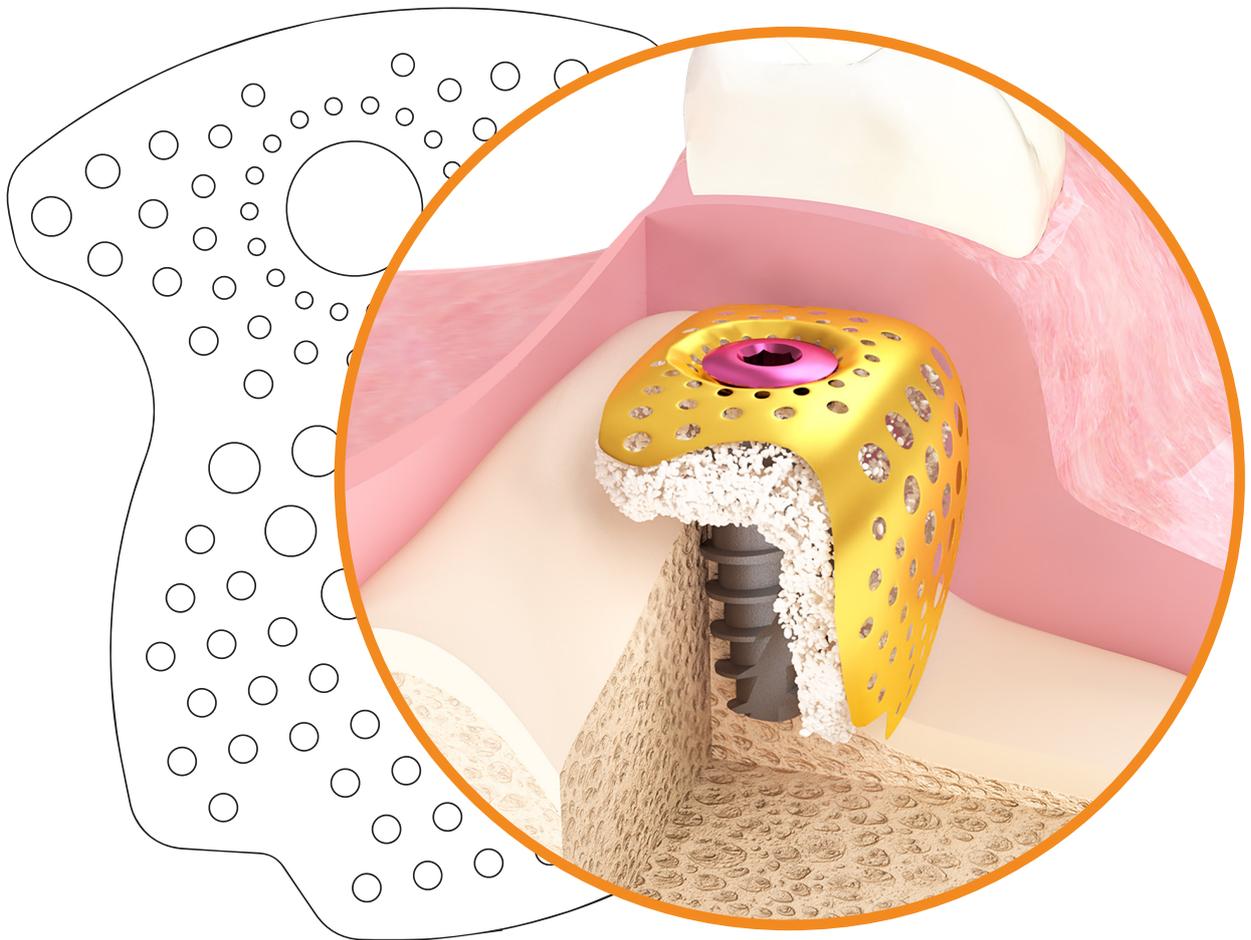


BONE SUBSTITUTION

SPECIAL MEMBRANES · SCREWS · RIVETS





Introduction

About the company..... 2

Technology and quality..... 3

Applied raw materials..... 5

BIONIKA Titanium membrane meshes

Titanium membranes..... 6

Special membrane meshes..... 8

3D Builder titanium membranes..... 10

Membrane rivets and bone screws..... 12

Replaceable inserting screwdriver set..... 14

Pin punch set..... 16



About the company

Bionika Medline Kft. was established in 1989 by private individuals as a family-owned Hungarian company. We have a 35-year-experience in the field of medical instruments and implant development, production and trade.

BIONIKA as a researcher, developer, manufacturer and distributor is present in dentistry, oral surgery, traumatology, orthopedics and rehabilitation in the medical-professional areas.

According to our objective and perception, we attach great importance to the word „BIONIKA“, which marks a scientific thinking on the boundaries of biology, technology and electronics that combines these three areas in our researching and developing work.

Clinical and technological experiences:

The continuous process, combination and utilization of clinical and technological experiences in development contributes to our success, up to the production base. Here you will find the best solutions and constructions suited to customer needs, which are under continuous development.

Development:

The owners of BIONIKA put great emphasis on continuous product and technological research and development. Our products are developed in close collaboration with doctors and engineers, enabling us to ensure the world-class quality and practical utilization.

Quality:

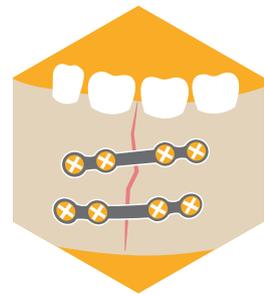
The quality of the products expected by our customers is guaranteed by design, manufacturing and quality management according to the harmonized European Union laws. The BIONIKA Medline Kft. is operated according to the EN ISO 9001 and the EN ISO 13485 quality management system. Our products are provided with CE marks.

Guarantee:

After inserting the implant - the risk of the ossification process is assumed by BIONIKA, independently of cause and effect relationship – exchange guarantee is ensured within one year after the purchase. Otherwise, we provide a long-term, 10-year guarantee for our products.



DENTISTRY



ORAL SURGERY



TRAUMATOLOGY



ORTHOPEDICS

Technology

BIONIKA Medline Kft. has 35 years of experience in the development and production of dental implants, dental insertion instruments and stomatological parts. During this time more than 40 types of implant systems have been developed and are being manufactured to date, including insertion instruments. Some of these parts have been developed for their own marketing in accordance with their own market needs.

Other systems - in cooperation with independent medical groups - are made to order, mainly developed and manufactured for foreign markets. (These are sold by the customers under their own brand name).

Our partners can choose from approximately 20.000 different parts of different sizes and shapes. Our manufacturing technology is flexible, we can quickly move from one component to another, and we are able to fulfill thousands of orders with a short turnaround time.

This area requires high precision production (in some cases it is necessary to hold 2-5µm tolerances).

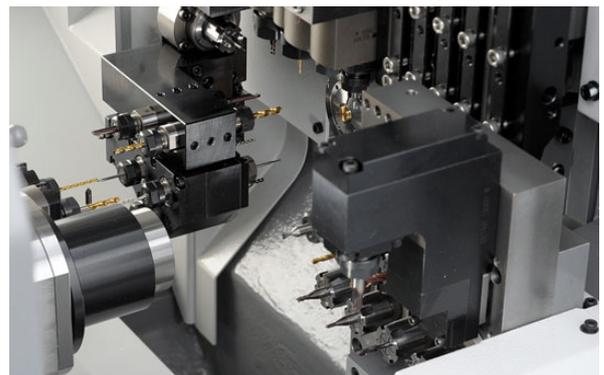
All the technological operations we carry out are from manufacturing, surface design, packaging. Our products are CE marked and the production process is under strict quality management system.

Biocompatible materials are the most important raw materials for dental, oral surgery, traumatology and orthopedic medical implants. Because relatively small series of customized solutions are required, they require fast programmable CNC machining technology.

Accordingly, we have molded CNC machining centers and Swiss type longitudinal machining centers. For machining more complex surfaces, an industrial 5-axis CNC center is used with CAD-CAM system support. Our machines are equipped not only with fixed cutting tools, but also with more machining. As a complementary technology, we have sandblasting, polishing titanium coloring and sterilization equipments.

The production of custom prosthetic components for dental applications is supported by the BIONIKA Milling center.

Our Partners



Quality management and guarantee

The quality of the products is guaranteed by design, manufacturing and quality management according to the harmonized European Union laws. The BIONIKA Medline Kft. is operated according to the EN ISO 9001 and the EN ISO 13485 quality management system. Our products are provided with CE marks, which is ensured by EMKI and QT-CERT.

We provide a long-term, 10-year guarantee for our products. After inserting the implant, reducing the medical risk of the ossification process, independently of cause and effect relationship – exchange guarantee is ensured within one year after the purchase for the dropped and fallen out implants.



BIONIKA Medline Kft. has always paid close attention to quality and reliability during its 35 years of existence. The D&B certificate is proof of our reliability and stability. BIONIKA received „Triple A” D&B qualification from 2016 to 2023.

At the Hungarian market only 0.63% of the companies have the AAA D&B rating. The financial risk of establishing business relationship with these business associations is extremely low - source: dnb.hu

Applied raw materials



Titanium Grade 2

Chemical composition

Elements	Threshold limit of constituents)
Fe	0,3 max.
O	0,25 max.
C	0,08 max.
N	0,03 max.
H	0,015max.
Ti	balance

Mechanical properties

solidity	360 MPa min.
dilation	30 %

According to the **ISO 5832-2** standard.

Titanium Grade 5

Chemical composition

Elements	Threshold limit of constituents
Al	5,5-6,75 max.
V	3,5-4,5 max.
Fe	0,3 max.
O	0,2 max.
C	0,08 max.
N	0,05 max.
H	0,015 max.
Ti	balance

Mechanical properties

solidity	860 MPa min.
dilation	10 %

According to the **ISO 5832-3** standard.

Bioline 316L

Chemical composition

Elements	Threshold limit of constituents
C	0,025 max.
Si	0,6 max.
Mn	1,7 max.
P	0,025 max.
S	0,003 max.
Cr	17,5 max.
Ni	14,0 max.
Mo	2,8 max.
Cu	0,10 max.
N	0,10 max.

Mechanical properties

solidity	1148,0 N/mm ²
----------	--------------------------

According to the **ISO 5832-1** standard.

Titanium membranes

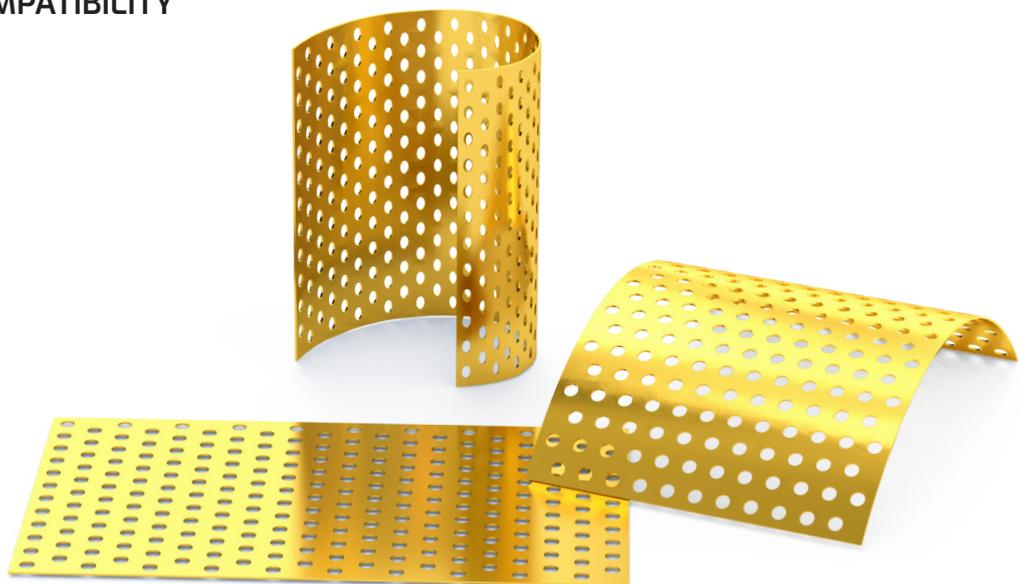
It is often necessary to replace the thinned bone before implantation. One of the most effective methods for bone substitution is the usage of titanium membrane nodes. The titanium plates made by Bionika are strong, flexible and available in a wide range of sizes. These are an adequate solutions for every situations.

The usage of the product is very simple, because of its slim design, it is flexible and moldable, so it can adapt perfectly to various surgical situations. The titanium raw material has excellent biological stability and is a preferred choice for ossification. Titanium membranes do not absorb but may remain for a long time before removal.

The advantage of titanium membranes is that they are stronger than the absorbent membranes and the free flow of body fluids is provided by a micro perforated surface. The titanium membrane accurately determines the location of the ossification and serves as a carrier for bone substitutes.

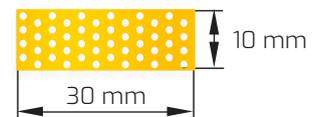
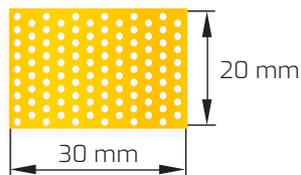
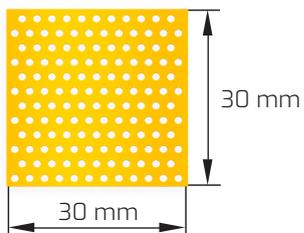
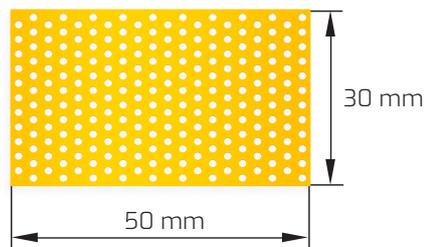
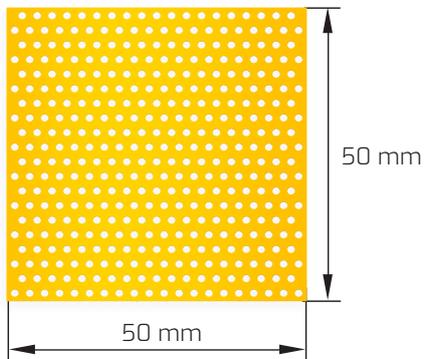
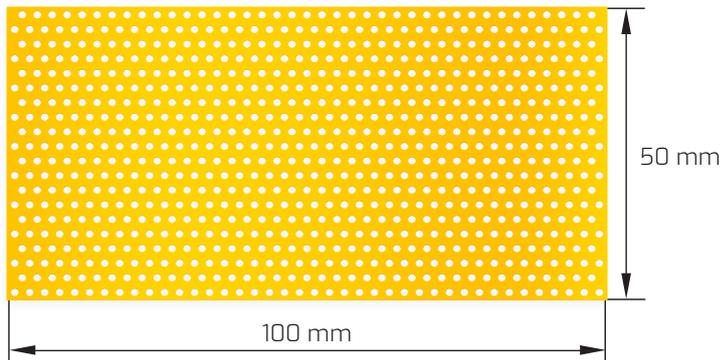
Titanium meshes

- EASY USE
- CUSTOMIZABLE SIZE AND FORM
- STRONG, BUT EASILY BENDABLE MATERIAL
- EXCELLENT BIOCOMPATIBILITY



Titanium membranes | Size range

Thickness on request: **0.1** or **0.2** mm



Special flat membranes

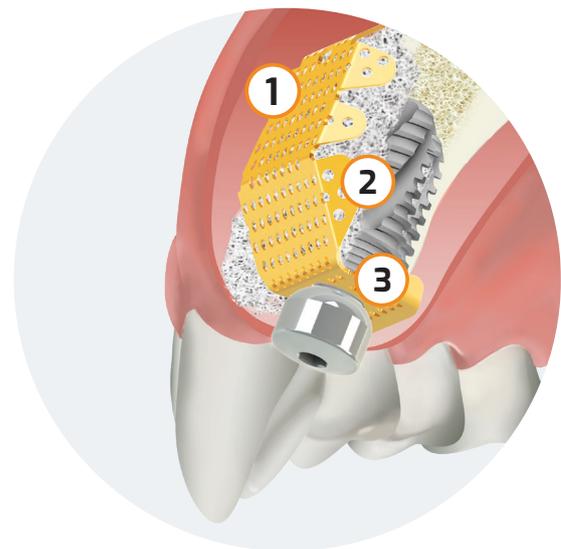
The special flat membranes are easily bendable and due to the customized form there is no need for its cutting. If you want to cut a piece off, you can perform it easily because it is very easy to cut due to its slim design. The thickness

of the sheets is optional, optionally made of 0.1 or 0.2 mm thick. The insertion and removal are even easier with special, customized titanium meshes. The removal of special membranes causes less damage to bone tissue.

The application of special membranes

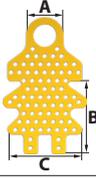
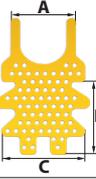
Our special membrane meshes are available in flat, expansive form, and can be formatted to the appropriate geometry by using a hand held pliers.

- ① **Bore-winged titanium membrane**
- ② **Bone augmentation material**
- ③ **Implant**



- EASY USE
- CUSTOMIZABLE SIZE AND FORM
- STRONG, BUT EASILY BENDABLE MATERIAL
- EXCELLENT BIOCOMPATIBILITY
- EASY FIXATION

Special membranes | Range of sizes

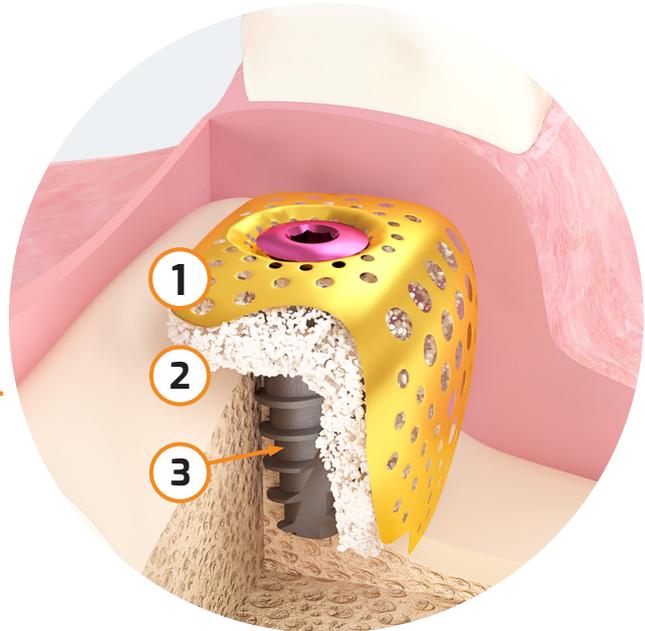
Denomination	Form	A (mm)	B (mm)	C (mm)
Bore		4	8	6
			10	8
				10
Forked		7	9	6
				8
				10
Winged		10	12	6
				8
				10
Bore-winged		7	9	6
				8
				10
		10	12	6
				8
				10
13	12	6		
		8		
		10		
Bore-winged		7	9	6
				8
				10
		10	12	6
				8
				10
13	12	6		
		8		
		10		

3D builder titanium membranes

Our embossed titanium membranes are almost the in material properties with the special membranes, except that they are also available in flat and pre-formed forms.

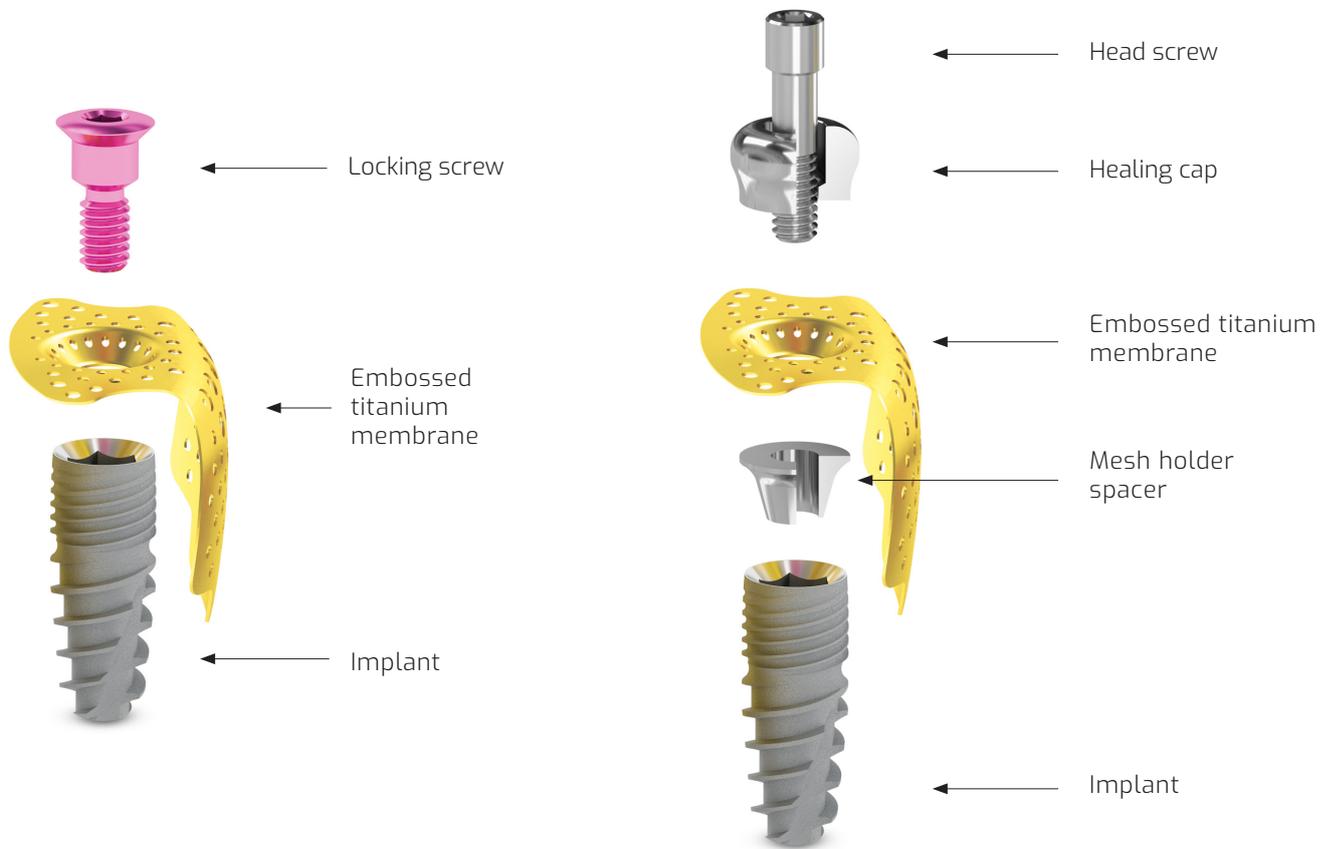
Application of embossed membranes

- ① „A form” membrane mesh
- ② Bone augmentation material
- ③ Implant

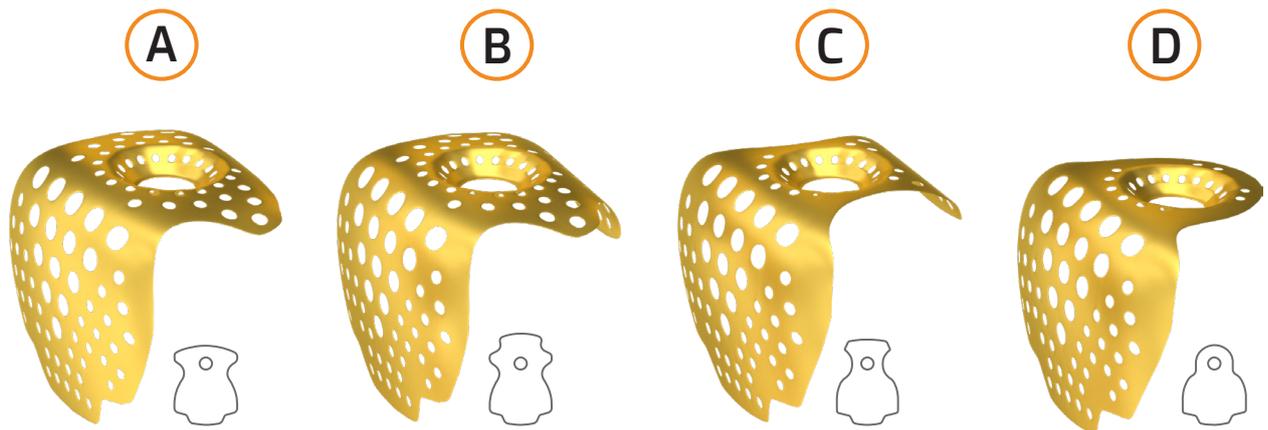


- BONE AUGMENTATION WITH IMPLANTATION
- STRONG, YET EASILY BENDABLE MATERIAL
- EXCEPTIONAL BIOCOMPATIBILITY
- EASY FIXATION WITH IMPLANT LOCKING SCREW

Embossed titanium membranes | Application



Forms



The 3D Builder titanium mesh is usually suitable for bone substitution in one tooth place. It is available in four geometrical (A, B, C, D) shapes.

Type A: The implanted bone section is used to hold the top of the implant and one side of the bone substitute material.

Type B: It is suitable for supporting bone replacement on the wider and lateral section of the jaw bone.

Type C: It is suitable for retaining bone substitute material on the jaw bone and on both sides of the jaw section.

Type D: It is recommended in the case of fixing a bone substitute material on one side of the jaw section and on the narrow (between two teeth) spine.

Membrane rivets and bone screws

BIONIKA membrane rivets and bone screws for transplant bone blocks and membrane mesh fixation.

Flat head membrane rivet

Diameter (mm)	Length (mm)	
	3	5
∅ 1,0	●	●



Threaded membrane rivet

Hexagonal titanium rivet with an inner key aperture for the easy stabilization of membranes, which can be inserted without the help of a pre-drill. 1.27- spliced and compatible with multiple keys.

Diameter (mm)	Length (mm)	
	3	5
∅ 1,0	●	●
∅ 1,2	●	●



Transplant bone screw with an inner key aperture

Hexagonal titanium screw with an inner key aperture for the easy stabilization of membranes and transplant bone blocks. 1.27- spliced and compatible with multiple keys.

Diameter (mm)	Length (mm)				
	4	6	8	10	12
∅ 1,2	●	●	●	●	●
∅ 1,5	●	●	●	●	●



Bone screws



Conical bone screw

Diameter (mm)	Length (mm)	
Ø 1.5	3	5
	●	●



Transplant cross headed bone screw

Diameter (mm)	Length (mm)									
	3	4	5	6	7	8	9	10	11	12
Ø 1.2	●	●	●	●	●	●	●	●	●	●
Ø 1.5	●	●	●	●	●	●	●	●	●	●

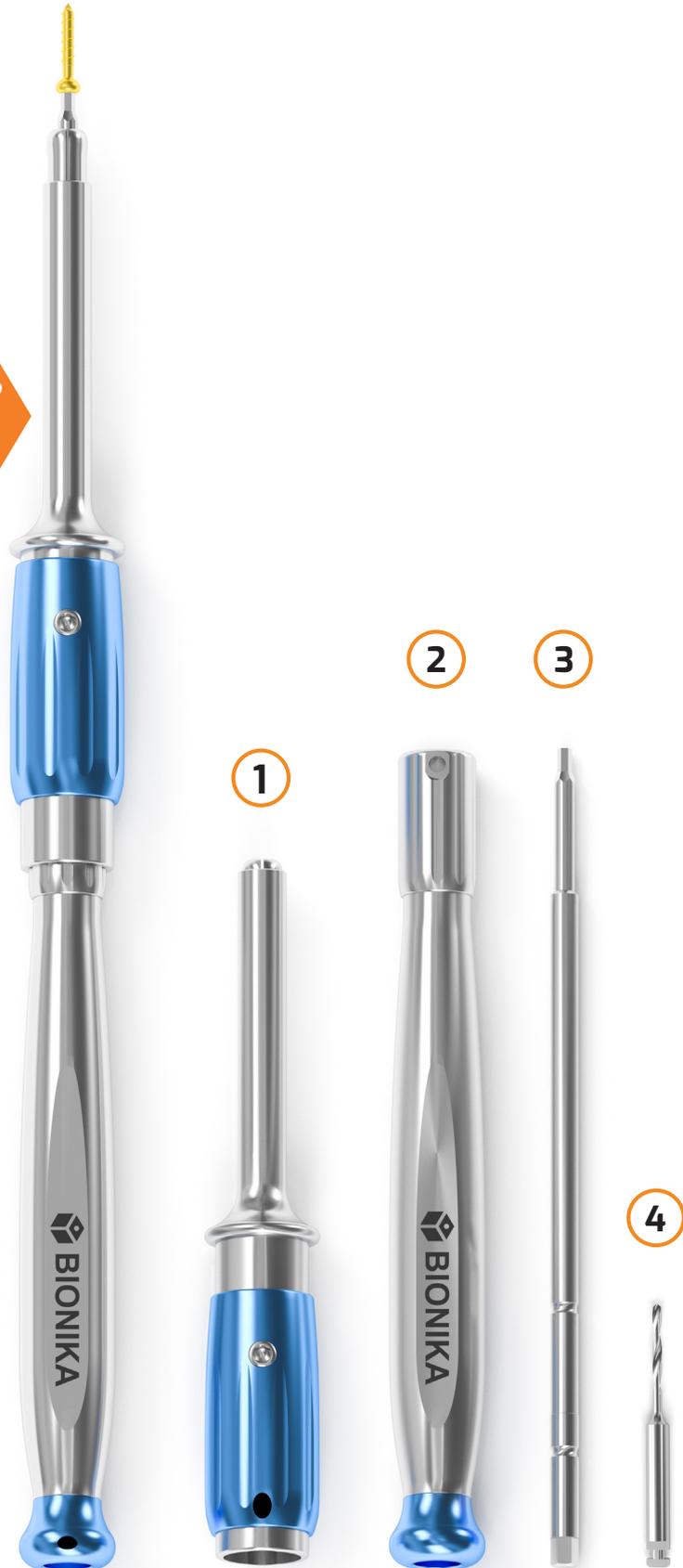
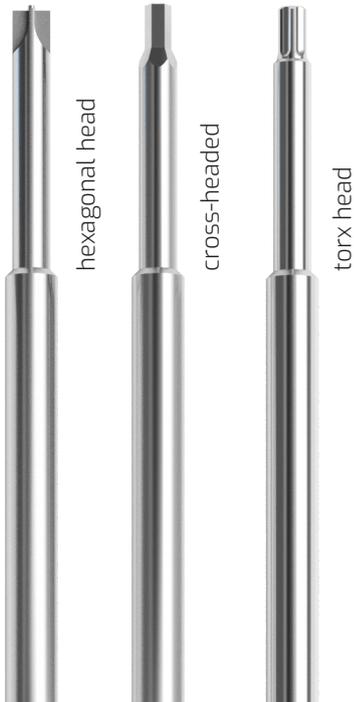
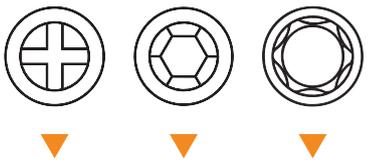


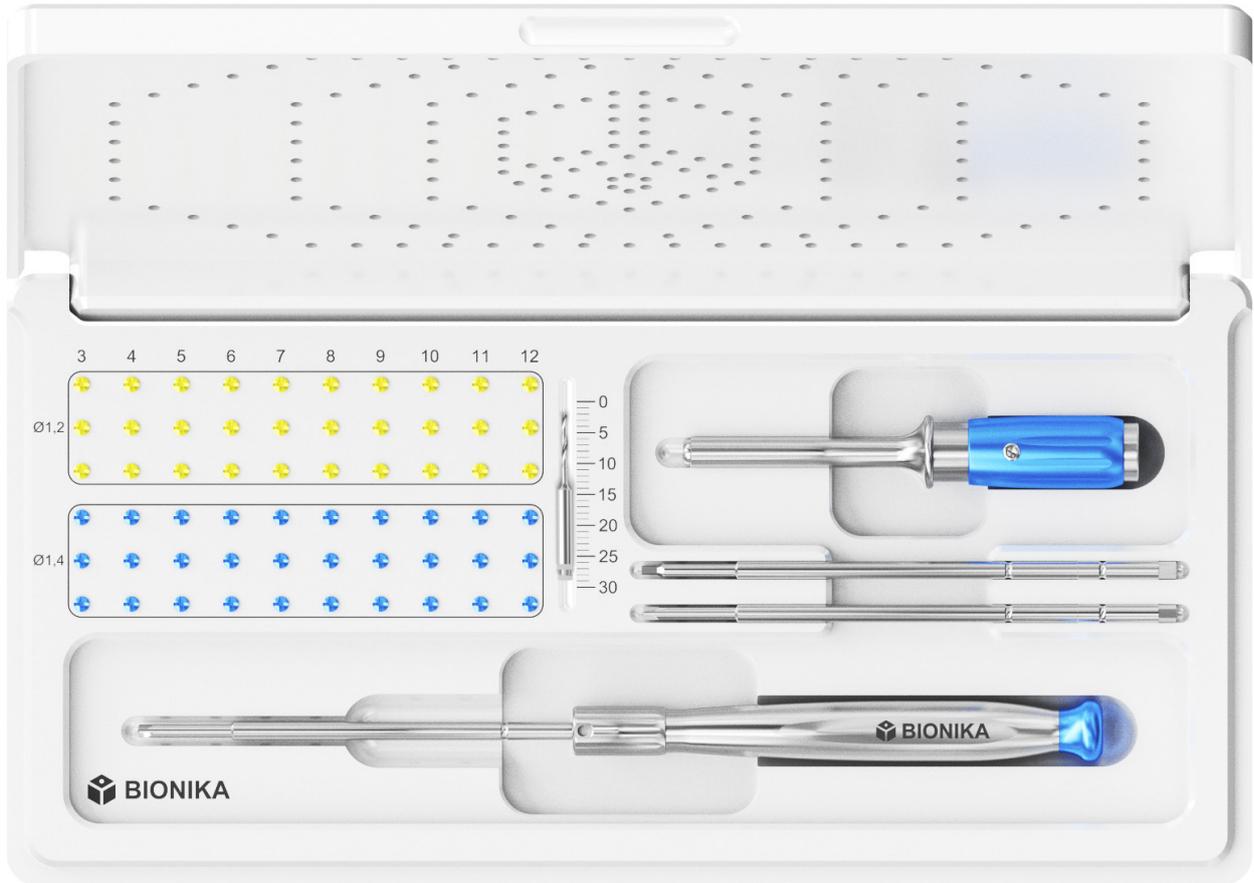
Replacable inserting screwdriver set

The replacable inserting screwdriver set consists of three independent elements:

1. SCREW HEAD GRIPPER
2. SCREWDRIVER HANDLE WITH BLADE CLAMP
3. SCREWDRIVER BLADE
4. MECHANICAL DRILL

Screwdriver blade versions





Screws

The kit contains screws of 1.2 and 1.4 mm in diameter from 3 mm to 12 mm length. Their headforms are cross or hexagon recessed head. These are also available with a torx key aperture on request.



Pin punch set



APPLICATOR



PIN PUNCH



MANUAL KEY



We have developed our Pin punch set for fixing the membrane and titanium nets to the soft tissues. The kit consists of a curved and straight applicator as well as a curved and straight rivet insertion kit, a membrane rivet holder (the rivets can be ordered separately) and

a manual key. The membrane rivets can be found in the circular holder which will hold the membrane plates. The holder is designed in a way that the end of the rivet insertion can be clicked to the head of the rivet. The elements of the set can be bought separately.





Get to know our other products!

Ask for our catalogs or visit one of our websites below:



www.bionika.hu



www.shop.bionika.hu





 **BIONIKA MEDLINE KFT** • info@bionika.hu • www.bionika.hu • www.shop.bionika.hu
3516 Miskolc, Tégla u. 29. • Mobil.: +36 70 362-9235

K-MD07-027-v01-191108-EN