

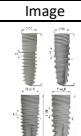

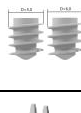
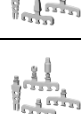

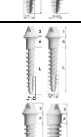



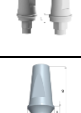
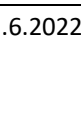
Instructions for use: Dental Implants and accessories




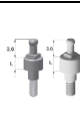



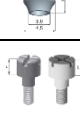


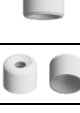

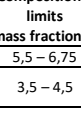
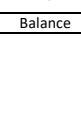


Dental Implant MV, SVMB, MI, MTI, MTID; Abutment MP, MP14L; Direct Abutment MPP; Narrow Abutment MPU; Angled Abutment MPS; Ball Abutment MPG; Healing Screw MVS; Screw MS; Healing Abutment MVV, MVVK, MVVU; Abutment P; Thread Cover P; Abutment Cover KP; Cover Screw KS.

Characteristics:

Dental implants and accessories manufactured and distributed by MARTIKAN s.r.o. is a set of medical devices used in dental medicine. Dental implants are surgically inserted in the place of the missing tooth, thereby creating an artificial tooth root, or superstructures (abutments) are applied to which a crown or bridge is attached. This creates an artificial tooth to restore the patient's chewing function.

Description of dental implants and accessories

Type	Model	Image	Description
Dentálny Implant MV	MV 3,6 MV 4,5		-cylindrical shape with an external thread along the entire length, -outer surface sandblasted, -outer diameter 3,6; 4,5 mm, -length 8 to 16 mm, -an internal square with a thread for storing the superstructure. -Titanium alloy Ti6Al4V according to ISO 5832-3
	MV 3,0		-cylindrical shape with external thread length L, -the outer surface of the intraosseous part is sandblasted, -outer diameter 3,0 mm, -external square for storing the superstructure and internal thread, -length 8 to 14 mm. -Titanium alloy Ti6Al4V according to ISO 5832-3
	MV 5,0 MV 6,0		-cylindrical shape with an external thread along the entire length, -outer surface sandblasted, -outer diameter 5,0 and 6,0 mm and length 6 mm, -an internal square with a thread for storing the superstructure -Titanium alloy Ti6Al4V according to ISO 5832-3
Dental Implant MTI	MTI		-Single-phase blade implants of a thin wedge (tree) shape of various types, -they consist of the body of the blade (the intrabony part), the neck and the superstructure part. -pure titanium according to ISO 5832-2
Dental Implant MTID	MTID		-two-phase thin wedge-shaped blade implants of various types, -they consist of the body of the blade (intrabony part), the neck and the threaded superstructure part. -the intraosseous part is sandblasted -pure titanium according to ISO 5832-2
Dental Implant SVMB	SVMB 2,6 SVMB 3,0 SVMB 3,6 SVMB 4,5		-valcový tvar s vonkajším závitom na dĺžke L, -závitová (vnútrokostná), gingiválna a nadstavbová časť, -povrch vnútrokostnej závitovej časti je pieskovaný, -vonkajší priemer 2,6; 3,0; 3,6; 4,5 mm a dĺžka závitovej časti 8 až 14 mm, -vonkajší štvorhran na nadstavbovej časti pre zavádzanie. -Titanová zliatina Ti6Al4V podľa ISO 5832-3
	SVMB 2,6 14A SVMB 3,0 14A SVMB 3,6 14A SVMB 4,5 14A		-valcový tvar s vonkajším závitom na dĺžke L, -závitová (vnútrokostná), gingiválna a nadstavbová časť, -povrch vnútrokostnej závitovej časti je pieskovaný, -vonkajší priemer 2,6; 3,0 mm a dĺžka závitovej časti 8 až 14 mm, -vonkajší štvorhran na nadstavbovej časti pre zavádzanie a guľôčka pre kotvenie hybridnej protézy. -Titanová zliatina Ti6Al4V podľa ISO 5832-3
	SVMB 2,6 G SVMB 3,0 G		-valcový tvar s vonkajším závitom na dĺžke L, -závitová (vnútrokostná), gingiválna a nadstavbová časť, -povrch vnútrokostnej závitovej časti je pieskovaný, -vonkajší priemer 2,0 mm a dĺžka závitovej časti 10 až 14 mm, -vonkajší štvorhran na nadstavbovej časti pre zavádzanie. -Titanová zliatina Ti6Al4V podľa ISO 5832-3
Dental Implant MI	MI		-valcový tvar s vonkajším závitom na dĺžke L, -závitová (vnútrokostná), gingiválna a nadstavbová časť, -povrch vnútrokostnej závitovej časti je pieskovaný, -vonkajší priemer 2,0 mm a dĺžka závitovej časti 10 až 14 mm, -vonkajší štvorhran na nadstavbovej časti pre zavádzanie. -Titanová zliatina Ti6Al4V podľa ISO 5832-3
	MI G		-valcový tvar s vonkajším závitom na dĺžke L, -závitová (vnútrokostná), gingiválna a nadstavbová časť, -povrch vnútrokostnej závitovej časti je pieskovaný, -vonkajší priemer 2,0 mm a dĺžka závitovej časti 10 až 14 mm, -vonkajší štvorhran na nadstavbovej časti pre zavádzanie a guľôčka pre kotvenie hybridnej protézy. -Titanová zliatina Ti6Al4V podľa ISO 5832-3
Abutment MP	MP 3,6 MP 4,5 MP 5,0 MP 6,0		-abutments for MV dental implants with an external square for placement and positioning in the implant, -the gingival part with a height of 1 to 3 mm, -conical part for cemented restorations, -internal hole for screw. -Titanium alloy Ti6Al4V according to ISO 5832-3
	MP 3,0		-abutments for dental implants MV 3.0 with an internal square for placement and positioning in the implant, -the gingival part with a height of 1 to 3 mm, -conical part for cemented restorations, -internal hole for screw.

Direct Abutment MPP	MPP 3,6 MPP 4,5 MPP 5,0 MPP 6,0		-Titanium alloy Ti6Al4V according to ISO 5832-3 -cylindrical shape of the abutments, -external thread for creating a connection with a dental implant, -height of the gingival part from 1 to 5 mm, -conical part for cemented restorations. -Titanium alloy Ti6Al4V according to ISO 5832-3
Narrow Abutment MPU	MPU 3,0		-abutments for dental implants MV 3.0 with an internal square for placement and positioning in the implant, -the gingival part with a height of 2 to 4 mm, -conical part for cemented restorations, -internal hole for screw. -Titanium alloy Ti6Al4V according to ISO 5832-3
	MPU 3,6 MPU 4,5 MPU 5,0 MPU 6,0		-abutments for MV dental implants with an external square for placement and positioning in the implant, -gingival part with a height of 1 to 3 mm, -conical part for cemented restorations, -internal hole for screw. -Titanium alloy Ti6Al4V according to ISO 5832-3
Angled Abutment MPS	MPŠ 3,6 MPŠ 4,5 MPŠ 5,0 MPŠ 6,0		-angled abutments for MV dental implants with an external square for placement and positioning in the implant, -gingival part with a height of 1 to 3 mm, -internal hole for screw, -15°, 30° and 45° angulation. -Titanium alloy Ti6Al4V according to ISO 5832-3
Ball Abutment MPG	MPG 3,6 MPG 4,5 MPG 5,0 MPG 6,0		-abutments for MV dental implants with a ball for anchoring a hybrid dental prosthesis, -an external square for introducing the abutment into the implant, -external thread for creating a connection with a dental implant, -gingival part with a height of 1 to 5 mm. -Titanium alloy Ti6Al4V according to ISO 5832-3
Abutment MP14L	MP14L 3,6 MP14L 4,5 MP14L 5,0 MP14L 6,0		-external thread for creating a connection with a dental implant, -height of the gingival part 1 to 3 mm, -internal thread for screw and conditionally removable dental prosthesis, -outer square for introducing the abutment into the implant. -Titanium alloy Ti6Al4V according to ISO 5832-3
	MVS 3,0		-external thread for creating a connection with a dental implant, -head for anchoring the healing abutment to the implant, -cross grooves for a screwdriver.
Healing Screw MVS	MVS 3,6 MVS 4,5 MVS 5,0 MVS 6,0		-external thread for creating a connection with a dental implant, -head for sealing the implant opening, -cross grooves for a screwdriver. -Titanium alloy Ti6Al4V according to ISO 5832-3
	MS 3,0 MS 3,6 MS 4,5 MS 5,0 MS 6,0		-external thread for creating a connection with a dental implant, -head for anchoring the abutment to the implant, -cross grooves for a screwdriver. -Titanium alloy Ti6Al4V according to ISO 5832-3
Healing Abutment MVV	MVV 3,0		-cylindrical shape and height from 4 to 7 mm, -internal square for creating a connection with a dental implant. -Titanium alloy Ti6Al4V according to ISO 5832-3
	MVV 3,6 MVV 4,5 MVV 5,0 MVV 6,0		-cylindrical shape, -cylindrical gingival part with a height of 2 to 5 mm, -cross grooves for a screwdriver. -Titanium alloy Ti6Al4V according to ISO 5832-3
Healing Abutment MVVK	MVVK 3,6 MVVK 4,5 MVVK 5,0 MVVK 6,0		-cylindrical shape and height 2 to 5 mm, -conical gingival part with a height of 2 to 5 mm, -cross grooves for a screwdriver. -Titanium alloy Ti6Al4V according to ISO 5832-3
Healing Abutment MVVU	MVVU 3,0		-cylindrical shape and height 4 to 6 mm, -internal square for creating a connection with a dental implant. -Titanium alloy Ti6Al4V according to ISO 5832-3
Abutment P	P		-cylindrical shape of the abutment, -internal thread for creating a connection with a dental implant, -height of the gingival part 4 to 8 mm, -conical part for cemented restorations. -Titanium alloy Ti6Al4V according to ISO 5832-3
Thread Cover P	P		-cylindrical shape of the cover, -internal thread for creating a connection with a dental implant, -slot for a screwdriver -Titanium alloy Ti6Al4V according to ISO 5832-3
Abutment Cover KP	KP		-the cylindrical shape of the abutment cover, -hole for the cover screw. -Titanium alloy Ti6Al4V according to ISO 5832-3
Cover Screw KS	KS		-external thread for creating a connection with a dental implant, -header for anchoring the abutment cover to the implant, -cross grooves for a screwdriver. -Titanium alloy Ti6Al4V according to ISO 5832-3

Composition according to ISO 5832-3	
Element	Compositional limits mass fraction %
Aluminium Al	5,5 – 6,75
Vanadium V	3,5 – 4,5
Residual elements Fe, O, C, N, H	≤ 0,3
Titanium Ti	Balance

Composition according to ISO 5832-2	
Element	Compositional limits mass fraction %
Nitrogen N	≤ 0,03
Hydrogen H	≤ 0,08
Carbon C	≤ 0,012
Iron Fe	≤ 0,3
Oxygen O	≤ 0,25
Titanium Ti	Rovnováha

Expected clinical benefit:

The medical device has an indirect clinical benefit to restore the chewing function of the patient's dentition with a missing tooth, a large gap, a shortened dental arch and an edentulous jaw. Dental implants and accessories achieve a clinical benefit by the fact that, depending on the type of dental implant, dental implants alone or with the use of accessories enable the creation of a basic structure for the subsequent fabrication of a prosthetic replacement, and thus it is possible to restore the chewing function of the patient's dentition in the case of a missing tooth, a large gap, a shortened dentition arch and toothless jaw.

Intended use:

Intended indications:

Dental implants **MV**, **MTI**, **MTID**, **SVMB**, **MI** are indicated for the creation of a construction for a prosthetic tooth replacement in the upper or lower jaw with a missing tooth, a large gap, a shortened dental arch and a toothless jaw. Dental implants **MV** a **SVMB** are indicated for fixed dentures, conditionally removable dentures and hybrid dentures. Bone thickness of at least 2 mm around the implant. Dental implants **MI** are indicated for fixed and hybrid dental prostheses. Bone thickness at least 2 mm around the implant. Dental implants **MTI** and **MTID** are indicated for fixed dentures. Bone thickness at least 3 mm. The accessories are indicated according to the used dental implant model or accessories to create a structure for a prosthetic tooth replacement in the upper or lower jaw in the case of a missing tooth, a large gap, a shortened dental arch and an edentulous jaw.

Model	Indication		other		
	Model of the Implant or accessory	Dental replacement, denture			
MP 3,6	MV 3,6	Fixed	- a single implant or multiple implants - parallel placement of the implant - the variant is indicated according to the height of the gingiva		
MP 4,5	MV 4,5				
MP 3,0	MV 3,0				
MP 5,0	MV 5,0				
MP 6,0	MV 6,0				
MPP 3,6	MV 3,6				
MPP 4,5	MV 4,5				
MPP 5,0	MV 5,0				
MPP 6,0	MV 6,0				
MPU 3,6	MV 3,6			- for multiple implants - parallel placement - the variant is indicated according to the height of the gingiva	
MPU 4,5	MV 4,5				
MPU 3,0	MV 3,0				
MPU 5,0	MV 5,0				
MPU 6,0	MV 6,0				
MPS 3,6	MV 3,6				
MPS 4,5	MV 4,5				
MPS 5,0	MV 5,0				
MPS 6,0	MV 6,0				
MPG 3,6	MV 3,6		Hybrid		- for multiple implants - parallel placement - the variant is indicated according to the height of the gingiva
MPG 4,5	MV 4,5				
MPG 5,0	MV 5,0				
MPG 6,0	MV 6,0				
MP14L 3,6	MV 3,6				
MP14L 4,5	MV 4,5				
MP14L 5,0	MV 5,0				
MP14L 6,0	MV 6,0				
MVS 3,6	MV 3,6	Conditionally removable		- a single implant or multiple implants - parallel placement of the implant - variant according to the height of the gingiva	
MVS 4,5	MV 4,5				
MVS 3,0	MV 3,0; MVV 3,0; MVVU 3,0				
MVS 5,0	MV 5,0				
MVS 6,0	MV 6,0				
MS 3,6	MP 3,6; MPU 3,6; MPS 3,6		N/A		- temporary covering of the implant opening during its healing period
MS 4,5	MP 4,5; MPU 4,5; MPS 4,5				
MS 3,0	MP 3,0; MPU 3,0				
MS 5,0	MP 5,0; MPU 5,0; MPS 5,0				
MS 6,0	MP 6,0; MPU 6,0; MPS 6,0				
MVV 3,6	MV 3,6	N/A		- forming the gingiva for the abutment - the variant is indicated according to the height of the gingiva	
MVV 4,5	MV 4,5				
MVV 3,0	MV 3,0				
MVV 5,0	MV 5,0				
MVV 6,0	MV 6,0				
MVVK 3,6	MV 3,6				
MVVK 4,5	MV 4,5				
MVVK 5,0	MV 5,0				
MVVK 6,0	MV 6,0				
MVVU 3,0	MV 3,0				
P	MTID	Fixed	- temporary covering of the implant during its healing period (variant P21) - for multiple implants - parallel placement - the variant is indicated according to the height of the gingiva		
KP	SVMB 2,6 14A; SVMB 3,0 14A; SVMB 3,6 14A; SVMB 4,5 14AMP14L 3,6; MP14L 4,5; MP14L 5,0; MP14L 6,0	N/A	- temporary covering of the abutment part		
KS	KP	N/A	- screwing the abutment cover to the abutment		

Intended patient population:

Persons with completed development of the maxilla and mandible

Intended body part for application:

Bone tissue of the maxilla and mandible and gingiva.

Intended user profile:

A dentist with a certificate in dental surgery and implantology uses dental implants and accessories during surgery.

Dental technicians with appropriate education use accessories related to the prosthetic part of the work.

The patient uses dental implants in the post-implantation phase and accessories associated with the dental implant that create a dental prosthesis.

Prostredie použitia:

- sterile medical device
- for single use
- surgery/implantation - dental implants and accessories:
 - dental clinics (dental implants and accessories)
 - standard dental and protective equipment
- prosthetic part - accessories:
 - dental prosthetics laboratories (accessories)
 - standard prosthetic and protective equipment
- dental prosthesis care:
 - household
 - dental hygiene
 - common protective equipment for dental hygiene

Operating principle:

Dental implants use their shape and the biocompatible properties of the material to form a firm connection with the bone tissue at the implant site, allowing the construction of a prosthetic restoration in the upper or lower jaw for missing teeth, large gaps, shortened dental arches and edentulous jaws, either alone or with the use of an accessory corresponding to the dental implant model. The dental implant is surgically inserted into a pre-drilled hole (MV, SVMB and MI dental implants) or groove (MTI and MTID dental implants) using an insertion tool. In the case of single-phase implants (SVMB, MI, MTID), this creates the structure for subsequent prosthetic work.

In the case of two-phase implants (Dental Implants MV and MTID), accessories are used to cover the implant (MVS healing screw, Cover Nut P) for the duration of the implant healing, after which they are removed and, if necessary, gingival shaping accessories are applied (MVV healing roller, MVVK, MVVU). After removal of the gingiva shaping accessories, or if they are not used, the abutment is screwed to the implant structure separately (P-pillar, straight MPP pillar, spherical MPG pillar, MP14L pillar) or with the use of a screw (MS screw for MP Abutment, narrow MPU abutment; angled MPS abutment).

To protect the internal thread from contamination (Dental implant SVMB models SVMB 2.6 14A, SVMB 3.0 14A, SVMB 3.6 14A, SVMB 4.5 14A and Pillar MP14L) during the period of production of the prosthetic part of the dental prosthesis, the KP abutment cover is used.

Postup zavádzania:

Detailed procedure for inserting dental implants and accessories is on the manufacturer's website <https://www.martikan.eu/dokumenty/navody-na-pouzitie>

Kontraindikácie:

Intraoral:	Insufficient bone volume, Poor hygiene and untreated teeth, Unhealed bone after tooth loss, Pathological findings in the jaws, Periodontitis, Radiotherapy in the orofacial area, Malocclusion and functional disorders of the chewing apparatus (bruxism), Mucosal precancers and xerostomia.
Psychologically conditioned:	Insufficient cooperation of the patient, Unrealistic expectations, conflict and quarrelsome persons (so-called problem patients), Neuroses, Psychoses, Alcohol or drug abuse, Mental retardation
Temporary:	Acute febrile illnesses, Pregnancy, Medication.
General medical:	Diabetes mellitus, Cardiovascular diseases, Antiplatelet and anticoagulant therapies, Risk of infective endocarditis and focal infection, Hematological diseases, Osteoporosis, bisphosphonates, Corticosteroids, immunosuppressants, cytostatics, Immunity disorders, Epilepsy, Smoking, Age (unfinished development of the maxilla and mandible).

Reziduálne riziká a vedľajšie účinky:

Several factors influence the clinical outcome of the treatment. There are some possible residual risks and side effects associated with the use of this device, which may require further treatment in a dental clinic: Temporary pain, inflammation, hematoma, swelling, temporary or permanent nerve damage, bleeding, mucosal injury, longer rehabilitation period, loss of accessories, swallowing or inhaling small parts, mechanical damage to the implant, retreatment, risk of explantation, risk of infection, long-term irritation, discomfort in the oral cavity, sensitivity, replacement of accessories, other reactions, other injury requiring further treatment.

Storage:

Dry storage (humidity 35% to 50%), at room temperature (+15°C to +25°C).

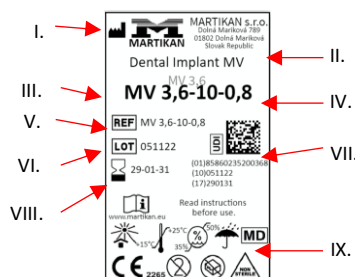
Packaging:

Dental implants and accessories are sealed in See-through packaging made of paper and film intended for sterilization, one piece at a time. They are delivered in a **non-sterile state**.

Labeling:

Medical devices are labeled with following informations:

- I. Manufacturer (logo, name, adress),
- II. trade name of the product,,
- III. product model,
- IV. designation (variant) of the product (=catalog number),
- V. catalogue number,
- VI. Batch code (lot number),
- VII. UDI – format HRI and GS1 Datamatrix,
 - (01)8586023xxxxx →UDI-DI (GS1 GTIN)
 - (10) lot number
 - (17) expiration date
- VIII. Expiration date,
- IX. Relevant symbols



Conditions of sterilization:

The medical device must be sterilized before use. Recommended sterilization parameters 121 °C, 205 kPa, for 20 min. moist heat –STEAM.

Warnings:

Dental implants can only be used and applied by dentists with a certificate in dental surgery and implantology. Accessories can only be used and applied by dentists and dental technicians with the appropriate education. In the event of a serious accident caused by the device, the doctor or patient should report this event to the manufacturer MARTIKAN s.r.o. and to the competent authority in the EU member state where the dentist or patient resides.

If the packaging of the medical device is damaged in any way, the medical device must not be used.

If the device becomes contaminated during use, do not continue to use the medical device.

Dental implants and accessories are intended for single use only! Medical devices intended for single use must not be used repeatedly. Repeated use poses a risk of contamination and subsequent transmission of a possible infection to the patient.

Work with dental implants and accessories in the oral cavity carefully and with increased attention to avoid possible swallowing or inhalation of small parts by the patient.

Compatibility:

The compatibility of individual medical devices is described in the catalogs on the manufacturer's website <https://www.martikan.eu/dokumenty/katalogy>.

Disposal of waste and consumables:

Contaminated devices (e.g. explants) and single-use packaging are considered biohazardous waste and must be disposed of as such in accordance with applicable legislation. Uncontaminated devices and packaging can be disposed of as normal waste.

Information for the patient:

The attending physician is obliged to provide the patient with information that contains the identification of the medical device, including its name, serial number, distribution batch number, UDI, model of the device, as well as the name/title, address and website of the manufacturer, warnings, preventive measures that the patient must take in connection with the medical device and information about the care of the device in the home environment and dental hygiene. The patient receives an implant card from the attending physician.






















The doctor must inform the patient about possible side effects in connection with the medical device.

The doctor must inform the patient about the clinical success rate of implantation, which according to available data is at the level of 98.85%.

In case of any complications associated with the medical device, the patient immediately contacts his attending physician. You can find more information on the manufacturer's website <https://www.martikan.eu/dokumenty/prepacienta>

Summary of safety and clinical performance (SSCP):

Available at <https://ec.europa.eu/tools/eudamed> or from the manufacturer on request.

Symbols (according to ISO 15223-1)	
	Manufacturer
	Date of manufacture
	Batch code
	Catalogue number
	Medical device
	Do not use if package is damaged
	Do not re-use
	Consult instructions for use
	Non - sterile
	Keep dry
	Marking of product conformity with MDR 2017/745 and number of the notified body assessing conformity
	Expiration date
	Keep away from sunlight
	Date
	Patient identification
	Patient information website
	Health care centre or doctor
	Temperature limit (°C)
	Humidity limitation (%)
	Unique device identifier
	Device identifier specific to a manufacturer and device