MGM IMPLANT

USER MANUALS FOR MGM IMPLANT DENTAL IMPLANTS

Intended Use

Implants: devices made of titanium alloy material, designed to be surgically inserted into the bones of upper or lower jaw arches to support the prosthetic devices such as artificial teeth and to improve the chewing function of patients.

Abutment: If the panoramic film of the patient indicates osseointegration of the implant with the bone, it is measured through abutment or a measurement transfer part.
This measure is sent to the laboratory. The abutment is performed based on patient. The abutment that is completed by the physician, is mounted to the patient. The duration of use is patient-specific. It is disposable. Its useful time is the same as the implant used. The abutment is the holder that carries the prosthesis used to replace the missing teeth.

Angled Abutment: The angled abutment is produced in a way that its angle is 15 degrees and 25 degrees. Its height is determined based on the thickness of gingival mucosa.
For the angled implant inserted, angled abutment is used to anatomically insert the dental prosthesis. It is the implant superstructure used after the gingival mucosa has healed.

Ball Attachment Abutment: Ball attachment is the holder that carries the prosthesis used to replace the missing teeth.

INDICATIONS

Indications for Use: Dental Implant products include one-piece and two-piece implants for obe- or two-stage surgical procedures. These implants are used as intermediate support for single or multiple unit restorations in patients that are partially or wholly edentulous in the lower and upper jaw. Due to the surface on which the implants are developed, and if their primary stabilization is equal at the insertion stage, there is an early loading function.

Indications for Implants (the ones with D1 and D2 Bone Quality)
The most common indications for dental implantation are as follows.
1) 1)It is used as an artificial tooth root to replace single missing tooth of the mandibular central, lateral incisors and maxillary lateral incisors.
2) It is used for multiple missing teeth or for bridge stabilization of the edentulous area. 3) For the support of removable dentures (full or partial dentures)
3) For the support of removable dentures (full or partial dentures)

Large Diameter Implants:
In patients with poor bone quality (the ones with D3 and D4 Bone Quality)
It is used in partially edentulous incisors in premolar, cuspid and maxillary areas in fixed single-tooth or fixed partially edentulous cases. These implants have the early loading indication, so long as four or more implants placed in edentulous areas of upper or lower jaws are connected to each other.
It is used to support bar overdentures and retention thereof or as terminal and it is used as intermediate attachment of screw fixed bridges.

Side Effects

- Loosening
- Breaking
- Soft tissue pain
- Infection, loss of teeth
- The patient has a disease
- Local soft tissue degeneration

User Group
It is only used by specialist or general dental practitioners.

Product Storage and Shipping Conditions

- During shipment and storage, the product must be protected from direct sunlight.
- It should be ensured that the product is dry in any environment.
- Implants should be stored in their original packaging in a dry place at room temperature, protected from direct sunlight.
- The environmental conditions that must be obeyed during product storage are indicated on the product labels and user manuals.

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- Improper storage of the product will lead to breakdown of the material and cause damage to the material and design characteristics of the product.

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- The product should not be used in case of damage to the tube / package that maintains sterility.
- The products must be kept in their original packaging.
- The products should be stored at a temperature of 17 - 27 °C in the original package, away from the sun, in a way that they do not come into contact with the liquid.

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- The shelf life of the products is 5 years for our sterile products.

Sterilization:

Our sterile products;
Our Implant and closure screws are supplied to the market in a sterile condition with Gamma.

Non-sterile products;
Gingiva Formers and Abutments are supplied to the market in a non-sterile condition. The user is recommended to sterilize it by the autoclave method before use. The recommended parameters for the sterile autoclave method are as follows;

Temprature (°C)	Duration (Minute)
121	30

Radioactivity

Our products do not have any radioactivity.

COMPANY INFORMATION	
Company Address	[illegible]
Mail	info@mgmimplant.de
Brand	MGM IMPLANT

DESCRIPTIONS OF SYMBOLS ON THE LABEL AND BOX

REF	REFERANCE NUMBER		SHOULD BE USED ONLY BY A SPECIALIST
LOT	LOT NUMBER		PLEASE REFER TO THE USER MANUAL
	PRODUCTION DATE		IF THE PACKAGE IS DAMAGED DO NOT USE
	DO NOT RE- USE		KEEP IT AWAY FROM SUNLIGHT
	CAUTION	CE	NOTIFIED BODY NUMBER
	MANUFACTURER INFORMATION		BARCODE NUMBER
	USE BY		STORAGE TEMPERATURE
	DO NOT RESTERILIZE IT TWICE	STERILE R	STERILIZED USING IRRADIATION
	STORE IN DRY AREA		NON- STERILE PRODUCT

Information about Product Use

They are devices made of titanium alloy material, designed to be surgically inserted into the bones of upper or lower jaw arches to support the prosthetic devices such as artificial teeth and to improve the chewing function of patients.
Dental implants are designed for surgical placement in the maxillary and / or mandibular arches to provide support for prosthetic restorations in edentulous or partially-edentulous patients. Dental implants are used for one-stage or two-stage surgery. Dental implants are designed for instant placement and function on single-tooth and/or multiple teeth procedures with proper occlusal loading, when good primary stability is achieved, to restore chewing factor. Multiple teeth procedures can be tightly splinted. Four or more implants should be used in edentulous patients.

In missing teeth treatments by dentists, the implant is first applied to the bone in patient's mouth and then the abutment designed to be used in prosthesis construction are attached to the implant and function as superstructure parts.

Contraindications are not completely restrictive

- Vascular diseases
- Uncontrolled diabetes
- Bleeding control problems
- Anticoagulant therapy
- Metabolic bone diseases
- Chemotherapy/Radiation therapy
- Chronic periodontal diseases
- Insufficient soft tissue formations
- Other metabolic or systemic disorders related to bone or wound healing. The use of cosmetic products that will prevent the formation of new bones. Disorders that will interfere with the patient's daily oral care.

Oral contraindications, but are not completely restrictive

- Uncontrolled parafunctional habits (bruxing, clenching, gnawing)
- Insufficient bone height and thickness.
- Insufficient surface area of the inter-arch.
- Intraoral infection
- Poor or problematic oral hygiene of the patient

WARNINGS! :

- The product sold as non-sterile should be sterilized before use.
- Each product is suitable for use only for one patient. The products have not been evaluated in terms of safety and compatibility in MRI environment. They have not been tested for heating, migration, or image artifact in MRI environment.
- The products are disposable products.
- The patient should be informed about the surgical risks before surgery.
- The products with damaged packaging should not be used.
- It might cause insufficient bone volume and/or poor-quality primary stability and thus to mobility or even to implant loss.

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