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About the company

BIONIKA Medline Orvostechnikai Kft. Is a member of a Hungarian-Swedish group of companies. It was founded in 1989. The owners of the company are Hungarian and Swedish citizens.

We have more than 30-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.

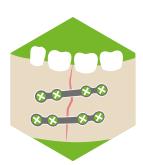
Clinical and technological experiences: The continuous process, combination and utilization of clinical and technological experiences in development contributes to our success, up to the production base. Here you will find the best solutions and constructions suited to customer needs, which are under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





ORAL SURGERY



TRAUMATOLOGY



ORTHOPEDICS

Technology

BIONIKA Medline Kft. more than 30 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 2-5 mm 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 , but also with propelled cutting instrument units, with which we can perform more complex spatial geometrical 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 ot he harmonized European Union laws. The BIONIKA Medline Kft. is operated according ot he EN ISO 9001 and the EN ISO 13485 quality management system. Our products are provided with CE marks, which was 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 more than 30 years of existence. The Bisnode certificate is proof of our reliability and stability. BIONIKA received "Triple A" Bisnode qualification from 2016 to 2022.

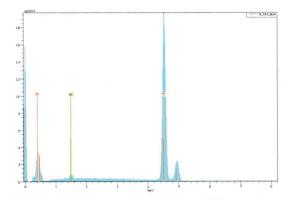
At the Hungarian market only 0.63% of the companies have the AAA Bisnode rating. The financial risk of establishing business relationship with these business associations is extremely low - source: dnb.hu

Superclean implant surface

BIONIKA demonstrates the best qualities of Grade 4 titanium used in implant manufacturing for dental implantology according to the ISO 5832-2 ASTM F67 standard. Due to its adequate purity the biocompatibility is exceptionally good as well as it is provided with exceptional solidity.

Initially, we and other implant manufacturers preferred the higher purity titanium but due to solidity reasons nowadays almost every implant is made of Grade 4 or other alloyed titanium in the world. In all cases of implant abutments, alloyed, high strength Grade 5 titanium is applied according to the ISO 5832-4 ASTM F136 standard. The titanium applied according to the standard is provided with exceptional biocompatibility, it is almost risk-free.

Almost all professionals see that the implantation success is best determined by the implantologist's practice, as well as surgical conditions, carefully maintained hygiene, and patient abilities.



Energy dispersive X-ray spectometric elemental analysis of Bionika implants*

The main steps of our BioTiS surface finish technology:

• Chemical, mechanical surface cleaning and surface dewing

• Special ultrasonic cleaning, surface cleaning and sterilization

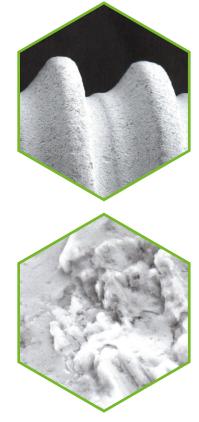
Transformation of surface structure by acidification process

Multi-stage dehumidification, cleaning

- Electrochemical surface modification
- sterilization
- Surface finish in physiological solution

These technological steps are always carried out under sterile conditions.

The final packaging of the implants is four-layered. The packaging is carried out in a sterile cabin. Final sterility is assured by an accredited 20 Rad gamma sterilization procedure.



Applied raw materials

Titanium grade 4

Chemical composition

Elements	Threshold limit of constituents(%)
0	0,4 max.
Fe	0,3 max.
С	0,1 max.
Ν	0,05 max.
Н	0,0125 max.
Ti	>99% / balance



Mechanical properties

solidity	680 MPa min.	
dilation	10 %	

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.
0	0,2 max.
С	0,08 max.
Ν	0,05 max.
Н	0,015 max.
Ti	balance

Mechanical properties

solidity	860 MPa min.	
dilation	10 %	

According to the ISO 5832-3 standard.

CoCr

Chemical composition

Elements	Threshold limit of constituents(%)
С	0,1 max.
Si	1,0 max.
Mn	1,0 max.
Р	0,005 max.
S	0,005 max.
Cr	30, 0 max.
Мо	7,0 max.
Ni	1,0 max.
Со	-
Ν	0,2250 max.

Mechanical properties

solidity	1240,00 MPa min.
elongation limit	900,00 min.
elongation at break	18,00 min.
fracture contraction	23,00 min.

According to the ISO 5832-4 standard.

Plastics

POM (polyoxymethylene) : Thermoplastic synthetic plastic, Excellent properties eg: high hardness, low wear, good flexibility, little absorbing ability. Density: 1.41 g / cm3. elongation at break: min. 30% Current Voltage: min. 65 Mpa. Its color is white.

PEEK (polyether ether ketone) :High heat-resistant plastic, suitable for all conventional sterilization methods (steam, dry heat, ethylene oxide, gamma radiation). Density: 1.30 1.41 g / cm3 Tensile strength: 115 Mpa. elongation at break: min. 17% Its colour is natural brownish gray.

eco-plant packaging









10-piece collection box

vial in sterile foil

removing the foil

sterile vial



removing the locking plug (1)



removing the locking plug (2)



the implant and the multifunctional head in the locking plug



using the implant key driver



Collection box

Depending on the order quantities, collection boxes with 5 and 10 pieces are applied.

eco-plant packaging



According to our endeavor, the raw materials used in packaging are almost 100% naturally occurring, environmentally-friendly, natural materials.

aluminum · titanium · glass · caoutchouc · paper

Vial

The first layer of the packaging is a transparent vial, which ensures the total, null colony-forming unit sterility. The locking plug of the vial holds the implant, the multifunctional implant head and the locking screw.

Eco, Normál Implantátum Ø 4,00 x L11,00 mm REF 501.001.380.110 ∭2016-06 LOT 160517-15 2021-06 C € 1008 (2) STERILER []cm 007 W S BIONIKA Medine Kft. www.bionika.hu

Paper box

The outer layer of the packaging is a paper box with a high density, which is for the physical safety. Every paper box is provided with colour-coded labels according to the different platform- diameters. The colour of the packaging is adjusted to this method.







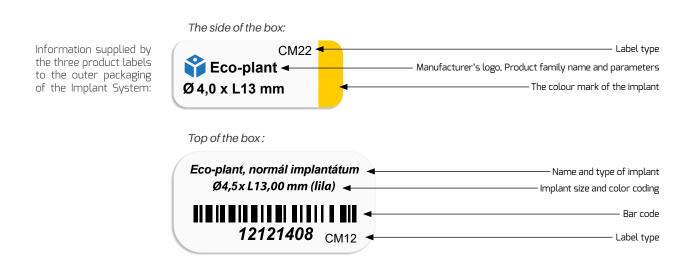
The first layer of the packaging is a transparent vial. The implant and the multifunctional head are held by the vial locking plug and with this they can be removed from the vial. The implant locking screw can be found in the vial locking plug as well. The **multifunctional head** doesn't only hold the implant in the packaging but also helps its inserting into the jaw bone, is suitable for closed spoon sampling and after this it can be drilled as a head for the glued toothwork.



eco-plant product labels and their notation

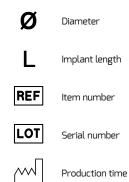
Differential platform diameters by colour:

🙆 3,5 mm - grey 👩 4,0 mm - yellow 🙆 4,5 mm - purple 👩 5,0 mm - blue 🙆 6,0 mm - green



The back of the box: Eco, Normál Implantátum ◄ Ø4,00xL13,00 mm ◄	Name and type of implant
REF 504.001.400.130 2016-06	
LOT 121214-08 2021-06	The colour code of the implant
BIONIKA Medline Kft. 3516 Miskolc Tégla utca 29. www.bionika.hu	The manufacturer's logo,

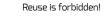
Explanation of label codes:







It is forbidden to use in the case of damaged packaging.



- **R** Sterilized with gamma rays
- **STERILE** sterilized with steam or dry heat



Ĩ

Non-sterile product in the package

Read the usage guide!



company code

Certification



Manufacturer's name and Contact

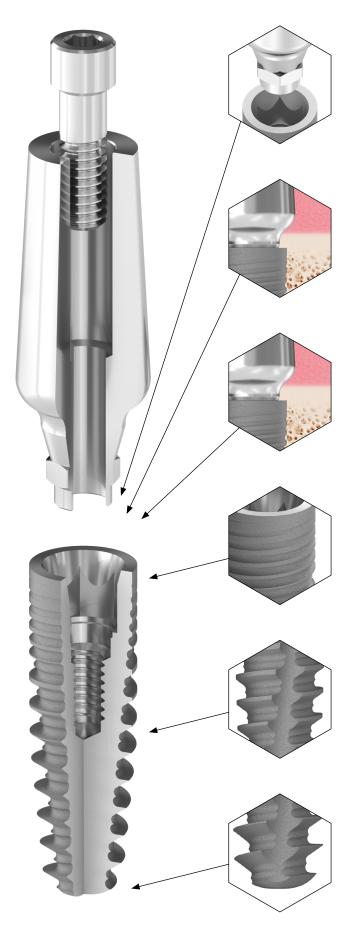


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Distinctive characteristics of the eco-plant implant system



Connection: Cone and hex and cyclinder

The most perfect fixation is provided which is well-proven in the engineering practice. 30 degree cone angle is applied which eventuates micromotor-free power transmission and offers favorable conditions for the accurate open or closed spooned sampling. It superimposes the powers deep right into the implant.

Cortical Level

The chances of the implant persistency are significantly improved by inserting the upper edge of the implant at the cortical level or below (from 0.5 to 1 mm) which is proven by surgical experiences on the long run.

Platform switching

The diameter of the abutment is smaller than the outer part of the implant which is connected to the bone. This way the soft tissue closes upon the ingoing aperture and the implant's connecting surface of the bone nest, covering, insulating that like as a sealing ring.

Spirally microstriated cortical surface

The multi- paragraphed microstriated spiral surface can function as a significant weight bearing element connected to the cortical and ensuring micromotor-free condition for the fast inserting. This self-closing thread structure due to the cycloid cord thread geometry helps facilitating dynamic force convection and ensures micromotor-free condition for fast insertion.

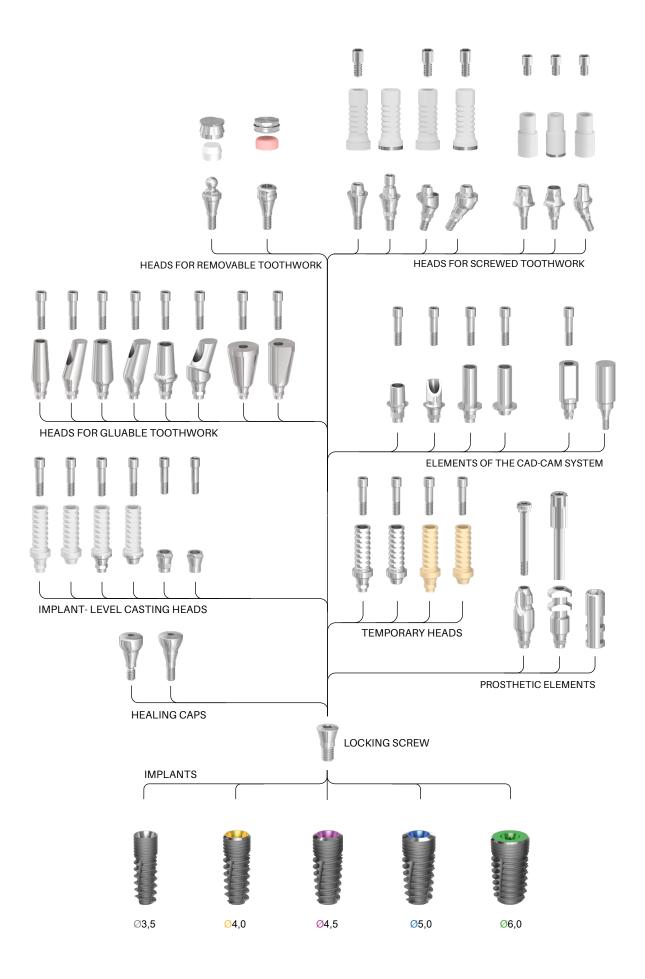
Anatomical root form

The Eco-plant follows the form of the anatomical tooth root. Due to the conicity, high thread pitch, high thread deepness, self-closing and self-tapping shaping of the implant screw thread, it has a bone-compacting effect. Thus, there is an option for immediate loadness of the implant as needed as a result of the high primer stability.

Rounded implant end

It helps facilitating the minor direction changes when inserting the implant.

The functional structure of the **eco-plant** system elements



The applicational fields of the eco-plant implant system



In the case of one tooth deficiency

In this case of the replacement of a tooth, we do not have to grind two healthy teeth for bridge replacement, but inserting an implant, then we need to glue a crown in the same way as the traditional one.

In the case of end of line tooth deficit(s)

In this case, in the absence of a pillar tooth, we are not able to make a fixed replacement (bridge). With the implantation of at least two implants, you are already make the (fixed) bridge replacement.





Removeable denture

In the case of total tooth deficit

In this case the patient has no tooth, complete tooth augmentation can be performed. In this case, there one solution is the removable denture: 2-4 implants are implanted, these will be the fixation for the removable tooth.

This brings a tremendous quality of life to the patient, as this way the denture will be very stable, so it can be used in chewing and speaking outright. There are two solutions possible in this case: ball head or locator head abutments can be applied.

With the implantation of several 6-8 implants, it is possible to make full fixation (round bridge) augmentation, which is both functional and aesthetically close to the natural teeth.

Screw-retained fixed dental prosthetics



Optimum Concept

Optimum Concept

All-on-4[®] type - Economical Solution

The Optimum Concept provides great stability, with only four implants being implanted.

- The temporary denture can be inserted on the day of surgery.
- Immediate improvement in function, speech and aesthetically.
- Treatment times are shorter and costs can be lower than conventional implant placement modes.
- Tilt rear implants can be fixed better into the front bone. This promotes prosthesis support.

Safe Concept

All-on-6® type - For extra stability

The stability of the toothwork can be increased with the Safe Concept. It is exceptionally advantageous in the case of extra chewing ability.

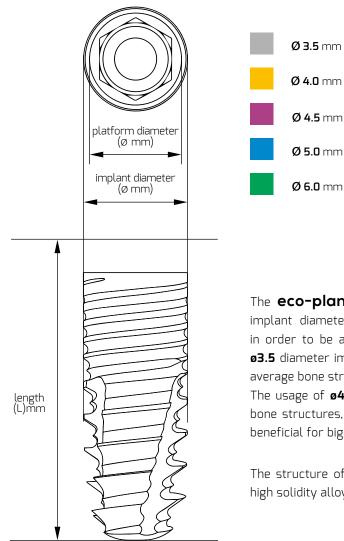
- The usage of oblique head implants allows longer implants to be used, avoiding the nerve canal.
- The usage of longer implants allows the bone and the implant to touch on a larger surface, thus making bone augmentation avoidable.
- Favorable bone level for tilted and axial implants.
- High remaining chances.





eco-plant implant system

Sizes available of the Eco-plant implants



The **eco-plant** implant system consists of five different implant diameters. Every implant diameter has five lengths in order to be an adequate solution for every situations. The **ø3.5** diameter implant is exceptionally suitable for thinner than average bone structures for holding toothworks on the long run. The usage of **ø4.0** and **ø4.5** diameter is beneficial for average bone structures, and the **ø5.0** and **ø6.0** diameter implants are beneficial for bigger than average bone stocks.

The structure of every Eco implant is homogeneous, made of high solidity alloyed titanium.



Ø 3.5					
inserting length (L):	7 mm	9 mm	11 mm	13 mm	15 mm
Ø 4.0					
inserting length (L):	7 mm	9 mm	11 mm	13 mm	15 mm
Ø 4.5					

1				
7 mm	9 mm	11 mm	13 mm	15 mm

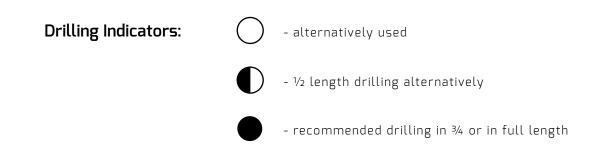
inserting length (L):

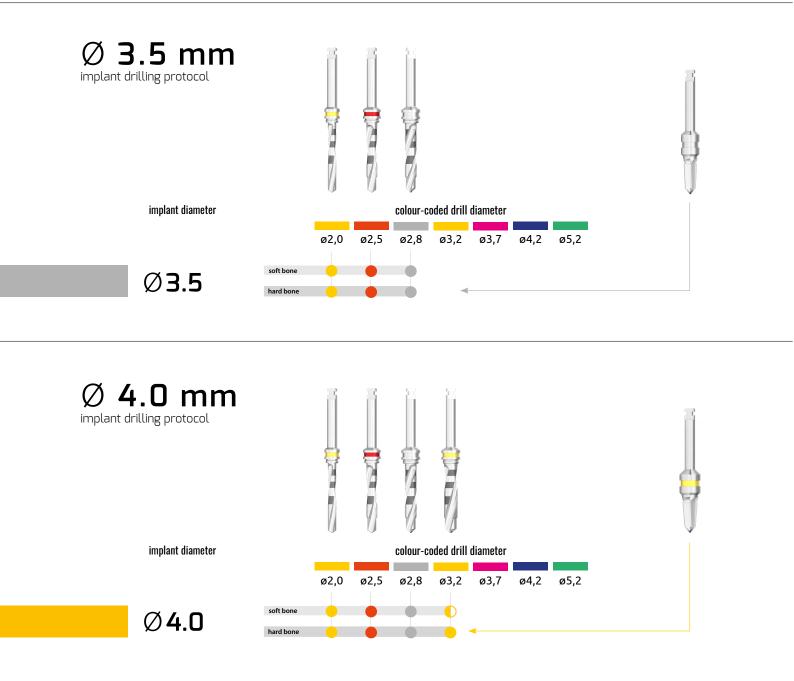
Ø **5.0**

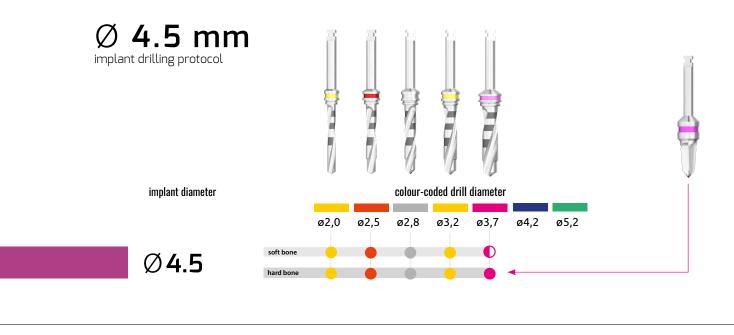
7 mm	9 mm	11 mm	13 mm	15 mm

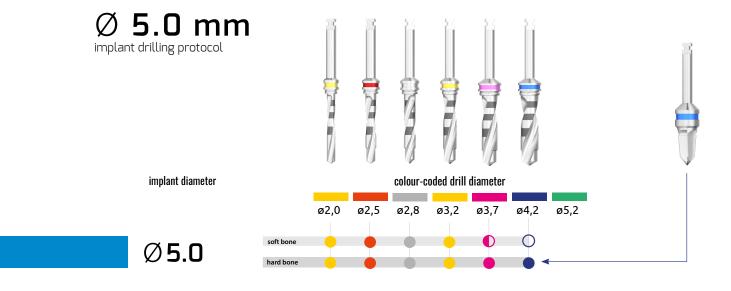
inserting	length (L):
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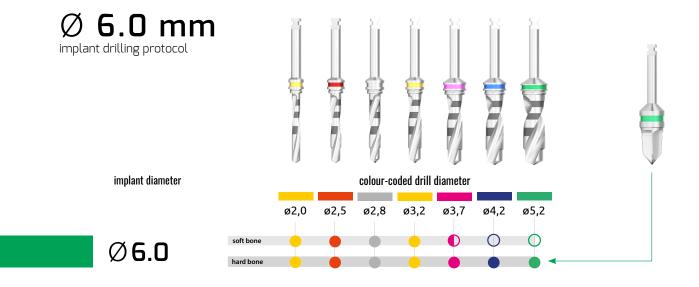
Ø 6.0					
inserting length (L):	7 mm	9 mm	11 mm	13 mm	15 mm













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The products in the publication are only illustrations, they do not cover the exact appearance and shape of the product.

eco-plant abutments

1. Implants

PROSTHETIC ELEMENTS

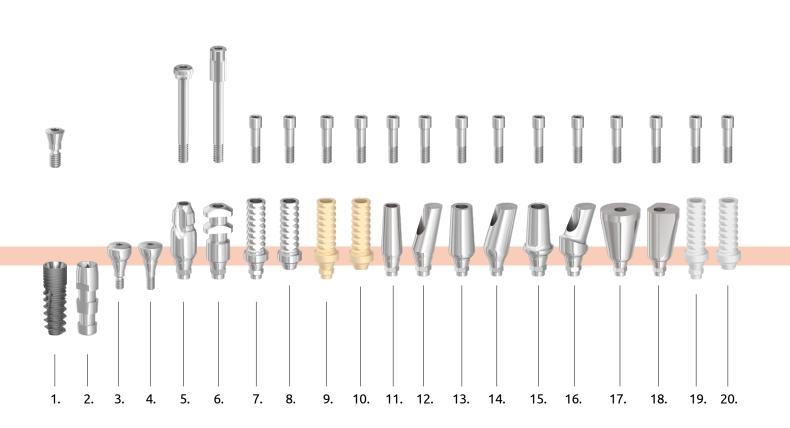
- 2. Technical implant
- 3. Healing cap, narrow
- 4. Healing cap, anatomical
- 5. Sampling head for closed spoon
- 6. Sampling head for open spoon
- 7. Temporary head, through-bolted, positioned
- 8. Temporary head, through-bolted, non-positioned
- 9. Temporary head, through-bolted, positioned, PEEK
- 10. Temporary head, through-bolted, non-positioned, PEEK

FOR GLUABLE TOOTHWORK

- 11. Narrow head, straight
- 12. Narrow head oblique
- 13. Universal head, straight
- 14. Universal head, oblique
- 15. Anatomical head, straight
- 16. Anatomical head, oblique
- 17. Trapezoidal head
- 18. Delta head

IMPLANT-LEVEL CASTING HEADS

- 19. Castable plastic head, positioned
- 20. Castable plastic head, non-positioned



- 21. Cobalt chromium-based casting head, positioned
- 22. Cobalt chromium-based casting head, non-positioned
- 23. Interface, positioned
- 24. Interface, non-positioned

FOR REMOVABLE TOOTHWORK

- 25. Ball-head
- 26. Locator head, straight

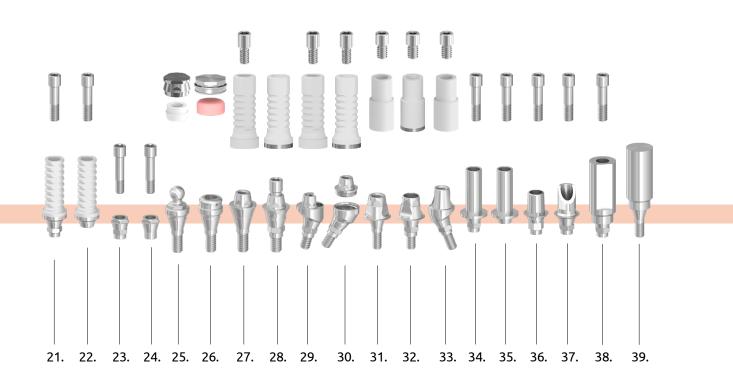
FOR SCREWED TOOTHWORK

- 27. Multi-unit head, straight
- 28. Multi-unit head, through-bolted
- 29. Multi-unit head, oblique
- 30. MC head, oblique

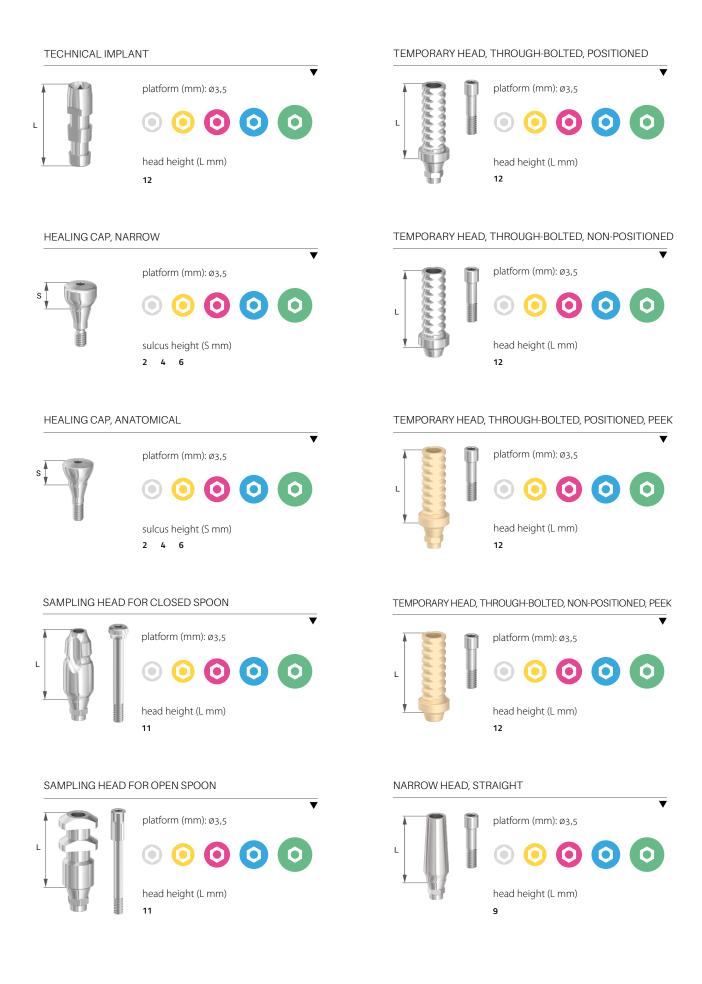
- 31. Multi-unit SR head, screwable
- 32. Multi-unit SR head, through-bolted
- 33. Multi-unit SR head, oblique

ELEMENTS OF CAD-CAM SYSTEM

- 34. Titanium base
- 35. Press ceramic base
- 36. Tube-head, positioned
- 37. Tube-head, non-positioned
- 38. Scanbody head, through-bolted
- 39. Scanbody head, screwable

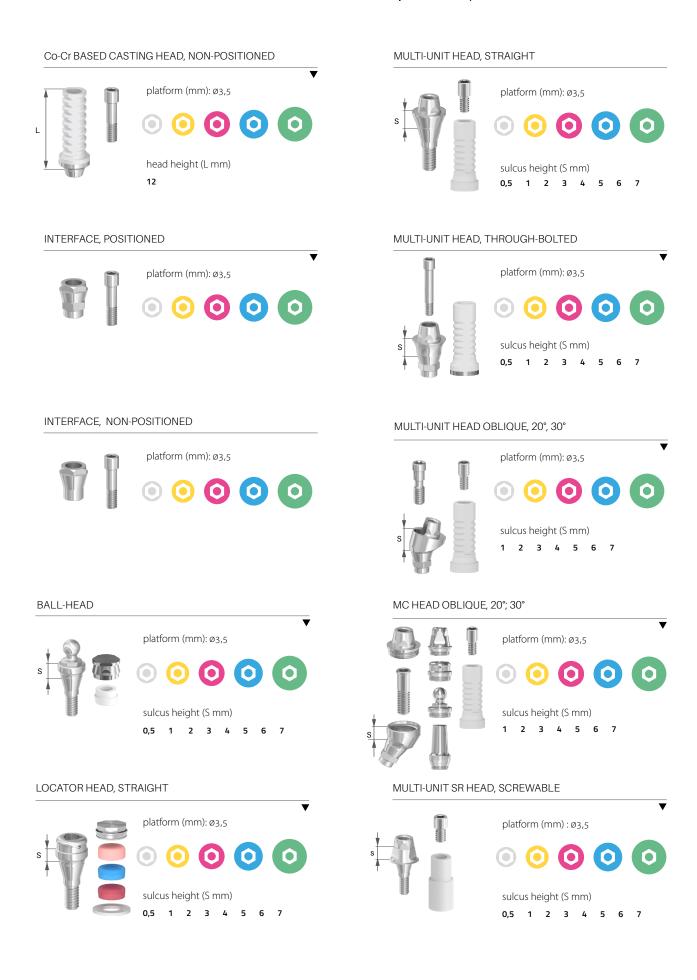


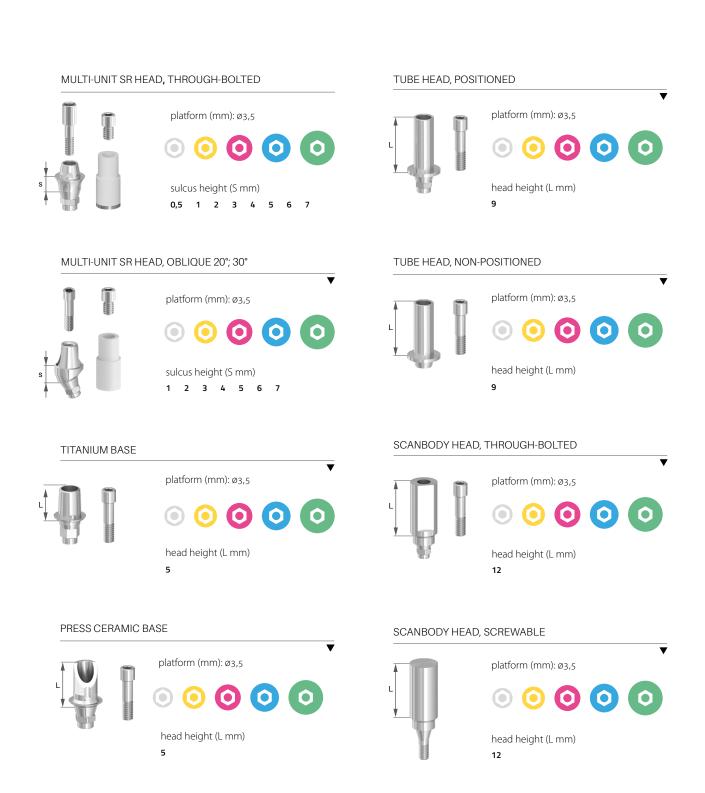
The abutments of the **eco-plant** implant system



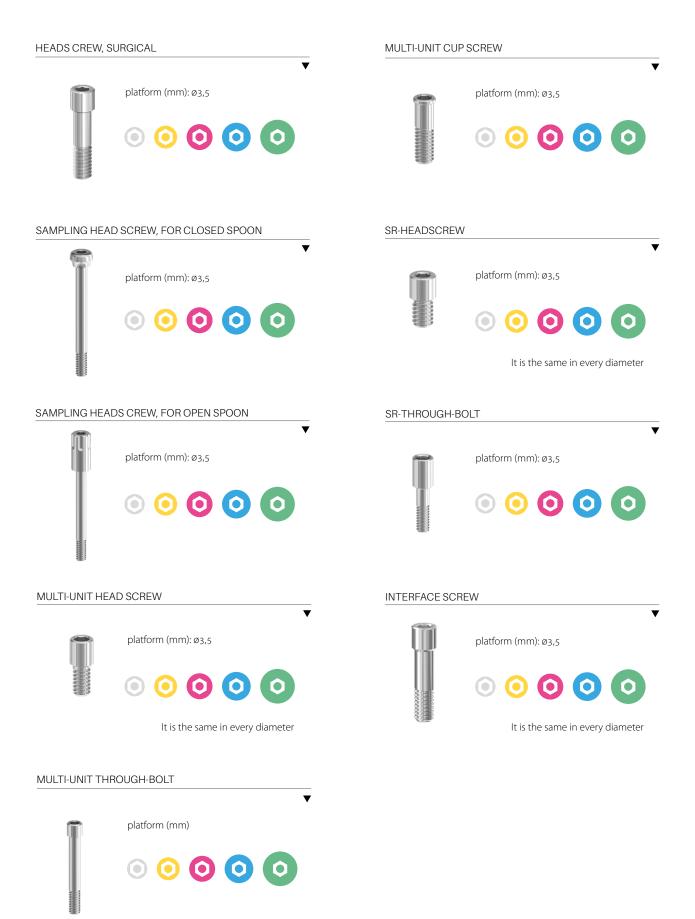


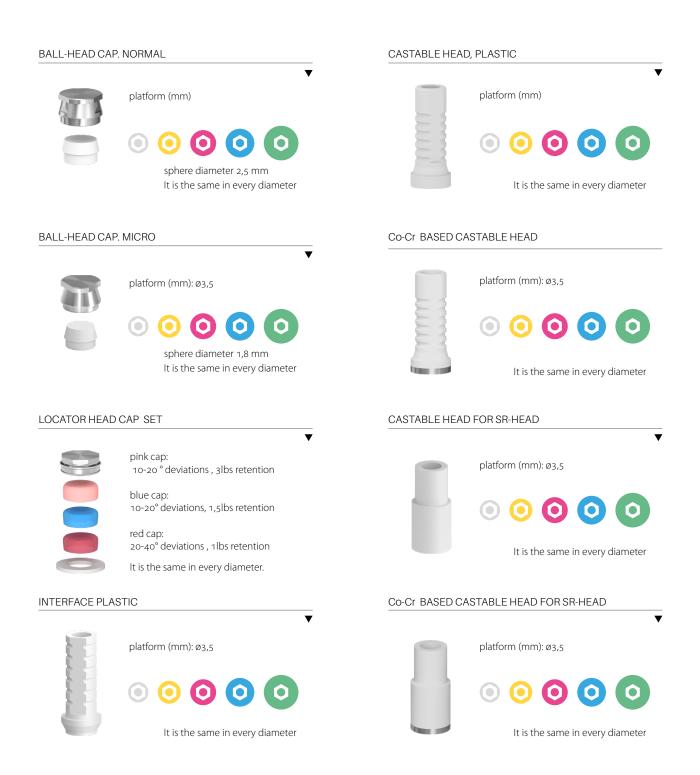
The abutments of the eco-plant implant system





Accessories of the eco-plant abutments







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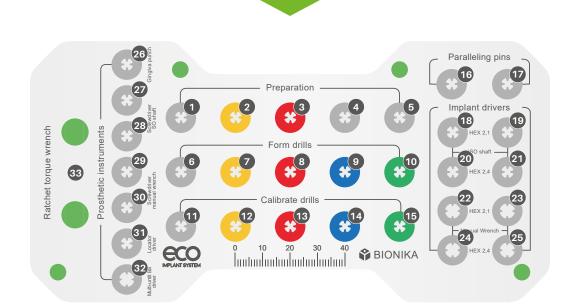


The products in the publication are only illustrations, they do not cover the exact appearance and shape of the product.

eco-plant large instrument kit

Our set of instruments includes instruments essential for dental implantation. The Eco-plant Large Instrument Kit contains 33 instruments, in a wide range of sizes, for a wide range of applications. The trays are structured according to the surgical order, labeling makes their usage easier. The tray is also suitable for sterilizing the instruments, this can be done together with the box or separately, as the tray can be uplifted from the box.

The layout of the Eco-plant Large Instrument Kit elements





Preparation





13

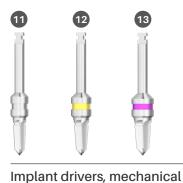
20. 6LT 2,4 x L6

21. 6LT 24 x L12

20

Thread calibration

11. Thread calibrator drill \emptyset 3.2 **14.** Thread calibrator drill \emptyset 4.7 **12.** Thread calibrator drill \oslash 3.7 **15.** Thread calibrator drill \varnothing 5.5 13. Thread calibrator drill \varnothing 4.2



18. 6LT 2,1 x L6

19. 6LT 2,1 x L12

18



Thread formation

6. Core drill, Ø 2.8 **7.** Core drill, Ø 3.2 8. Core drill, Ø 3.7

9. Core drill, Ø 4.2 **10.** Core drill, Ø 4.7

6 7 9 10

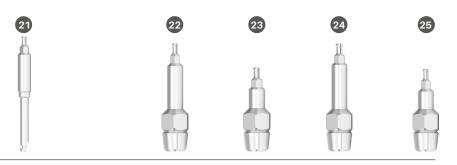
Paralleling pins

Paralleling pin, slim
Paralleling pin, thick



Implant drivers, manual

22. 6LT 2,1 x L6 23. 6LT 2,1 x L12 **24.** 6LT 2,4 x L6 25. 6LT 24 x L 12



Prosthetic tools

26. Gingiva punch Ø4,0xL15

19

- 27. Head wrench, mechanical 6Lt1,27xL10
- 28. Head wrench, mechanical 6Lt1,27xL15
- 29. Head wrench, manual 6Lt1,27xL10
- 30. Head wrench, manual 6Lt1,27xL15
- 31. Locator key
- 32. Multi-unit key 6LT2,7





Ratchet torque wrench

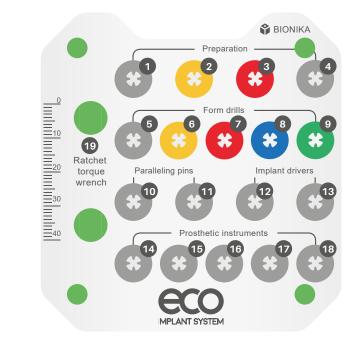
33

33. Ratchet torque wrench

eco-plant small instrument kit

The Eco-plant Small Instrument Kit is a practical, more economical solution. The instruments that are inevitable for surgeries can be found in the small tray as they can be found in the large tray as well, only in a smaller range of sizes. There are 19 instruments in the small instrument tray.

> The layout of the elements of the Eco-plant Small instrument kit







Thread formation

 5. Core drill, Ø 2.8
6. Core drill, Ø 3.2
7. Core drill, Ø 3.7 8. Core drill, Ø 4.2 9. Core drill, Ø 4.7 5 8 9 6 7 7

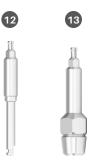
Paralleling pins

Paralleling pin, slim
Paralleling pin, thick



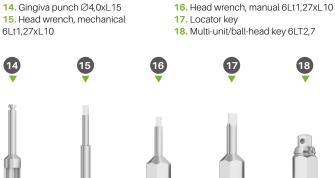
Implant drivers

12. Mechanical, 6LT 2,4 x L12 **13.** Manual, 6LT 2,4 x L12



Prosthetic tools

14





18

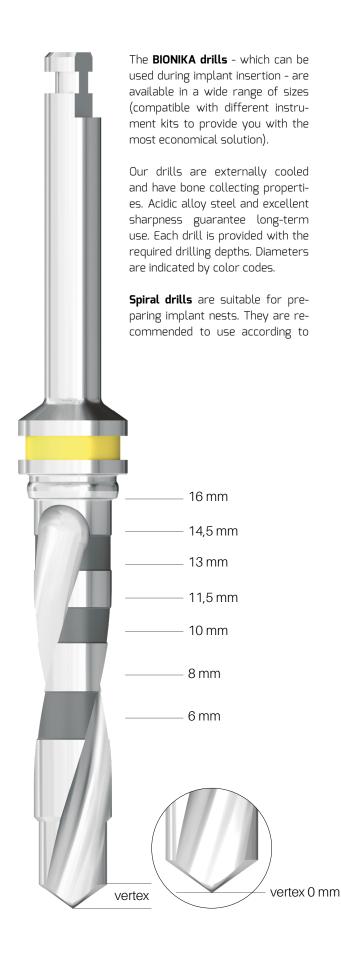


Ratchet torque wrench

19. Ratchet torque wrench



eco-plant surgical drills



the drilling protocol, in the case softer and harder bone structures.

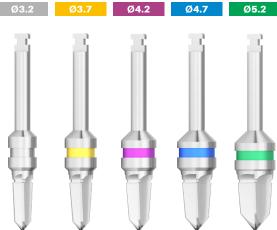
The Thread Calibrator Drills are suitable for expanding the implant nests as needed, so that we can extend the upper third of the bone nest. They are recommended to use in the case of harder than average bone structure.



Core drills



Thread groove calibrating drills



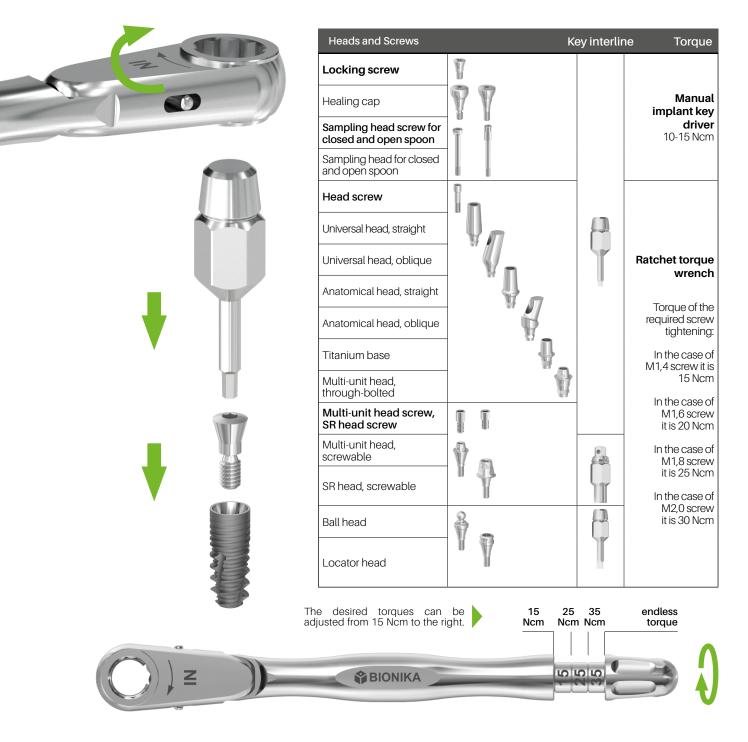
Ratchet torque wrench

The ratchet torque wrench is used to tighten and insert screws and implants. Using pre-set torque, this prevents the implant from fracturing and ensures the optimum power transfer when inserting the implant.

The scale of the torque rates from 15 to 35 Ncm. The

desired torques can be adjusted from 15 Ncm to the right for the desired scale. When the ratchet torque wrench adjuster screw bolted to the stop, the wrench of the torque can be infinite, so it can also be used to produce a much greater torque than the torque shown on the scale, as needed.

• ERGONOMIC CONSTRUCTION • STAINLESS STEEL • RELIABLE LIFETIME • REPLACABLE KEY INTERLINE • PRE-CISE TORQUE CONTROL • SOUND SIGNAL • PROFESSIONAL QUALITY • STABLE TORQUE SCALE DURING USE





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