency, including patients with HIV, undergoing chemotherapy, or awaiting organ transplants
- Systemic diseases, including severe blood disease (e.g. hemophilia)
- Strongly irradiated jaw bones

5. Relative Contraindications
Implants may be contraindicated in patients with the following conditions:
- Acute or chronic infectious diseases
- Sub-acute chronic jaw ostitis
- Hypertension
- Microvascular impairments
- Myocardial infarction within past six months
- Cerebral infarction and cerebral apoplexy: In cases where the condition of the disease is serious and the patient are concurrently taking anticoagulants.
- Diabetes
- Alcohol or drug abuse
- Pregnant or lactating women
- Chronic osteomyelitis
- Bruxism
- Mouth-closing disorder (temporomandibular joint disorder, temporomandibular joint ankylosis, post-tumour resection)
- Abnormal anatomical structures, e.g. maxillary sinus, inferior alveolar nerve, that may interfere with implants

Note
Please consider the general contraindications valid in the field of medical implants. Peri-dontal problems require appropriate treatment prior to implantation.

6. Side effects, interactions and precautions; complications with ZERAMEX® implants
Immediately after the insertion of dental implants, activities that demand considerable physical exertion should be avoided.

Information related to side effects, interactions and precautions, complications with ZERAMEX® implants should be provided to the patient.

Possible complications following the insertion of dental implants are:
Temporary symptoms: Pain, swelling, phonetic difficulties, gingival inflammation
More persistent symptoms: Chronic pain in connection with the dental implant, permanent paresthesia, dysesthesia, loss of marginal bone, osteolysis, poor or no osseointegration, localized or systemic infection, oroantral or oronasal fistulae, unfavorably affected adjacent teeth, irreversible damage to adjacent teeth, fractures of implant, jaw, bone or prosthesis, esthetic problems, nerve damage, exfoliation, hyperplasia.

7. Warning
One hundred percent implant success cannot be guaranteed. Failure to observe the indicated limitations of use and working steps may result in failure.
Products must be secured against aspiration when handled intraorally. Aspiration of products may lead to infection or unplanned physical injury.
Despite the high success rates with ZERAMEX® implants, failures cannot be excluded. Reasons are case-specific and often not obvious. They should be documented and reported to the manufacturer.

8. Caution / Precautions
a. Clinical use
Sterile handling is essential. ZERAMEX® implants and healing caps are for single use only. A previously used, non-sterile or contaminated implant or healing cap must not be used under any circumstances. Re-use of single use devices may lead to infections, inflammations or loss of the implant.

b. Handling of storage and sterile package
The storage package is only to be opened shortly before implantation. The sterile package has to be checked for damages prior to opening. Any damage of the sterile package (blister) might affect sterility of the contained products. When taking the implant out of the package, please follow the valid instructions regarding aseptic conditions. ZERAMEX® implants have to be stored in their original package and in a cool (ambient temperature) and dry environ ment and have to be protected against direct sunlight.

9. Sterilization
In compliance with the corresponding instructions, ZERAMEX® implants and healing caps are always subjected to steam sterilization.
Re-sterilization: If the package is damaged or not tightly closed, ZERAMEX® implants must not be used or re-sterilized. Same applies to expired implants. The manufacturer does not assume liability for re-sterilized implants.

10. Procedure
a. Pre-surgical preparation includes:
- General and local patient history, general medical examination (hemogram, diabetes, etc.), consultation with an internal medicine or general practice doctor as well as the local, clinical and radiological examination
- Patient information on indications, contraindications, possible success and failure
- Pre-surgical and prosthetic preparation and consultation with a dental technician
- Selection of an anatomically suitable implant based on X-ray and other techniques.

Detailed information regarding the handling of ZERAMEX® implant systems can be found in our brochure and in the instruction manual. Documentations are available on our website www. zeramex.com.

Note
Anatomic and hygienic conditions of each patient have to be assessed individually. In case of unfavorable conditions implantation is not indicated.

b. Healing time
For all ZERAMEX® implants the minimal healing time is considered 3 months in the lower jaw and 6 months in the upper jaw.

11. Please note
The preceding specifications are an outline of the most important operational steps. They are not supposed to be a complete instruction and are not suitable for immediate application of the ZERAMEX® system. We highly recommend a briefing by an experienced user. Documentation/ Traceability: The manufacturer recommends complete clinical, radiological, photographic and statistic documentation. Traceability of the implants has to be assured. Use the adhesive labels enclosed in the sphere package for documentation in the patient file.

12. Availability
Some of the ZERAMEX® products and services are not necessarily available in every country. For detailed information, please contact the Dentalpoint AG headquarters in Spreitenbach, Switzerland.

Manufacturer
Dentalpoint AG, Bodenäckerstrasse 5, CH-8957 Spreitenbach, Switzerland
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CE	0050		Caution, consult accompanying documents
REF	Catalogue number		Use-by date
LOT	Batch code		Consult instructions for use
	Do not re-use		Manufacturing date
STERILE	Steam sterilized		Manufacturer
	Non sterile		Do not use if packaging is damaged
	Keep dry		Keep away from sunlight
Rx Only	Prescription use only		

INSTRUCTIONS FOR USE ZERAMEX® XT IMPLANTS

ZERAMEX®

1. Disclaimer of liability
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2. Description
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Material: ZERAMEX® implants are made of biocompatible zirconia / zirconium dioxide.
Surface: ZERAMEX® implants are equipped with ZERAFIL™ surface (sandblasted and acid etched)

3. Indications for use
The ZERAMEX® Dental Implant System is intended to be surgically placed in the bone of the upper and lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore aesthetics and chewing function. The ZERAMEX® Dental Implant System can be used for single or multiple unit restorations. The ZERAMEX® implants are intended for delayed loading. The ZERAMEX® implants are specially indicated for patients with metal allergies/intolerances and chronic illness due to metal allergies/intolerances.

4. Contraindications
Implantation is contraindicated in patients with the following conditions:
- Poor bone quality, i.e. if a stable fit of the implant (primary stability) cannot be assured, even with bone grafts
- Patients with osteoporosis currently undergoing course of bisphosphonates
- Patients under the age of 15
- Smoking
- Poorly motivated, non-cooperative patients who cannot or will not comply with oral hygiene-directions and post-operative restrictions, including patients with certain mental diseases
- Active infection
- Intractable periodontitis and untreated severe periodontal disease
- Heart diseases affecting the valves, recent infarcts, severe cardiac insufficiency, cardiomy-opathy
- Severe immunodeficiency, including patients with HIV, undergoing chemotherapy, or awaiting organ transplants
- Systemic diseases, including severe blood disease (e.g. hemophilia)
- Strongly irradiated jaw bones

5. Relative Contraindications
Implants may be contraindicated in patients with the following conditions:
- Acute or chronic infectious diseases
- Sub-acute chronic jaw ostitis
- Hypertension
- Microvascular impairments
- Myocardial infarction within past six months
- Cerebral infarction and cerebral apoplexy: In cases where the condition of the disease is serious and the patient are concurrently taking anticoagulants.
- Diabetes
- Alcohol or drug abuse
- Pregnant or lactating women
- Chronic osteomyelitis
- Bruxism
- Mouth-closing disorder (temporomandibular joint disorder, temporomandibular joint ankylosis, post-tumour resection)
- Abnormal anatomical structures, e.g. maxillary sinus, inferior alveolar nerve, that may interfere with implants

Note
Please consider the general contraindications valid in the field of medical implants. Peridontal problems require appropriate treatment prior to implantation.

6. Side effects, interactions and precautions; complications with ZERAMEX® implants
Immediately after the insertion of dental implants, activities that demand considerable physical exertion should be avoided.

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Possible complications following the insertion of dental implants are:
Temporary symptoms: Pain, swelling, phonetic difficulties, gingival inflammation

More persistent symptoms: Chronic pain in connection with the dental implant, permanent paresthesia, dysesthesia, loss of marginal bone, osteolysis, poor or no osseointegration, localized or systemic infection, oroantral or oronasal fistulae, unfavorably affected adjacent teeth, irreversible damage to adjacent teeth, fractures of implant, jaw, bone or prosthesis, esthetic problems, nerve damage, exfoliation, hyperplasia.

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b. Handling of storage and sterile package
The storage package is only to be opened shortly before implantation. The sterile package has to be checked for damages prior to opening. Any damage of the sterile package (blister) might affect sterility of the contained products. When taking the implant out of the package, please follow the valid instructions regarding aseptic conditions. ZERAMEX® implants have to be stored in their original package and in a cool (ambient temperature) and dry environment and have to be protected against direct sunlight.

9. Sterilization
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Re-sterilization: If the package is damaged or not tightly closed, ZERAMEX® implants must not be used or re-sterilized. Same applies to expired implants. The manufacturer does not assume liability for re-sterilized implants.

10. Procedure
a. Pre-surgical preparation includes:
- General and local patient history, general medical examination (hemogram, diabetes, etc.), consultation with an internal medicine or general practice doctor as well as the local, clinical and radiological examination
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11. Please note
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12. Availability
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GUIDLINES FOR STERILIZATION AND INSTRUMENT CARE IN ACOORDANCE WITH EN ISO 17664

ZERAMEX®

Reprocessing and preparing medical devices / General requirements
Refer to the legal regulations and guidelines which are valid for medical office practices and hospitals in your country. This applies in particular to specifications for the effective denaturation of prions. Treatment always involves a risk of contamination and infection. Take preventive measures to actively eliminate the risk or to reduce it as much as possible.

These measures include: Evaluation of the risks that accompany the medical intervention; decision on appropriate protective measures; development of systematic procedures for the work flow, in order to prevent contamination and injuries careful recording of each patient's medical history to be aware of the individual contagion risk.

All medical devices that have been opened and laid out for use are to be considered contaminated and are to be reprocessed in the same way as used equipment. Organize the transport of contaminated devices in such a way that no staff members, co-workers or third parties are endangered. All personnel must wear the appropriate protective clothing and gloves.

Medical products may corrode if they are stored in a physiological saline solution. Instruments are to be submerged fully in the sterilization trays, without air bubbles. The use of demineralised water to rinse instruments after disinfection is absolutely necessary to prevent water spots and the formation of crystals. These disrupt the subsequent sterilization process.

You are responsible for the sterility of the products you use. For this reason, you must use validated procedures for the cleaning, disinfection, and sterilization of your medical devices and products. You must ensure regular maintenance of your equipment, and you must observe all process parameters in every cycle. Please note the shelf life of products in sterile packaging (manufacturer's data sheet). Reprocessing ends with the release for use. Sterilization indicator and sterilization date must be recorded on every sterile packing.

Important:
Products that are delivered in non-sterile condition (e.g. drills and abutments) must be sterilized before they are used on a patient the first time. After use, all reusable medical devices must be reprocessed in accordance with the described procedure.

Manual reprocessing
Place the products in a disinfectant solution after use to prevent them from drying out and as a personal protection measure. Remove large impurities (blood, tissue and bone fragments). To do this, take the instruments from the tray and clean them under cold, running water with a fine nylon brush. Never use a metal brush or steel wool for this step!

Ultrasonic cleaning (optional)
If the instruments are very soiled and it is not possible to remove large impurities manually, cleaning in an ultrasonic bath is recommended. Important: The cleaning agent must be compatible with the products. Please observe the application times and concentrations specified by the manufacturer.

Cleaning
Before cleaning the products, rinse them under a flow of cold, demineralised water. Disassemble all products that can be taken apart. A suitable cleaning agent is, for example „neodisher MediClean" (Dr. Weigert, Hamburg). Place the products in a fresh cleaning bath, in accordance with the manufacturer's information. Clean the parts with a nylon brush. Rinse the products several times with demineralised water and check for corrosion or damage.

Disinfection
Place the products that need to be disinfected in a fresh disinfectant bath. The liquid must cover them completely. ID 212 instrument disinfection (Dürr System Hygiene) is a suitable disinfectant, for example.

Rinsing and drying
After disinfection of the products, rinse thoroughly with demineralised water. Use residue-free compressed air to dry the instruments.

Automated reprocessing
For automated cleaning to be effective, it must be preceded by manual cleaning. This removes large impurities (blood, tissue and bone fragments). Rinse instruments under cold, running water immediately after use, and use a fine nylon brush to clean off the large impurities. Then place the instruments in the cleaning tray of your disinfection and cleaning device.

Ultrasonic cleaning (optional)
If the instruments are very soiled and it is not possible to remove large impurities manually, cleaning in an ultrasonic bath is recommended. Important: The cleaning agent must be compatible with the products. Please observe the application times and concentrations specified by the manufacturer.

Automated cleaning
Only use properly suited cleaning and disinfection equipment for your automated cleaning tasks. These should be validated by the user on the basis of established cleaning processes. Place parts in the cleaning tray in accordance with instructions provided by the manufacturer of the equipment. There are commercially available cleaning and disinfection agents. We recommend: „neodisher MediClean" and „neodisher Z" as the neutralising agent (both from Dr. Weigert, Hamburg). Follow the manufacturer's information on dosage and use. We recommend fully demineralised water to clean instruments and for the final rinsing procedure. The selected cleaning and disinfection program should run with the optimal temperature for removal of blood (45–55°C).

Example of a cleaning program:

• Pre-rinse with cold water	4 min
• Clean with alkaline cleaning agent at 45–55°	10 min
• Neutralise	6 min
• Intermediate rinse	3 min
• Disinfection	5 min
• Drying (max. 130°C)	5 min

Before the sterilization process, check the cleaned, dried and disinfected parts for corrosion and damage.

Sterilization
Re-assemble the dismantled medical devices before you start the sterilization procedure. Sort the separately cleaned and disinfected products into the appropriate sterilization tray. You may also sterilize products individually. Then pack the filled trays and/or the individual products in a non-reusable bag suitable for use in a steam sterilizer (single or double bags) and/or in a sterilization container. The validated procedures require the use of FDA-cleared sterilizers, sterilization trays, sterilization wraps, biological indicators, chemical indicators, and other sterilization accessories labeled for the sterilization cycle recommended. The health care facility should monitor the sterilizer for the facility according to an FDA recognized sterility assurance standard such as ANSI/AAMI ST79:2010. Two examples are: a non-reusable sterilization bag (single or double bag) with temperature tolerance of at least 137°C (ca. 278.6°F) and vapour permeability that allows adequate protection from mechanical damage, or else a sterilization container, which must undergo regular maintenance according to the specifications of the manufacturer. Instruments such as drills, thread cutters and depth gauges have dedicated positions in the ZERAMEX® XT Surgery tray, REF XT48850, where they can be placed for sterilization. Sterilization is achieved in the autoclave at USA: 132°C for the duration of at least 4 minutes holding time and subsequent 20 minutes drying. Rest of world: 134°C for the duration of at least 7 minutes holding time and subsequent 20 minutes vacuum drying. The parts should then be marked with a sterilization date and placed in dry and dust-free storage. USA: If the parts are stored after sterilization, they must be stored in FDA cleared accessories such as wraps and containers.

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