XGATE Dental Abutments Instructions for Use

1. Product Description:

XGATE Dental Abutments provides large range of compatible abutments with XGATE's Dental Implants as well as with other Dental Implants' systems as are listed below. The Dental Abutments Design is similar to all connections' types, with one difference of the internal connection type.

The Dental Abutments Design consists of: Healing caps, Multi Unit Abutments Straight/17° 30° 45° Angulated, Ti-Base Abutments, Ti-Base UNO Abutments Hex/Round, Titanium Sleeve, DLOC Attachments Straight/ 9° 15° 30° Angulated, Ball Attachments Straight/9° 15° 30° Angulated, Titanium Abutments Straight/15° 25° Angulated, Titanium Abutments with Shoulder Straight/15° 25° Angulated and UCLA Abutments. Abutments screws are included within the Abutments packaging. Abutments screws are also available in a single packaging.

XGATE Dental Abutments are provided CNC machined surface and are also available anodized-colored.

XGATE Dental Abutments platforms types are available as follow:

Internal Hex Regular, Internal Hex Slim, Conical Regular Platform, Conical Slim Platform, Conical Mini;

XGATE Dental Abutments are available in other connections compatible with the following companies:

OSSTEM, Nobel Active Narrow, Nobel Active Regular, Megagen Anyridge, MIS V3 Narrow, MIS V3/C1 Regular, Straumann Bone Level Regular 4.1-4.8, Neodent Grand Morse, Megagen AnyOne,, Astra® 3.5/4.0, Astra® 4.5/5.0;

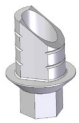
Dental Abutments available range of measurements –:

Diameter mm- 3.0 mm to 7.0 mm;

Profile Heights- 0mm, 1mm, 2mm, 2.5mm, 3mm, 4mm, 5mm, 6mm, 7mm;

Some products may not be regulatory cleared for sale in your market. Please contact your local sales representative. For the availability of the measurements go to XGATE online catalog: www.XGATE.Dental

Healing Cap 	Straight abutment 	Angled Abutment 
Straight Anatomic Abutment 	Titanium Abutments with Shoulder 	Screw for abutment 

Straight multi unit abutment D-type, V-type 	Straight multi unit abutment D-type, V-type 	Angled multi unit abutment D-type , C-Type 
Ti-Base A-type, M-type hex/round 	Ti-Base UNO hex / Round connection 	Ti-Base, Monolith direct hex/round 
Titanium Sleeve Abutment 	Ball attachment abutment 	Angled ball attachment abutment 
DLOC attachment abutment 	Angled DLOC attachment abutment 	UCLA Titanium base 

Note: Dental Abutments are provided non sterile, for single use, with a screw. Abutments screw is available also in single packaging. Related Dental Instruments involved in the surgical procedure e.g. abutment driver, screwdriver, ratchet and prosthetics protocols are within *XGATE* Surgical & Prosthetic Manual TF-MDR-1000-17.3 Surgical Prosthetic Manual. Processing of Dental Surgical Instruments Reusable refer to IFU TF-MDR-2000-17.1

2. Intended Use:

XGATE dental implants can be used for all indications requiring oral, endosseous implants for functional, aesthetic rehabilitation of edentulous and partially dentate upper or lower jaws. The restoration may comprise of single crowns, bridges and partial or full dentures connected to the implants with abutments.

3. Intended Users and Patient Groups

XGATE medical devices are intended to be used by dental health care professionals.

XGATE medical devices are intended to be used in partially and/or fully edentulous patients subject to dental implantation and/or restoration treatment.

4. Indication for Use:

XGATE Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, to restore the patient's chewing function. XGATE Dental Implants System is indicated

also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Dental Abutments are intended to be connected into a dental implant to restore artificial teeth.

Healing Caps are intended to be temporarily connected into a dental implant or abutment to support healing stage of the soft tissue.

5. Materials:

XGATE Dental Abutments: Titanium alloy Ti-6Al-4V, Tri-Sodium phosphate dodecahydrate.

6. Contraindications:

Dental Abutments are contraindicated for:

Patients allergic or intolerance or hypersensitive to Titanium Ti-6Al-4V (titanium, aluminum, vanadium), Stainless Steel (Surgical Instruments, Dental Drills are with or without DLC Diamond Like Carbon).

Patients medically unfit for operation and/or surgical procedures: Severe uncontrollable systemic disease, metabolic bone disorders, uncontrolled hemorrhagic diseases, uncooperative/unmotivated patient, drug, alcohol or tobacco abuse, psychotic diseases, long standing, therapy-resistant functional disturbances, xerostomia, compromised immunoresistance and leucocytic malfunctioning, illnesses requiring periodic administration of steroids or anticonvulsant, uncontrollable endocrine diseases. Relative contraindications: Previous bone radiotherapy, diabetes mellitus, medicinal anticoagulation / hemorrhagic diatheses, bruxism, parafunctional habits, complicated anatomical bone conditions, uncontrolled periodontitis, diseases of the temporomandibular joint, pathological diseases of the jaw and mucous membranes which can be treated, pregnancy, inadequate oral hygiene.

Local contraindications: Insufficient bone and inadequate bone quality, local root debris or location of vital blood vessels, nerves, maxillary sinus, soft tissue space, and their relation to implant placement.

7. Warning:

XGATE Dental Medical Devices are intended for use by trained dental specialists.

It is recommended that practitioners attend hands-on training courses in order to learn proper techniques, including biomechanical requirements and radiographic evaluation.

To achieve the desirable performance, XGATE's medical devices must be used with accordance to XGATE's Surgical Prosthetic Manual (TF-MDR-1000-17.3), IFU Dental Surgical Instruments Reusable TF-MDR-2000-17.1. (IFU of Dental Implants TF-MDR-1000-17.2).

Dental Abutments are provided Non- Sterile and are for Single Use, do not re-sterilize and do not re-use!

Prior to their use these must be sterilized with accordance to these instructions.

Use of non-sterile device may lead to infection of tissues or infectious diseases.

For small size devices, components and detachable devices attention must be made to not swallow

or aspirated by patient. Use your supporting medical devices to prevent aspiration or sallowness e.g throat shield.

Deficiencies in patient evaluation, pre-operative diagnosis and treatment planning may cause to implant failure or patient injury.

Drilling beyond the depth intended from lower jaw surgery may potentially results in permanent numbness to the lower lip and chin or lead to a hemorrhage in the floor of the mount.

Periodic follow-up evaluations including radiographs are recommended. Special attention should be put on oral hygiene and habits, occlusion adjustments and the stability of the prosthesis.

8. Precautions:

Thorough screening of prospective implant candidates must be performed. Visual inspection as well as panoramic and periapical radiographs are essential to determine anatomical landmarks, occlusal conditions, periodontal status, and adequacy of bone. Lateral cephalometric radiographs, CT Scans, and tomograms may also be beneficial.

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

In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism or unfavorable jaw relationships reappraisal of the treatment option may be considered.

Use of the implant may require preoperative antibiotic prophylaxis. In type I or II bone when you feel strong a resistance at the time of placing the implant, remove the mount and place the insertion tool 2.5mm, rotate back (counterclockwise) 2-3 rounds then continue to screw clockwise. Small diameter implants and angled abutments are not recommended for use in the posterior region of the mouth. The maximum insertion torque is 45 Ncm.

9. Sterilization

Dental Abutments, including Healing Caps and Screws are provided Non-Sterile and for Single Use. Prior to use, these must be sterilized in an autoclave by gravity displacement, in compliance with the manufacturer’s instructions, with accordance to the following parameters:

Gravity displacement, seal single device within - FDA Cleared pouch - and steam sterilization cycles: 121°C for 30 minutes; Drying time 30 minute.

After sterilization these devices for immediate use. Do not reprocess and do not reuse.

10. Adverse Effects:

Loss of implant anchorage (failure to osseointegerate) and loss of the prosthesis are possible occurrences after surgery. Lack of quantity or quality of remaining bone, infections, poor patient oral hygiene or cooperation, and generalized diseases (diabetes, etc.) are some potential causes for loss

of anchorage.

11. Surgical Procedure:

Surgical procedures and drilling protocol are within XGATE's Surgical Prosthetic Manual (TF-MDR-1000-17.3).

Tightening limits recommendations:

Implant installation for desired position use insertion torque max 50 Ncm. Do not exceed 50 Ncm.

For immediate function, the implant should be able to withstand a final torque between 35-45 Ncm.

The tightening of the healing abutment on the implant 5-10 Ncm.

The tightening of the abutment screw on the implant analog 10-15 Ncm.

The tightening of the abutment screw on the implant 30-35 Ncm.

12. Clinical Benefits and Undesirable Side Effects

Clinical Benefits associated with XGATE Dental Implants System and Instruments:

XGATE Dental Implants system consists of Implants, Abutments, screws, accessories and instruments being used with surgical implantation procedures and restorative application. The clinical benefits arising from these procedures are to restore missing teeth, restore missing crown and restoring patient chewing function.

Undesirable Side Effects associated with XGATE Dental Implants System and Instruments:

The surgical implantation procedure involves risks which may be associated with typical side effects such as localized swelling, infection, inflammation, tenderness of short duration, edema and hematoma or bleeding. Numbness of the lower lip and chin region following lower jaw surgery and of the tissue beside the nose following upper jaw surgery is a possible side-effect of the surgery. Though it would most probably be of a temporary nature, in very rare cases, the numbness has been permanent. Gingival-mucosal (gum tissue) ulceration, tissue reaction or infection may occur but generally responds to local care.

Complications associated with dental implants include, but are not limited to: Temporary complaints such as Pain, swelling, speech impediments, Gingival infections, Inadequate function or device failure (mobility, loss of integrity), Injury during surgery, bone fracture, perforation (sinus, alveolar plates),post-surgical parathesia.

Complications associated with dental abutments include, but are not limited to: Inadequate function (incompatibility), Device failure (mobility, loss of integrity), Damage to existing dentition.

During use of dental surgical instruments and implantation the pharyngeal (gag) reflex may be triggered in patients with a sensitive gag reflex.

Longer-term complaints: Chronic pain related to the dental implant, permanent paresthesia, dyesthesia, loss of bone in the upper / lower ridges, Damage to existing dentition, local or systemic infections including bacterial endocarditis, oroantral fistulae, oronasal fistulae, discoloration in the mucosal area, adversely affected adjacent teeth, irreversible injury to adjacent teeth, fractured implant, jaw, bone, or restoration, problems with aesthetics, nerve damage, exfoliation, hyperplasia.

Per European Medical Device Regulation MDR EU 2017/745 requirements XGATE Summary of Safety and Clinical Performance SSCP is available for XGATE Dental Implants & Abutments at following website: https://ec.europe.eu/tools/eudamed .
(website available upon launch of the European Database on Medical Devices EUDAMED).

Serious Incident Notice

For a User/Patient/third party in the European Union and in countries having identical regulatory requirements, in the case of during use with this device or as results of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority.

13. Magnetic Resonance Imaging (MRI) – Safety Information

The XGATE Dental Implants System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the XGATE Dental Implants System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

14. Storage, Handling and Transportation

The products must be stored in a dry conditions in their original packaging at room temperature and not exposed to direct sunlight. Incorrect storage and transportation may influence device characteristics leading to failure.

15. Disposal

Product disposal shall be with accordance to local regulations and environmental requirements considering different contamination levels.

Manufacturer: Xgate Dental Group GMBH
Falkensteiner Straße 77, 60322 Frankfurt am Main, Germany
Tel.: +49 69 95 90 840 – 0 https://xgate.dental/

Distributor: XGATE Dental Inc
24A Trolley Square Unit #4038 Wilmington, DE 19806
Tel: (302) 498-8373 www.XGATE.Dental

CE **1282**

Prescription device: Rx Only
Caution: Federal law restricts this device to sale by or on the order of a licensed physician or dentist.

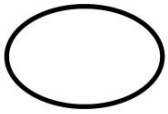
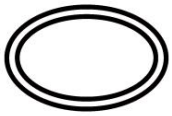
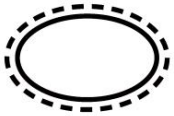
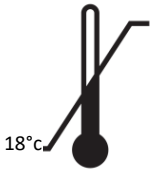
Basic UDI-ID Information:

Product	Basic UDI-ID Number
Dental Abutments	42558958XGAbutmentCY

Symbols Glossary:

The following symbols may be presented on the device labeling or/and accompanied information.

	Catalogue Number		Lot Number
	Use-by date		Do not use if package is damaged and consult instructions for use
	Consult instructions for use or consult electronic instructions for use		Caution
	Manufacturer Details		Authorized Representative in the European Community
	CE Mark		Medical device
Rx only	Caution: Federal law restricts this device to sale by or on the order of a physician or dentist.		Unique Device Identifier
	Date of manufacture		Non-pyrogenic
	Sterilized using irradiation		Non sterile

	Do not resterilize		Do not re-use
	Single sterile barrier system		Double sterile barrier system
	Single sterile barrier system with protective packaging inside		Single sterile barrier system with protective packaging outside
	Keep away from sunlight		Keep dry
	Temperature limit		Humidity limitation - Standard ambient condition
	Date		Information website for patients
	Patient Name or patient ID		Name and Address of the implanting healthcare institution/provider