

CONIENT



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Bio3 IMPLANTS company





Bio3 Implants GmbH is a German company that offers doctors the best solutions of the highest quality and accuracy in implantology

REPRESENTATIVE OFFICES



Azerbaijan

Albania

Armenia

Belgium

Denmark

Egypt

Finland

France

Greece

Indonesia

Iraq

Jordan

Kazakhstan

Kosovo

Kuwait

Lebanon

Macedonia

Morocco

Mongolia

Netherlands

Norway

Nigeria

Oman

Pakistan

Poland

Russia

Saudi Arabia

Syria

Spain

Sweden

Tajikistan

Taiwan

Tunisia

Turkey

Uganda

Ukraine

UAE

United Kingdom

Vietnam



Main advantages of Bio3 Implants

RELIABILITY OF GERMAN MANUFACTURER





Das ist: **KONUS**





Technological manufacturing cycle of **Bio3** Implants dental implants is secured by high standards of German quality. All products go through several stages of quality control.

We are proud to be part of the German manufacturing quality culture



RELIABILITY AND QUALITY









Company has extended its production with modern technical equipment.

At the Bio3 Implants plant, modern

Japanese equipment is installed, which has the most accurate characteristics. ISO7 class clean room

QUALITY CERTIFICATES



bsi.



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

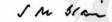
Bio3 Implants GmbH Hanauer Strasse 8 75181 Pforzheim Germany

Holds Certificate Number:

MD 679530

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, manufacturing and marketing of dental implants and accessories



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2019-02-05 Latest Revision Date: 2019-11-06



Effective Date: 2019-02-05 Expiry Date: 2022-02-04

Page: 1 of 1

...making excellence a habit."

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>ordine</u>.

Printed copies can be validated at www.bisiorup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowihill, Milton Keynes MKS 8PR, Tel: + 44 345 080 9000 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A Member of the BSI Group of Companies.





EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.

auad Tar

CE 630493 Bio3 Implants GmbH Hanauer Strasse 8 Pforzheim 75181 Germany

In respect of

The design and manufacture of sterile "Advanced" and "Progressive" dental implants, nonsterile abutments and prosthetic accessories.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex III section 4 entities is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary C Stade

Gary E Slack, Senior Vice President Medical Devices

First Issued: 2015-09-10

Date: 2020-12-22

Expiry Date: 2024-05-26

...making excellence a habit.

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the require syrrelance activities of the Netfield 6xVf. this approvide accusted all products designed and/or manufactured by a third party on behalf of the company raised on this certificate, unless specifically agreed with BSI. This certificate was assisted destroctivals and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 076 BSI Group The Netherlands B.V. registered in The Netherlands under 33/64/284.

Bio3 Implants

conducts continuous and systematic quality control of all products that is confirmed by international quality certificates ISO 13485, CE2797

ACTIVE SURFACE



The surface of Bio3 Implants - Active is formed by coarse sandblasting with corundum particles, due to which a macro-roughness of the titanium surface is achieved. And then - acid etching to obtain microroughness. As a result, microdepressions 2-4 microns in size are formed and the surface acquires an ideal topography for cell attachment. This surface is not microporous and therefore provides a site for tissue inclusion, which reduces bacterial colonization.

ACTIVE surface of **Bio3 Implants** dental implants



ACTIVE SURFACE

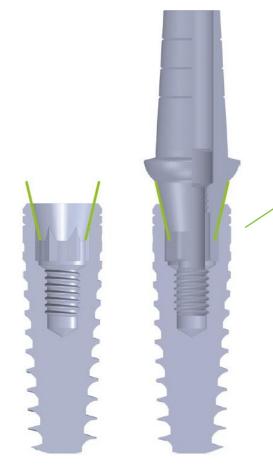


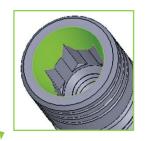
Microporous structure of **Bio3 Implants ACTIVE** surface stimulates active growth of bone tissue throughout entire implant surface that results in high mechanical stability and osseointegration within shorter period of time. It can be used with one or two-stage protocol

1800 magnification 3000 magnification 5000 magnification

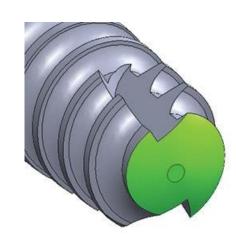
CONCAL CONNECTION & APICAL PART







Bio3 Implants tapered implant system ensures perfect tight connection between implant and abutment



Precise design of implant apical part prevents from damage of anatomical bone structure and provides the implantologist with possibility to decrease the time of surgical stage of implantation

TITANIUM GRADE 4







Titanium Grade 4 is used for production of premium dental implants

COMPLEMENT

Bio MPLANTS

Unique and perfect package



Implant complement:

- Implant in titanium flask
- Cover screw
- Instruction
- Sticker with lot number
- Double sterile package
- Warranty booklet
- USB flash drive



Contact of the implant with foreign particles is completely excluded. **Titanium flask** + titanium implant – the same material. Convenient removal of the implant using any instrument at doctor's choice

COMPLEMENT

Bio MPLANTS

Patient care



We care for our patients, that is why each implant is supplied with USB-flash drive allowing:

➢ record information of the patient (anamnesis, CT data and X-ray images)

record data of the installed implant

describe the clinical case as well as surgical protocol

>provide the patient with complete information of the operation

render full service for the patient. Our clients know what they pay for!

LIFETIME WARRANTY AND IDENTIFICATION



Each patient who has chosen high quality of **Bio3 Implants** is given the guaranty plastic card **providing lifetime warranty for dental implant. Lifetime warranty is valid globally**





All patient's data are specified on the card and the sticker with lot number, implant type and size is glued in.

Each **Bio3 Implants** product is assigned with a unique serial number that allows tracking product manufacturing from the first to the final stage

INDIVIDUAL RECOMMENDATIONS ON ORAL CAREFOR EACH PATIENT





For each implant the patient is given a book containing main recommendations on oral care after dental implantation

IMPLANTS



Implant **Bio3 Progressive**

is the latest development. Self-tapping, it provides excellent hold and primary stability. The spiral shape of the implant with varying thread depth is designed for better bone compression when used in types III-IV.



Implant Bio3 Advanced

has a unique design designed to provide ideal clinical results for a variety of dental implantation procedures. Its tapered shape and self-tapping triple thread simplifies the implantation process and provides a high level of primary stability. The micro-threaded cervical part of the implant reduces cortical stress and prevents bone resorption.

Bio3 Advanced

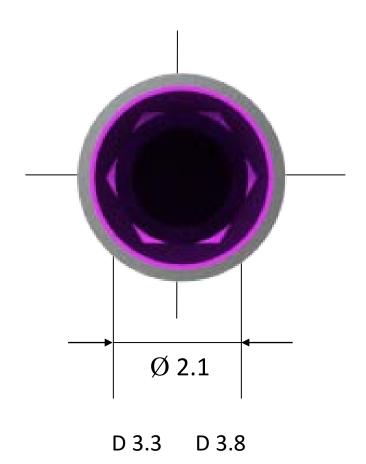
Implant Implant Bio3 Progressive



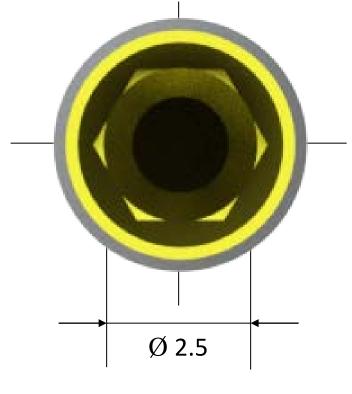
PLATFORMS



STANDARD PLATFORM



WIDE PLATFORM



D 4.2 D 5.0

SUPRASTRUCTURES





HEALING CAPS





STANDARD PLATFORM

d 4.2

WIDE PLATFORM

d 5.5

STANDARD PLATFORM

d 4.2

WIDE PLATFORM

d 5.5

HEALING CAPS







HEALING CAPS











STANDARD PLATFORM

d 3.2

WIDE PLATFORM

d 4.0

COVER SCREW HEALING CAPS





ABUTTIVENTS





WIDE PLATFORM

STRAIGHT ANATOMIC ABUTMENTS





STANDARD PLATFORM

WIDE PLATFORM

ANGULATED ANATOMIC ABUTMENTS 15





STANDARD PLATFORM

WIDE PLATFORM

STRAIGHT ABUTMENTS





STANDARD PLATFORM

WIDE PLATFORM

ANGULATED ANATOMIC ABUTMENTS 25





MULTUNTS



STANDARD PLATFORM

WIDE PLATFORM

ANGLED MULTIUNITS 17°

SCREW RETAINED ABUTMENTS















STANDARD PLATFORM





WIDE PLATFORM



STANDARD PLATFORM

WIDE PLATFORM

ANGLED MULTIUNITS 30°













BALL ATTACHMENT & LOCATORS



STANDARD PLATFORM

WIDE PLATFORM

BALL ATTACHMENTS









WKBA

SKBA

FKBA

PRB











STANDARD PLATFORM

LOCATORS

WIDE PLATFORM



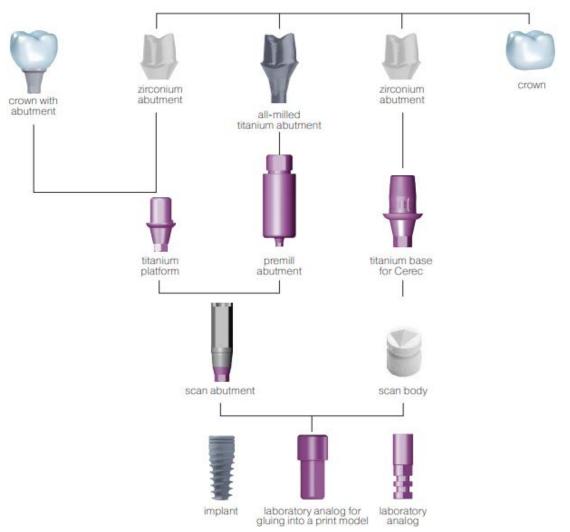


CAD/CAM





Company **Bio3 Implants** is presented in **"3Shape"** and **"Exocad"**



TRANSFERS&ANALOGS





WIDE PLATFORM







STANDARD PLATFORM

WIDE PLATFORM

DIGITAL ANALOGS





STANDARD PLATFORM

WIDE PLATFORM

IMPRESSION TRANSFERS FOR OPEN TRY





STANDARD PLATFORM

WIDE PLATFORM

IMPRESSION TRANSFERS FOR CLOSED TRY





BIOLINE SUPRASTRUCTURES





BIOLINE SUPRASTRUCTURES are

identical to section shape of natural teeth.

- Biological construction is identical to natural tooth shape
- Scalloped edges coincide with gingival margin line
- ➤ High precision of implantabutment connection

BIOLINE HEALING CAPS





STANDARD PLATFORM

WIDE PLATFORM

STANDARD PLATFORM

WIDE PLATFORM

HEALING CAPS FOR INCISORS





HEALING CAPS FOR PRE-MOLAR





HEALING CAPS FOR CANINES





HEALING CAPS FOR MOLARS





BIOLINE ABUTIMENTS





WIDE PLATFORM

ABUTMENTS FOR INCISORS/ CANINES







STANDARD PLATFORM

WIDE PLATFORM

ANGULATED ABUTMENTS INCISORS TYPE 15° /25°





STANDARD PLATFORM **ABUTMENTS FOR PRE-MOLARS/ MOLARS**

WIDE PLATFORM







STANDARD PLATFORM

WIDE PLATFORM

ANGULATED ABUTMENTS CANINE TYPE 15° /25°







SURGICAL KIT







Bio3 Surgical Kit is intended for prompt and convenient installation of two types of implants – **standard and wide** platform

TOOLS





GUIDE SURGICAL KIT







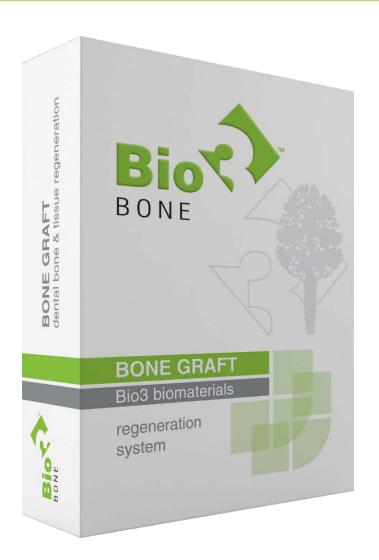


Bio3 Guide Surgical Kit is intended for prompt and convenient installation of two types of implants – standard and wide platforms

SPECIAL PROPOSAL FOR DOCTOR & PATIENT

MATERIAL FOR BONE REGENERATION





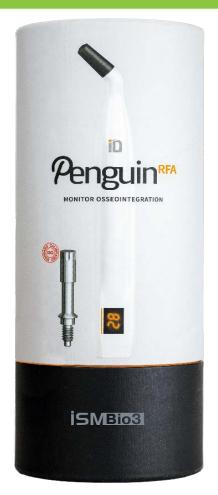
- Bovine bone
- Synthetic substitute

Due to hydrophilic surface of **Bio3 BONE** its mixing with blood or normal saline ensures optimal viscosity and plasticity. 3D porous structure facilitates fast penetration of serum and proteins that is a factor of bone tissue growth

Bio3 PENGUIN MONITOR OSSEOINTEGRATION





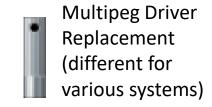


PenguinRFA - Removes Doubt

In todays' implant dentistry, the trend is to use short or no healing periods before loading. This places high demands on the clinical team. If conditions are not optimal, poor primary stability may increase the risk of implant failure.

PenguinRFA provides accurate and objective measurements of implant stability, serving as a reliable support when taking decisions when to load.





Resonance Frequency Analysis (RFA) was introduced in implant dentistry more than 20 years ago. A peg attached to an implant is excited and the vibration frequency is picked up by the instrument and presented as an ISQ (Implant Stability Quotient) value.

Bio3 VITAMIN COMPLEX

Bio MPLANTS

Bio3 Formula is a unique vitamin complex developed by Bio3 Implants GmbH, to enhance the process of osseointegration.





It is a course that consists of three stages:

- 1. PRE IMPLANT
- 2. COMPLEX REGENERA COMPLEX
- 3. POST IMPLANT COMPLEX

Bio3 IMPLANTS FOAM



Unique formula of **Bio3 IMPLANT CARE FOAM** accelerates process of gingiva healing, reduces the risk of edema and maintains oral hygiene after surgical stage of implantation. Researches show that in contrast with use of other liquids, application of **Bio3 IMPLANT CARE FOAM**

in first days after implantation shortens the period of implant survival and prevents complications in post-operative period

Product for oral care after implantation













MARKETING SUPPORT

MARKETING SUPPORT









bio3-implants.com info@bio3-implants.com Range of advertising tools to ensure effective sales of the Dealer

EXCURSIONSTOBIO3 IMPLANTS PRODUCTION SITE





Quarterly trips to
Bio3 Implants
production site in
Germany



PARTICIPATION IN INTERNATIONAL EXHIBITIONS









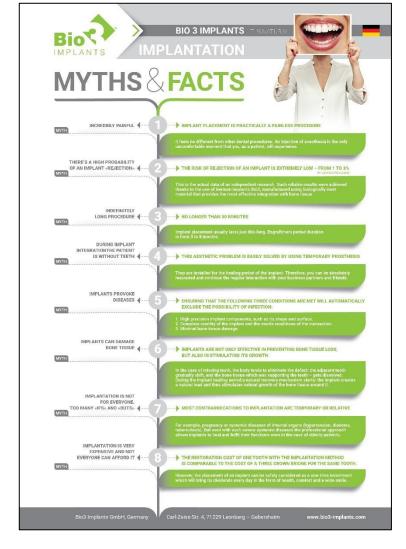
USEFUL MATERIALS FOR PATIENTS







Posters for waiting rooms: Main Stages of Implantation



Posters for waiting rooms: **Myths & Facts**

USEFULMATERIALS FOR PATIENTS



Bio3 it is natural

GUIDELINES FOR CARE OF YOUR MOUTH



AFTER DENTAL IMPLANT TREATMENT

Thank you for using our implant system Bio3 Implants. We give a lifetime warranty on our products. We want your recovery to be as smooth and pleasant as possible and it is vital to follow these instructions very carefully.

The long-term success of a dental implant hinges on the patient's home care, and it involves two stages:

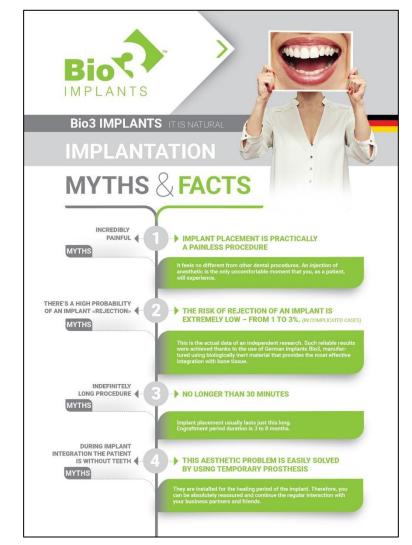
- During and immediately after your implants are placed.
- Continuing care after your implants have established themselves.

Proper home care of your dental implants will help prevent peri-implant gingivitis (a mild form of gum infection), peri-implant ostelits (inflammation of the bone), and damage to the artificial tooth

IMMEDIATELY AFTER SURGERY

- If antibiotics or/and pain medication are prescribed, follow your dentist's post operative instructions, regarding the dosage and proper time to take your medicines. Especially for antibiotics, you should take them for as many days as directed by your dentist, don't stop them earlier.
- Some bleeding is normal for 24 hours. Bleeding can be controlled by biting on a gauze pad
 or a moist tea bag placed directly on the bleeding wound for 30 minutes. If there is excessive
 bleeding or it continues beyond the second day call your dentist.
- Do not take any aspirin or aspirin compounds because it may induce bleeding.
- Don't spit or suck on straws. This can dislodge blood clots and slow healing.
- Keep physical activities to a minimum immediately following surgery.
- Swelling is a normal occurrence after surgery. You may use an ice pack on the side of your face and the sides of your jaws for the first 48 hours after surgery to reduce swelling.
- You should not eat or drink hot foods for 24 hours after your surgery. Hot food and/or drinks
 can cause bleeding or an increase in bleeding. Drink plenty of fluids.
- Do not smoke because it delays healing and increases the chance of infection.
- Please start to use the chlorhexidine mouthwash that you will be given, on the evening of surgery and continue for 1 week. You should hold half a cap-full over the surgical site for 1 minute, twice times a day for 7 days. This will keep the healing site clean even if you are not able to clean it with a toothbrush.
- A fairly soft diet should be maintained for several months following surgery while the implant area heals. Avoid hard or crusty foods, especially during the first part of the postoperative phase. Proper diet is an essential part of dental implant surgery aftercare.

Instruction for patients on oral care



Implantation: Myths & Facts (Leaflet)

USEFUL MATERIALS FOR PATIENTS





Personal calendar of implantation

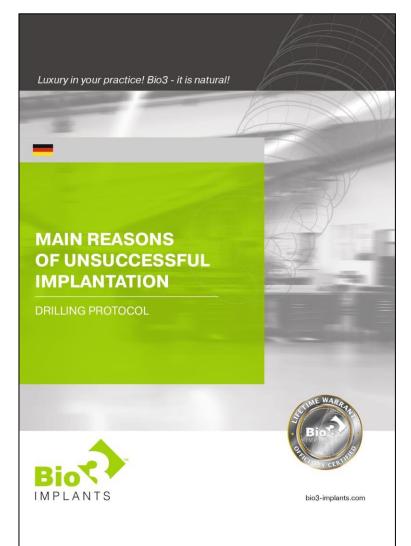


6 reasons to install Bio3 Implants dental implants



USEFUL MATERIALS FOR DOCTORS





Reasons of unsuccessful implantation — the most complete guidelines to minimize the risks of implant failure

Bio3

INSTRUCTIONS

FOR USE FOR Bio3
IMPLANTS PRODUCTS



General precaution

Before using Bio3 Implants product, the operating surgeon/practitioner in charge should carefully study the indications, contraindications, recommendations, warnings and instructions, as well as all other product specific information (technical product description, description of the surgical and restorative technique, catalogue sheet, etc.) and fully comply with them. The manufacture, the importer and the suppliers of Bio3 Implants products are not liable for complications, other negative effects or damages that might occur for accessors such as incorrect indications or surgical technique, unsuitable choice of material or handling thereof, unsuitable use or handling of the instruments, asepsis and so on. The operating surgeon is responsible for any such complications or other consequences.

Cautions and Warning

- Bio3 Implants Drills are to be used only by a licensed dentist who has the specialization, skills and the
 appropriate training in dental implants and restoration in order to assure successful treatment.
- Always wear Gloves when handling contaminated instruments.
- Eye protection must be worn to protect against ejected particles.
- Surgical mask must be worn to avoid inhalation of aerosol or dust generated.
- Inspect the drill for damage or wear before each use and discard/return to manufacturer defective drills.
- Ensure that the drill is fully seated and gripped in the handpiece collet before use.
- Maintain handpiece in good working order and correctly lubricated.
- . Do not exceed the maximum speeds indicated in this leaflet.
- Avoid excessive drilling speed and/or drilling duration in order to avoid overheating and associated complications.
- Move the drill continuously when in use to avoid localized heating.
- Clean and sterilize the drills in accordance with the directions below before first use and before each reuse.

Introduction - Intended Use

Bio3 Implants¹ Drill is for preparation of the jawbone for dental implant. The Implant Drill Accessories assist the Implant Drill in its use.

General Information

All instruments must be cleaned and sterilized prior to use. The drills have been marked with sizes and color coded for ease of identification. Size marking and color coding should be used to select proper drill for each surgical procedure.

Implant Drills are susceptible to damage and wear and should be inspected before use.

1 The drills and accessories shank meets the requirements of ISO 1797-1.

Instruction on surgical tools processing

USEFUL MATERIALS FOR DOCTORS





Implantation Check List

DISINTEGRATED	IMPLANT		BIO VIMPLANTS
Doctor's name: Clinic name: Clinic address: Return date	Jay month, year		
Implant: Size	Code		Jaw: maxilla mandible
Failure date		Installation date	
Osseointegration period:	implantation date less than 3 months after im more than 3 months after in		
After loading: (period from the restoration day	on restoration day less than 3 months from the 3-6 months from the restora 6-12 months from the restora	tion day	1-3 year 3-5 year 5-7 year
Patient's name:			Age Sex
Health condition, bad habits	smoking, if yes - number per poor oral cavity hygiene hormonal dysfunction medicines administration	r day	diabetes somatic diseases no systemic disease
Bone type: 1	2 3 4		
	Trea	tment	
		two-stage	immediate
Surgical stage	Protocol: one-stage	two-stage	
Surgical stage Loading (force)	Protocol: one-stage	Primary stabilit	y index
		100000 10000 10000 10000 10000 10000 10000 10000 10000 10000 10000 10000 10000 10000 10000 10000 10000 10000 1	y index
Loading (force)		Primary stabilit	
Loading (force) Number of installed impl		Primary stabilit	yes no

Replacement Form for disintegrated implant

TRAININGS FROM Bio 3 IMPLANTS







- monthly webinars on company products and their practical application
- regular seminars and master classes (theory and practice) for doctors of different competence level

Top specialists, the most relevant topics!

Each participant obtains name certificate of training completion

Bio3 IMPLANTS ADVANCED+





Bio3 Implants GmbH is a German company that offers doctors the best solutions of the highest quality and precision in implantology. Designs, manufactures and markets a reliable and high quality premium tapered implant system. The Bio3 Implant Advanced system update is now being prepared, which we are looking forward to.

GOALS





your customer's smile is our mutual success!

