Table of contents

Bauer's Implants	03
Helix dental implant	06
SLA surface	08
Titan Grade 4	10
Application protocol	11
Single product	12
Implants	14
Prosthetic components	18
Prosthetic Protocol for implant level	25
Multi-unit system	26
Prosthetic Protocol for Multi-unit level	32
Dental Surgical kit	33
Surgical Protocol	38
Subcrestal implant installation	41
Certificates	42

IT HAS BEEN A LONG JOURNEY OF TRIAL AND IMPROVEMENT...

10.3

Bauer's Implants

The production of dental implants certified according to the European standards at the prices that make them affordable for a wide range of customers in Ukraine, was launched under the TM *Bauer's Implants*. It took three years to implement the project from the idea to the release of the first product output at the ultramodern enterprise ABM Technology, including two years for active preclinical trials.

Developers from Switzerland and Estonia actively participated in creation of the first Ukrainian implants with suprastructures that compete favourably with the best specimens in the global market. The leading specialists in maxillofacial surgery gave the benefit of their experience and knowledge in dental implantology and all the wishes of domestic implantologists were taken into account.

It has been a long journey of trial and improvement. The final result, which combined all advanced achievements in implantology, was worth the hassle.

With the products of TM *Bauer's Implants*, dental implantology in Ukraine will move to the whole other level. After all, the only fundamental difference of domestic implants is their low cost in comparison with foreign analogues. Modern methods of dental restoration become available for the most patients in our country.

The high-technology Japanese equipment allows for great accuracy in production. The multistage quality control system eliminates any errors. The use of hypoallergenic high-purity titanium and improved design, which reduces pressure on the outer layer of the bone, minimize undesirable effects and contribute to the rapid survival of the implant.





OUR AIM

The dental implantology is not only intended to solve the aesthetic problems of the oral cavity, but also helps to improve the quality of life of the patients. TM *Bauer's Implants* will make it easy for dentists and affordable for Ukrainians. We guarantee reliability, safety and high quality of our products confirmed by international certificates and highly appreciated by specialists.

Bauer's Implants

HELIX Cone implant

Deep thread produced over the total length of the implant contributes to a good primary stability during implant installation and reduces pressure on the cortical bone.



A single 22° orthopedic conical platform forms a tight seal at the implant abutment– connection interface.

The unique shape of the antirotation furrow reduces axial load and reduces excess pressure on the bone during installation.

The flattened apical part prevents damage to the Schneiderian membrane.

Helix dental implant is a proprietary innovative solution of the Ukrainian manufacturer TM *Bauer's Implants*. The model was created by domestic designers together with European specialists in laboratory medicine and embodied all the advanced technologies and achievements in the field of implantology.

Being not inferior in quality to the best world analogues, Helix implant is distinguished by a significantly lower cost, which makes aesthetic and reliable restoration of lost teeth affordable for a wide range of consumers.

The implant itself is made of hypoallergenic high-purity grade 4 titanium (Titan Grade 4). The bioinert surface of the implant is not involved in the bone metabolism process and ensures excellent osseointegration (implant survival). The solution of TM *Bauer's Implants* is highly hydrophilic and does not limit the blood flow. A single 22° orthopedic conical platform forms a tight seal at the implant abutment–connection interface. The flattened apical part protects the Schneiderian membrane from damage.

An antirotational furrow is applied to the implant surface. The unique shape of the furrow allows to reduce the load on the bone during installation and reduces pressure on the bone tissue. Deep thread runs over the total length of Helix implant ensuring high primary stability of implants.

We provide a lifetime warranty for all implants produced under the TM *Bauer's Implants*. The implants are delivered in sterile sealed package. Products are given a unique identification number and protective marking is made.

TM *Bauer's Implants* products have been successfully tested in accordance with international standard ISO 14801 "Dentistry – Implants – Dynamic fatigue test for endosseous dental implants".

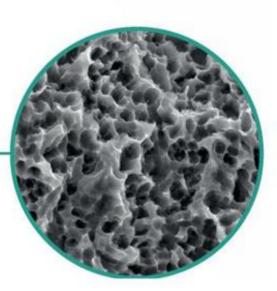
SLA BIOINERT SURFACE OF THE IMPLANT

The unique bioinert surface of SLA implant provides a reliable physicochemical binding with the bone matrix, and it is not involved in the bone metabolism process. High osseointegration is achieved due to several complex processes of treatment of the titanium dental implant surface.

The first stage is sandblasting. The surface macroroughness is achieved as a result of the treatment with aluminum oxide particles (grains with different diameters). The second stage is the chemical treatment of the titanium implant. Intensive acid etching under an elevated temperature in different acids produces micropits on the metal surface.

Rough surface of SLA, as compared to smooth surfaces, increases the bone-to-implant contact. At the same time, the surface itself is not microporous, which reduces the likelihood of bacterial colonization.

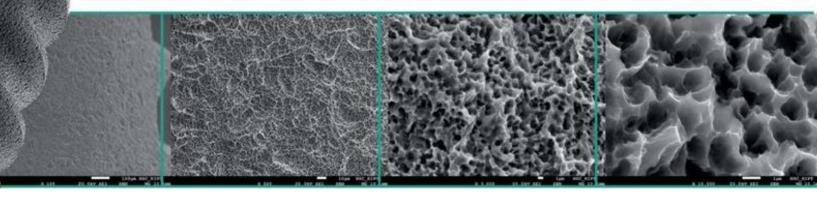
Osteoblasts growing on the surface of SLA implants demonstrate the properties of highly differentiated bone cells, proving its osteoinductivity and allowing to accelerate bone regeneration at the sites where it is difficult if not impossible. The use of SLA implants significantly reduces the clinical period before the prosthetic repair.



The **10000x** magnification image of structure

Surface characteristics of dental implants were tested for contamination using Scanning electron microscopy (SEM) with Energy dispersive X-ray spectroscopy (EDX). Besides, EDX spectrum of basic material was recorded to determine the composition. Images of the structure are presented with the following magnifications: 500x, 1000x, 1500x, 2000x, 2500x, 5000, 7500x and 10000x.

Scanning electron microscopy was performed in accordance with SOP M2618: 2014-06 for microscopic examination of surfaces of the specimen (Instrument: Hitachi S-3700N scanning electron microscope with EDAX XM2, Apollo SDD 40 detector).





TITAN GRADE 4

Titan Grade 4 is an unalloyed high-purity grade 4 titanium. It is a versatile material for the manufacture of dental implants, which has outstanding biocompatibility and antiallergic properties alongside with extreme mechanical strength and oxidation stability.

The leading global producers use Titan Grade 4 for the manufacture of dental implants. It is also called "commercially pure titanium" (standardized by the American company ASTM).

Advantages of Titan Grade 4 over other grades of pure titanium:

- It does not contain toxic vanadium, which makes the implant completely safe;
- It has more durable mechanical properties;
- It has better biological compatibility;
- It 100% eliminates any allergic reactions.

The mere fact that Titan Grade 4 was standardized by ASTM for manufacture of dental implants is declarative of its outstanding properties.

APPLICATION PROTOCOL



Open the outer flask.



Turn over a flask for implant removal.



Remove a small lid from the inner flask.



Remove the implant using an implant driver.



Turn over a flask and remove a large lid for removal of the closure screw.



Remove the closure screw using a screwdriver.

HELIX IMPLANT WITH ZIRCONIUM CROWN

We increase opportunities!

It is a unified solution for our customers. All HELIX implants are completed with a basic all-zirconium monochrome crown.

A high-quality XT zirconium disk is used to produce a crown.

UNIQUE BARCODE FOR CROWN FABRICATION

Each implant has a unique individual barcode.

This code is a relevant marker that individualizes the crown manufacturing order in the unique digital dental laboratory Amel CAD / CAM Lab.

Crown fabrication protocol:

When it comes time to make a prosthetic appliance for tooth, you can choose one of the methods for the placement of the crown manufacturing order.

You can send a scan in STL file or analogue implant impression directly to the laboratory.

The crown is manufactured within 3-5 days, after which it will be delivered to you.



IMPLANTS



The product line of the Company originally included the implant sizes that could cover most clinical events. Designers and clinicians have conducted a detailed analysis of required shapes, diameters and lengths, in consequence of which we can maintain that with *Bauer's Implants* implants it is easy to achieve the most predictable positive results during rehabilitation of patients.

All implants in a linear series have exactly the same taper shape (in the context of one given diameter) along the length from the neck to a distance of 6 mm.



Implant HELIX Ø 3.5

Trades code	IH 35070	IH 35085	IH 3510	IH 35115	IH 3513	
L (mm)	7.0	8.5	10.0	11.5	13.0	
Ø (mm)	3.5					

It provides the same strength in the entire linear series and stability of clinical and physical parameters, regardless of the length of implant used. When performing the fatigue test, the weak section of all implants is measured at a distance of 3 mm from the implant neck. Therefore, it's fair to say that the cross section of all implants to diameter in a linear series is equally reliable and equal in strength.

Besides, according to clinical studies, the first 6 mm of implant length have a dominant role in osseointegration.



Trades code	IH 40070	IH 40085	IH 4010	IH 40115	IH 4013	
L (mm)	7.0	8.5	10.0	11.5	13.0	
Ø (mm)	4.0					

Implant HELIX Ø 4.5



Trades code	IH 45070	IH 45085	IH 4510	IH 45115	IH 4513	
L (mm)	7.0	8.5	10.0	11.5	13.0	
Ø (mm)	4.5					

Trades code	CS 2040
L (mm)	8.0
Ø (mm)	3.5



All implants are completed with a closure screw

Length (L) should be understood to mean the length of implant. Drills are marked 0.5 mm longer than the implant length, which corresponds to the principle of implant installation 0.5 mm below the cortical layer. Diameter (\emptyset) should be understood to mean the average diameter over the total length of implant.

PROSTHETIC COMPONENTS



Healing abutments Ø 4.5



Trades code	HA 4530	HA 4540	HA 4550	HA 4560	HA 4570	
L (mm)	8.0	9.5	11.0	12.5	12.5	
H (mm)	3.0	4.0	5.0	6.0	7.0	
Ø (mm)	4.5					

Healing abutments Ø 5.5



Trades code	HA 5530	HA 5540	HA 5550	HA 5560	HA 5570	
L (mm)	9.10	10.10	11.10	12.10	13.10	
H (mm)	3.0	4.0	5.0	6.0	7.0	
Ø (mm)	5.5					

Straight titanium abutments Ø 4.5 Straight abutment is completed with two fixing screws SF2040



Trades code	STA 454015	STA 454025	STA 454035	STA 455515	STA 455525	STA 455535
L (mm)	8.20	9.20	10.20	9.70	10.70	11.70
H1 (mm)	4.00	4.00	4.00	5.50	5.50	5.50
H2 (mm)	1.50	2.50	3.50	1.50	2.50	3.50

Straight titanium abutments Ø 5.5 Straight abutment is completed with two fixing screws SF2040



Trades code	STA 554015	STA 554025	STA 554035	STA 555515	STA 555525	STA 555535
L (mm)	8.20	9.20	10.20	9.70	10.70	11.70
H1 (mm)	4.00	4.00	4.00	5.50	5.50	5.50
H2 (mm)	1.50	2.50	3.50	1.50	2.50	3.50

Ø 5.5

15° angled titanium abutments Angled abutment is completed with two fixing screws SF2040



Trades code	ATA 452515	ATA 454515	ATA 552515	ATA 554515		
L (mm)	12.2	14.2	12.2	14.2		
Ø (mm)	4.5	4.5	5.5	5.5		
H1 (mm)	2.5	4.5	2.5	4.5		
H2 (mm)	7.0					

25° angled titanium abutments

Angled abutment is completed with two fixing screws SF2040







Trades code	ATA 452525	ATA 454525	ATA 552525	ATA 554525	
L (mm)	12.2	14.2	12.2	14.2	
Ø (mm)	4.5	4.5	5.5	5.5	
H1 (mm)	2.5	4.5	2.5	4.5	
H2 (mm)	7.0				

Fixing screw

All abutments are completed with two fixing screws



The 1.2 mm allen wrench is used to tighten the fixing screws. We recommend a tightening torque of 35 Ncm.

Trades code	SF2040S SF2040		
L (mm)	6.80		
Ø (mm)	3.50		
Material	Grade 5		
Color	Steel	Gold	

Transfers and analogs



Name	Laboratory analog	Impression coping for use in an open tray	Impression coping for use in a closed tray
Trades code	LAN/LAN 7*	IP 5011	IT 6060
L (mm)	13.5	13.35	8.65
Ø (mm)	4.0	5.0	6.0

* Laboratory analog L = 7 mm

Titanium platforms Ø 4.5

Titanium platform is completed with two fixing screws SF2040



Titanium ball abutments Ø 4.5

Titanium ball abutment is completed with three plastic caps of various degrees of hardness and one metal cap



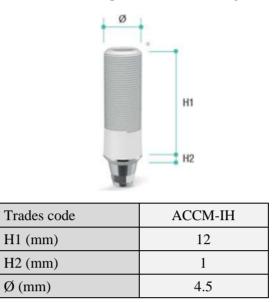
Trades code	BAA 4510	BAA 4520	BAA 4530	BAA 4540
L (mm)	10.25	11.25	12.25	13.25
H1 (mm)	1.00	2.00	3.00	4.00

* Varieties of plastic caps:

orange (soft) - soft, transparent (normal) - average hardness, white (hard) - hard.

Semi-burnout abutment for implant

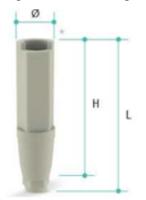
Semi-burnout abutment is completed with two fixing screws SF2040



* Manufacturing material - cobalt-chromium alloy

CAD/CAM scan abutments for titanium platforms

Scan abutment is completed with a fixing screw SF2040



Trades code	SA-CAD_CAM
L (mm)	15.9
H (mm)	13
Ø (mm)	4

* Manufacturing material - PEEK

PROSTHETIC PROTOCOL IMPLANT LEVEL



* Laboratory analog L = 7 mm

MULTI UNIT SYSTEM



Bauer's Implants represents the Multi-unit system that expands the variety of options for doctors and their patients.

Multi-unit abutments provide a means of retention of dental prosthesis via screw-retained fixation without the use of cement, which in turn represents an opportunity to remove the dental prosthesis if necessary.

Multi-unit abutments are designed for use with prostheses supported by two or more implants with a screw-retained fixation. Multi-unit abutments are available in various options: straight multi-unit abutments, as well as 17 and 30 degrees angled multi-unit abutments with a gingival height from 1.5 to 4.5 mm.

Angled Multi-unit abutments have a single prosthetic platform in the form of cone with hexagon.

We recommend a tightening torque of 35 Ncm for fixation of Multi-unit abutment and 15 Ncm for prosthetic screw.

Straight Multi-unit abutments

Straight Multi-unit abutment is completed with an inserting device HF-STA MU



Trades code	STA MU 4815	STA MU 4825	STA MU 4835	STA MU 4845
H (mm)	1.5	2.5	3.5	4.5
Ø (mm)	4.8			

17° angled Multi-unit abutments

Angled Multi-unit abutment is completed with one fixing screw SF-ATA-MU-2040



Trades code	ATA MU 1725	ATA MU 1735	ATA MU 1745
H (mm)	2.5	3.5	4.5

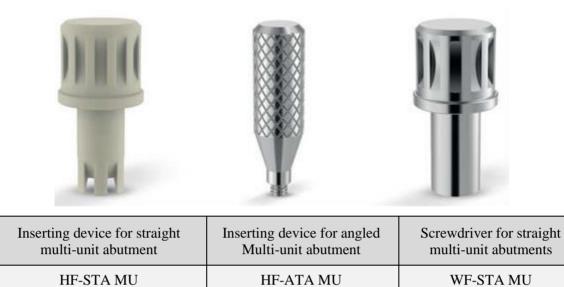
30° angled Multi-unit abutments

Angled Multi-unit abutment is completed with one fixing screw SF-ATA-MU-2040



Trades code	ATA MU 3035	ATA MU 3045
H (mm)	3.5	4.5

Multi-unit inserting devices and screwdriver



Multi-unit healing abutments

Multi-unit healing abutment is completed with one fixing screw SF-AMU -1430



Trades code	HA-AMU	HAW-AMU
Туре	straight	wide
L (mm)	4.2	4.2
Ø (mm)	4.9	6.8
d (mm)	3.4	4.9

Multi-unit transfers and analogs



Trades code	IP-AMU	LAN-AMU
L (mm)	10.7	11.2
Ø (mm)	4.8	4.8

Multi-unit temporary abutment

Abutment is completed with two screws SF-AMU-1430

Trades code	TC-AMU
L (mm)	12.0
D (mm)	4.8
d (mm)	3.35

Multi-unit Semi-burnout cap



Semi-burnout cap is completed with two fixing screws SF-AMU-1430

Trades code	OBS-AMU
L (mm)	14.9
D (mm)	4.8
d (mm)	3.35

* Manufacturing material – cobalt-chromium alloy



Titanium platform for Multi-unit CAD/CAM scan abutment

Titanium platform is completed with two fixing screws SF-AMU-1430

Trades code	PF-CAD/CAM-AMU
L (mm)	5.8
D (mm)	5.5
d (mm)	4.25



Multi-unit CAD/CAM scan abutment

Scan abutment is completed with a fixing screw SF-AMU-1430

Trades code	SA-AMU
L (mm)	13.0
D (mm)	4.8



Fixing screws

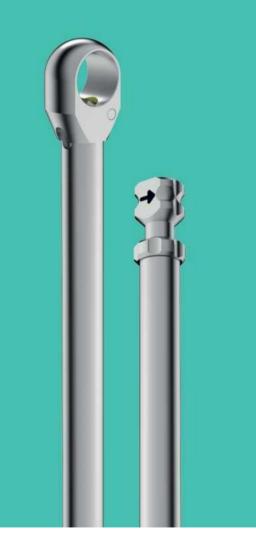


Trades code	SF-AMU-1430	SF-ATA-MU-2040
L (mm)	3.4	6.75
D (mm)	2.0	2.35

PROSTHETIC PROTOCOL MULTI-UNIT LEVEL Titanium platform for Multiunit CAD/CAM scan abutment Multi-unit Semi-burnout cap Multi-unit temporary abutment Multi-unit impression coping Multi-unit CAD/CAM Multi-unit abutment for use in an open tray scan abutment laboratory analog Straight Multi-unit 17° Multi-unit 30° Multi-unit Multi-unit abutment abutment abutment healing abutment Ø 3.5 Ø4.0 Ø 4.5

HELIX implants

DENTAL SURGICAL KIT





- 1. Wrench Ratchet
- 2. Pilot Drill Ø 1.5
- 3. Start Drill Ø 2.0
- 4. Start Drill Ø 2.8
- 5. Conical drill Ø 3.45
- 6. Conical drill Ø 3.9
- 7. Conical drill Ø 4.3

- 8. Parallel pin
- 9. Parallel pin
- 10. Hand Hex Driver 1.20 9 mm
- 11. Hand Hex Driver 1.20 18 mm
- 12. Implant driver for Hand Piece 9 mm
- 13. Implant driver for Hand Piece 18 mm
- 14. Implant driver adaptor

Pilot Drill Ø 1.5	Start Drill Ø 2.0	Start Drill Ø 2.8
PD15	SD20	SD28



Conical drill Ø 3.45	Conical drill Ø 3.9	Conical drill Ø 4.3
CD345	CD39	CD43



Hand Hex Driver 1.20, 9 mm	Hand Hex Driver 1.20, 18 mm	Implant driver adaptor
HD Hex. 1.20 - 9	HD Hex. 1.20 - 18	DA



Implant driver for Hand Piece, 18 mm	Implant driver for Hand Piece, 9 mm	Parallel pin
IHP18	IHP9	РР

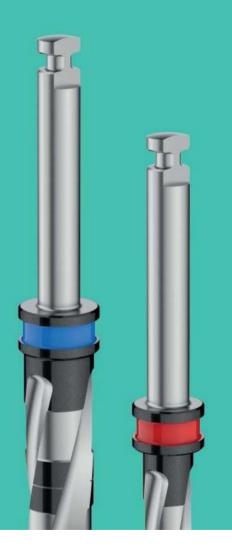






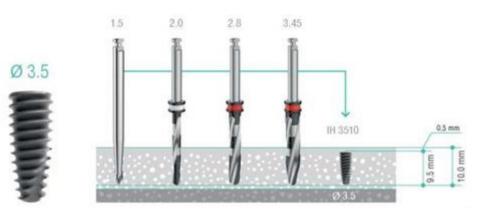
* Torque-controlled adapter is included in the enhanced surgical kit

SURGICAL PROTOCOL

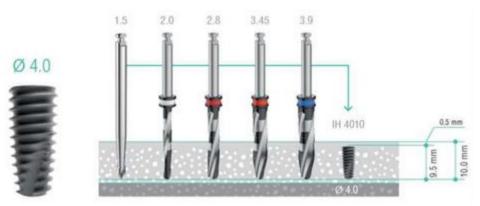


Milling sequence

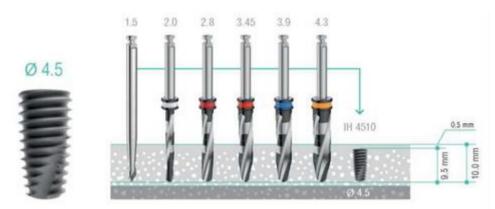
- While meeting the Drilling Protocol, optimal primary stability of HELIX implants can be achieved.
- The concept of HELIX implants implies the subcrestal submergence of implant to a depth of 0.5 mm.



Protocol for Ø 3.5* implant installation * When installing an implant 10 mm long.



Protocol for Ø 4.0* implant installation * When installing an implant 10 mm long.



Protocol for Ø 4.5* implant installation * When installing an implant 10 mm long.

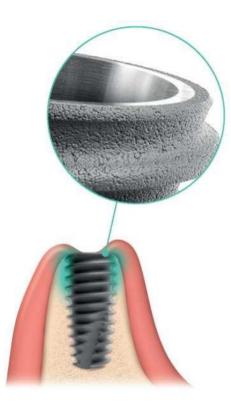


Protocol for use of surgical drills

Drill diameter, mm	1.5	2.0	2.8	3.45	3.9	4.3
Drilling speed, rpm	D1 800-1200 D2 800-1200 D3 800-1000 D4 800-1000	D1 800-1000 D2 800-1000 D3 700-900 D4 600-800	D1 600-800 D2 600-800 D3 500-600 D4 400-500	D1 500-700 D2 600-800 D3 500-600 D4 400-500	D1 400-600 D2 500-700 D3 500-600 D4 400-500	D1 400-600 D2 500-700 D3 500-600 D4 400-500

SUBCRESTAL IMPLANT INSTALLATION

Implant submergence depth is easily controlled due to the straight shape of implant neck resulting in minimization of bone atrophy.



Reduction of load on the cortical bone



Decreased load

Increased load

Attention! The actual length of HELIX implants is 0.5 mm less than the declared length, which contributes to the submergence of implant below the level of the cortical layer.

CERTIFICATES



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/IMQ as an IQNet Partner hereby states that the organization

ABM TECHNOLOGY, LLC

147, PROSPEKT BOGDANA KHMELNITSKOGO, DNIPRO, 49033, UKRAINE

for the following scope:

Development, production of dental implants, superstructures and instruments

has implemented and maintains a **Quality Management System** which fulfills the requirements of the following standard

ISO 13485:2016

Issued on: 2017 - 12 - 14 First issued on: 2017 - 12 - 14 for the validity date, please refer to the original certificate* issued by IMQ A prerequisite for concluding contracts with consumers is the certification of the production quality management system according to DSTU ISO 13485 (ISO 13485), which guarantees the consistency of performance and safety of *Bauer's Implants* products, as well as compliance of products with national technical regulations and international directives.

The high quality of *Bauer's Implants* products is confirmed by the Certificate of Conformity to Technical Regulations for Medical Devices approved by Decree No. 753 of the Cabinet of Ministers of Ukraine.













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