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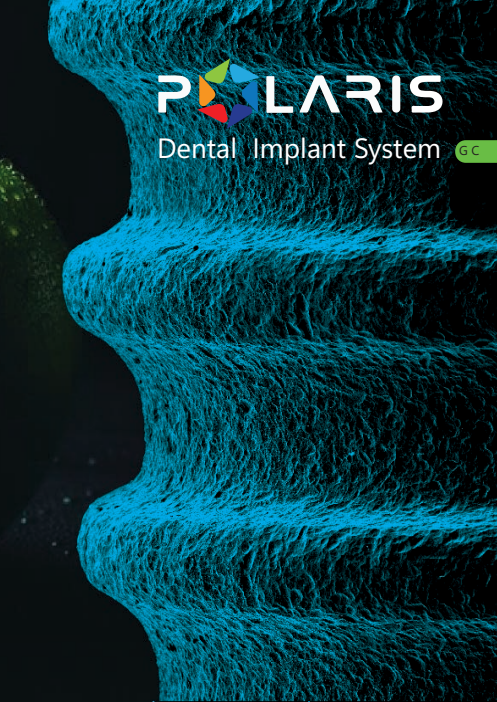

POLARIS
Dental Implant System
GC

GC, Dental Implant System

POLARIS

Finds the Way...

Introducing the Implant Project

This company started a novel 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 transfered 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 includes a broad spectrum of the group of equipment and materials in the field of dentistry and dental prosthetics. It 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.

Dental implant surgery has emerged as a highly effective and reliable solution for replacing the roots of missing natural teeth, with success rates exceeding %95 over 10 years in clinical studies. This proven track record has led to a significant increase in the adoption of implantology worldwide, making it the gold standard for tooth replacement.

The success of an implant system depends on several critical factors, including the design of the implant's external surface, the type of connection, the coating technology, the range of prosthetic components, and the precision of the surgical kit. Here, we provide a detailed overview of the Polaris BLP portfolio, a comprehensive and innovative solution designed to meet the highest standards in dental implantology, ensuring optimal outcomes for both clinicians and patients.

Standards

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

NARROW

Connection:

Morse 11°

Hex: 1.7

M 1.4 Thread

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

Cutting Edge

- 3 Cutting Edges
- Rounded Tip

Our portfolio includes implants in Narrow and Regular lines, with the Regular line also featuring short implants for versatile clinical applications. Additionally, a Wide line will soon be introduced, maintaining the same connection type as the Regular line for consistency and ease of use. The Narrow line features a 1.7 mm hex, while the Regular line is designed with a 2.5 mm hex, ensuring precision and adaptability for a wide range of clinical scenarios.

REGULAR

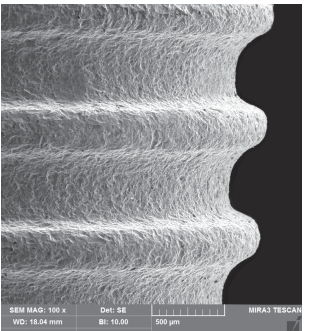
Connection:
Double Morse 11°
Hex: 2.5
M2 Thread

Coronal
With Morsed Tapered Connection
Easy Handling,
Confident Positioning,
Sustainable Stability

Straight Body

Tapered Apex
Provides a High Primary
Stability in Soft Bone

To complement our implant systems, we offer a comprehensive range of prosthetic components designed to meet diverse clinical needs. Our portfolio includes standard prosthetic parts, digital solutions for streamlined workflows, and customized abutments tailored to individual patient anatomy for optimal aesthetics and functionality.



Enhanced Osseointegration: SLA surface promotes osseointegration through increased cell adhesion and bone formation around the implant.

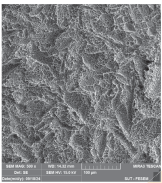
Surface Roughness (2.2 - 2.5 Micrometers): The treatment creates both macro and micro roughness on the implant surface. This roughness increases the surface area and energy, which helps in better bone to implant contact (BIC). The rough surface allows for better mechanical interlocking with the bone, enhancing the primary stability of the implant.

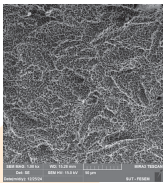
Reduced Healing Time: SLA surface shows a shorter healing period. The optimized surface topography allows bone cells to colonize the implant more quickly, and accelerates the healing process and enables earlier oading.

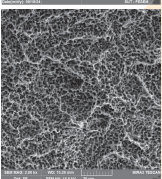
Increased Wettability (Hydrophilicity): The SLA surface improves the wettability of the implant, which enhances the initial interaction between the implant and the biological environment , further supporting osseointegration.

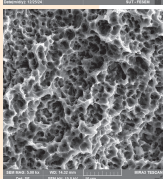
SLA SURFACE

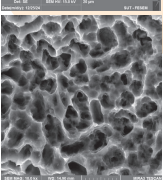
(SANDBLAST LARGE GRIT ACID ETCH)









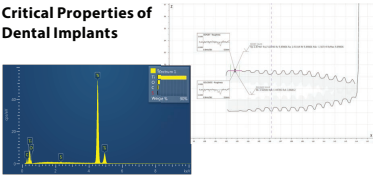


What we are looking for from the manufacturer's viewpoint to the SLA surface in different zoomed areas is to create proper morphology for well cell positioning. Smaller magnifications such as 500x indicates the affect of sandblast, and higher magnifications shows the pure effect of chemical treatments. Most of the SLA brands are similar in these scales, however, the correlation effect is seen in the between zooms.

State-of-the-Art Manufacturing Infrastructure

The foundation of high-quality dental implant manufacturing lies in advanced infrastructure and precision-driven processes. At our facility, we have established a modern manufacturing line equipped with cutting-edge technology to ensure the highest standards of accuracy, consistency, and reliability. Our production process utilizes CNC machines for precise machining, a highly accurate measurement system for quality control, and a sandblast machine for optimal surface texture. Additionally, we employ a semi-robotic surface treatment process to enhance implant biocompatibility and performance. To maintain the utmost hygiene and sterility, our manufacturing takes place in a certified ISO-class cleanroom, ensuring that every implant meets stringent international standards. This robust infrastructure enables us to deliver implants that are not only durable and functional but also tailored to meet the diverse needs of clinicians and patients worldwide.

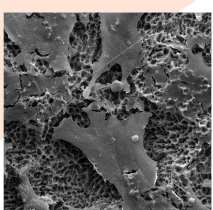
Critical Properties of Dental Implants

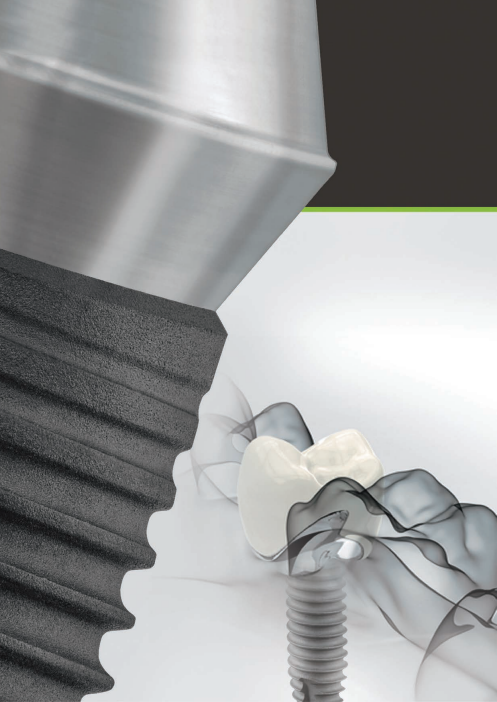


The success of dental implants hinges on three fundamental aspects: physical properties, chemical properties, and cellular response. The physical properties, such as surface texture, design, roughness, hydrophilicity and mechanical strength, ensure the implant can withstand functional loads and integrate seamlessly with surrounding bone.

From the chemical composition viewpoint, the implant material must exhibit high biocompatibility and corrosion resistance to prevent adverse reactions in the biological environment.

Most importantly, the cellular response to the implant— dictated by surface characteristics and material composition—plays a pivotal role in osseointegration, ensuring stable and long-lasting integration with the jawbone. By optimizing these properties using the results of MTS, cell adhesion, ALP and cell differentiation tests, we create implants that not only perform reliably but also promote natural healing and patient satisfaction.





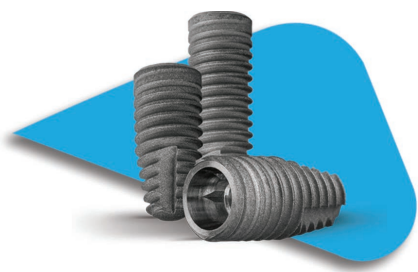
Packing & Labeling

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

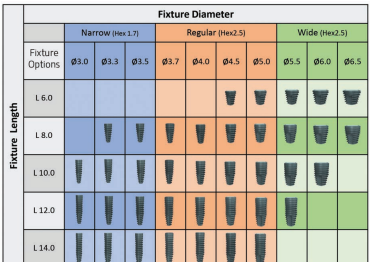
LOT	Lot number
REF	Reference code
STERILE R	Sterilized by gamma radiation
	Use before expiry date
2	For single use only
	Read this notice carefully
	Temperature limitation
	Keep away from sun
	Keep away from water
	Produce date

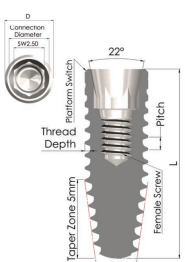
How to open the package & remove the implant from the capsule

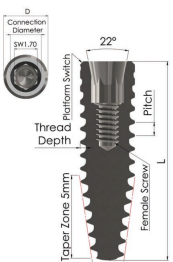
BLP Implant



Wisely Chosen, Simply Done...


Fixture Diameter
Narrow (Hex 1.7)
Regular (Hex2.5)
Wide (Hex2.5)
Fixture Options
Ø3.0
Ø3.3
Ø3.5
Ø3.7
Ø4.0
Ø4.5
Ø5.0
Ø5.5
Ø6.0
Ø6.5
Fixture Length
L 6.0
L 8.0
L 10.0
L 12.0
L 14.0

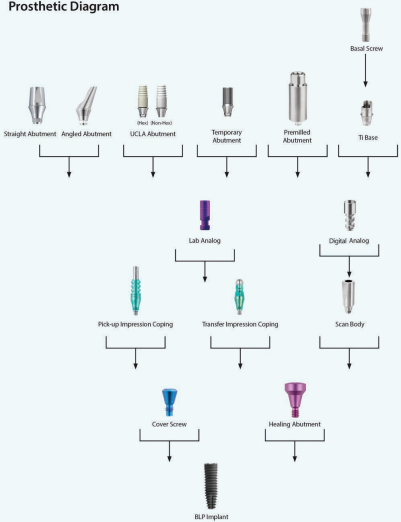

D
Connection Diameter
SW2.50
22°
Platform Switch
Pitch
Thread Depth
L
Female Screw
Taper Zone 5mm
16°


D
Connection Diameter
SW1.70
22°
Platform Switch
Pitch
Thread Depth
L
Female Screw
Taper Zone 5mm
16°

Prosthetics & Auxiliaries

Wisely Chosen, Simply Done...

Prosthetic Diagram



Cover Screw

Tightening torque:
Manual or Max 5 NCm

N Narrow BPC51425N

R Regular BPC52034

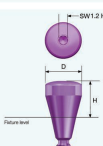
Instruction from Expert Users' Experience :
1. Fasten Manually
2. Then Unfasten 180 degrees
3. Fast again Manually

Healing Abutment

Tightening torque:
Manual or Max 10 NCm

N Narrow

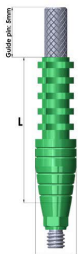
R Regular



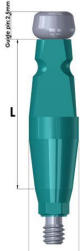
D \ H	3.0	4.0	5.0	6.0	7.0
Ø 4.0	BPHA4030N	BPHA4040N	BPHA4050N	BPHA4060N	BPHA4070N
Ø 4.5	BPHA4530N	BPHA4540N	BPHA4550N	BPHA4560N	BPHA4570N

D \ H	3.0	4.0	5.0	6.0	7.0
Ø 4.5	BPHA4530	BPHA4540	BPHA4550	BPHA4560	BPHA4570
Ø 5.0	BPHA5030	BPHA5040	BPHA5050	BPHA5060	BPHA5070
Ø 6.0	BPHA6030	BPHA6040	BPHA6050	BPHA6060	BPHA6070

Impression Coping Pickup



Impression Coping Transfer



Type		Diameter	Length	Ref.
Regular line				
Pickup	Short	4.5	11.0	ICPS 4511
		5.0	11.0	ICPS 5011
	Long	4.5	16.0	ICPL 4516
		5.0	16.0	ICPL 5016
Transfer	Short	4.5	8.5	ICTS 4585
		5.0	8.5	ICTS 5085
	Long	4.5	14.0	ICTL 4514
		5.0	14.0	ICTL 5014
Narrow line				
Pickup	Short	4.0	11.0	ICPS 4011N
	Long	4.0	16.0	ICPL 4016N
Transfer	Short	4.0	8.5	ICTS 4085N
	Long	4.0	14.0	ICTL 4014N

Straight Abutment Cementable

- Recommended tightening torque: 20 NCm

Narrow	H \ G/H	0.0	1.0	2.0	3.0
D Ø 3.5	5.5	BPSAC3505N	BPSAC3510N	BPSAC3520N	BPSAC3530N
D Ø 4.0	5.5	BPSAC4005N	BPSAC4010N	BPSAC4020N	BPSAC4030N
D Ø 4.5	5.5	BPSAC4505N	BPSAC4510N	BPSAC4520N	BPSAC4530N
D Ø 3.5	7.0	BPSAC3505070N	BPSAC351070N	BPSAC352070N	BPSAC353070N
D Ø 4.0	7.0	BPSAC4005070N	BPSAC401070N	BPSAC402070N	BPSAC403070N
D Ø 4.5	7.0	BPSAC4505070N	BPSAC451070N	BPSAC452070N	BPSAC453070N

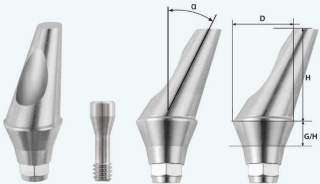
- Recommended tightening torque: 30 NCm

Regular	H \ G/H	0.0	1.0	2.0	3.0	4.0
D Ø 4.0	5.5	BPSAC4005	BPSAC4010	BPSAC4020	BPSAC4030	BPSAC4040
D Ø 4.5	5.5	BPSAC4505	BPSAC4510	BPSAC4520	BPSAC4530	BPSAC4540
D Ø 5.0	5.5	BPSAC5005	BPSAC5010	BPSAC5020	BPSAC5030	BPSAC5040
D Ø 6.0	5.5	BPSAC6005	BPSAC6010	BPSAC6020	BPSAC6030	BPSAC6040
D Ø 4.5	7.0	BPSAC450570	BPSAC451070	BPSAC452070	BPSAC453070	BPSAC454070
D Ø 5.0	7.0	BPSAC500570	BPSAC501070	BPSAC502070	BPSAC503070	BPSAC504070
D Ø 6.0	7.0	BPSAC600570	BPSAC601070	BPSAC602070	BPSAC603070	BPSAC604070

BPBS1412N
Narrow

BPBS2012
Regular

Angled Abutment Cementable



• Recommended tightening torque: 30 NCm

Narrow	H	G/H	1.0	2.0	3.0	4.0
α=15° DØ 4.0	7.5		BPAAC401015N	BPAAC402015N	BPAAC403015N	BPAAC404015N
α=15° DØ 4.5	7.5		BPAAC451015N	BPAAC452015N	BPAAC453015N	BPAAC454015N

Regular	H	G/H	1.0	2.0	3.0	4.0
α=15° DØ 4.5	7.5		BPAAC451015	BPAAC452015	BPAAC453015	BPAAC454015
α=15° DØ 5.0	7.5		BPAAC501015	BPAAC502015	BPAAC503015	BPAAC504015
α=15° DØ 6.0	7.5		BPAAC601015	BPAAC602015	BPAAC603015	BPAAC604015
α=25° DØ 4.5	7.5		BPAAC451025	BPAAC452025	BPAAC453025	BPAAC454025
α=25° DØ 5.0	7.5		BPAAC501025	BPAAC502025	BPAAC503025	BPAAC504025
α=25° DØ 6.0	7.5		BPAAC601025	BPAAC602025	BPAAC603025	BPAAC604025

BPBS1412N
Narrow

BPBS2012
Regular

UCLA Abutment

Basal Screw

D Ø 4.0 N

G/H	1.0	
Type	Hex	Non-Hex
	BPUAH1012N	BPUANH1012N

D Ø 4.5 R

G/H	1.0	
Type	Hex	Non-Hex
	BPUAH1012	BPUANH1012

Temperory Abutment

Basal Screw

D Ø 4.0 N

G/H	1.0	3.0
	BPTA4010N	BPTA4030N

D Ø 4.5 R

G/H	1.0	3.0
	BPTA4510	BPTA4530

Ball Abutment

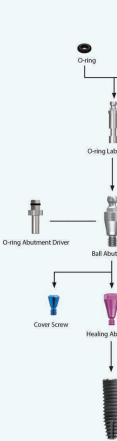
D Ø 3.5 N

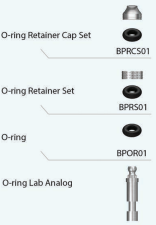
G/H	1.0	2.0	3.0	4.0	5.0
	BPBA3510N	BPBA3520N	BPBA3530N	BPBA3540N	BPBA3550N

D Ø 3.5 R

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

Prosthetic Diagram
Ball Abutment Overdenture





Pre Milled Abutment

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

Holder	System	Daimeter	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

Surgical Plan

simple & friendly

POLARIS Surgical Kit

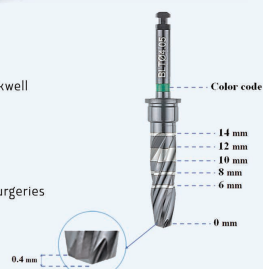
BLT Drill

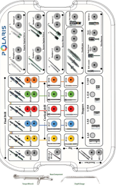
Hardening with 60 Rockwell

Sharp drill with 3 Flute

Coated with AlTiN

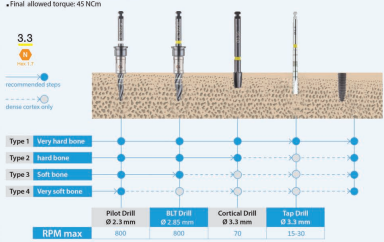
Life length up to 200 surgeries




POLARIS
Final Drill
Cortical drill
Stoppers
Torque Wrench
Depth Gauge

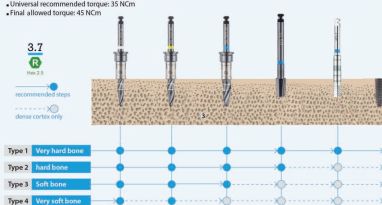
Surgical Procedure

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



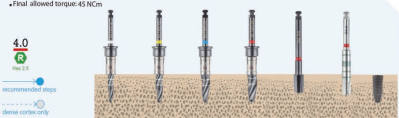
	Pilot Drill Ø 2.3 mm	BLT Drill Ø 2.85 mm	Cortical Drill Ø 3.3 mm	Tap Drill Ø 3.3 mm
RPM max	800	800	70	15-30

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



	Pilot Drill Ø 2.3 mm	BLT Drill Ø 2.85 mm	BLT Drill Ø 3.25 mm	Cortical Drill Ø 3.7 mm	Tap Drill Ø 3.7 mm
RPM max	800	800	600	70	15-30

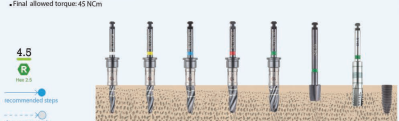
- Universal recommended torque: 35 NCm
- Final allowed torque: 45 NCm



Type 1	Very hard bone
Type 2	hard bone
Type 3	Soft bone
Type 4	Very soft bone

	Pilot Drill Ø 2.3mm	BLT Drill Ø 2.85 mm	BLT Drill Ø 3.25 mm	BLT Drill Ø 3.55 mm	Cortical Drill Ø 4.0 mm	Tap Drill Ø 4.0 mm
RPM max	800	800	600	500	70	15-30

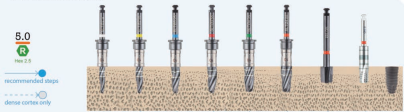
- Universal recommended torque: 35 NCm
- Final allowed torque: 45 NCm



Type 1	Very hard bone
Type 2	hard bone
Type 3	Soft bone
Type 4	Very soft bone

	Pilot Drill Ø 2.3mm	BLT Drill Ø 2.85 mm	BLT Drill Ø 3.25 mm	BLT Drill Ø 3.55 mm	BLT Drill Ø 4.05 mm	Cortical Drill Ø 4.6 mm	Tap Drill Ø 4.6 mm
RPM max	800	800	600	500	400	70	15-30

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



		Pilot Drill Ø 2.3mm	BLT Drill Ø 2.85mm	BLT Drill Ø 3.25 mm	BLT Drill Ø 3.55 mm	BLT Drill Ø 4.05 mm	BLT Drill Ø 4.55mm	Cortical Drill Ø 5.0 mm	Tap Drill Ø 5.0 mm
Type 1	Very hard bone								
Type 2	hard bone								
Type 3	Soft bone								
Type 4	Very soft bone								
RPM max		800	800	700	600	500	400	70	15-30

Note: