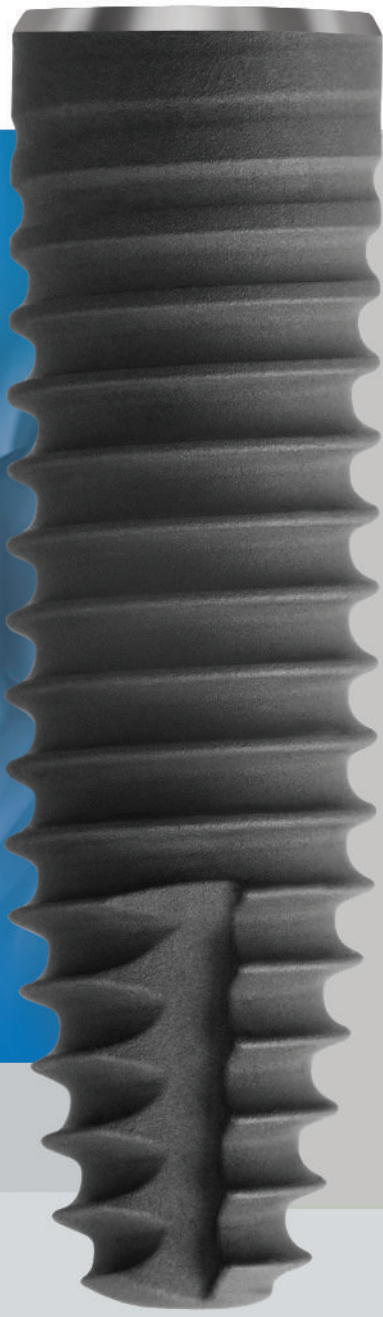




POLARIS Dental Implant System



POLARIS
BLP
Portfolio

Finds the Way ...



INDEX

Introducing



Products



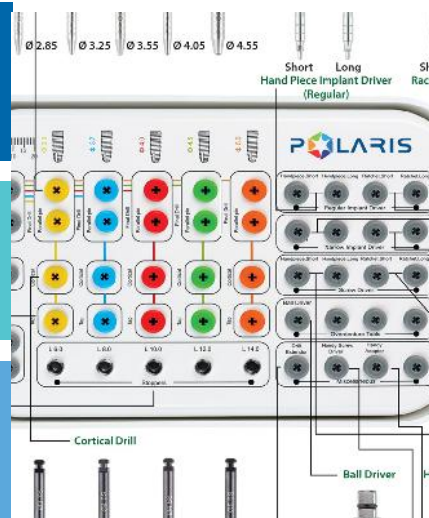
About the System



BLP Implant

Prosthetics & Auxiliaries

Surgical Plan



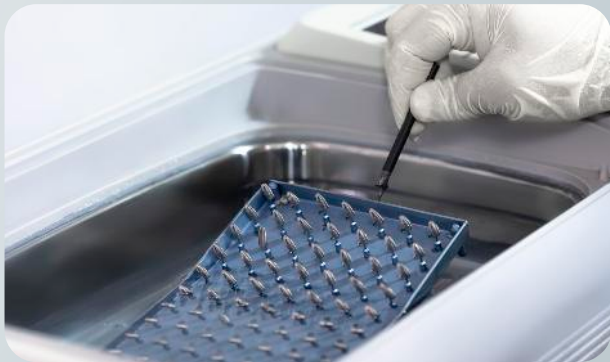
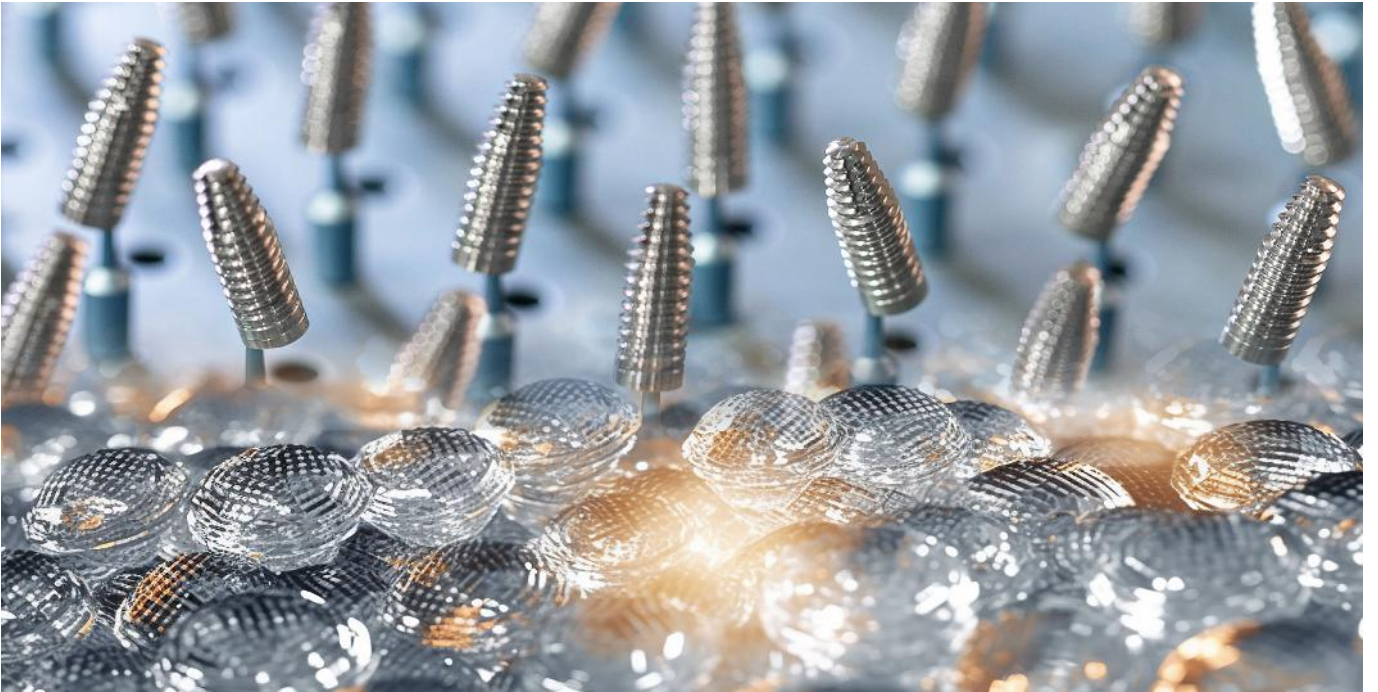
Introducing



Introducing the Implant Project

This company started the noble plan of “Manufacturing the Group of Dental Implant Products” in 2016 and localized the knowledge of manufacturing this product with the help of the educated youth and scientific elites and transferring technology from the top companies in the world. The company exploited this invaluable plan in the field of health industry in 2020 through employing the world’s latest and the most advanced equipment and number one European raw materials and by supplying the specialized installations and infrastructure equipment, implementing international systemic and technical standards, and through effective cooperation with the accredited international universities and international reference laboratories. The company’s Portfolio including a broad spectrum of the group of equipment and materials in the field of dentistry and dental prosthesis will be improved by introducing this new product and the company will get one step closer to its main goal, which is supplying the dental technology and commodity requirements to its fullest extent.





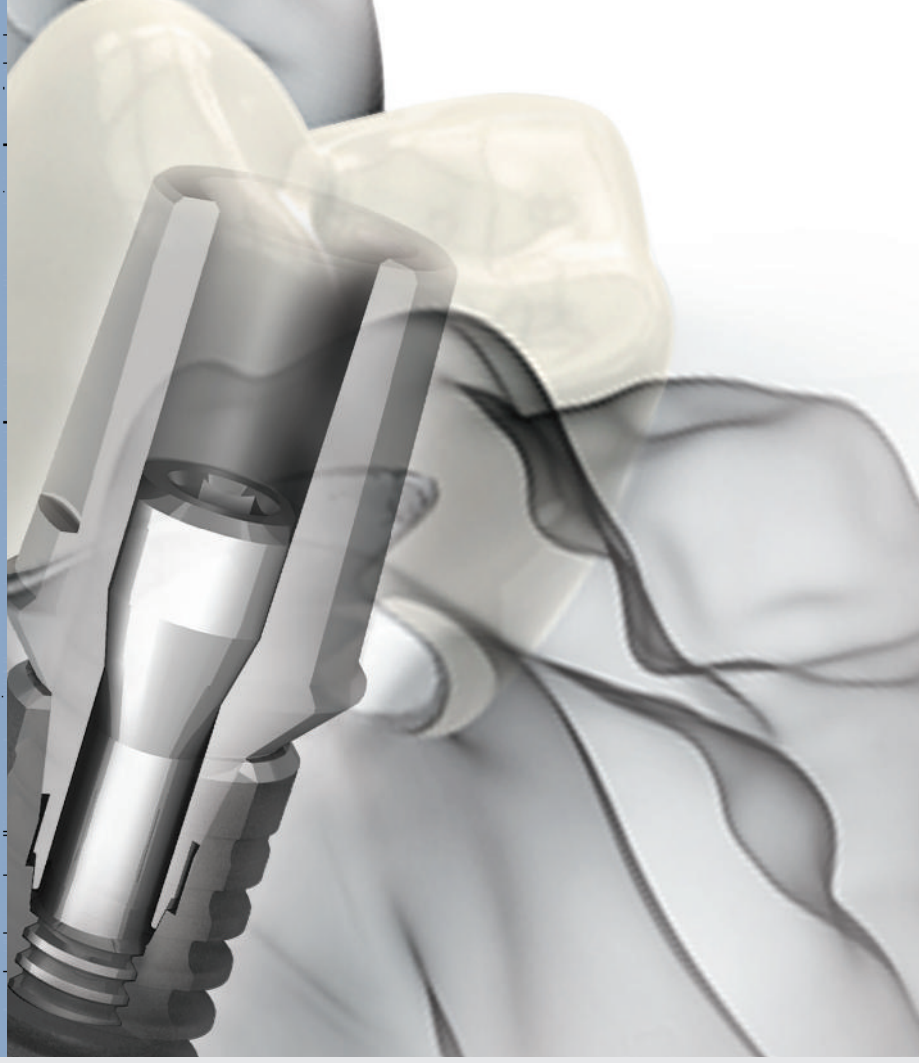
Introducing

No	Standard No	Subject
1	ISO 13485: 2016	Medical devices Quality management systems Requirements for regulatory purposes
2	ISO 14971:2007	Medical devices — Application of risk management to medical devices
3	ISO 13504: 2012	Dentistry - General requirements for instruments and related accessories used in dental implant placement and treatment
4	ISO 16443:2014	Dentistry — Vocabulary for dental implants systems and related procedure
5	ISO/TR 11175:1993	Dental implants — Guidelines for developing dental implants
6	ISO 10451:2010	Dentistry — Contents of technical file for dental implant systems
7	ISO 128: 1999	Technical drawings — General principles of presentation
8	ISO 2768-1	General tolerances — Part 1: Tolerances for linear and angular dimensions without individual tolerance indications
9	ISO 14405: 2016	Geometrical product specifications (GPS) - Dimensional tolerance
10	ISO/NP 22683	Dentistry — Adaptability test between implant body and abutment in dental implant system
11	ASTM F67:2013	Standard Specification for Unalloyed Titanium, for Surgical Implant Applications
12	ASTM F136:2012	Standard Specification for Wrought Titanium6-Aluminum4-Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications
13	ASTM E8/E8M :2016a	Standard Test Methods for Tension Testing of Metallic Materials
14	ISO/TS 18130:2016	Dentistry — Screw loosening test using cyclic torsional loading for implant body/implant abutment connection of endosseous dental implants
15	ISO/TS 13498:2011	Dentistry — Torsion test of implant body/connecting part joints of endosseous dental implant systems
16	ISO 14801:2016	Dentistry — Implants — Dynamic loading test for endosseous dental implants
17	ISO 10993-1:2009 AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
18	ISO 10993-2: 2006	Biological evaluation of medical devices, Part 2: Animal welfare requirements.
19	ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for Geno toxicity, carcinogenicity and reproductive toxicity
20	ISO 10993-5:2009	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
21	ISO 10993-6:2016	Biological evaluation of medical devices Part 6: Tests for local effects after implantation
22	ISO 10993-10:2013	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
23	ISO 10993-11:2018	Biological evaluation of medical devices Part 11: Tests for systemic toxicity
24	ISO 10993-12:2012	Biological evaluation of medical devices — Part 12: Sample preparation and reference materials
25	ISO 7405: 2018	Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
26	ISO 10993-11: 2017 " Annex G	Test for material-mediated pyrogens in medical devices
27	ISO 16498:2013	Dentistry — Minimal dental implant data set for clinical use
28	ISO/TS 22911:2016	Dentistry — Preclinical evaluation of dental implant systems — Animal test methods
29	ISO 11953:2010	Dentistry- Implants- clinical performance of hand torque instruments
30	ISO 14155:2011	Clinical investigation of medical devices for human subjects – Good clinical practice
31	ISO 14644-1:2015	Cleanrooms and associated controlled environments -- Airborne Particulate Cleanliness Classes in Cleanrooms and Clean Zones
32	EN 556-1&2:2001/AC:2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" – Part 1
33	EN 556-2:2015	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" – Part 2
34	ISO 11137-3:2017	Sterilization of health care products – Radiation – Part 3: Guidance on dosimetry aspects of development, validation and routine control
35	ISO 11737-1: 2006	Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products
36	ISO 11737-2:2009	Sterilization of medical devices — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization processvalidation and maintenance of a sterilization process
37	ISO 11607: 2019	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
38	ISO 11607-2: 2019	Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes
39	ASTM F1980	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
40	EN 1041:2008	Information supplied by the manufacturer of medical devices

STANDARDS



About the System

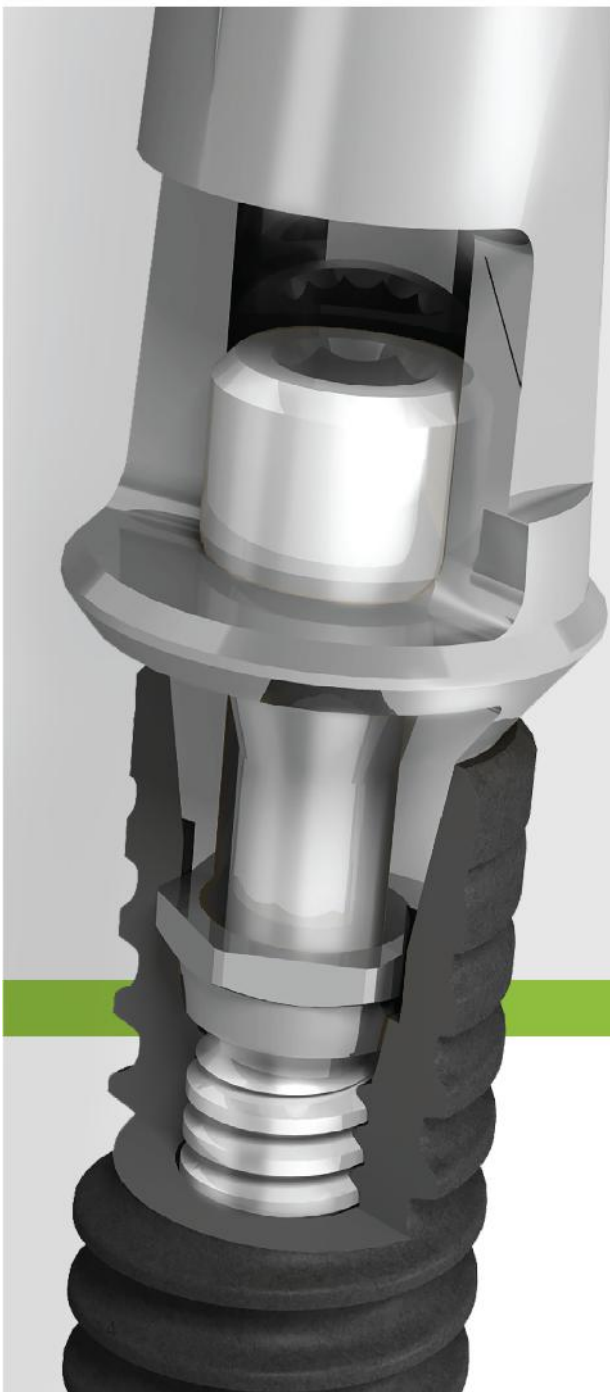


About the system

Dental implant has proved successful in the replacement of the roots of missing natural teeth. Application of this method has been on the increase in recent years.

Implant design, type of connection, coating, range of

prosthetic parts, and professional surgical kit are the most important factors in a successful implant system. What follows is the more detailed information of AVITA's BLP portfolio for dental implants.



Design

- Bone level implant with platform switching
- External geometry with tapered effect
- Mono thread structures with V-shaped cross section and reverse buttress
- With cutting edge at the apex
- Minimum tension in the application of torsional torque while implanting
- Maximum post-implant bone-to-implant contact with optimized stress shieldin
- Optimal curvature angle radius at the apex for the uniform distribution of stress using Pure Titanium Grade 4 ASTM F67 material

Secure connection

- Internal connections of narrow and regular sizes
- Conical support for maximized contact and sealing
- Hexagonal area (hex) for rotational stability
- Apex for angulation of hands and easy placement of parts

BLP PORTFOLIO



Morsed Tapered Connection 11°

Platform Switching

Bone Level Features

- Bone Control Design with optimized crestal bone preservation
- Soft tissue stability.
- Consistent Emergence Profile

Material

- Pure Titanium Grade 4
- Excellent performance in long term clinical investigation

Hybrid Design

Tapered Apex

TiPower Surface

- Thick & passive TiO₂ layer
- Micro/Nano surface roughness up to %150 increase of contact area
- Great hydrophilicity
- Ideal porous morphology for well cell positioning

Cutting Edge

3 cutting edges
Rounded tip

Coronal
with morsed tapered connection
easy handling,
confident positioning,
sustainable stability

Straight body
Bone Condensing
Easy insertion

Tapered Apex
Provides a high primary
stability in soft bone



Cutting Edge
Rounded tip

TiPower coat

TiPower is the brand name of the coating used in Polaris dental implant system. TiPower coat is an eco-friendly coating based on combined processes for coat preparation, derived from reliable and up to date sources from around the world.

It affects the oxidation, coarseness, morphologic Nano structure, and chemical parameters of the coat to modify and improve the quality of implant to optimize osseointegration and to increase the success rate of dental implant plan.

TiPower Performance on Implant Body:

TiO₂ Layer formation

Thick layer 10~12 μm
High passivity and strength against wear

Surface Roughness

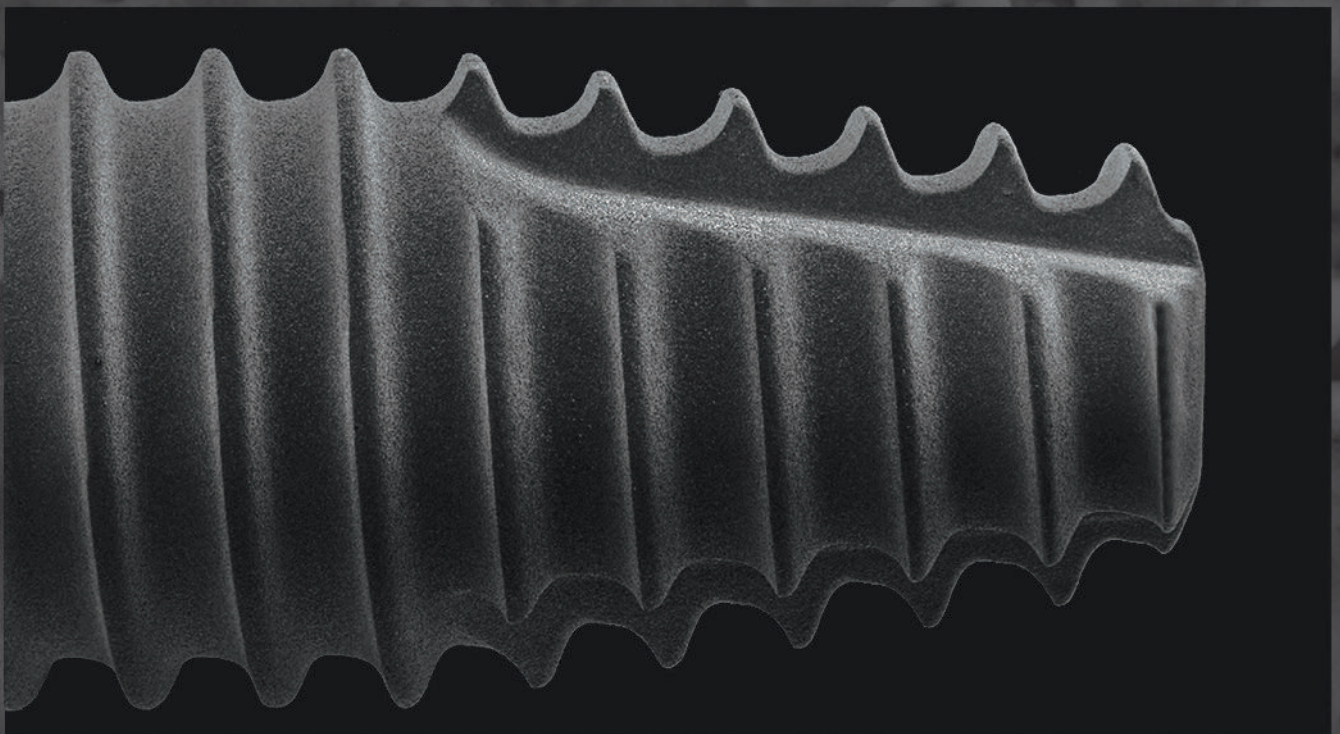
Micro texture with roughness Sa~1.8 μm & Ra~1.5 μm
Increase of contact area

Surface Morphology

Fine homogeneous structure
Well cell positioning

Surface Hydrophilicity

Provider of adhesion points for proteins and cells
Increase of tissue affinity



TiPower creates a resistant, chemically inactive layer of titanium oxide of 5µm thickness on the implant coat, which results in higher resistance against corrosion. Roughness of this layer is as follows:

Sa=1.8 µm

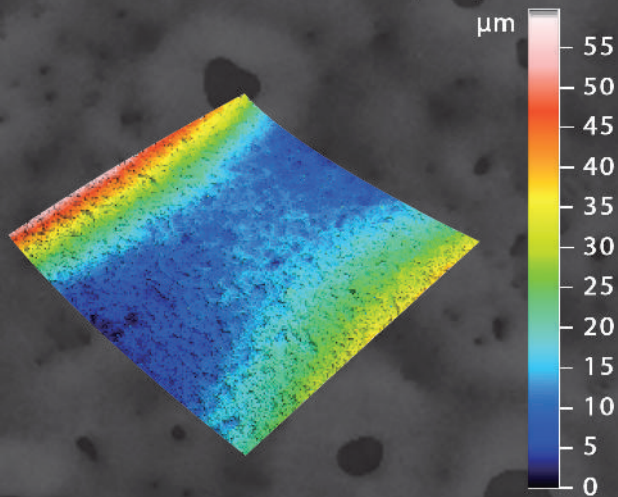
Ra= 1.5µm

Also, it features a highly porous integrated morphologic structure in Nano scale, which increases the

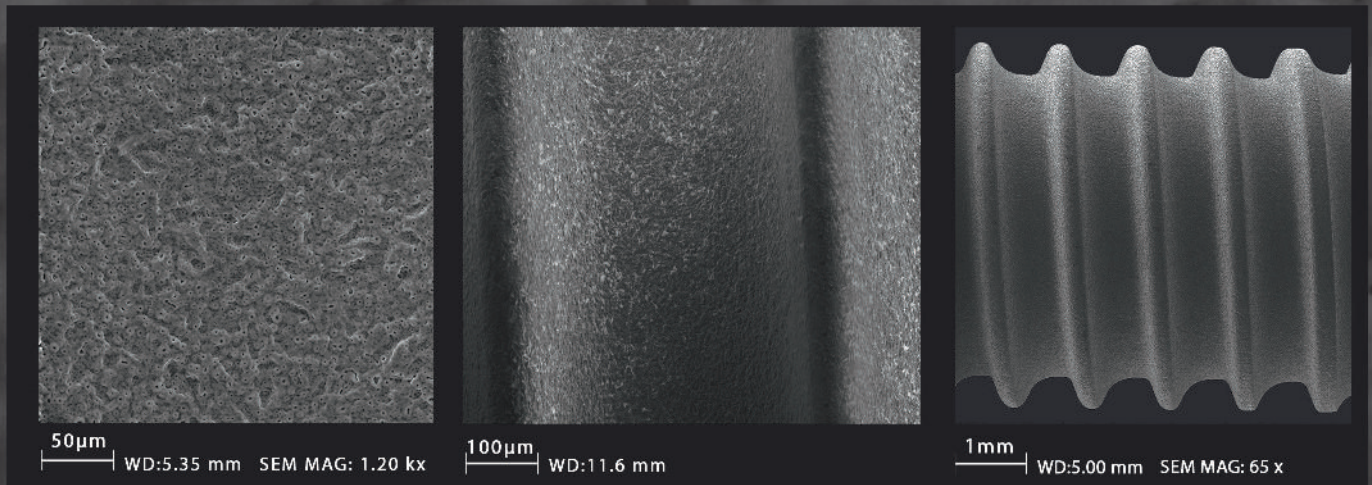
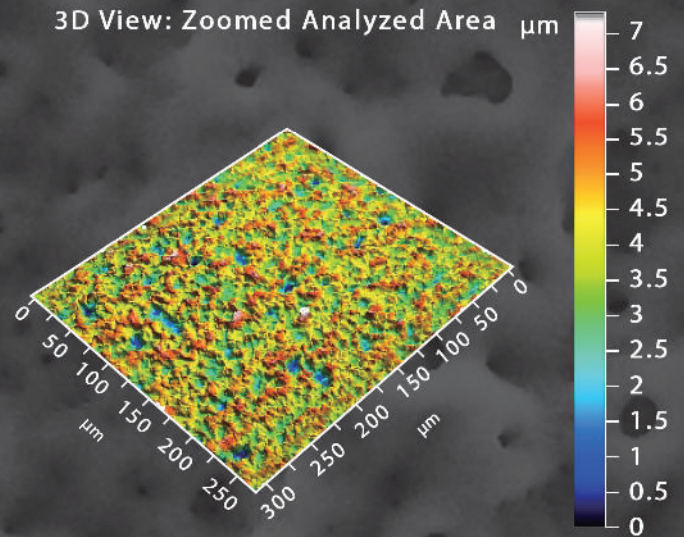
bone-to-implant contact by 150%, and results in the optimized placement of osteogenic cells. It also creates numerous OH groups to make the implant coat more hydrophilic, which in turn increases the absorption of proteins and cells due to the heightened viscosity of the coat, decreases the time required for bone grafting, and increases the secondary resistance of the implant.

In Vitro and In Vivo tests, including animal tests and clinical assessments, all prove the successful performance of TiPower and its sublime benefits as compared to other methods of coat processing.

3D View: Measured Topography Layer



3D View: Zoomed Analyzed Area



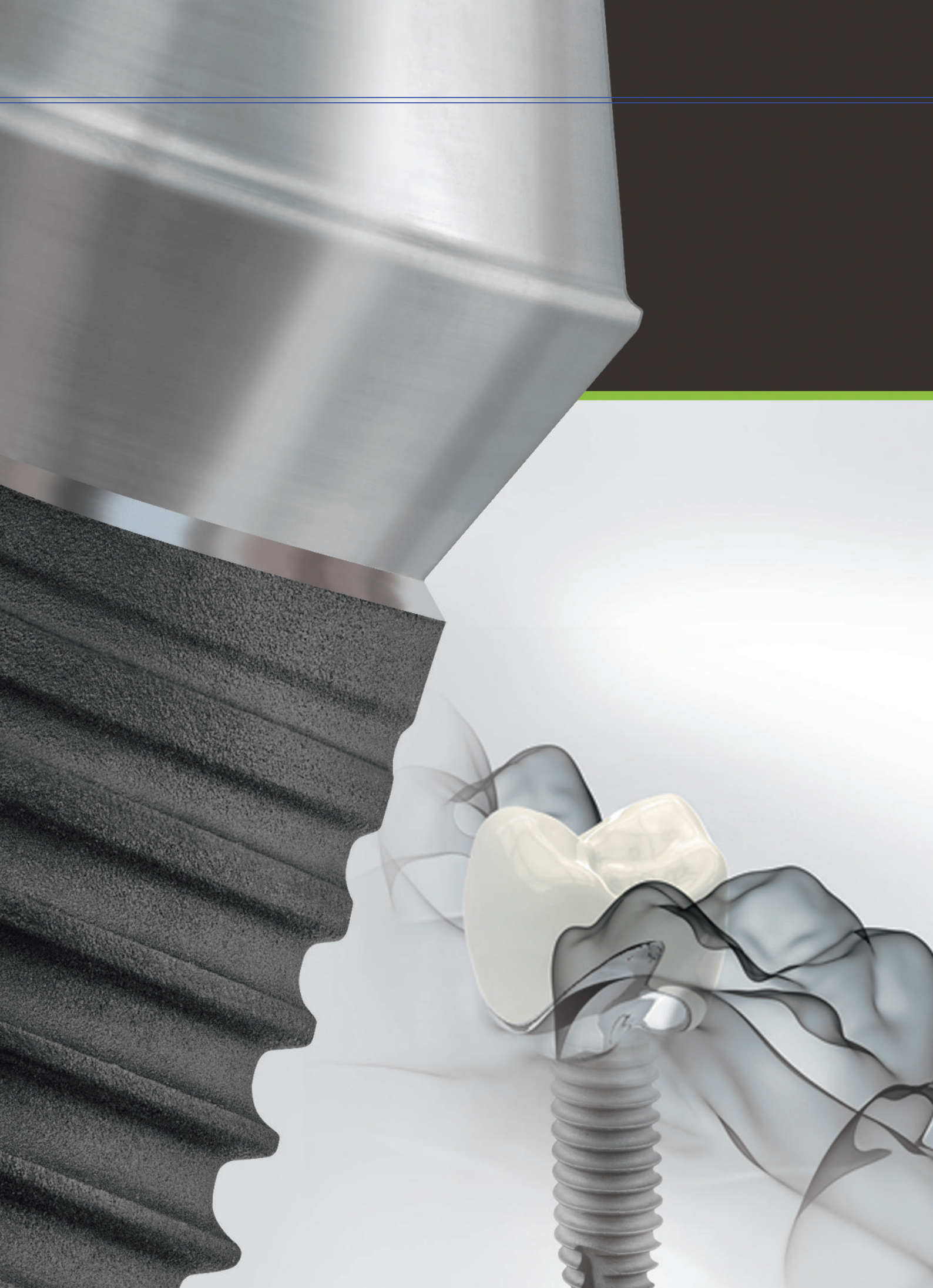
About the System/ TiPower

This method includes sandblasting, acid etching, and electrochemical deposition in a completely robotic process (German technology), using materials and solutions of supreme quality (approved by Swiss authorities), inside cleanroom workspace to reach particular structures compatible with the bone environment.

All these processes are carried out with instrumentation and state-of-the-art surface engineering equipment, and are constantly controlled and monitored.

All prosthetic parts of Polaris dental implant system are also processed under color anodizing surface processing operation in the cleanroom, using a mechanized procedure.





Packing & Labeling

- Double Sealing
- Including isolation Capsule & Blister Layer
- 5-year-period Sterilization



- LOT** Lot number
- REF** Reference code
- STERILE R** Sterilized by gamma radiation



Use before expiry date



For single use only



Read this notice carefully



Temperature limitation



Keep away from sun



Keep away from water



Produce date



◀ How to open the package & remove the implant from the capsule





Products





BLP Implant
wisely chosen, simply done

3.3



Hex 1.7



Length			10 mm	12 mm	14 mm
Ref. Code			BPI3310	BPI3312	BPI3314

3.7



Hex 2.5



Length		8 mm	10 mm	12 mm	14 mm
Ref. Code		BPI3708	BPI3710	BPI3712	BPI3714

4



Hex 2.5



Length		8 mm	10 mm	12 mm	14 mm
Ref. Code		BPI4008	BPI4010	BPI4012	BPI4014

4.5



Hex 2.5



Length	6 mm	8 mm	10 mm	12 mm	14 mm
Ref. Code	BPI4506	BPI4508	BPI4510	BPI4512	BPI4514

5



Hex 2.5

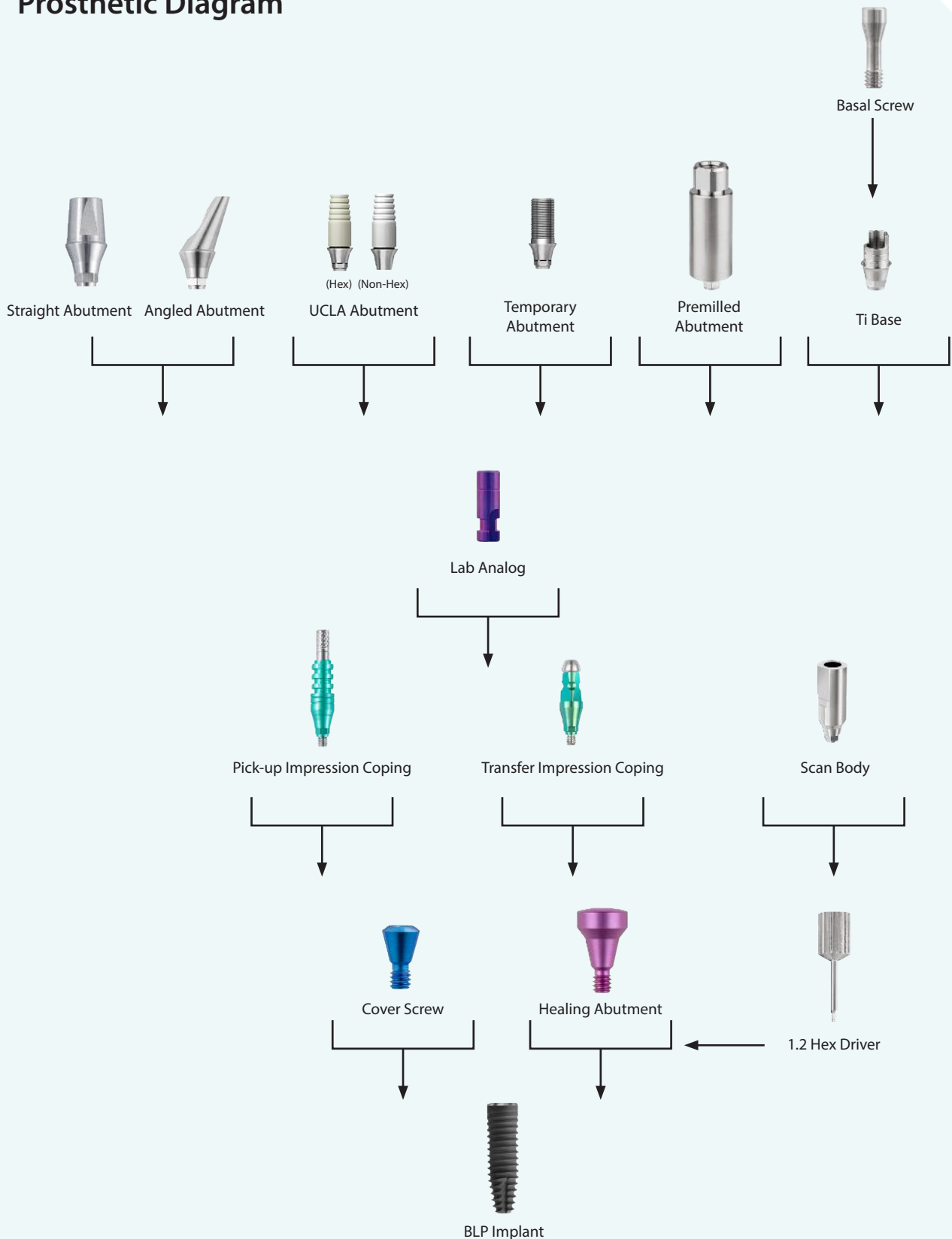


Length	6 mm	8 mm	10 mm	12 mm	14 mm
Ref. Code	BPI5006	BPI5008	BPI5010	BPI5012	BPI5014



Prosthetics & Auxiliaries
widespread & colorful

Prosthetic Diagram



Cover Screw



Healing Abutment

SW 1.2 Hex

D

H

Fixture level

N Narrow

R Regular

D \ H	3.0	4.0	5.0	6.0	7.0
	BPHA4030N BPHA4530N	BPHA4040N BPHA4540N	BPHA4050N BPHA4550N	BPHA4060N BPHA4560N	BPHA4070N BPHA4570N
	Ø 4.0	Ø 4.5			
D \ H	3.0	4.0	5.0	6.0	7.0
	BPHA4530	BPHA4540	BPHA4550	BPHA4560	BPHA4570
	BPHA5030	BPHA5040	BPHA5050	BPHA5060	BPHA5070
	BPHA6030	BPHA6040	BPHA6050	BPHA6060	BPHA6070
	Ø 4.5	Ø 5.0	Ø 6.0		

Pick-up Impression Coping

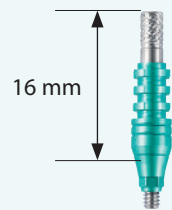
N Narrow

R Regular

D \ L

16

Giude Pin



Ø 4.0
Ø 4.5

BPICP4011N
BPICP4511



BPICSP1422N
BPICSP2022

Transfer Impression Coping

N Narrow

R Regular

D \ L

11

Giude Pin

Type



Ø 4.0
Ø 4.5

BPICT4085N
BPICT4585



BPICST1416N
BPICST2016

Lab Analog

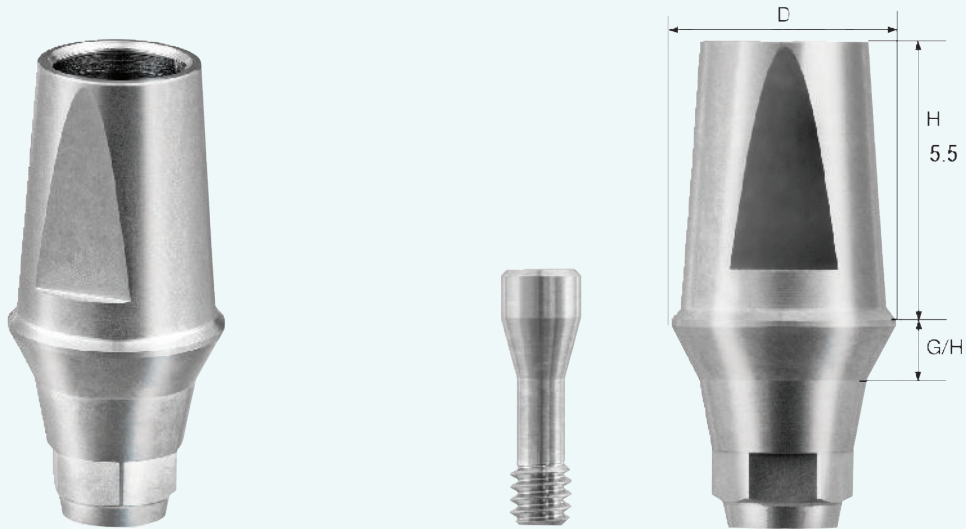


BPLA3312N
Narrow



BPLA4012
Regular

Straight Abutment Cementable



• Recommended tightening torque: 30 NCm

N	Narrow	H \ G/H					
		0.0	1.0	2.0	3.0		
D Ø 4.0	5.5	BPSAC4000N	BPSAC4010N	BPSAC4020N	BPSAC4030N		
D Ø 4.5	5.5	BPSAC4500N	BPSAC4510N	BPSAC4520N	BPSAC4530N		
D Ø 4.0	7.0	BPSAC400070N	BPSAC401070N	BPSAC402070N	BPSAC403070N		
D Ø 4.5	7.0	BPSAC450070N	BPSAC451070N	BPSAC452070N	BPSAC453070N		

R	Regular	H \ G/H					
		0.0	1.0	2.0	3.0		
D Ø 4.5	5.5	BPSAC4500	BPSAC4510	BPSAC4520	BPSAC4530		
D Ø 5.0	5.5	BPSAC5000	BPSAC5010	BPSAC5020	BPSAC5030		
D Ø 6.0	5.5	BPSAC6000	BPSAC6010	BPSAC6020	BPSAC6030		
D Ø 4.5	7.0	BPSAC450070	BPSAC451070	BPSAC452070	BPSAC453070		
D Ø 5.0	7.0	BPSAC500070	BPSAC501070	BPSAC502070	BPSAC503070		
D Ø 6.0	7.0	BPSAC600070	BPSAC601070	BPSAC602070	BPSAC603070		

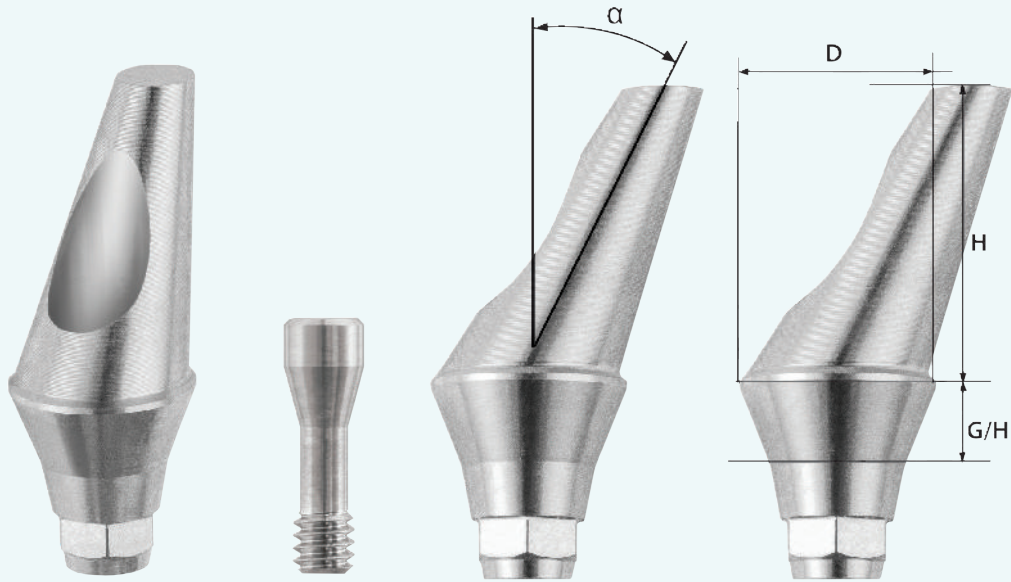


BPBS1412N
Narrow



BPBS2012
Regular

Angled Abutment Cementable



• Recommended tightening torque: 30 NCm

N	Narrow	H	G/H	G/H			
				1.0	2.0	3.0	4.0
α=15°	D Ø 4.5	7.5		BPAAC154510N	BPAAC154520N	BPAAC154530N	BPAAC154540N
α=25°	D Ø 4.5	7.5		BPAAC254510N	BPAAC254520N	BPAAC254530N	BPAAC254540N

R	Regular	H	G/H	G/H			
				1.0	2.0	3.0	4.0
α=15°	D Ø 4.5	7.5		BPAAC154510	BPAAC154520	BPAAC154530	BPAAC154540
α=15°	D Ø 5.0	7.5		BPAAC155010	BPAAC155020	BPAAC155030	BPAAC155040
α=15°	D Ø 6.0	7.5		BPAAC156010	BPAAC156020	BPAAC156030	BPAAC156040
α=25°	D Ø 4.5	7.5		BPAAC254510	BPAAC254520	BPAAC254530	BPAAC254540
α=25°	D Ø 5.0	7.5		BPAAC255010	BPAAC255020	BPAAC255030	BPAAC255040
α=25°	D Ø 6.0	7.5		BPAAC256010	BPAAC256020	BPAAC256030	BPAAC256040

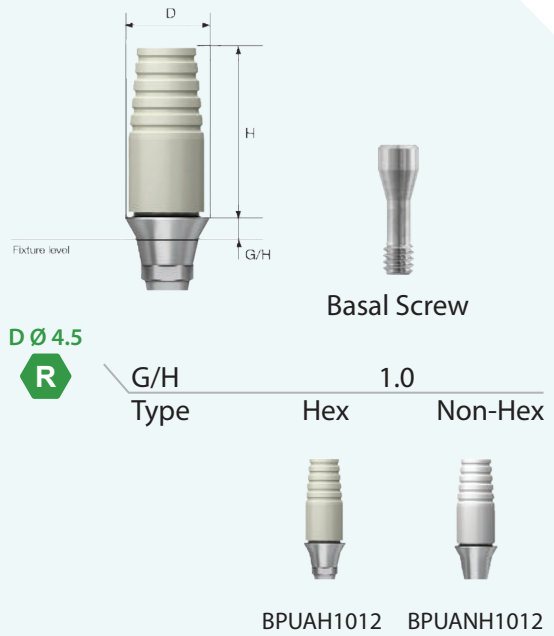


BPBS1412N
Narrow

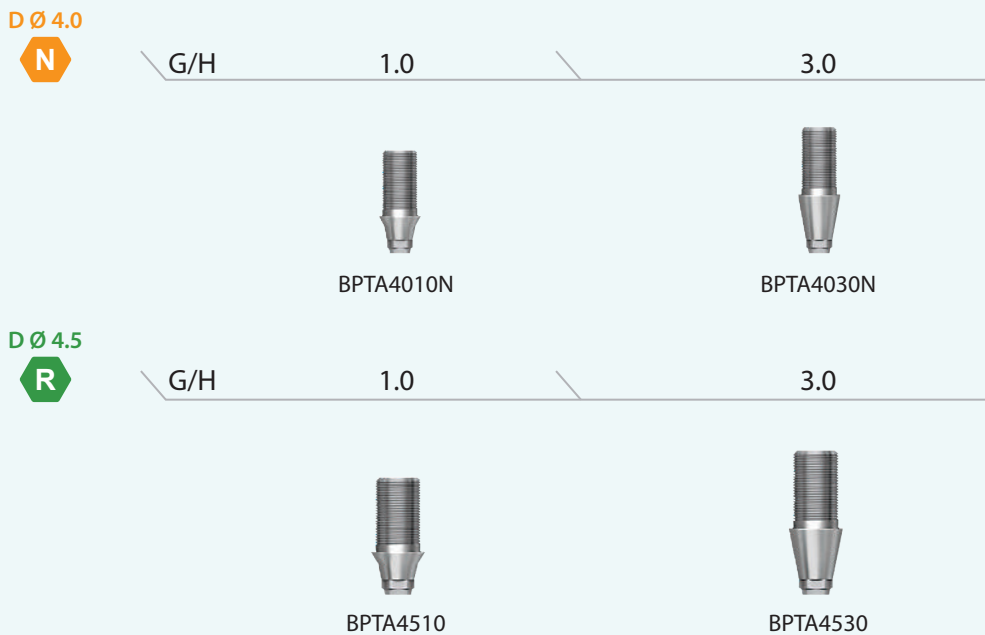
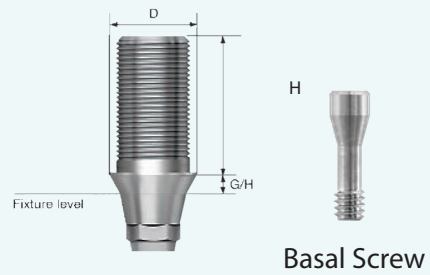


BPBS2012
Regular

UCLA Abutment



Temporery Abutment



Pre Milled Abutment

Holder	System	Diameter	Ref. Code
Arum	Narrow	10	BPPA0110N
Arum	Narrow	12	BPPA0112N
Arum	Narrow	14	BPPA0114N

Holder	System	Diameter	Ref. Code
Arum	Regular	10	BPPA0110
Arum	Regular	12	BPPA0112
Arum	Regular	14	BPPA0114



Basal Screw

Scan Body

Holder	System	Ref. Code
Arum	Narrow	BPSB01N
Arum	Regular	BPSB01



Basal Screw

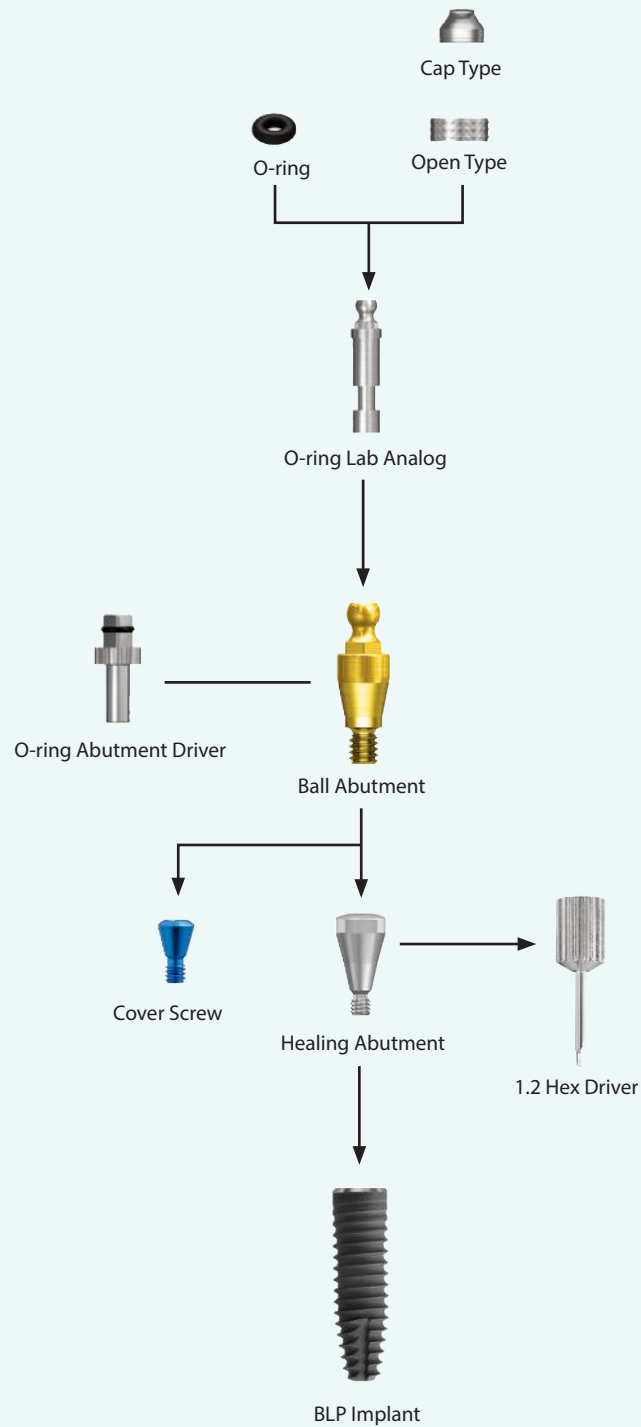
Ti Base

Holder	System	Ref. Code
Arum	Narrow	BPTB01N
Arum	Regular	BPTB01

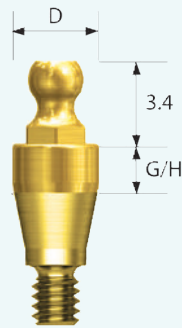


Basal Screw

Prosthetic Diagram Ball Abutment Overdenture



Ball Abutment

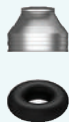


D Ø 3.5
N


G/H	1.0	2.0	3.0	4.0	5.0
	BPBA3510N	BPBA3520N	BPBA3530N	BPBA3540N	BPBA3550N


D Ø 3.5
R

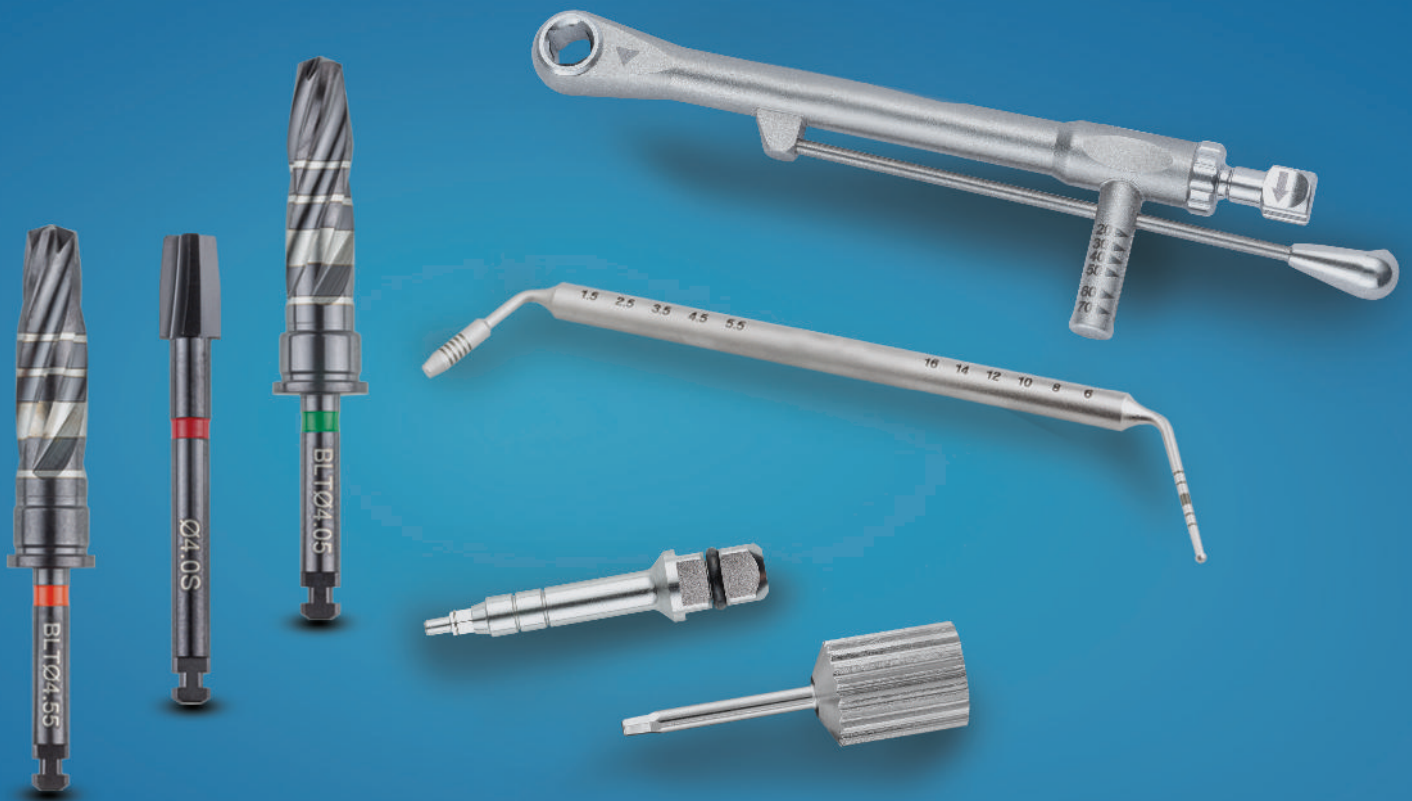
G/H	1.0	2.0	3.0	4.0	5.0
	BPBA3510	BPBA3520	BPBA3530	BPBA3540	BPBA3550

O-ring Retainer Cap Set 
BPRCS01

O-ring Retainer Set 
BPRS01

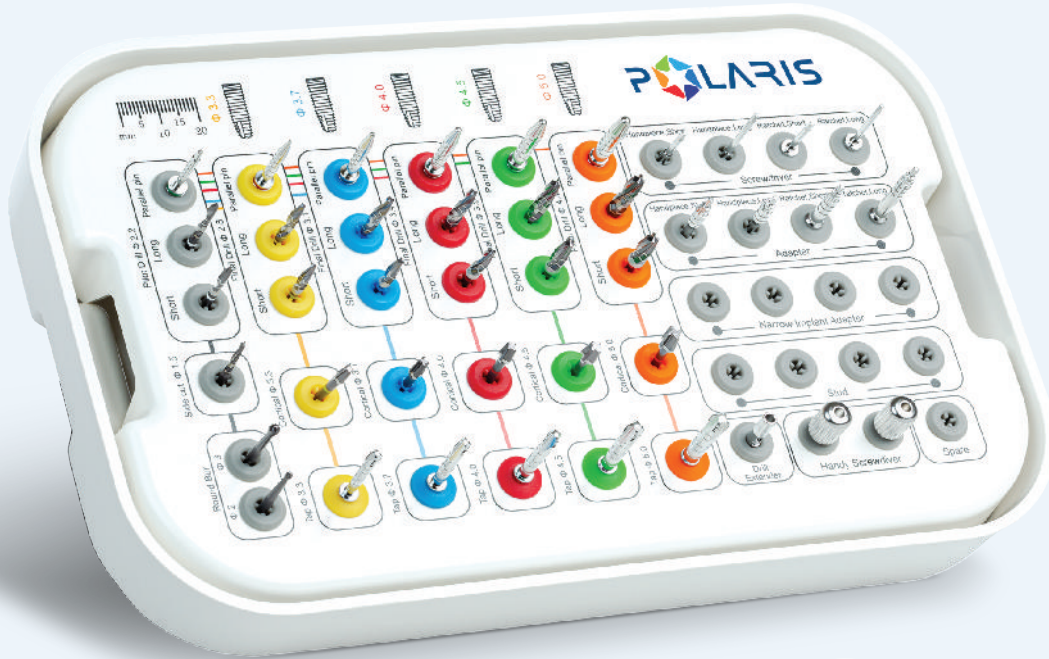
O-ring 
BPOR01

O-ring Lab Analog 
BPBLA



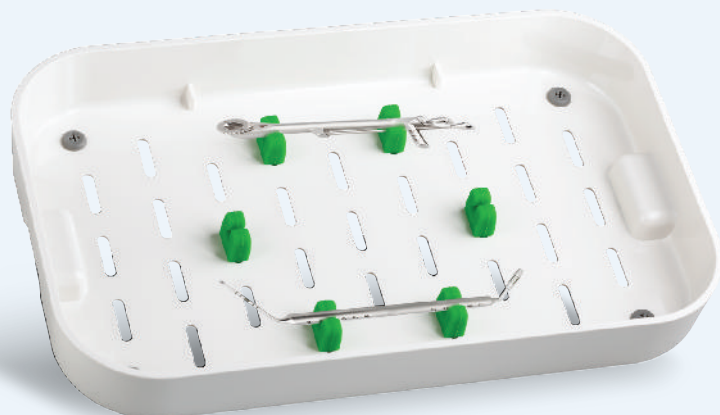
Surgical Plan
simple & friendly

POLARIS Surgical Kit

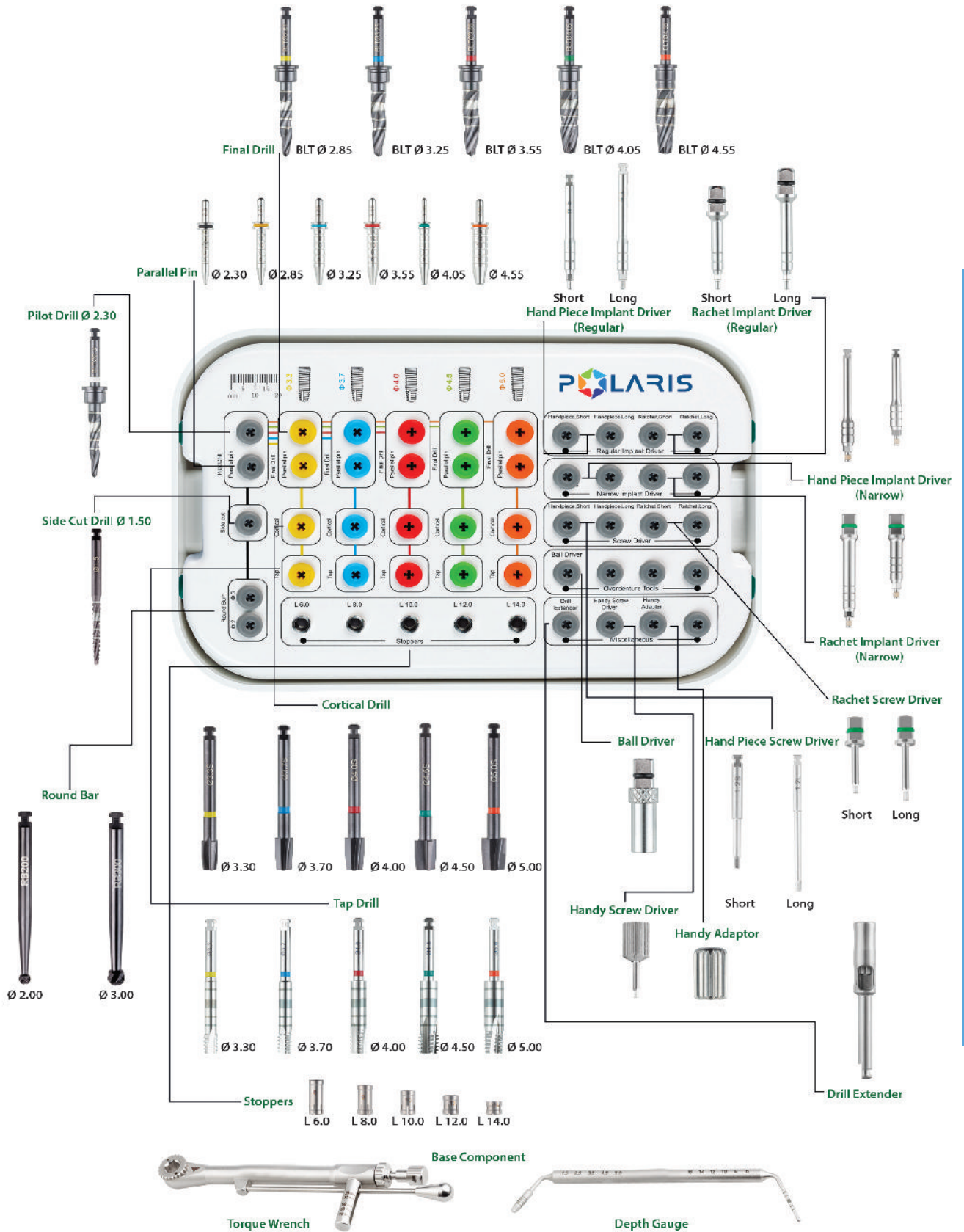


COLOR CODE

- 14 mm
- 12 mm
- 10 mm
- 8 mm
- 6 mm
- 0 mm



Products/ Surgical plan



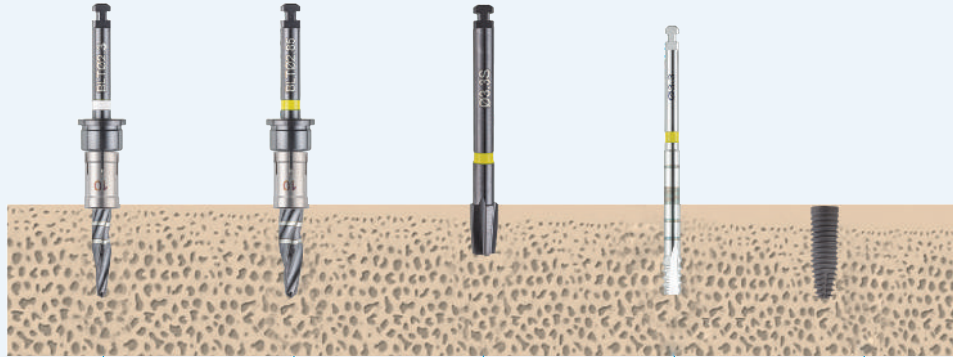
Surgical Procedure

- Universal recommended torque: 35 NCm
- Final Allowed torque: 45 NCm

3.3

N
Hex 1.7

→ ● recommended steps
- - - ○ dense cortex only



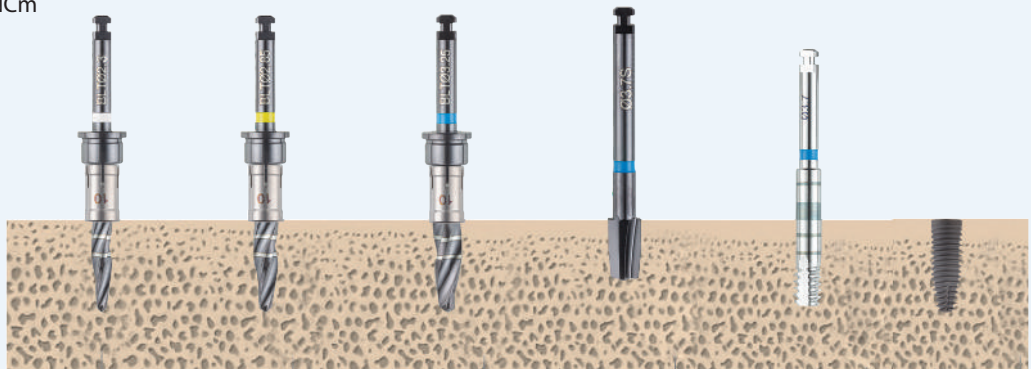
Type 1	Very hard bone	●	●	●	→ ●	→ ●
Type 2	hard bone	●	●	→ ●	- - - ○	→ ●
Type 3	Soft bone	●	→ ●	- - - ○	→ ●	→ ●
Type 4	Very soft bone	→ ●	- - - ○	- - - ○	- - - ○	→ ●
		Pilot Drill Ø 2.2 mm	BLT Drill Ø 2.8 mm	Cortical Drill Ø 3.3 mm	Tap Drill Ø 3.3 mm	
	RPM max	800	800	300	15	

- Universal recommended torque: 35 NCm
- Final Allowed torque: 45 NCm

3.7

R
Hex 2.5

→ ● recommended steps
- - - ○ dense cortex only



Type 1	Very hard bone	●	●	●	→ ●	→ ●	→ ●
Type 2	hard bone	●	●	→ ●	→ ●	- - - ○	→ ●
Type 3	Soft bone	●	●	→ ●	- - - ○	→ ●	→ ●
Type 4	Very soft bone	→ ●	●	- - - ○	- - - ○	- - - ○	→ ●
		Pilot Drill Ø 2.2 mm	BLT Drill Ø 2.8 mm	BLT Drill Ø 3.1 mm	Cortical Drill Ø 3.7 mm	Tap Drill Ø 3.7 mm	
	RPM max	800	800	600	300	15	

Products/ Surgical plan

- Universal recommended torque: 35 NCm
- Final Allowed torque: 45 NCm

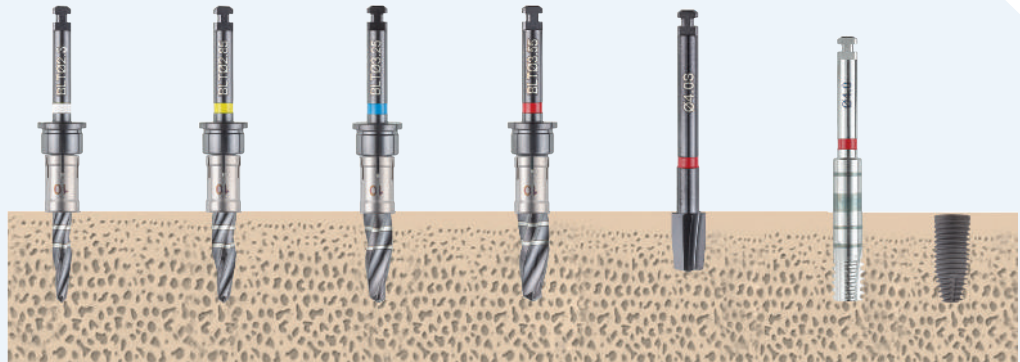
4.0



Hex 2.5

→ recommended steps

- - - dense cortex only



Type 1	Very hard bone	●	●	●	→ ●	→ ●	→ ●	→ ●
Type 2	hard bone	●	●	→ ●	→ ●	→ ●	- - - ●	→ ●
Type 3	Soft bone	●	●	→ ●	→ ●	- - - ●	- - - ●	→ ●
Type 4	Very soft bone	→ ●	→ ●	→ ●	- - - ●	- - - ●	- - - ●	→ ●
		Pilot Drill Ø 2.2 mm	BLT Drill Ø 2.8 mm	BLT Drill Ø 3.1 mm	BLT Drill Ø 3.4 mm	Cortical Drill Ø 4.0 mm	Tap Drill Ø 4.0 mm	
	RPM max	800	800	600	500	300	15	

- Universal recommended torque: 35 NCm
- Final Allowed torque: 45 NCm

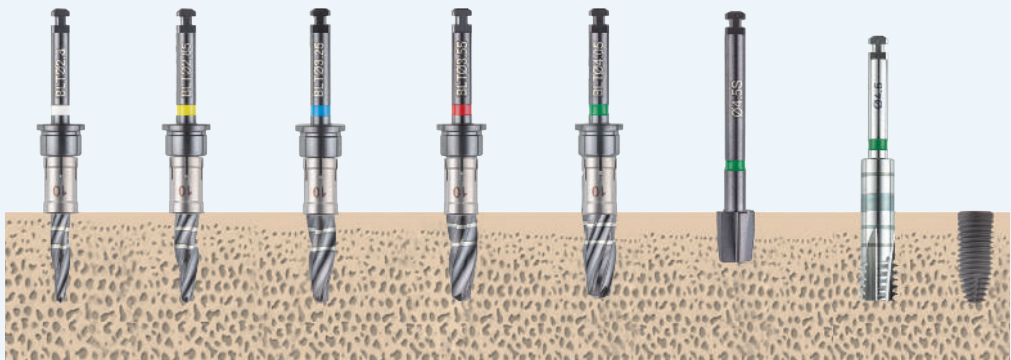
4.5



Hex 2.5

→ recommended steps

- - - dense cortex only



Type 1	Very hard bone	●	●	●	→ ●	→ ●	→ ●	→ ●
Type 2	hard bone	●	●	→ ●	→ ●	→ ●	- - - ●	→ ●
Type 3	Soft bone	●	→ ●	→ ●	→ ●	- - - ●	- - - ●	→ ●
Type 4	Very soft bone	→ ●	→ ●	→ ●	→ ●	- - - ●	- - - ●	→ ●
		Pilot Drill Ø 2.2 mm	BLT Drill Ø 2.8 mm	BLT Drill Ø 3.1 mm	BLT Drill Ø 3.4 mm	BLT Drill Ø 3.9 mm	Cortical Drill Ø 4.5 mm	Tap Drill Ø 4.5 mm
	RPM max	800	800	600	500	400	300	15

- Universal recommended torque: 35 NCm
- Final Allowed torque: 45 NCm

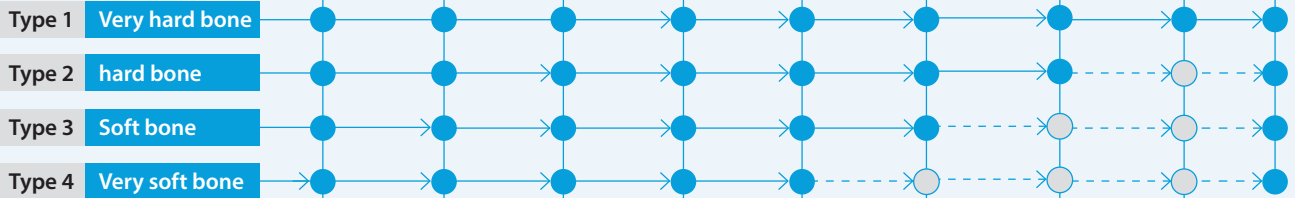
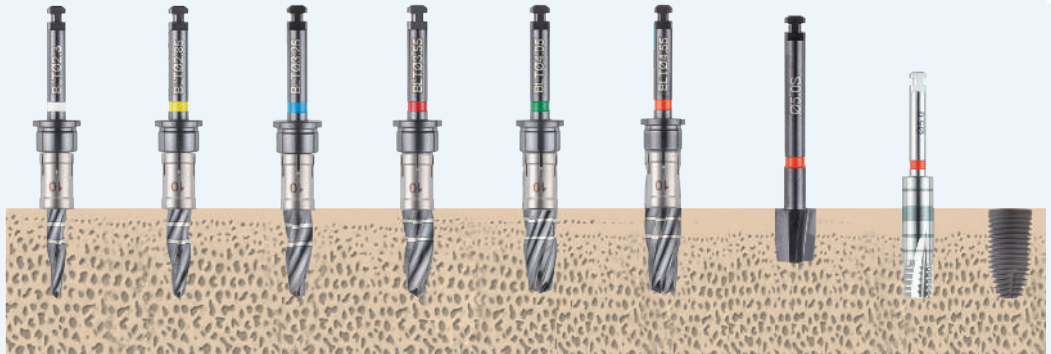
5.0



Hex 2.5

→ ● recommended steps

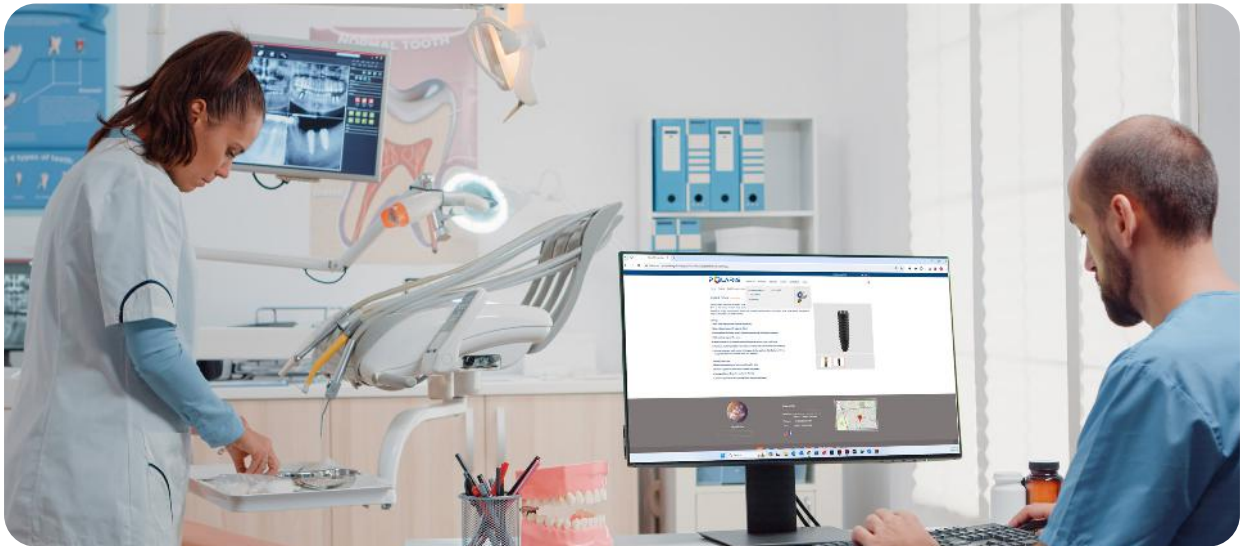
- - - ○ dense cortex only



	Pilot Drill Ø 2.2 mm	BLT Drill Ø 2.8 mm	BLT Drill Ø 3.1 mm	BLT Drill Ø 3.4 mm	BLT Drill Ø 3.9 mm	BLT Drill Ø 4.4 mm	Cortical Drill Ø 5.0 mm	Tap Drill Ø 5.0 mm
RPM max	800	800	700	600	500	400	300	15

Note:





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