

HYBRIDmini

IMPLANT SYSTEM

 **BIONIKA MEDLINE KFT.**

3516 Miskolc, Tégla u. 29. • Mobil.: +36 20 964-4146 • info@bionika.hu • www.bionika.hu • www.implantshop.hu

HYBRIDmini

IMPLANT SYSTEM

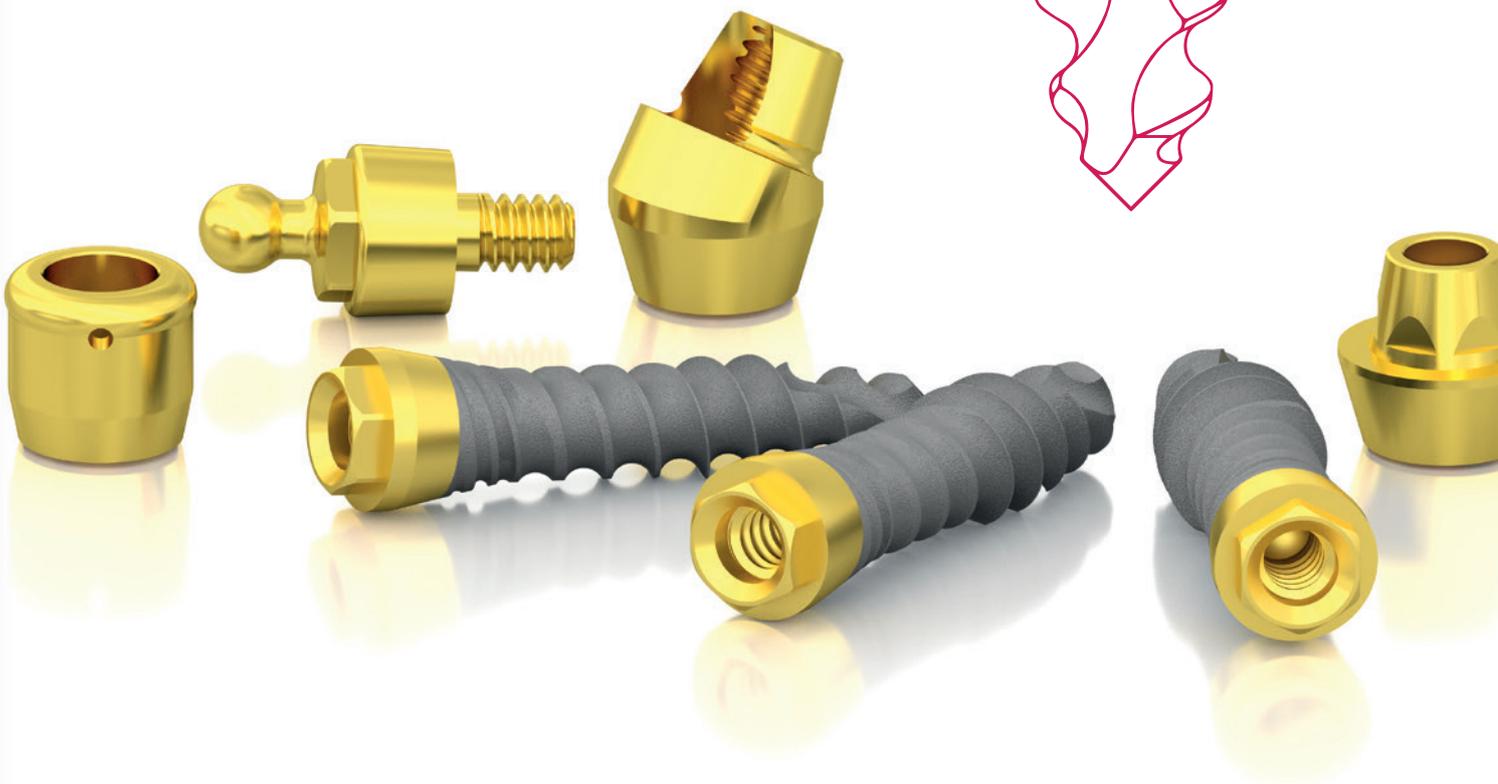
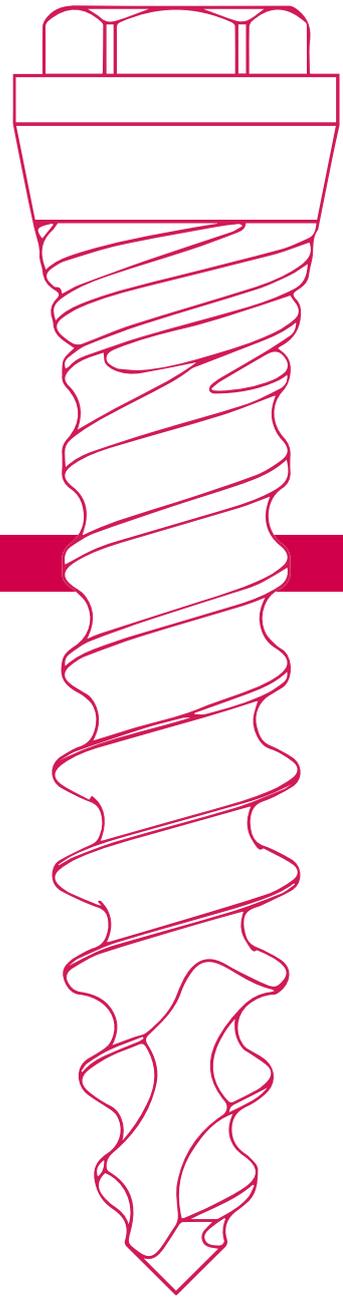


Table of contents

INTRODUCTION

HYBRID mini proposer	2
About the company	5
Technology and quality	6
Implant surface finish	8
Materials used	9

HYBRID IMPLANT SYSTEM

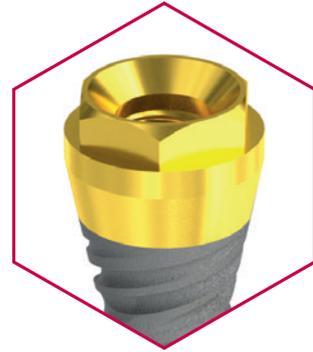
Distinctive characteristics of the HYBRID Implant	16
The applicational fields of HYBRID	18
Sizes available of the Implant	20

HYBRID ABUTMENT SYSTEM

HYBRID abutments	26
------------------------	----

Instruments

HYBRID instrument kits	28
Ratchet torque wrench	30



HYBRID MINI IMPLANT is the new trend

It offers a versatile, complex, multifunctional solution customized to your needs for cases solved by mini implant tooth augmentation with **removable abutments**. This is single and biphasic, that can be loaded immediately, extra thin, normal and extra shortly round-headed, locator headed, conical, multiunit headed Hybrid implants offer a wide range of applicational possibilities for, plastic, zirconium, titanium and cobalt-based teethworks.

- Versatility is more important than size but the Hybrid system is also inimitable in **range of sizes**. This is a newly **customized way** in implantology. The R&D&I development technological system of the manufacturer guarantees the most optimal, unique size option individually. The patient is not a "serial" product. You plan the customized implant for them, we only guarantee the compliance of medical products according to ISO EN 13485.
- **Intelligent** implant system. The manufacturer follows and improves introducing all scientific results from the classic to the most modern principles. It not only takes into account the demands of the patient but also the medical work efficiency improving researches.
- This is a unique Biomimitek technology. Although the intelligence is more important than the raw power but with the **BIONIKA „Biotis” surface integration technology** the Hybrid is exceptionally superior in primer stability and **unconquerable in osseointegration**.
- **Total functional abutment system** - There is also one that only exists in your imagination, if it can be devisable by present-day 's state of technology. The freedom of biological adaptation is Yours as well as the success. You are able to follow conscientiously the jaw structure of your patients for the implantation.
- **The solution is in the Hybrid system**. The manufacturer contributes with effective improvements, innovations, professional support and service to make you more productive with Hybrid than any other product.
- It is a **guaranteed gurantee**, this means the manufacturer guarantees the replacement of the implant even if there are no guaranteed conditions. The Hybrid shows a return at all events It is a timeless investment.



Hajdú József
executive director -BIONIKA Medline Kft.



The Hybrid mini implant and its abutments





About the company

BIONIKA Medline Orvostechnikai Kft. Is a member of the Hungarian-Swedish group of companies. The predecessor of it was founded in 1989. The owners of the company are Hungarian-Swedish citizens. We have 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 at 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.

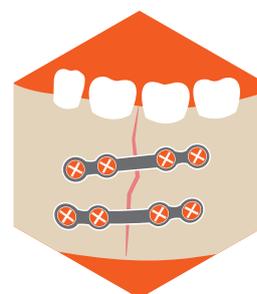
Development: The owners of BIONIKA put great emphasis on continuous product and technological research and development. Our products are developed in close collaboration with doctors and engineers, enabling us to ensure the world-class quality and practical utilization.

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.



FOGÁSZAT



SZÁJSEBÉSZET



TRAUMATOLÓGIA



ORTOPÉDIA

Technology

BIONIKA Medline Kft. has 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.

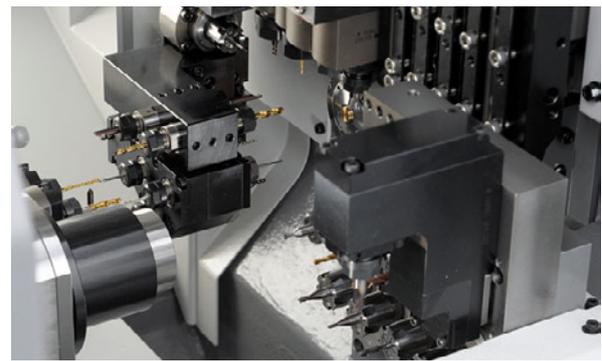
Some of these parts have been developed for their own marketing in accordance with their own market needs.

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.

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 was ensured by EMKI.

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 nearly 30 years of existence. The Bisnode certificate is proof of our reliability and stability. BIONIKA also received a "Triple A" Bisnode qualification in 2016-2019.

With AAA (triple A) rating, only 0.63% of companies in Hungary have the financial risk of establishing a business relationship with them - source: bisnode.hu

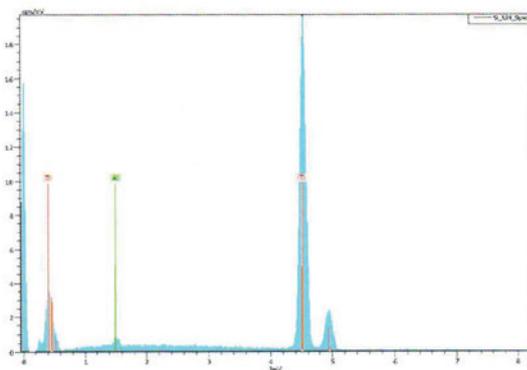
Superclean implant surface

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.



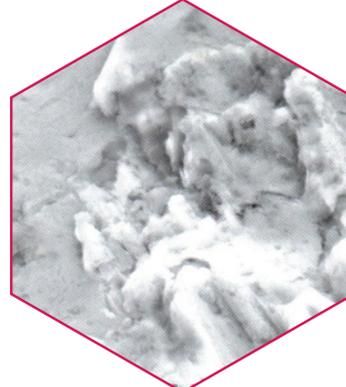
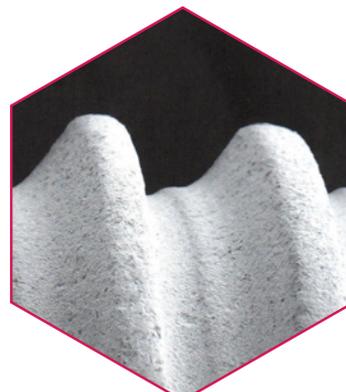
*Energy dispersive X-ray spectrometric elemental analysis of Bionika implants**

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.



*Bionika implant electron microscope image **

*Source: FOGORVOSI SZEMLE, year 106. No. 4 2013. 135-143

Applied raw materials



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.

CoCr

Kémiai összetétel

Elements	Threshold limit of constituents(%)
C	0,1 max.
Si	1,0 max.
Mn	1,0 max.
P	0,005 max.
S	0,005 max.
Cr	30,0 max.
Mo	7,0 max.
Ni	1,0 max.
Co	-
N	0,2250 max.

Mechanical properties

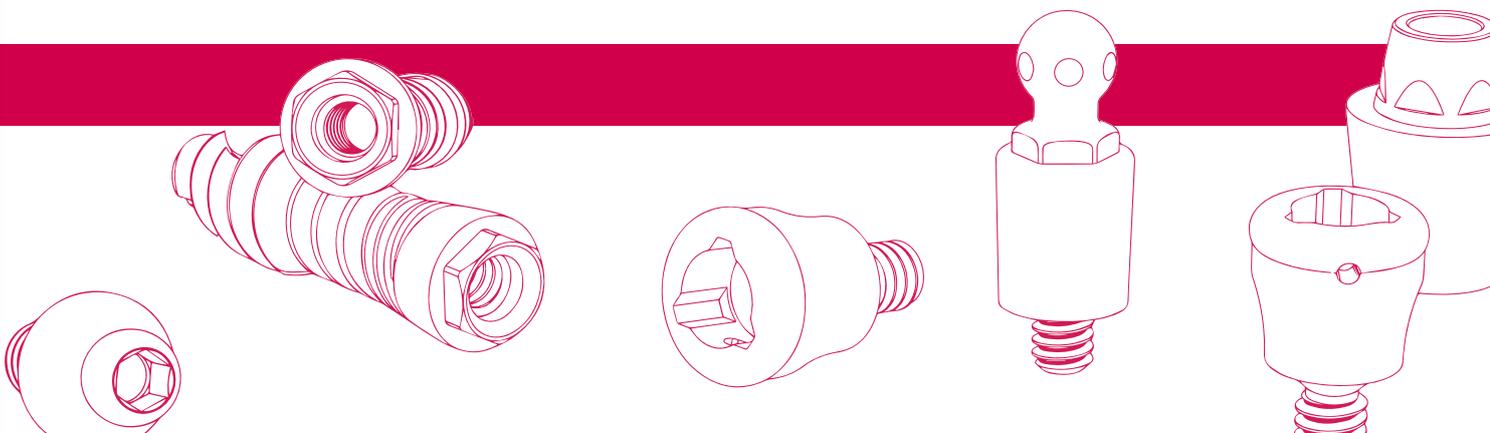
solidity	1240,00 MPa min.
elongation limit	900,00 min.
elongation at break	18,00 min.
fracture contraction	23,00 min.

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.



HYBRID Packaging



10 - piece collection box



vial in sterile foil



removing the foil



sterile vial



removing the locking plug
(1)



removing the locking plug
(2)



removing the implant and
the multifunctional head



using the implant key driver



Collection box

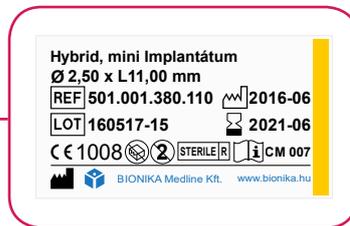
Depending on the order quantities, collection boxes with 5 and 10 pieces are applied.

HYBRID Packaging



Vial

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



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.

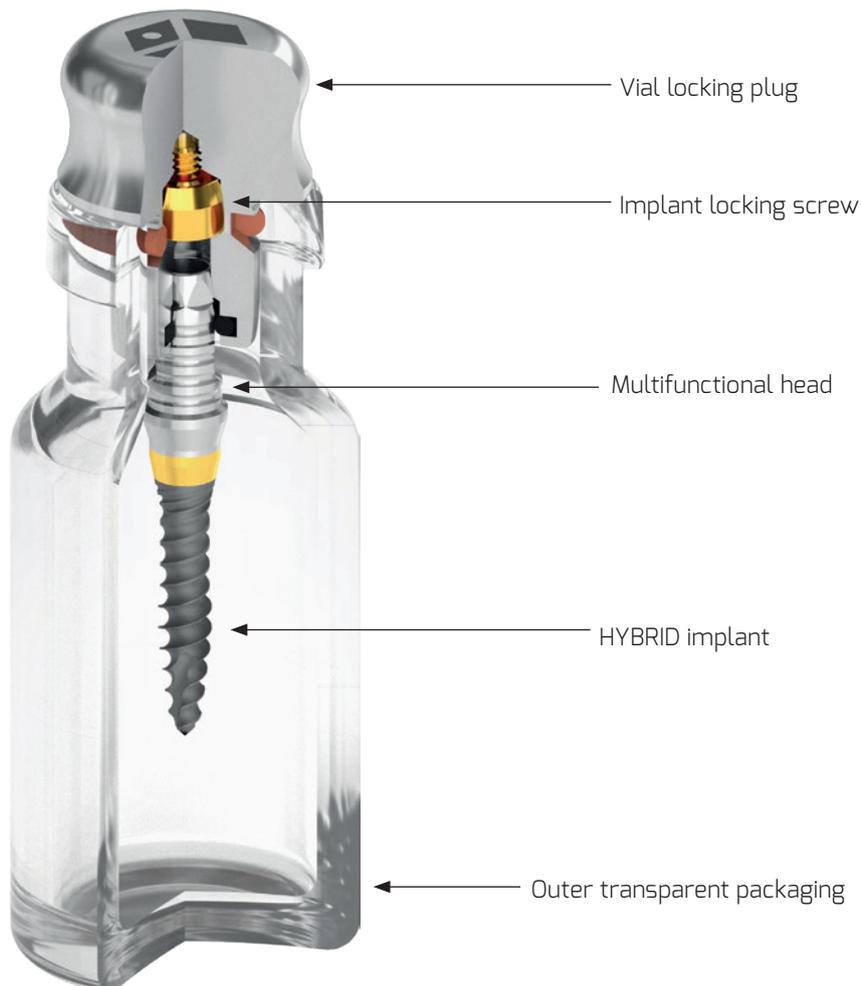


The sectional image of the **HYBRID** packaging and its accessories



The first layer of the packaging is a transparent vial. The implant, locking screw and the multifunctional head are held by the vial locking plug and with this they can be removed from the vial. The multifuncti-

onal 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.



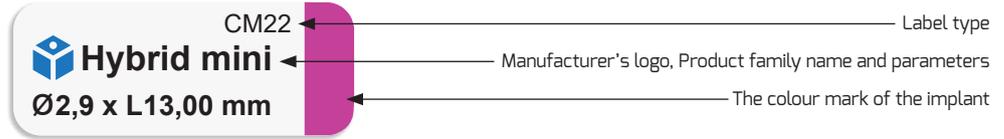
HYBRID product labels and their notation

Differential platform diameters by colour and diameter:

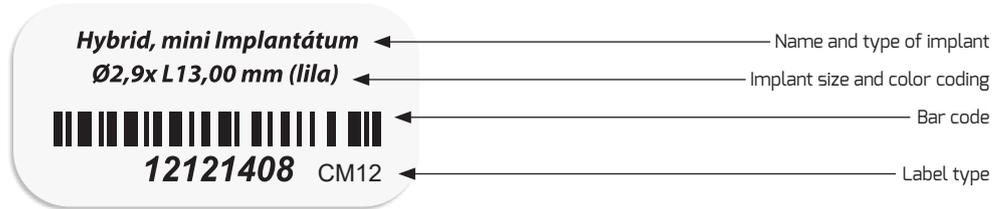
- ∅ 2,5 mm - yellow
- ∅ 2,9 mm - purple
- ∅ 3,3 mm - blue

Information supplied by the three product labels to the outer packaging of the Implant System:

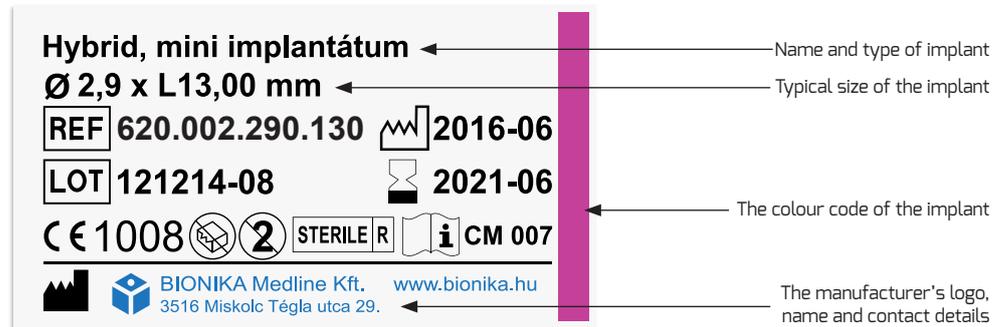
The side of the box:



Top of the box:



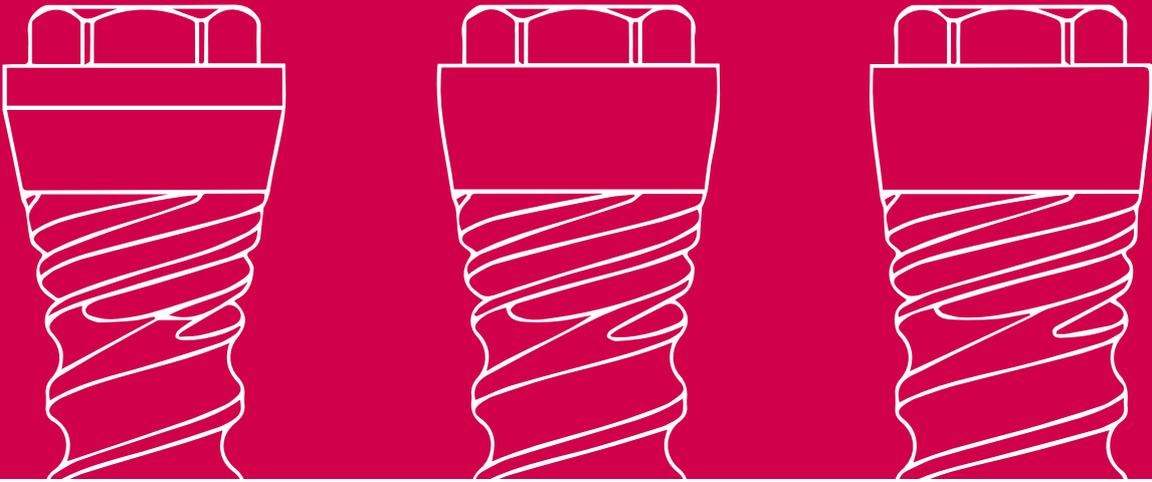
The back of the box:



Explanation of label codes:

	Diameter		Expiration date		Non-sterile product in the package
	Implant length		It is forbidden to use in the case of damaged packaging.		Read the usage guide!
	Item number		Reuse is forbidden!		Certification company code
	Serial number		Sterilized with gamma rays		Manufacturer's name and Contact
	Production time		sterilized with steam or dry heat		

HYBRID | Implant System

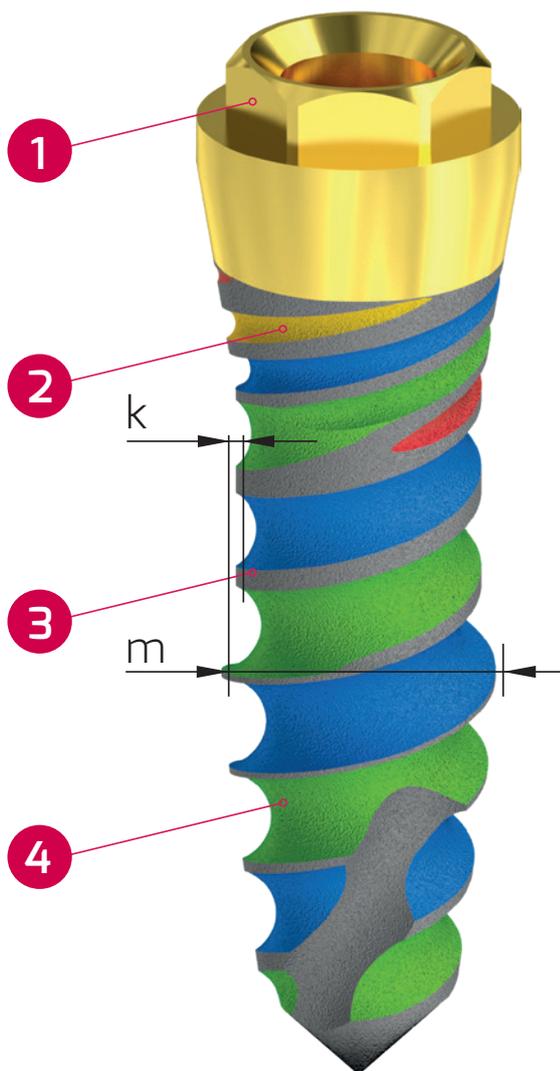


Distinctive characteristics of the **HYBRID** two-piece mini implant

It offers a versatile, complex, multifunctional solution customized to your needs for cases solved by tooth replacement. This is single and biphasic, that can be loaded immediately, extra thin, normal and extra shortly round-headed, locator headed, conical, multiunit headed, Hybrid implants which offer a wide range of applicational possibilities for plastic, zirconium, titanium and cobalt-based toothworks.

The geometry of the HYBRID implant

The structural parts of the HYBRID implant body



1. It is a Brönemark type hexagonal cross section head with inner cone and screw thread.

2. Micro thread structure with a four paragraphed cortical cord thread.

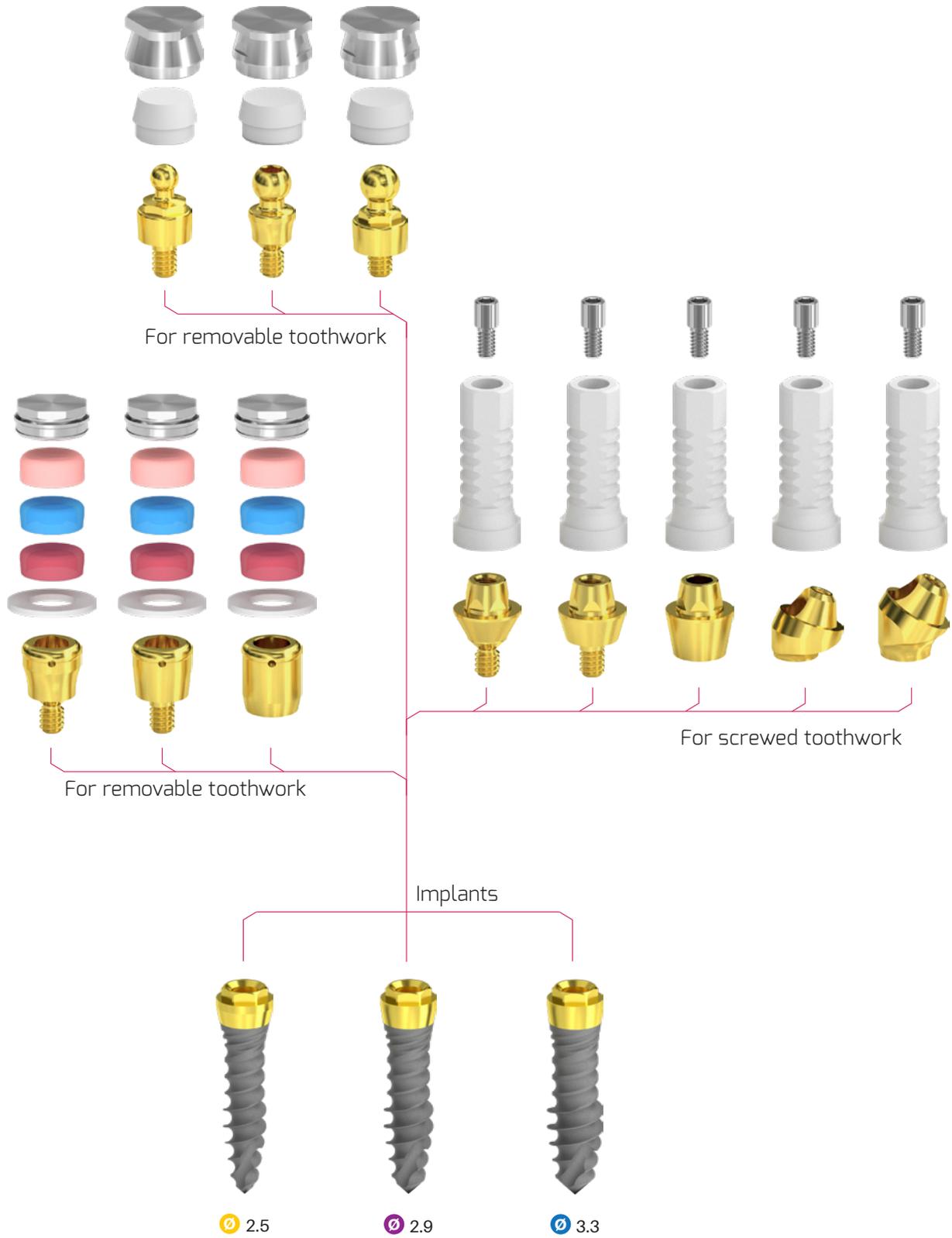
3. Double paragraphed normal cord thread body part for dynamic force reduction.

4. With increased contour and increased thread depth, the cycloid thread structure with primary stability, self-cutting edge and anti-rotation groove.

The main characteristics of the BIONIKA Hybrid Implant System is that, each element of the screw thread has a radius-shaped, continuously variable cross-section according to the natural analogy.

The „3” cord thread screw section is a smaller diameter with „k” than the „m” thread formation of the apical part providing the primary stability with the sharper cycloid thread.

The functional structure of the **Hybrid** Implant System elements



The applicational fields of the **Hybrid** implant

There are more and more patients with a small bone supply, who naturally have the needs of regaining the 100% function of their teeth. BIONIKA has developed the Hybrid implant system, which enables us to produce toothworks for versatile usage in the case of those patients.

Removable toothworks

If the patient does not have a tooth, complete tooth replacement can be made. In this case one of the solutions is the removable denture. Usually removable toothworks are 2-4, possibly 6-8 implants are implanted into the upper jaw, considering bone quality, according to load conditions. The round-head solution is a classic solution. The most common fixing solution. Both the 1.8 mm (micro) and 2.5 mm (normal) diameter ball head implants can be found in the Hybrid mini systems. A (medium) ball head with a 2,3 mm diameter can be ordered on request.

BIONIKA also provides ball heads with a corrected size as a unique service, depending of the required retaining force.

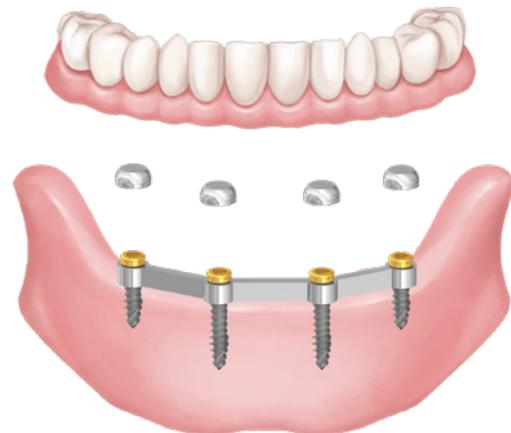
The application of the locator torsion-shaped head single-phase or biphase mini implants are relatively new compared to this. These are also able to provide greater stability to the denture in the case of less implants.

The great advantage of the HYBRID solution is the replacement possibility of worn out ball heads and locator heads



Implanted removable dentures splinted together

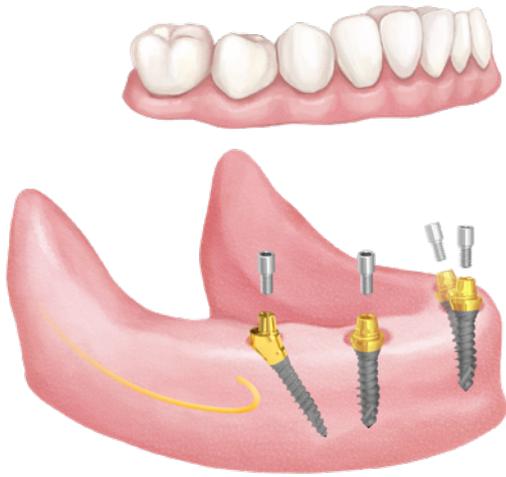
Beside the implants, an individually prepared metal splint can be inserted screwed to the implants, which even provides greater support and stability for the denture. The splint is fastened to 2-5 implants. Thus, the loading of implants is better distributed, thus increasing their life-time.



In the case of toothworks splinted together, the dentist and the dental technician may also have the possibility that the ball head or the locator head be designed and constructed not into the axis of the implant but in the optimum position.

The implant tooth fixations also provide a tremendous quality of life for the patient in the case of removable toothworks, as this will make the denture much more stable than conventional removable dentures, possibly with dentures fixed with denture adhesive. It gives a sense of perfection in chewing and talking as well.

Advantageous solutions with mini **Hybrid** implants



Optimum Concept

All-on-4® type - Economical Solution

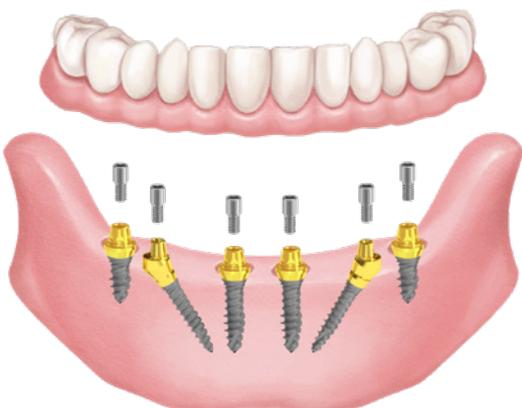
The thin Hybrid mini implants are also suitable for screw-retained fixed dental prosthetics with the use of only 4 implants. The temporary denture can be inserted on the day of surgery.

Immediate improvement in function, speech and aesthetically. Treatment times are shorter and costs can be lower than conventional implant placement methods.

Safe Concept

All-on-6® type - For Extra Stability

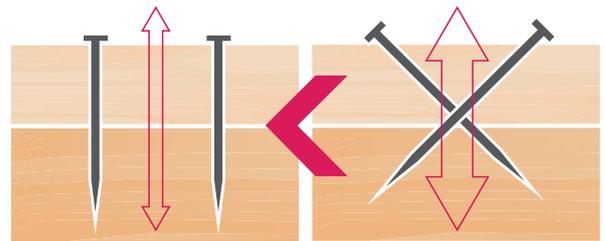
The stability of the toothwork can be increased with the use of 6 implants. The Safe Concept is exceptionally advantageous in the case of extra chewing ability. The usage of longer implants allows the bone and the



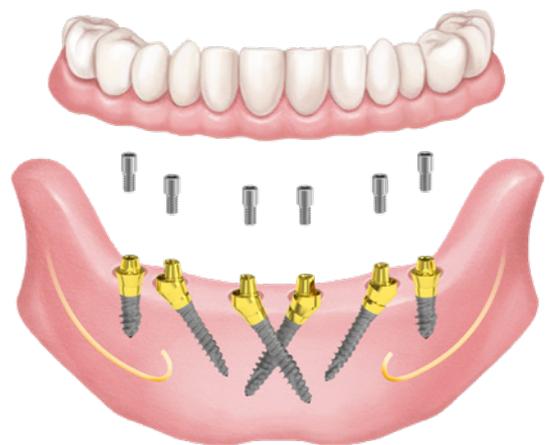
implant to touch on a larger surface, thus making bone augmentation avoidable. Favorable bone level for tilted and axial implants. High remaining and osseointegration chances.

X Cross-Implantation

A German dentist's acquaintance reminded me of the long-forgotten technology of crate nailing. Upon his proposal we began the development of the Hybrid implant system, with the aim of finding a solution to produce high-strength toothworks for patients with low bone supply.



The attached illustration clearly explains the load bearing capacity of the crate nail depending on the direction of insertion.

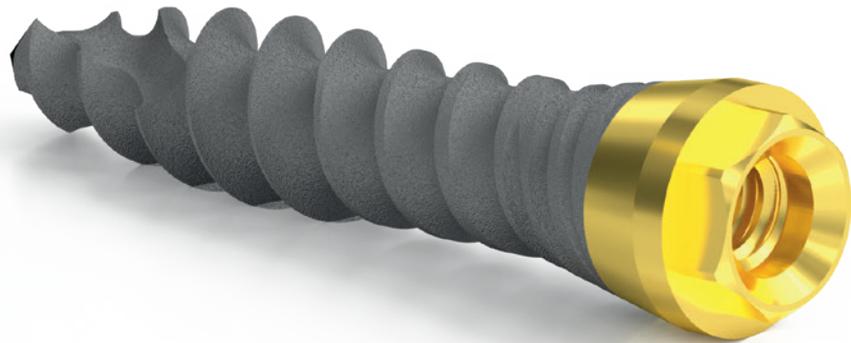
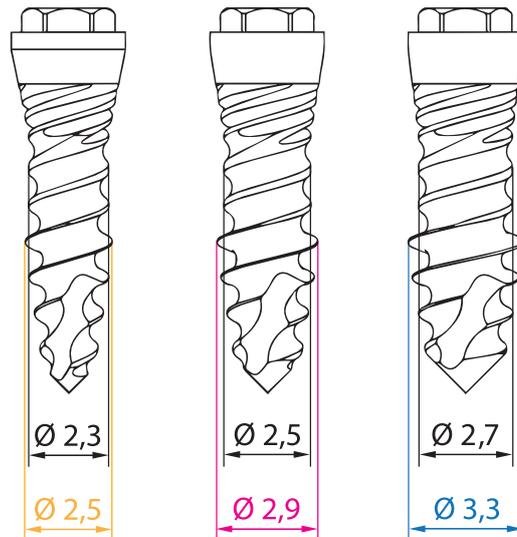


The well-constructed new X Cross-Implantation system significantly rearranges the jawbone energies and provides high stability results. The thread diameter of the thin HYBRID mini implants has been designed so that the cross-implantation can be solved in the case of thin bone structures. That is why the middle thread section is thinner.



The two-piece **Hybrid** mini implant

The Hybrid mini implants are applied in the case of average hard and thin bone structure, for removable or screwed toothworks depending on the used abutments.



Hybrid manual implant key driver



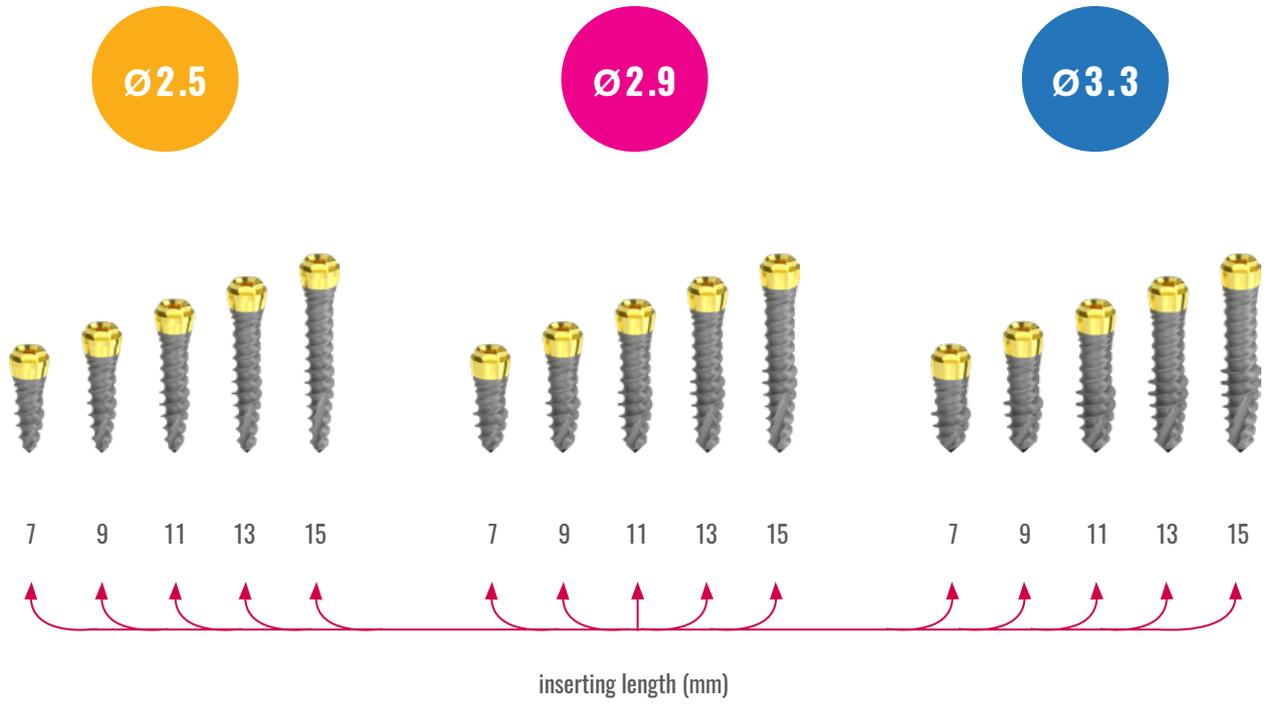
6Lt 2.7 mm

Hybrid mechanical implant key driver



6Lt 2.7 mm

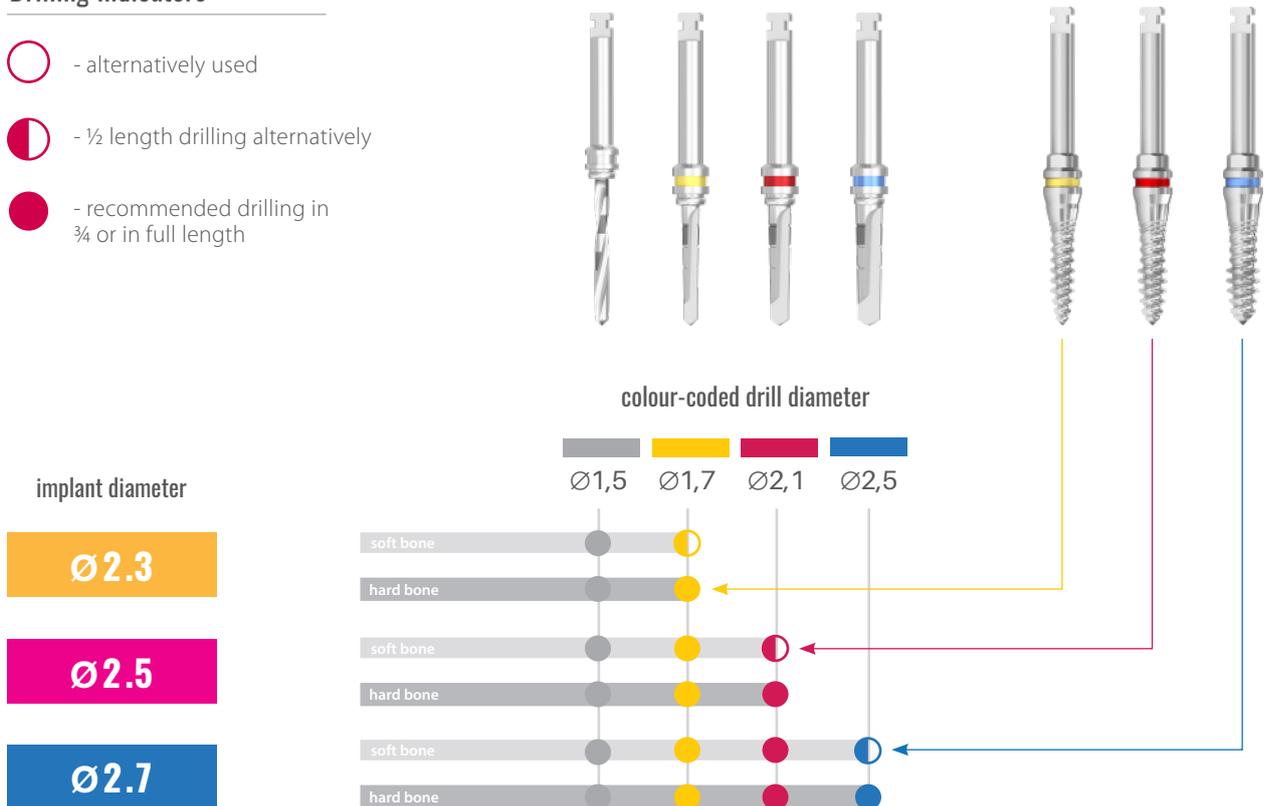
Sizes available of the **Hybrid** mini two-piece implant



Drilling protocol of the **Hybrid** mini

Drilling Indicators:

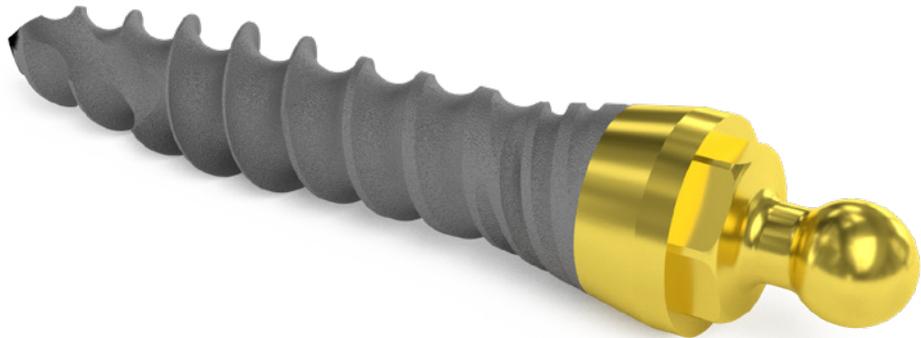
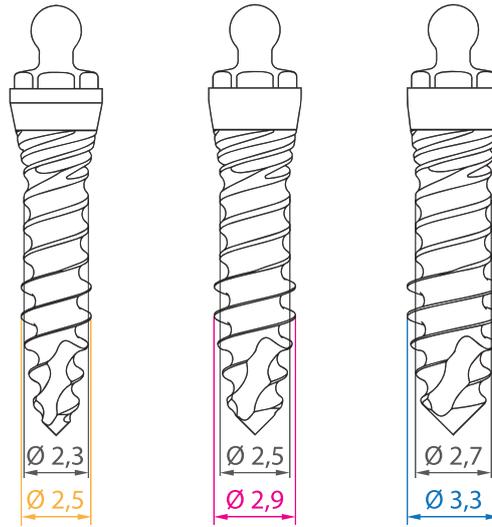
-  - alternatively used
-  - ½ length drilling alternatively
-  - recommended drilling in ¾ or in full length





HYBRID mini ball-head implant, micro

The HYBRID mini multi-unit headed implant is suitable in the case of average hard and thin bone structures for removable toothworks.



Hybrid manual implant key driver



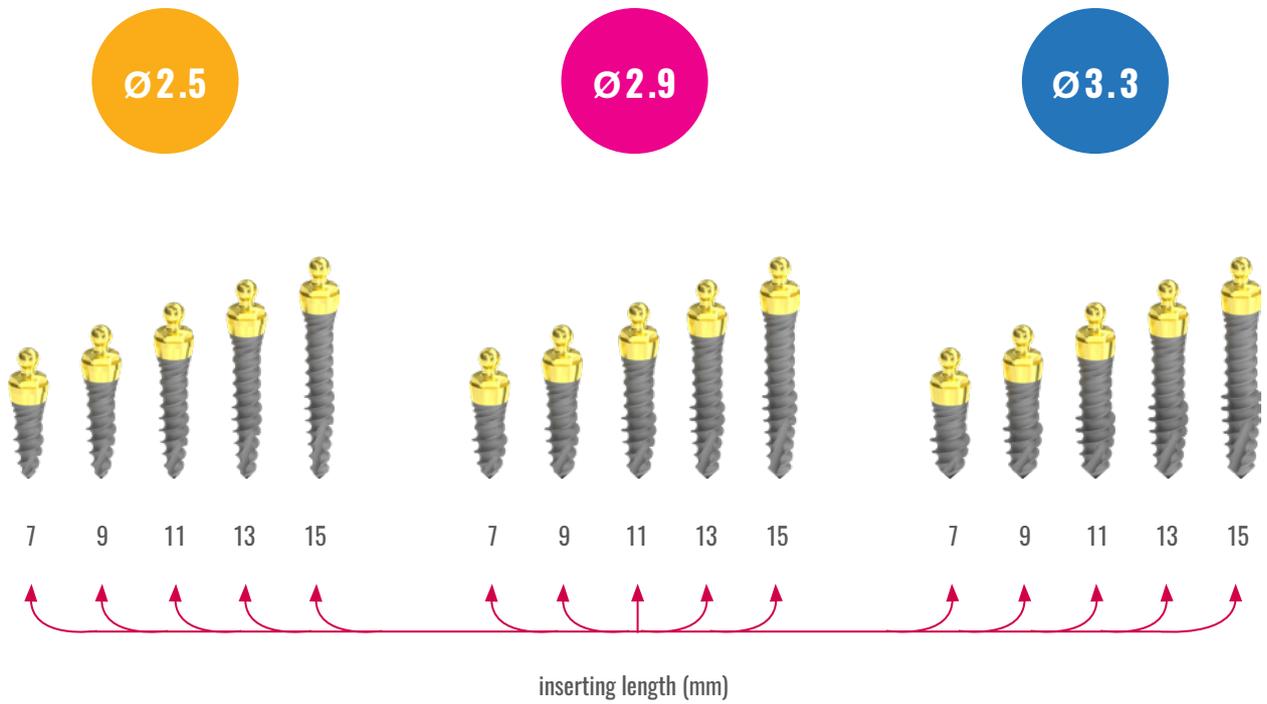
6Lt 2.7 mm

Hybrid mechanical implant key driver



6Lt 2.7 mm

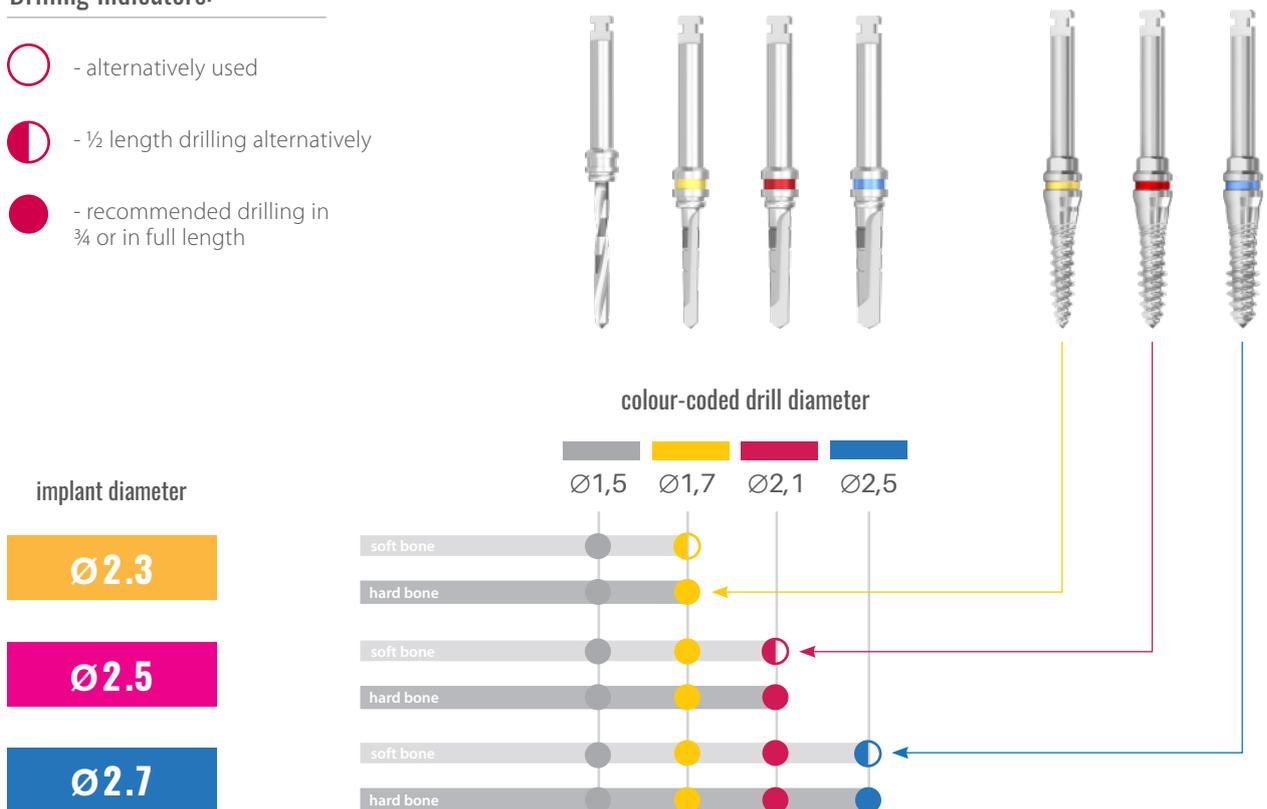
Sizes available of the **Hybrid** mini ball-head implant



Drilling protocol of the **Hybrid** mini

Drilling Indicators:

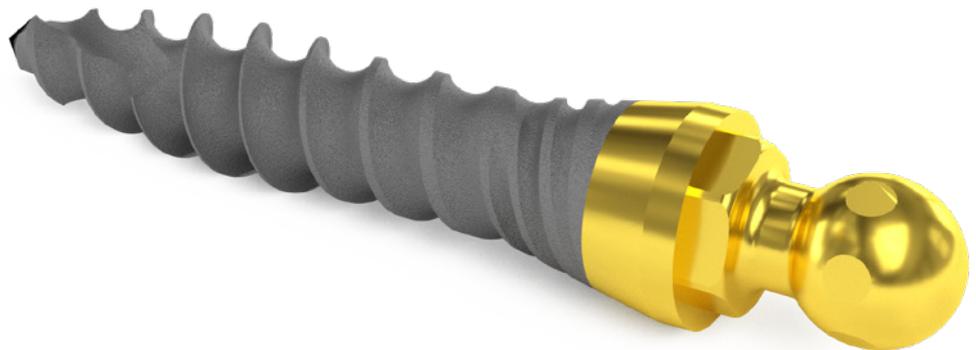
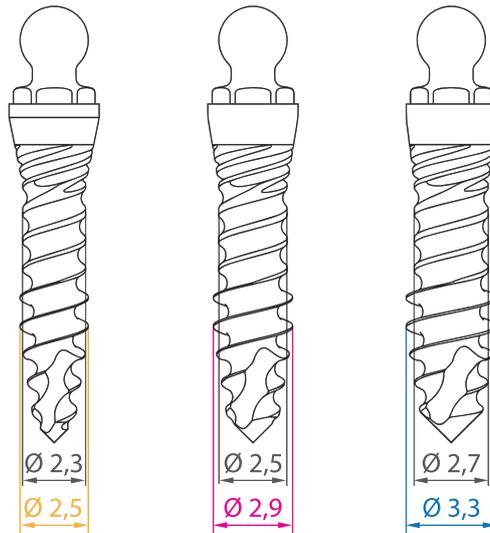
-  - alternatively used
-  - ½ length drilling alternatively
-  - recommended drilling in ¾ or in full length





HYBRID mini ball-head implant, normal

The HYBRID mini multi-unit headed implant is suitable in the case of average hard and thin bone structures for removable toothworks.



Hybrid manual implant key driver



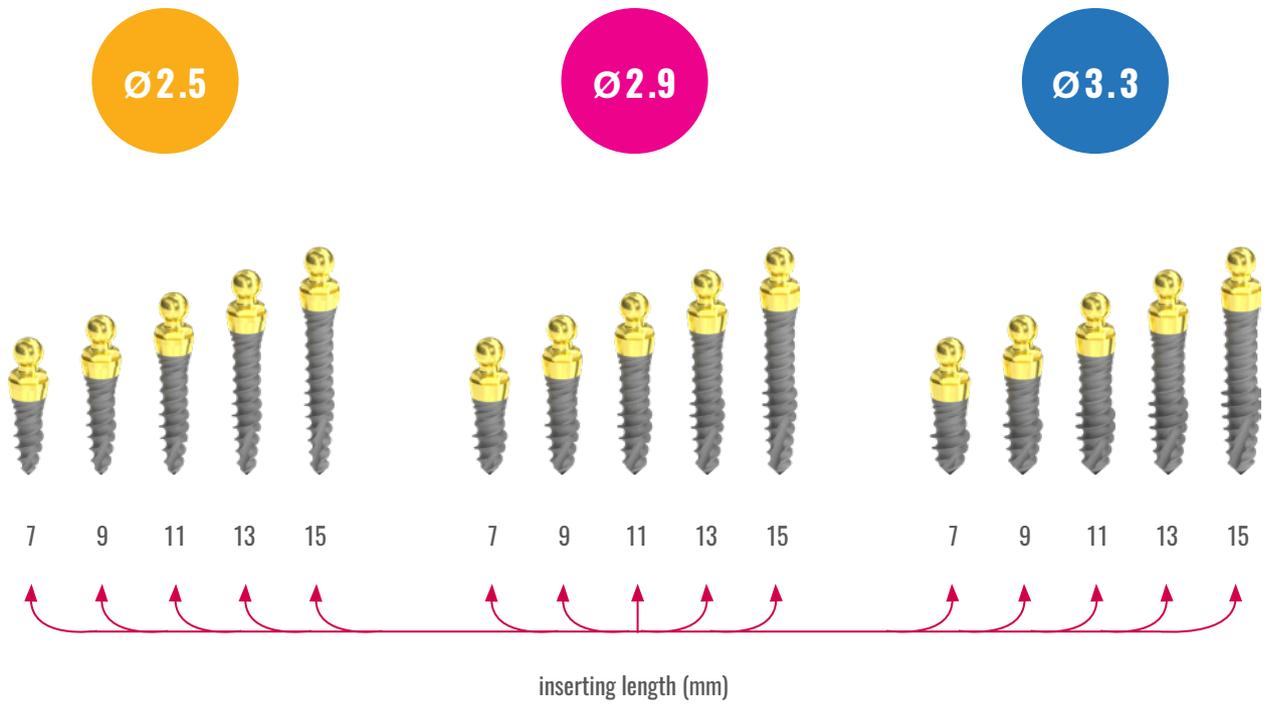
6Lt 2.7 mm

Hybrid mechanical implant key driver



6Lt 2.7 mm

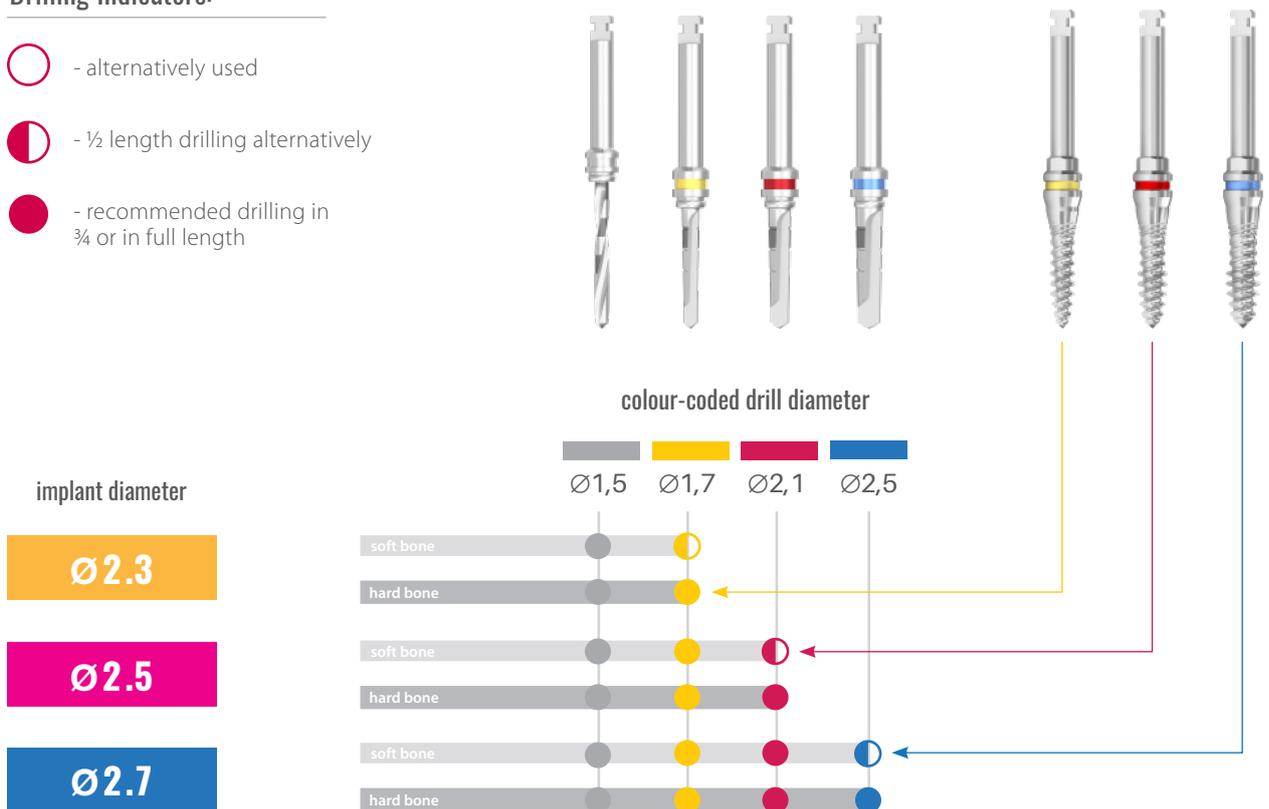
Sizes available of the **Hybrid** mini ball-head implant



Drilling protocol of the **Hybrid** mini

Drilling Indicators:

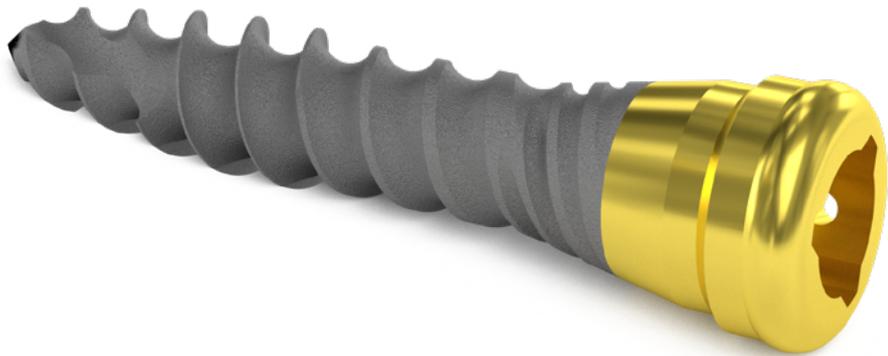
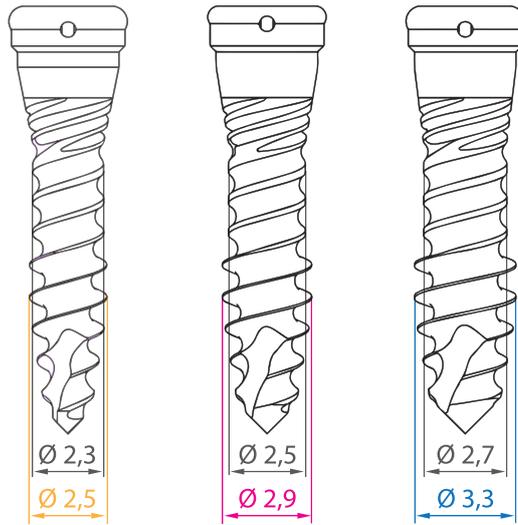
-  - alternatively used
-  - ½ length drilling alternatively
-  - recommended drilling in ¾ or in full length





HYBRID mini locator-headed implant

The HYBRID mini multi-unit headed implant is suitable in the case of average hard and thin bone structures for removable toothworks.



Hybrid manual implant key driver



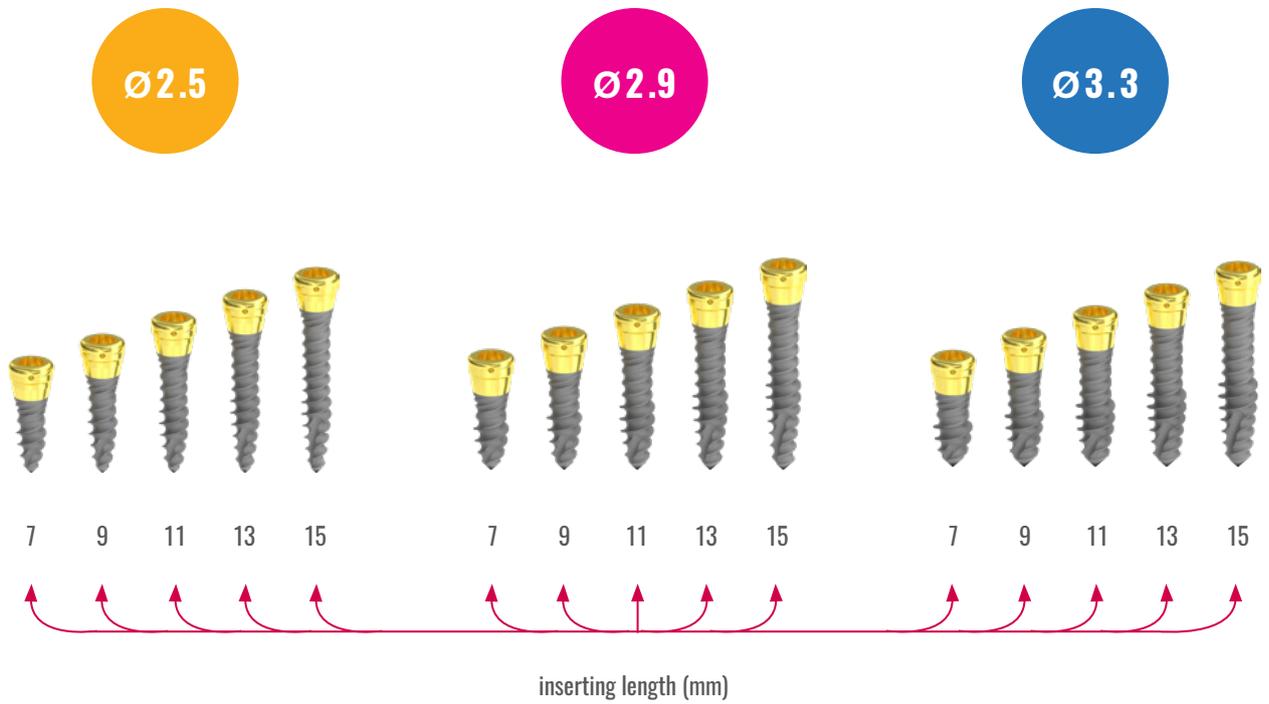
△ 3Lt 2.15 mm
L 10 mm

Hybrid mechanical implant key driver



△ 3Lt 2.15 mm
L 10 mm

Sizes available of the **Hybrid** mini locator-headed implant



Drilling protocol of the **Hybrid** mini

Drilling Indicators:

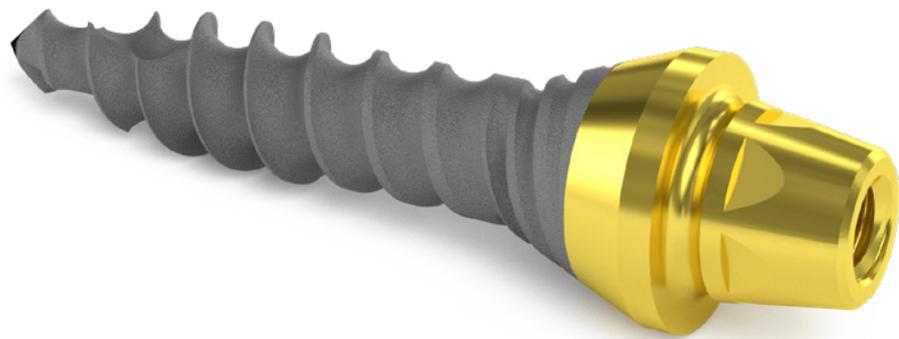
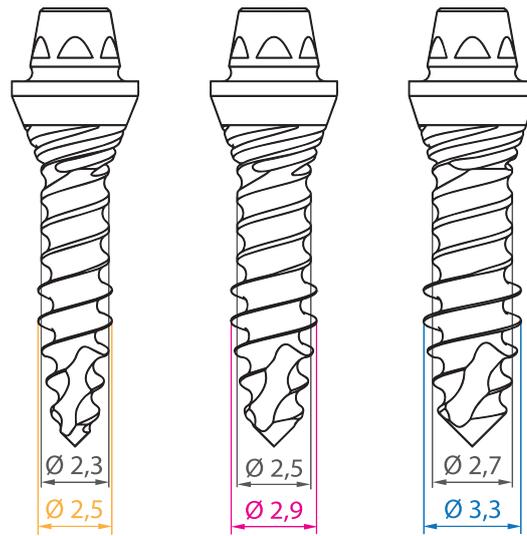
-  - alternatively used
-  - ½ length drilling alternatively
-  - recommended drilling in ¾ or in full length





HYBRID mini Multi-unit headed implant

The HYBRID mini multi-unit headed implant is suitable in the case of average hard and thin bone structures for screwed toothworks.



Hybrid manual implant key driver



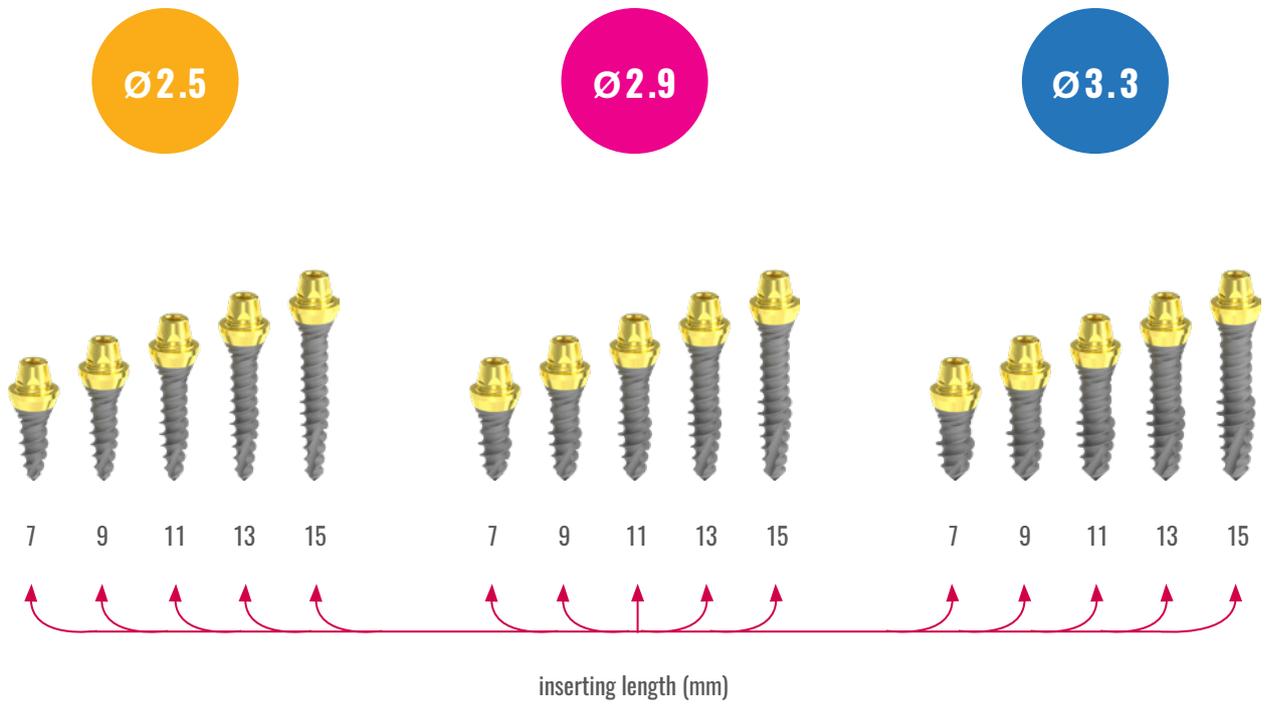
6Lt 2.7 mm

Hybrid mechanical implant key driver



6Lt 2.7 mm

Sizes available of the **Hybrid** mini Multi-unit headed implant



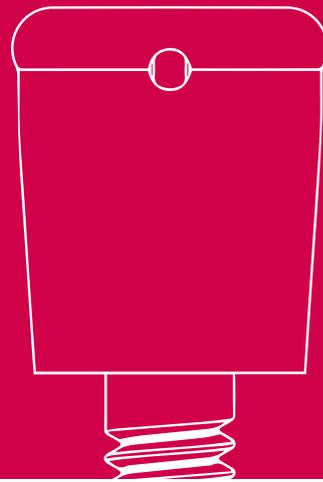
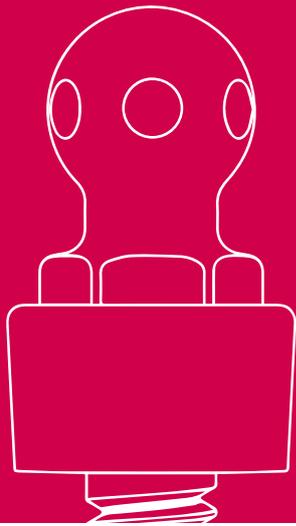
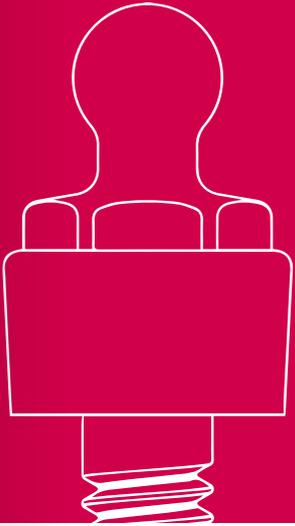
Drilling protocol of the **Hybrid** mini

Drilling Indicators:

-  - alternatively used
-  - ½ length drilling alternatively
-  - recommended drilling in ¾ or in full length



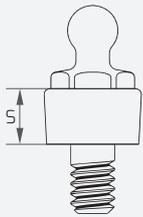
HYBRID | Abutment system





The abutments of the **HYBRID mini** implant

Ball head, micro



implant diameter (mm)

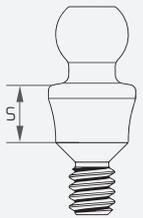
- Ø 2.5
- Ø 2.9
- Ø 3.3



sulcus height (S mm):



Ball head, normal



implant diameter (mm)

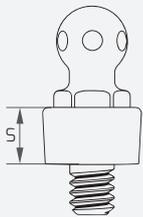
- Ø 2.5
- Ø 2.9
- Ø 3.3



sulcus height (S mm):



Ball head, normal



implant diameter (mm)

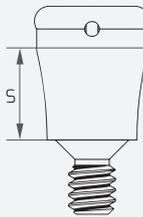
- Ø 2.5
- Ø 2.9
- Ø 3.3



sulcus height (S mm):



Locator head, screwable



implant diameter (mm)

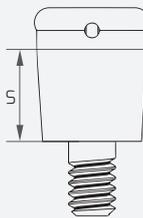
- Ø 2.5
- Ø 2.9
- Ø 3.3



sulcus height (S mm):



Locator head, screwable



implant diameter (mm)

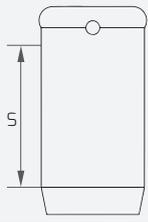
- Ø 2.5
- Ø 2.9
- Ø 3.3



sulcus height (S mm):



Locator head, through-bolted



implant diameter (mm)

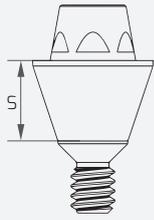
- Ø 2.5
- Ø 2.9
- Ø 3.3



sulcus height (5 mm):



Multi-unit head, screwable



implant diameter (mm)

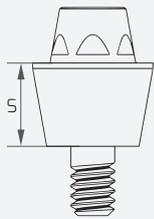
- Ø 2.5
- Ø 2.9
- Ø 3.3



sulcus height (5 mm):



Multi-unit head, screwable



implant diameter (mm)

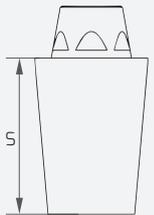
- Ø 2.5
- Ø 2.9
- Ø 3.3



sulcus height (5 mm):



Multi-unit head, through-bolted



implant diameter (mm)

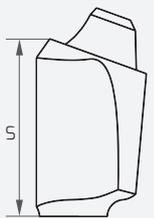
- Ø 2.5
- Ø 2.9
- Ø 3.3



sulcus height (5 mm):



Multi-unit head, oblique 20°



implant diameter (mm)

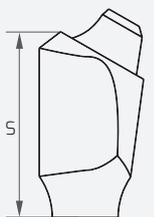
- Ø 2.5
- Ø 2.9
- Ø 3.3



sulcus height (5 mm):



Multi-unit head, oblique 30°



implant diameter (mm)

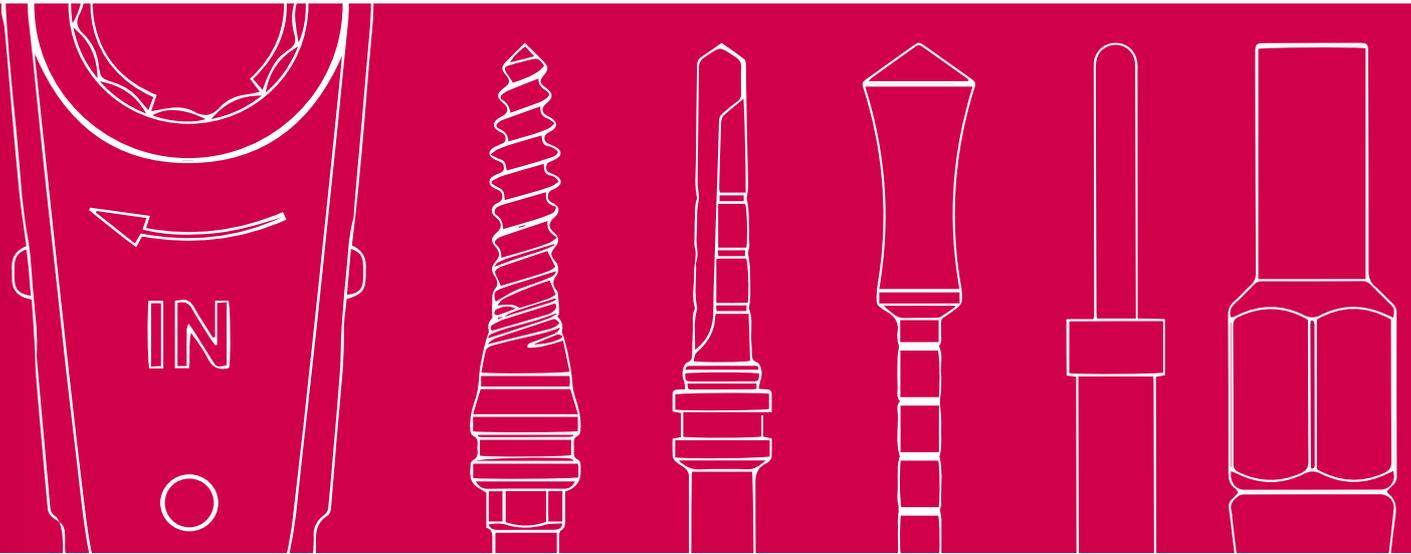
- Ø 2.5
- Ø 2.9
- Ø 3.3



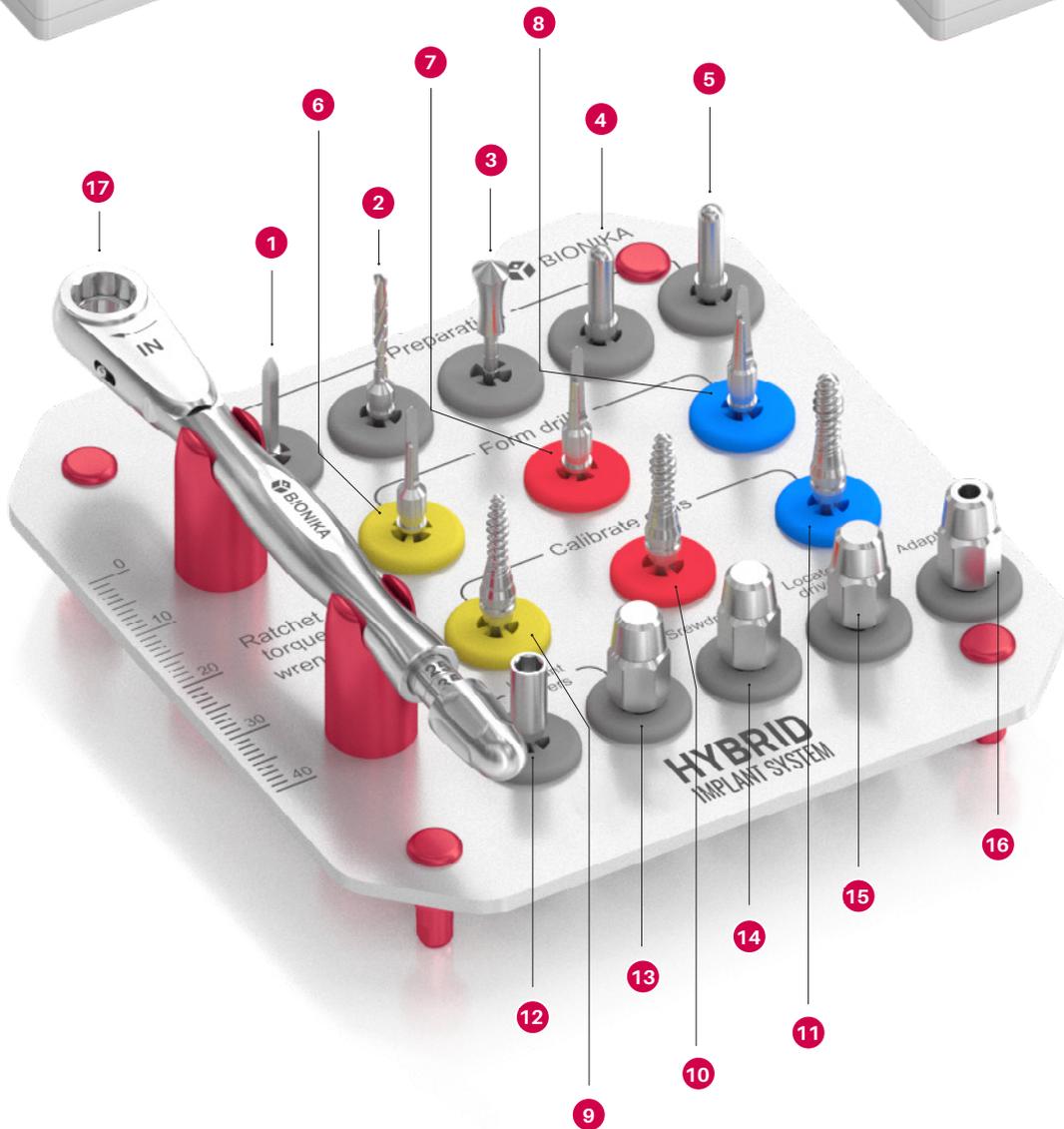
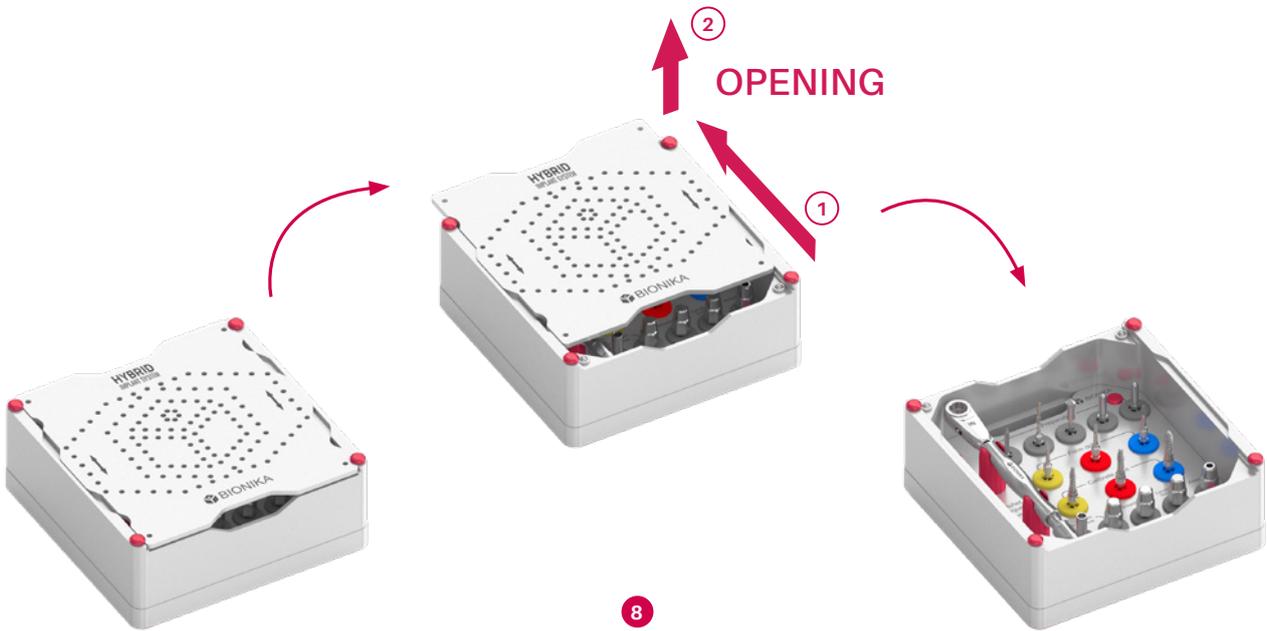
sulcus height (5 mm):



HYBRID | Instrument kit



HYBRID mini instrument kit



Content of the **HYBRID** mini instrument kit

- 1 Spear-pointed drill ▼



- 2 Pre-drill ▼



- 3 Depth gauge ▼



- 4 Paralleling pin, thin ▼



- 5 Paralleling pin, thick ▼



- 6 Core drill Ø1,7xL11 ▼



- 7 Core drill Ø2,1xL11 ▼



- 8 Core drill Ø2,5xL11 ▼



- 9 Thread groove calibrating drill Ø2,3/2,5xL11 ▼



- 10 Thread groove calibrating drill Ø2,5/2,9xL11 ▼



- 11 Thread groove calibrating drill Ø2,7/3,3xL11 ▼



- 12 Implant driver, mechanical 6Lt 2,4xL10 ▼



- 13 Implant driver, manual 6Lt 2,4xL10 ▼



- 14 Head wrench 6Lt 1,27xL10 ▼



- 15 Locator key ▼



- 16 Converter adapter ▼



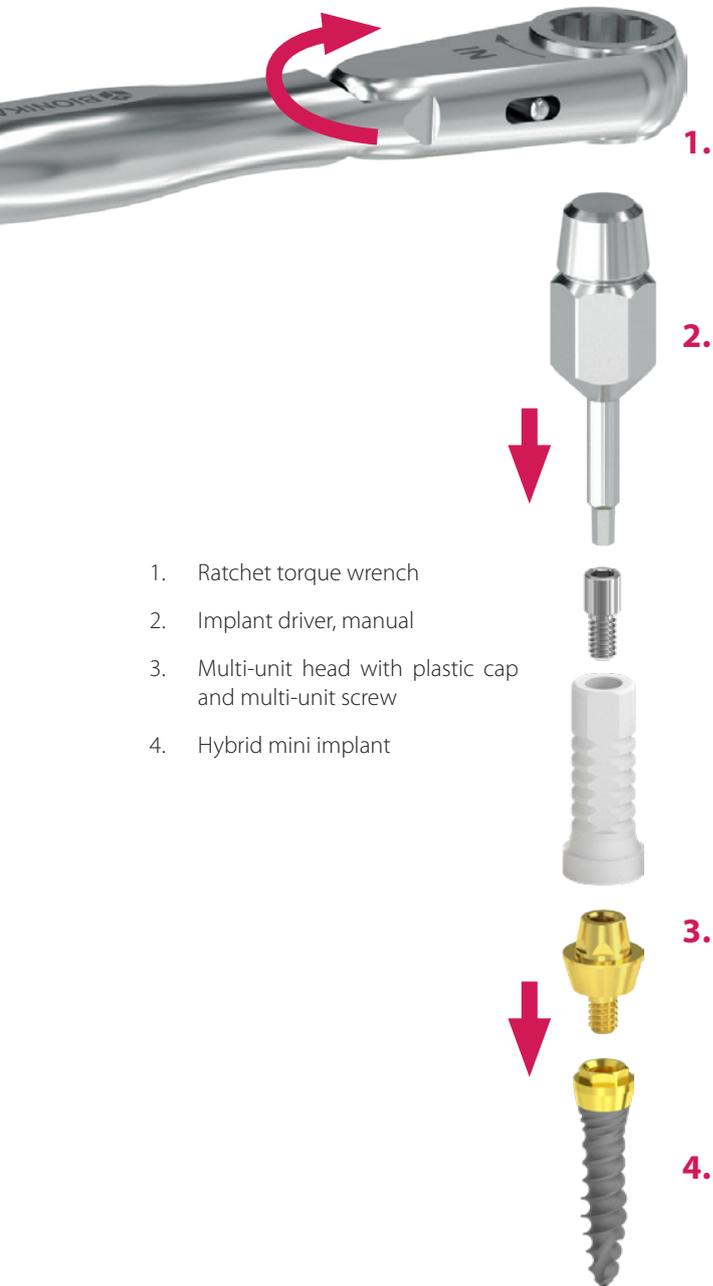
- 17 Ratchet torque wrench ▼



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, with plus or minus 5% accuracy. The scale on the opposite side can be used as a reverse torque. The ratchet torque wrench can also function as a simple ratchet.

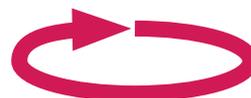


1. Ratchet torque wrench
2. Implant driver, manual
3. Multi-unit head with plastic cap and multi-unit screw
4. Hybrid mini implant



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

- 15 Ncm
- 25 Ncm
- 35 Ncm
- endless torque



The desired torques can be adjusted from 15 Ncm to the right by rotating to 35 Ncm. It can be infinite by screwing out the collision.

Applications of Ratchet torque wrench



HEADS AND SCREWS		KEY INTERLINES	TORQUE
Ball head			Ratchet torque wrench 20 Ncm
Locator head			Ratchet torque wrench 20 Ncm
Multi-unit head screw			Ratchet torque wrench 20 Ncm
Multi-unit head			Ratchet torque wrench 25 Ncm



Get to know our other products!

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



www.bionika.hu



www.implantshop.hu



