THOMMEN Medical

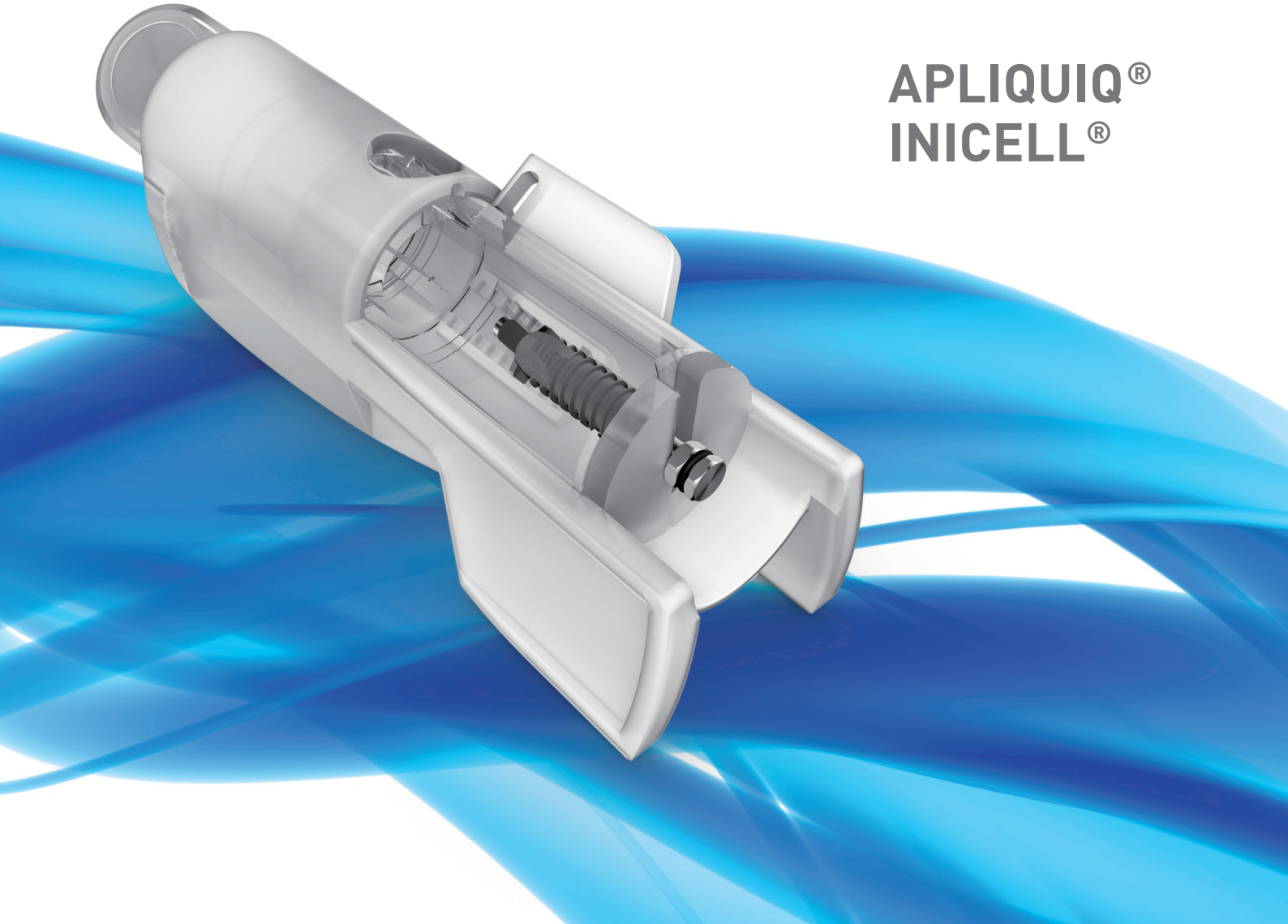
INICELL® APLIQUIQ®

The Innovation is in the Conditioning

Product documentation

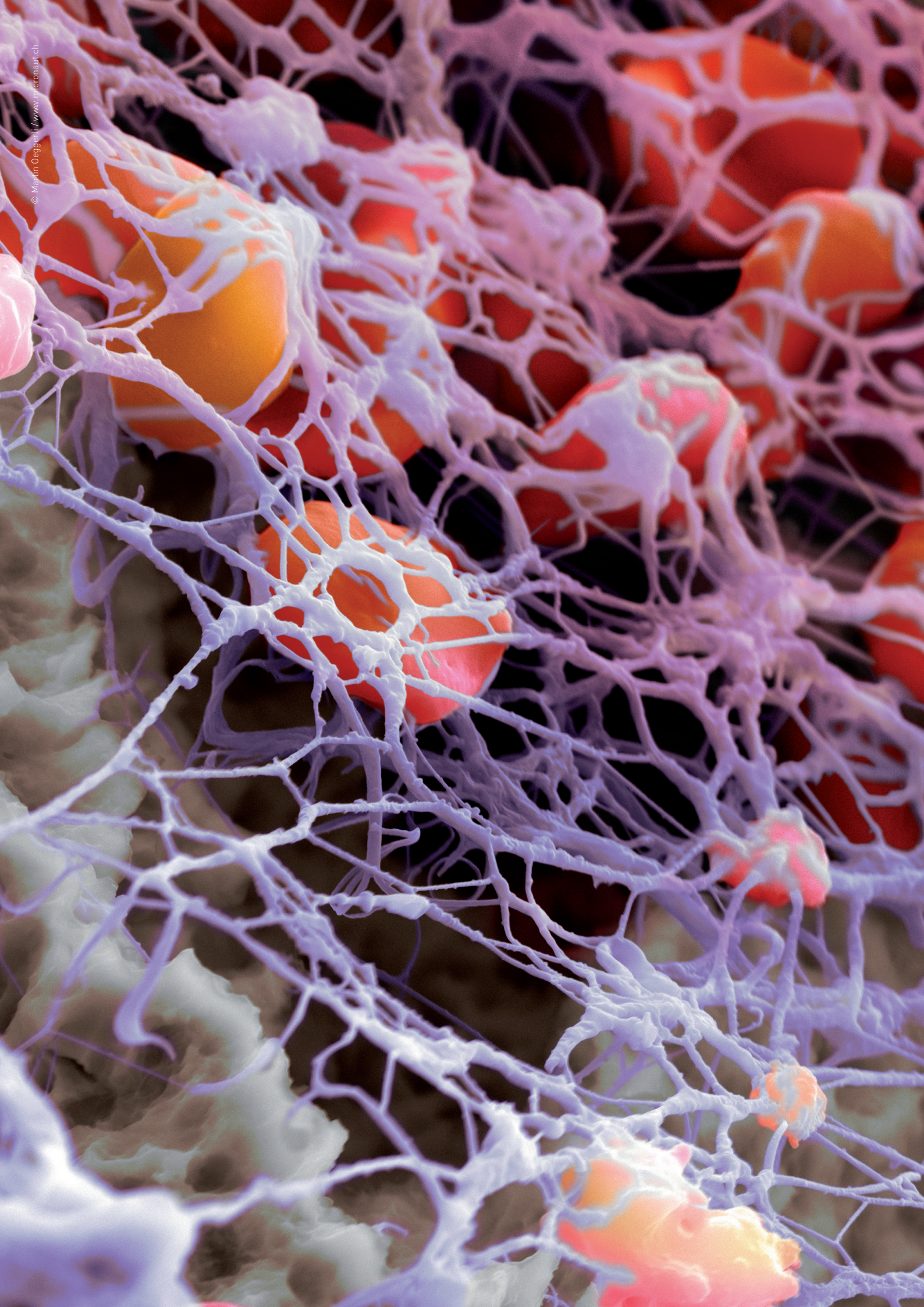
Driven by science, not trends.

The Innovation is in the Conditioning.



APLIQUIQ®
INICELL®

Contents



INICELL®

Evolution in surface technology.

The concept

"Gold standard" surface topography

INICELL represents the further development of the sandblasted and thermal acid-etched Thommen surface. In today's dental implant field, sandblasted and thermal acid-etched surfaces are considered the "gold standard" (page 6). Results obtained from investigations of the proven microrough Thommen implant surface have confirmed this fact (page 7).

Picture left: Fibrin network on the microrough Thommen surface

Surface chemistry and conditioning

INICELL is the conditioned state of the sandblasted and thermal acid-etched Thommen implant surface. During conditioning the surface chemistry of the microrough surface is slightly modified. Conditioning occurs immediately before implantation through contact with the conditioning agent (patent pending). The result of this process is increased surface energy and improved wettability due to superhydrophilic properties (page 9).

Protein adsorption and blood coagulation

Biologically, improved wettability leads to a homogenous adsorption of proteins on the implant surface (page 10). This leads to more activated thrombocytes and a homogenous, thicker fibrin network in the early stages of osseointegration (page 11).

Animal scientific research on osseointegration

The animal studies on INICELL implants in comparison with unconditioned Thommen implants have shown that osseointegration occurs faster with INICELL than with the unconditioned surface in the dog mandible. Based on higher removal torque values, the biomechanical investigations for INICELL suggest increased implant stability in the early healing phase, though without statistical significance (pages 12–13).

Implants with INICELL may be loaded in 3 weeks in most cases. This translates into greater treatment flexibility. Although results in animal studies are not necessarily predictive of human clinical results, and although more studies are necessary to confirm trends and establish statistical significance, early scientific research in animal studies suggests:

- Continued increase in stability during the first 8 weeks following placement* (page 12)
- Higher implant stability during the early healing phase** (page 12)
- Higher bone-to-implant contact in the early healing phase of 2–4 weeks as well as with immediate placement protocols* (page 13)

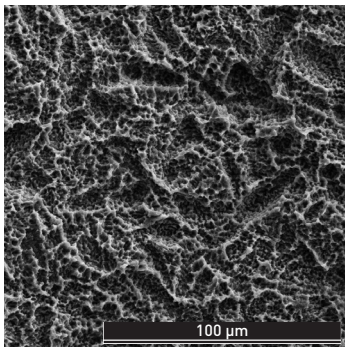
Clinical data

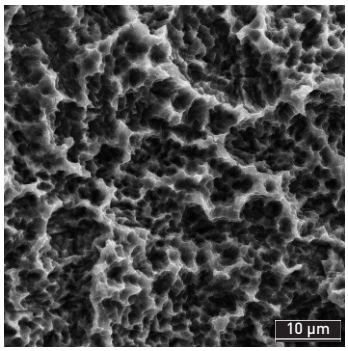
Broad clinical research is conducted to demonstrate the advantage of INICELL in the early healing phase of typical cases in good as well as in poor bone quality and high-risk patients (page 15).

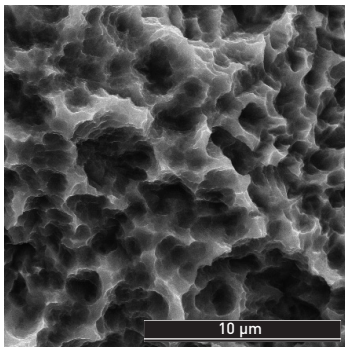
* Statistically significant ($p<0.001$)

** Not statistically significant

“Gold standard” surface topography







Scanning electron microscopic images of the microrough sandblasted and thermal acid-etched surface of Thommen implants with increasing magnification

Based on the results of clinical studies and clinical experience, microrough implant surfaces have almost completely replaced “machined” smooth surfaces. The functional and structural anchorage of load-carrying implants in the bone is possible due to osseointegration, i.e. the direct contact between the implant surface and the surrounding bone.[1, 2]

The sandblasted and thermal acid-etched surface

Among the surface topography modification techniques, subtractive procedures, such as sandblasting, acid-etching, or a combination of both, are largely preferred over additive surface enlargement procedures, such as titanium plasma spray (TPS) or hydroxyapatite (HA) coatings.

Many consider the microrough surface created by a combination of sandblasting and thermal acid-etching to be the “gold standard” for implant surface modification.[3, 4, 5, 6, 7, 8, 9]

All Thommen implants use sophisticated sandblasted and thermal acid-etched surface modification technology.

Advantages of microrough surfaces

Sandblasted and thermal acid-etched implant surfaces establish excellent functional and structural connections between the bone and the implant surface, leading to higher intrinsic implant stability.[10] Specifically, the microroughness enhances the interlocking of the implant surface with bone and has been shown to promote the differentiation of osteogenic cells in vitro.[11]

1 Albrektsson T, Brånemark PI, Hansson HA, Lindström J. Acta Orthop Scand. 1981; 52(2): 155-70.
2 Brunette DM, Tengvall P, Textor M, Thomsen P. Titanium in medicine: material science, surface science, engineering, biological responses and medical applications. Springer-Verlag Berlin, Heidelberg, New York 2001.
3 Albrektsson T, Wennerberg A. Int J Prosthodont. 2004; 17(5): 536-43.
4 Albrektsson T, Wennerberg A. Int J Prosthodont. 2004; 17(5): 544-64. Review.
5 Cochran DL, Buser D, ten Bruggenkate CM, Weingart D, Taylor TM, Bernard JP, Peters F, Simpson JP. Clin Oral Implants Res. 2002; 13(2): 144-53.
6 Wennerberg A, Albrektsson T. Clin Oral Implants Res. 2009; 20 Suppl 4: 172-84. Review.
7 Junker R, Dimakis A, Thoneick M, Jansen JA. Clin Oral Implants Res. 2009 Sep; 20 Suppl 4: 185-206.
8 Bornstein MM, Lussi A, Schmid B, Belser UC, Buser D. Int J Oral Maxillofac Implants. 2003; 18(5): 659-66.
9 Bornstein MM, Schmid B, Belser UC, Lussi A, Buser D. Clin Oral Implants Res. 2005; 16(6): 631-38.
10 Buser D, Nydegger T, Oxland T, Cochran DL, Schenk RK, Hirt HP, Snétivy D, Nolte LP. J Biomed Mater Res. 1999; 45(2): 75-83.
11 Boyan B et al. Titanium in medicine. Brunette DM et al. (eds.) Springer, 2001: 562-79.

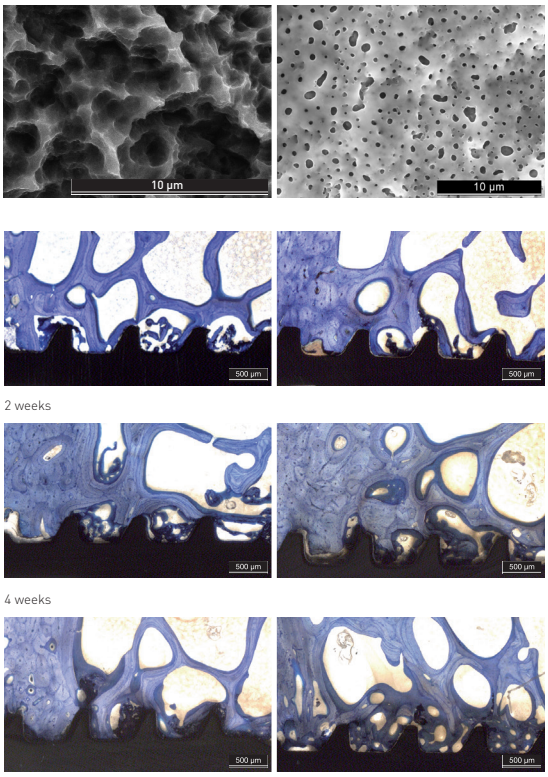
Experimental comparison of surface topographies[12, 13]

The microrough, sandblasted and thermal acid-etched surface of Thommen implants has been investigated in various studies. The studies have shown the biomechanical and histological properties of the Thommen surface to exhibit advantages over the alternate topographies of other implant surfaces in regards to osseointegration.[14]

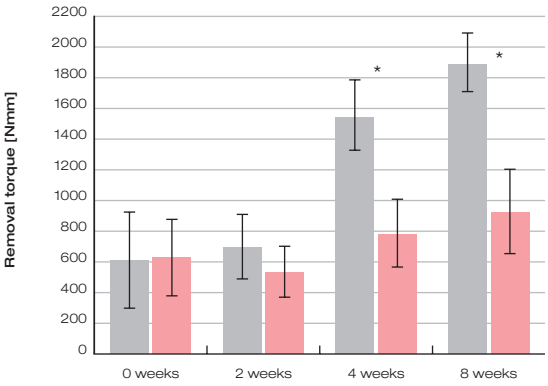
Reference ELEMENT implants having the microrough Thommen surface show a significantly higher removal torque after 4 and 8 weeks healing time in animals as compared to ELEMENT implants having an experimental porous titanium oxide surface of which the structure was produced by anodic plasma chemical (APC) oxidation.
Initially, both surfaces achieve comparable biomechanical implant stability (internal data). After 8 weeks of healing time the biological secondary implant stability of the microrough reference surface was significantly higher.
It is clearly evident from analysis of the macroscopic, radiographic, and histomorphometric results that the osseointegration of the microrough reference surface in the period of 2 to 8 weeks after implantation is continuously progressive.

Conclusion

The osseoconductive properties of Thommen implants with the microrough reference surface are confirmed in animals by the increase in the bone-to-implant contact (BIC) in the postoperative observation period of 8 weeks.
Based on the biomechanical data, the positive effect of this increase in BIC on biological secondary implant stability can be seen.



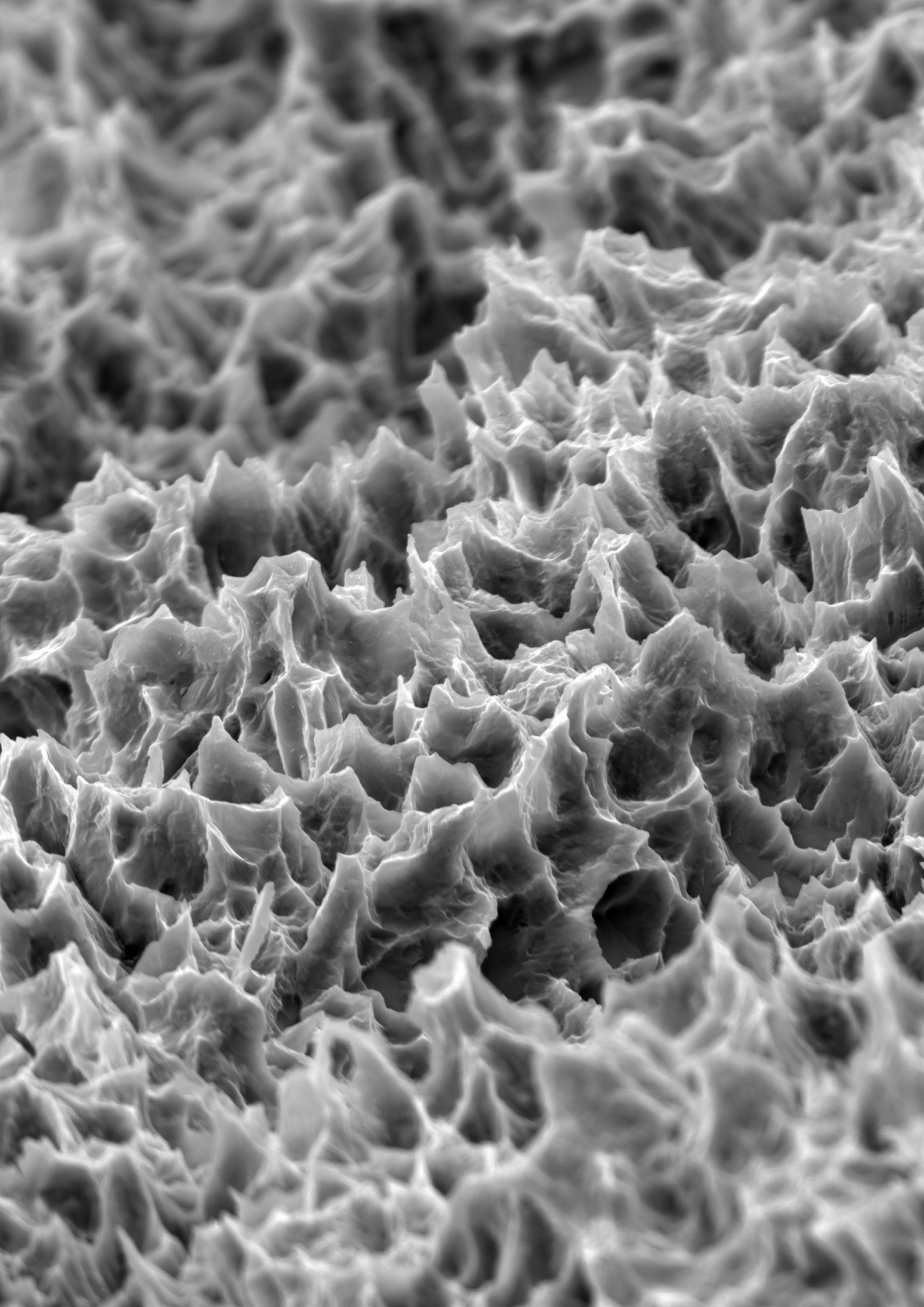
Pictures on top row: Scanning electron microscopic images of the investigated microrough unconditioned Thommen surface (left) and the porous APC-modified surface (right)
Pictures below: The histograms show the interface of bone and implant surface at the indicated time points (left with microrough unconditioned Thommen surface and right with porous APC-modified surface)



Microrough unconditioned Thommen surface
Porous surface (APC)
* Statistically significant (p<0.001)

The graph shows the continuous increase of stability of implants with reference surface of Thommen implants

12 Ferguson SJ, Langhoff JD, Voelter K, von Rechenberg B, Scharnweber D, Bierbaum S, Schnabelrauch M, Kautz AR, Frauchiger VM, Mueller TL, van Lenthe GH, Schlottig F. Int J Oral Maxillofac Implants. 2008; 23(6): 1037-46.
13 Langhoff JD, Voelter K, Scharnweber D, Schnabelrauch M, Schlottig F, Hefti T, Kalchofner K, Nuss K, von Rechenberg B. Int J Oral Maxillofac Surg. 2008; 37(12): 1125-32.
14 Publications on the Thommen Implant System are listed on the website: www.thommenmedical.com

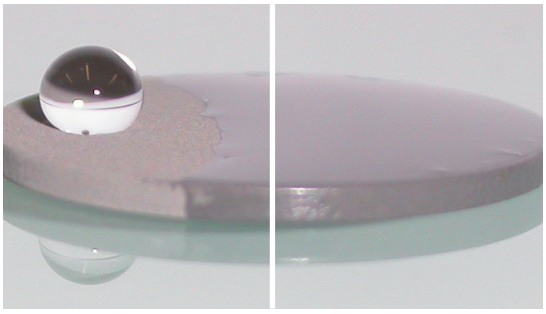


Surface chemistry and conditioning

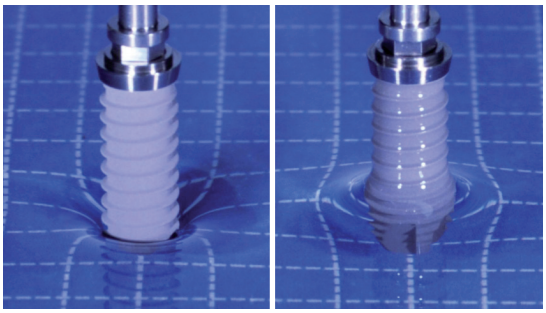
The surface chemistry of titanium implants is mainly determined by the presence of a natural oxide layer with a thickness in the nanometer range.
The physicochemical properties of this titanium dioxide layer are altered, as during handling and storage such surfaces will react with air over time, leading to a reduction in surface energy. As a result, over time titanium implants usually develop a hydrophobic, i.e. water-repellent, surface.[15] A hydrophobic surface is generally considered to have a water contact angle of more than 90 degrees.

By slightly changing the surface chemistry, it is possible to increase surface energy and change a hydrophobic surface into a hydrophilic (water-attracting) or, ideally, a superhydrophilic surface. Superhydrophilic surfaces exhibit a water contact angle of less than 5 degrees (spontaneously wetting).

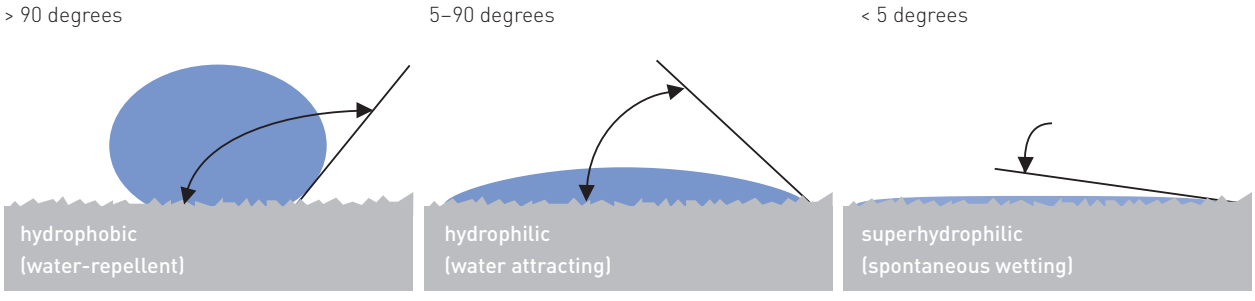
With APLIQUIQ, the surface chemistry of the microrough implant surface is slightly modified during the conditioning process, resulting in the superhydrophilic implant surface INICELL.
These properties of INICELL promote spontaneous and complete wetting of the implant with physiological fluids, particularly blood.[16]



Sandblasted and thermal acid-etched model substrate with water on the unconditioned (left) and conditioned (right) surface



Wetting experiment with a ELEMENT implant with unconditioned surface (left) and INICELL (right)

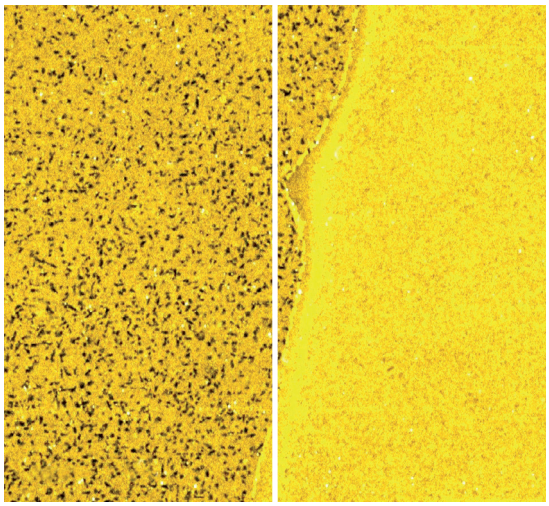


Schematic illustration and classification of water contact angles on microrough surfaces

Picture left: Scanning electron microscopic image of the sandblasted and thermal acid-etched Thommen surface at 17,000 times magnification. By courtesy of Martin Oeggerli (www.micronaut.ch).

15 Massaro C, Rotolo P, De Riccardis F, Milella E, Napoli A, Wieland M, Textor M, Spencer ND, Brunette DM. J Mater Sci Mater Med. 2002 Jun; 13(6): 535-48.
16 Tugulu S, Löwe K, Scharnweber D, Schlottig F. J Mater Sci Mater Med. 2010; 21(10): 2751-63.

Primary contact and protein adsorption



Fluorescence microscopic pictures of the protein film on model substrates five minutes after primary contact with protein solution (left unconditioned, right conditioned surface)

Surface energy and hydrophilicity play a crucial role in the primary interaction of an implant with its physiological environment.[17]

This interaction begins immediately upon the first blood contact, in the form of rapid adsorption of a film of plasma proteins. The quantity, composition, homogeneity and functionality of the protein film deposited on the implant surface directly influences the healing and osseointegration processes to follow.[18]

In-vitro data on protein adsorption[19]

Primary contact of an implant surface with its physiological environment can be simulated and investigated in studies of protein adsorption. The quantity and homogeneity of the adsorbed protein film as a function of time can be visualized directly using microscopic procedures.

The superhydrophilic surface INICELL was compared to the unconditioned microrough Thommen reference surface. Fluorescence microscopic pictures of a model substrate illustrate the primary contact after the addition of a physiological protein solution.

The protein film on INICELL is formed homogeneously and completely. In contrast, the reference surface shows an incomplete and inhomogeneous protein film due to non-wetted surface cavities. In the micrograph the protein film appears in yellow whereas the areas non-covered by protein remain black.

Conclusion

The improved and homogenous adsorption of proteins is expected to favor the subsequent healing and osseointegration process.

17 Brodbeck WG, Patel J, Voskerician G, Christenson E, Shive MS, Nakayama Y, Matsuda T, Ziats NP, Anderson JM. Proc Natl Acad Sci USA. 2002; 99(16): 10287-92.
18 Tengvall P. In Bio-Implant Interface: Improving Biomaterials and Tissue Reactions. Ellingsen JE, Lyngstadaas SP (eds.), CRC Press: Boca Raton, London, New York, Washington D.C. 2003, Chapter 16.
19 Tugulu S, Hall H, Schlottig F. Clin Oral Implants Res. 2009; 20(9): 1024-25 (poster no. 376) and Tugulu S, Löwe K, Scharnweber D, Schlottig F. J Mater Sci Mater Med. 2010; 21(10): 2751-63.

Blood coagulation and tissue formation

The blood coagulum can be considered as the first provisional tissue that forms around an implant. The fibrin matrix and activated thrombocytes can be considered as key players within the coagulum by providing a scaffold for the invasion of osteogenic cells and by releasing cytokines and growth factors for cell recruitment and differentiation, respectively.

The biological activity of the blood coagulum is directly linked to the physicochemical properties of the implant by the adsorption and activation of blood coagulation factors on the implant surface.

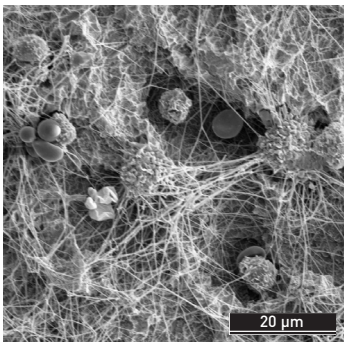
In-vitro data on thrombocyte activation and blood coagulation [20]

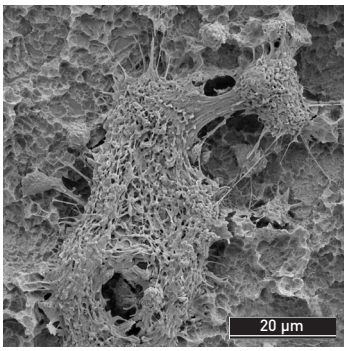
In an in-vitro study the activation of the blood coagulation cascade and the formation of a blood clot on the superhydrophilic surface INICELL and on an unconditioned microrough reference substrate were compared.

The composition, structure and organization of the forming blood clot did significantly differ on the two substrate types. Both the activation of blood coagulation and the number of activated thrombocytes were increased on INICELL substrates.

Conclusion

The results of this study suggest that the faster osseointegration of microrough implants with INICELL might be linked to an accelerated wound healing resulting from variations in the activation of blood coagulation and the structure of the forming coagulum.
The animal data shown in the following pages suggest that this hypothesis may be true, though additional studies are needed to confirm the trends shown in these studies.



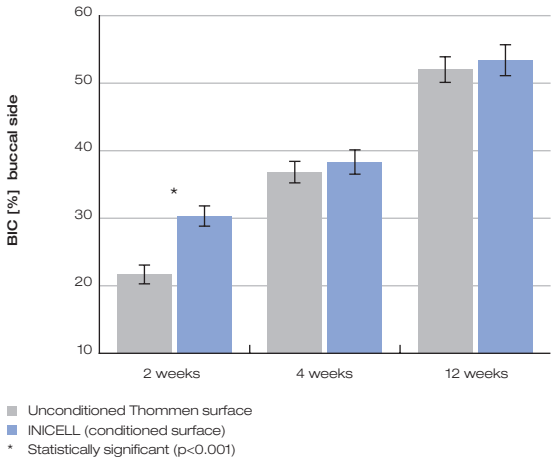


Scanning electron microscopic pictures of the blood coagulum on model substrates 10 min after primary contact with blood

Above: INICELL (conditioned surface) with fibrin network, thrombocytes and leucocytes
Below: unconditioned surface with thrombocytes and few fibrin fibres

20 Milleret V, Tugulu S, Schlottig F, Hall H. Eur Cell Mater. 2011; 21: 430-44; discussion 444.

Animal scientific data on osseointegration



The graph shows 40% higher buccal BIC with INICELL in the early healing phase of the beagle dog model.

The performance and benefits of INICELL have been investigated in a number of preclinical animal studies.
These results confirm in-vitro and animal studies from the published literature which highlight the advantages of superhydrophilic, microrough surfaces.

Evaluation of INICELL in different animal models

ELEMENT implants with INICELL were compared to unconditioned reference implants of the same type in the following three different animal models:

- pelvis of sheep [21]
- mini-pig mandible [22]
- beagle dog mandible [23]

All relevant macroscopic, radiographic, histomorphometric, and biomechanical parameters were taken into consideration.

Biomechanical results

In the pelvis of sheep as well as the mandibula of mini-pigs the mean removal torque of INICELL was increased by approximately 10% after 2 weeks compared to the unconditioned reference surface. However, these data were not statistically significant.

In the mini-pig mandible, a continuous statistically significant improvement in mean removal torque for both INICELL and reference surface was seen from two weeks to four and eight weeks ($p<0.001$).

21 Ferguson SJ, Langhoff JD, Voelter K, von Rechenberg B, Scharnweber D, Bierbaum S, Schnabelrauch M, Kautz AR, Frauchiger VM, Mueller TL, van Lenthe GH, Schlottig F. Int J Oral Maxillofac Implants. 2008; 23(6): 1037-46.
22a Stadlinger B, Lode AT, Eckelt U, Range U, Schlottig F, Hefti T, Mai R. J Clin Periodontol. 2009; 36(10): 882-91.
22b Stadlinger B, Ferguson SJ, Eckelt U, Mai R, Lode AT, Loukota R, Schlottig F. Br J Oral Maxillofac Surg. 2012; 50(1): 74-9.
23 Calvo-Guirado JL, Ortiz-Ruiz AJ, Negri B, López-Marí L, Rodriguez-Barba C, Schlottig F. Clin Oral Implants Res. 2010; 21(3): 308-15.

Histological results

Histomorphometric and radiographic analysis confirmed good osseointegration with well-formed bone-to-implant contact (BIC) after only two weeks for both surfaces in the following animal models:

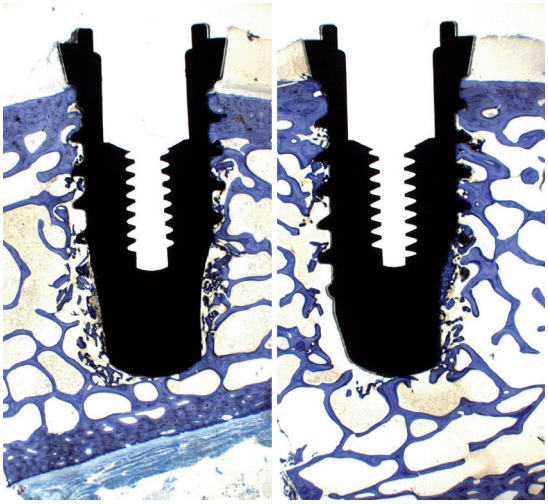
In the pelvis of sheep the results of the INICELL surface suggested an increase in bone-to-implant contact up to 18% after two weeks of healing time, though the differences were not statistically significant.

In the mini-pig mandible implants with INICELL showed a trend of 20% higher mean BIC compared to the reference surface after only two weeks of healing time. However, these trends were not statistically significant.

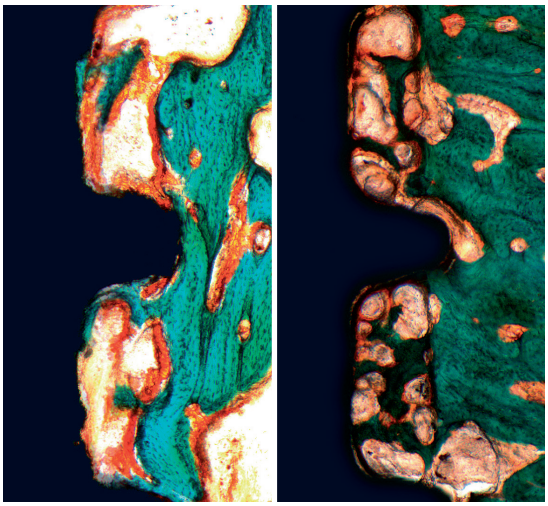
In the beagle dog mandible the implants with INICELL showed an advantage in the context of a more challenging immediate-placement surgical protocol:
On the buccal side, histomorphometric analysis demonstrated that mean BIC was greater by approximately 40% after 2 weeks in comparison to implants with the reference surface ($p<0.001$). Differences on the buccal side at 4 weeks and 12 weeks were not statistically significant.
On the lingual side, the implants with INICELL showed a mean BIC approximately 30% greater after 4 weeks and 15% after 12 weeks respectively in comparison to the reference surface ($p<0.0001$). Differences on the lingual side after 2 weeks were not statistically significant.

Conclusion

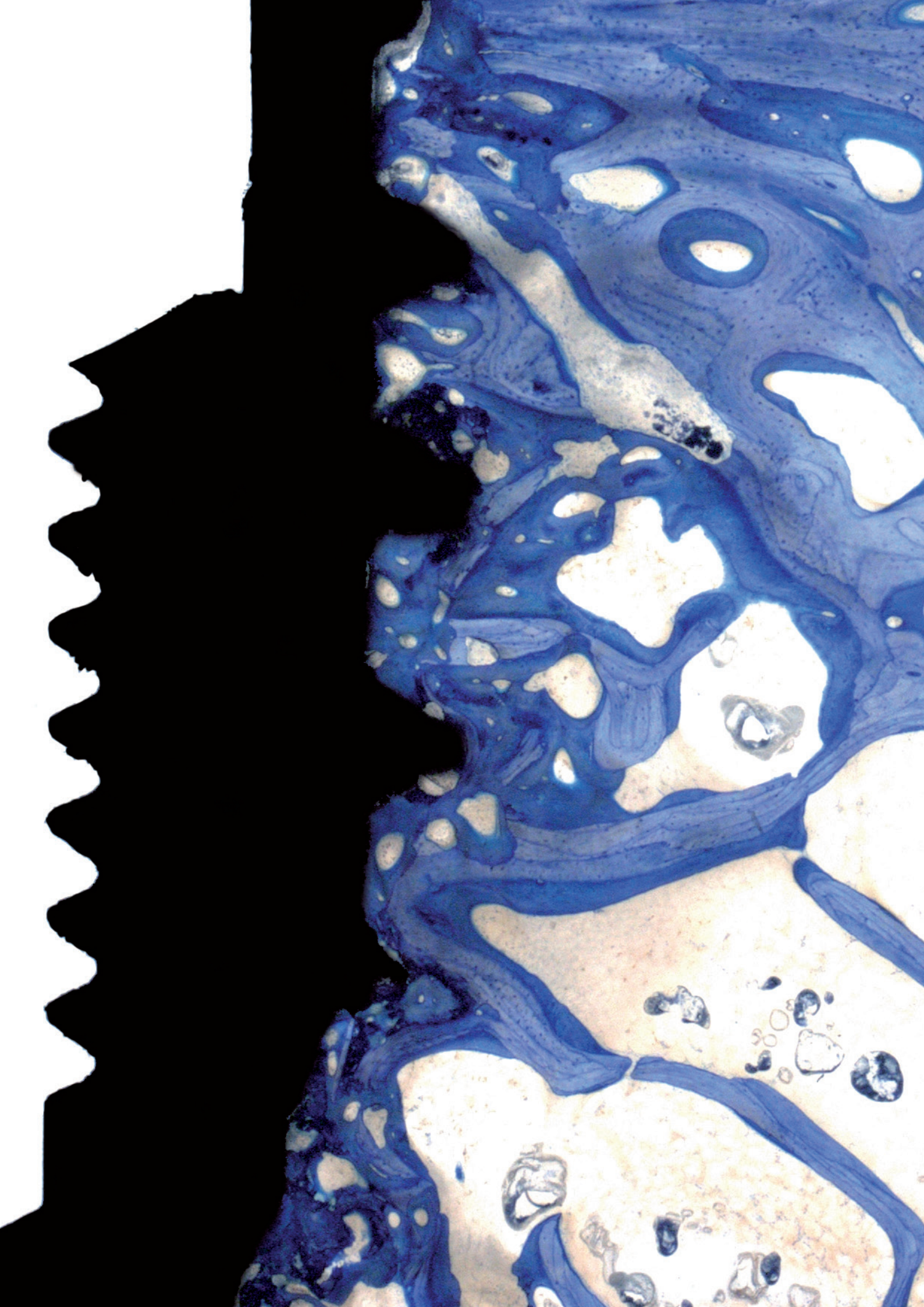
The advantage of the INICELL surface in the early stages of healing was readily apparent. After 4, 8 then 12 weeks respectively INICELL was slightly above the high level of the Thommen unconditioned reference surface.
Results in animal studies are not necessarily predictive of human clinical results. More studies are necessary to confirm trends and establish significance.



The pictures show the bone-to-implant interface in the early healing phase of the sheep model (left with unconditioned Thommen surface and right with INICELL)



The pictures show the bone-to-implant interface in the early healing phase of the mini-pig model (left with unconditioned Thommen surface and right with INICELL)



Clinical data on INICELL®

Early experience [24]

First clinical use of INICELL was documented in two independent multicenter case collections, in three and ten European centers respectively. In both series, patients with partially edentulous jaws and defects in the premolar and molar regions (mandible and maxilla) were treated with standard one- and two-stage surgical protocols. Shorter healing time was recommended i.e. three weeks in good bone quality (class I–III) and eight weeks in weak bone (class IV). In total 65 patients have received 146 ELEMENT implants with INICELL. Both case series have confirmed that early loading of implants with INICELL is feasible with favorable clinical outcome.

Short-term osseointegration of SPI®ELEMENT implants with INICELL in patients with bone quality type III and IV [25]
(Dr. Uwe Held, CFC Hirslanden Aarau, Switzerland)

The aim of this ongoing single center clinical study is to confirm the short-term osseointegration using the two-stage procedure (submerged) in complex cases.
Some of the patients underwent previous tumour/X-ray treatment. 1 year after loading implant stability will be assessed clinically. 10 patients have received 1–5 ELEMENT INICELL implants. Preliminary results indicate that all implantation sites were class III and IV (one additional site was class II). A continuous increase in implant stability in the early healing phase was observed.

Short-term osseointegration of SPI®ELEMENT implants with INICELL
(Drs. Hinkle, Lemler, Rimer and Prof. Schneider, USA)

The aim of this multicenter study is the clinical confirmation of short-term osseointegration of ELEMENT implants with INICELL in patients with bone quality type I–III (good bone). Implants will be placed in premolar (maxilla and mandible) and molar (mandible) regions. Implants with good primary stability (insertion torque ≥ 5 Ncm) will be loaded into occlusion with single crowns three weeks after insertion. Clinical and radiographic outcome and implant stability will be assessed up to 1 year after loading.

Early loading of SPI®ELEMENT implants with INICELL
(Prof. Dr. D. Buser, Prof. Dr. U. Brägger, Dr. M. Frei, Dr. S. Hicklin, University of Bern, Switzerland)

The goal of this clinical study is to assess the long-term clinical and radiographic outcome in the posterior mandible of partially edentulous patients. At least 30 patients will receive more than 50 implants. An early loading protocol will be followed, i.e. occlusal loading is scheduled at exactly 21 days postsurgery. Implant stability will be assessed. Crestal bone level changes will be assessed radiographically using standardized radiograms. The planned follow-up time is 3 years.

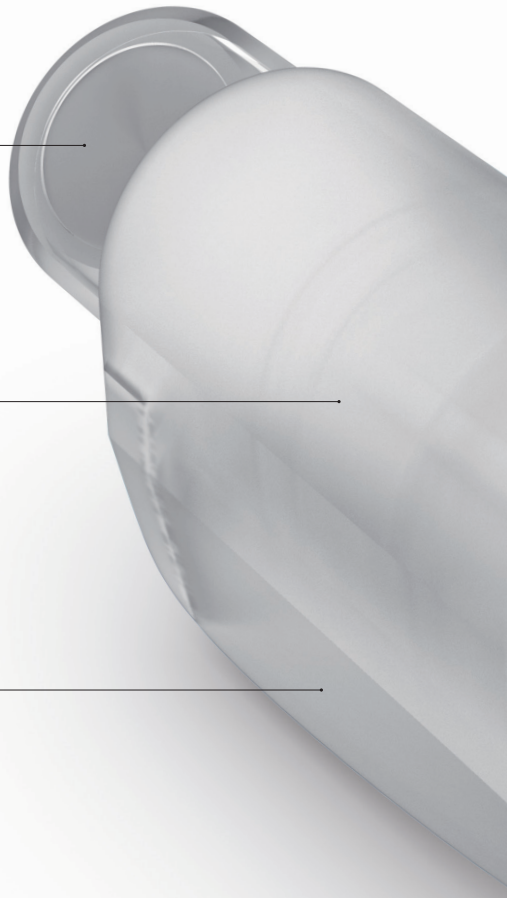
Picture left: Microscopic view of the bone-to-implant interface in the early healing phase

24 Data published in TMScientifics no. 4.
25 Held U. Data presented at Thommen Connecting Science Podium Event, November 2010.

APLIQUIQ®

Designed for function.

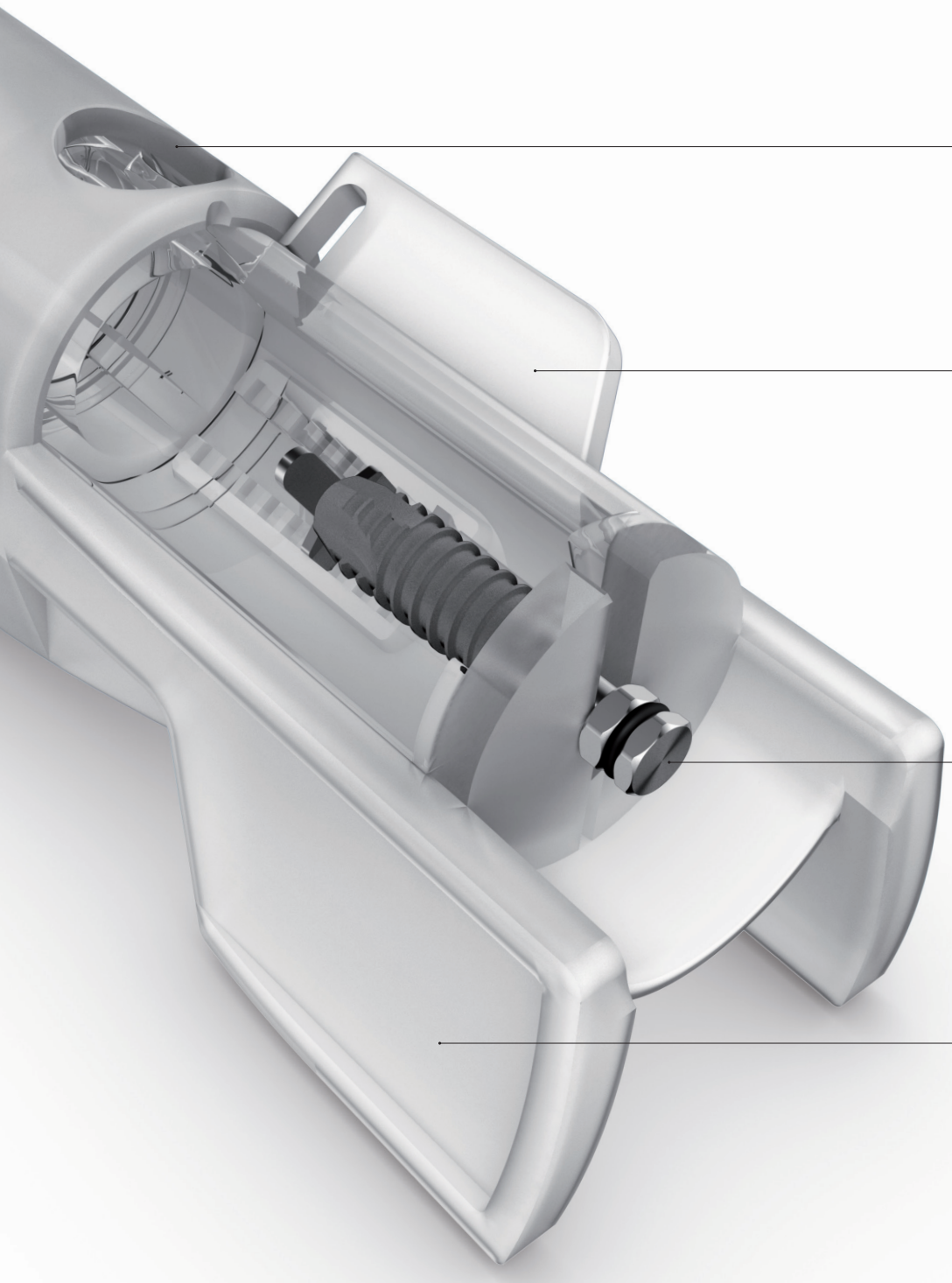
APLIQUIQ is the fast and effective chairside conditioning system used to produce the superhydrophilic implant surface INICELL.



Cartridge
The cartridge contains the conditioning agent and is sealed with a foil seal.

Body
The body is the central part of APLIQUIQ and protects the dry mounted implant during storage and conditioning.

Reservoir
The integrated reservoir catches the liquid after the conditioning process and prevents spillage.



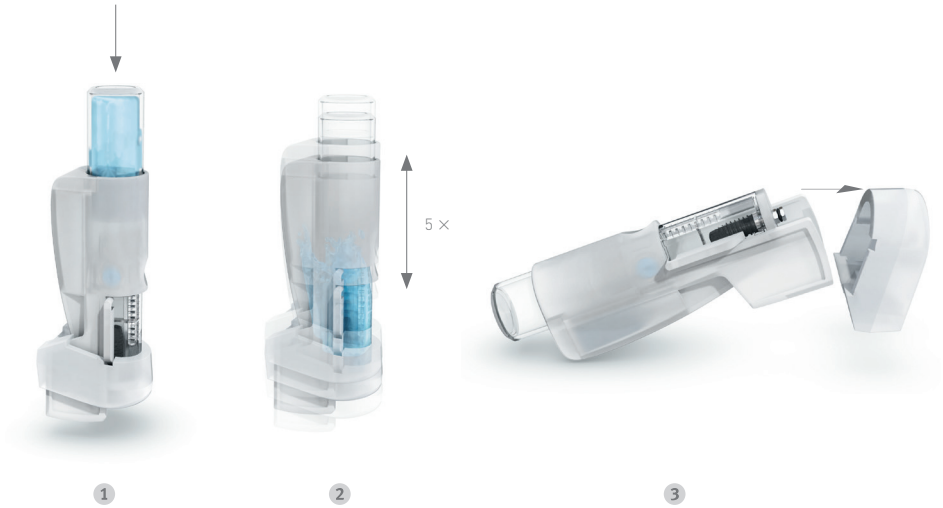
Healing cap
The healing cap is safely embedded in the rotating lid and can be removed only in the half-open position of the lid.

Lid
The rotating lid offers access to the implant and covers the passage to the reservoir in its fully open position.

Implant
Implants are mounted on the insertion aid.

Winglets
The winglets allow secure handling of APLIQUIQ. When pressed together the clamping force on the insertion aid is released and the implant is removed easily.

Handling instructions

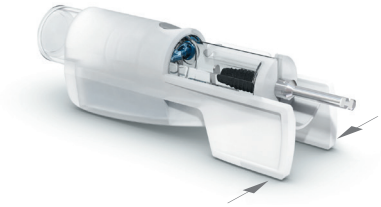


Step 1:
Open the outer package
APLIQUIQ is sterile packaged in a blister which in turn is contained in a protective outer box. The sterile applicator contains one implant and one healing cap in a dry state, and the liquid conditioning agent in an integrated/preassembled sealed cartridge.

Step 2:
Condition the implant
Remove APLIQUIQ from the blister in a sterile environment. Push the cartridge into the applicator body (picture 1). Hold the applicator vertically with the cartridge on top and shake it at least 5 times (picture 2).

Important
Conditioning must be performed to create the INICELL surface.

Step 3:
Remove the rubber cap and open the lid
Pivot the APLIQUIQ horizontally, allow the conditioning agent to flow into the integrated reservoir and carefully remove the rubber cap.
Peel off the rubber cap in direction indicated by the arrow (picture 3)
Rotate the lid to the fully open position.



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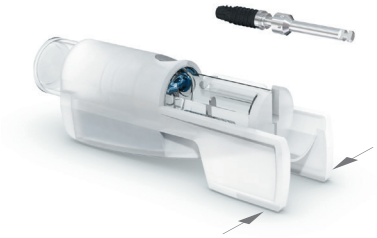

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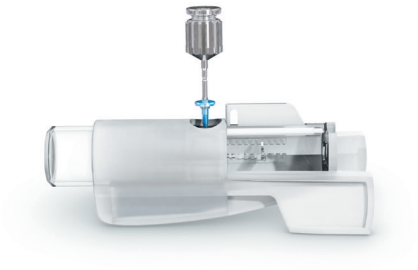

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Step 4:
Remove the implant
Attach the MONO insertion device or adapter for handpiece to the insertion aid.
Apply light pressure to the applicator wings to release the clamping force on the insertion aid (picture 4).

Lift the implant out of the applicator (picture 5).

The implant may be kept in the applicator for several hours following conditioning without diminishing the INICELL surface properties.

Insert the INICELL surface implant into the osteotomy using common surgical procedures as described in the "Surgical Procedure" brochure (Fo_22d009).

Step 5:
Remove the healing cap
Rotate the lid back to the middle position to expose the healing cap.
Remove and place the healing cap using a 4-lobe screwdriver (picture 6) and following the procedures described in the "Surgical Procedure" brochure.

Clean the internal connection of the implant thoroughly before placing the healing cap.

Important
Once the healing cap is removed, return the lid back to the fully open position to seal the reservoir and prevent spills of the conditioning agent.

Disposing of the applicator
Dispose of both items in accordance with local regulations. If required the conditioning agent* may be dispensed and discarded by opening the lid to the middle position and tilting the applicator.

* Warning: the conditioning agent is an irritant. Do not ingest. If swallowed, immediately drink copious amounts of water and seek medical attention. Prevent exposure to the eyes. In the event of exposure, rinse eyes well with water and seek medical attention. For further details refer to the packaging leaflet.

Shortened healing time thanks to higher bone-to-implant contact and higher implant stability in the early healing phase

3 weeks minimum healing phase is recommended with INICELL:
- with good bone quality and adequate bone volume
- with implants of lengths from 8.0 mm and endosseous ∅ 4.0 mm and larger

8 weeks minimum healing phase is recommended with INICELL:
- with cancellous bone quality
- with implants of length of 6.5 mm
- with implants of endosseous ∅ 3.5 mm

12 weeks minimum healing phase is recommended with INICELL:
- for CONTACT PF ∅ 3.5 mm with an endosseous ∅ 2.7 mm

The healing phase recommendations according to the packaging leaflet are the same for the maxilla and mandible.
In situations where the endosseous surface is not completely in contact with the bone or where bone augmentation is necessary, a healing phase in accordance with these specific conditions must be planned.
A radiographic check is recommended after a healing phase of 3–12 weeks or latest before starting the prosthetic restoration.

SPI®ELEMENT and SPI®CONTACT
Healing caps are also conveniently provided in the sterile ampoule.

SPI®ELEMENT and SPI®CONTACT implants PF ∅ 3.5 mm

Indications

- Partially edentulous lower and upper jaw – The implants PF ∅ 3.5 mm are suitable for alloplastic replacement of the lateral incisors (FDI Two-Digit Notation: 12, 22) in the upper jaw and the central and lateral incisors (FDI Two-Digit Notation: 41, 31, 42 and 32) in the lower jaw.
- Edentulous lower jaw – Four implants PF ∅ 3.5 mm must be connected with a bar.
- Edentulous lower and upper jaw – For complete bridges use implants PF ∅ 3.5 mm only in combination with Thommen implants PF ∅ 4.0/4.5/5.0 and 6.0 mm.

Contraindications

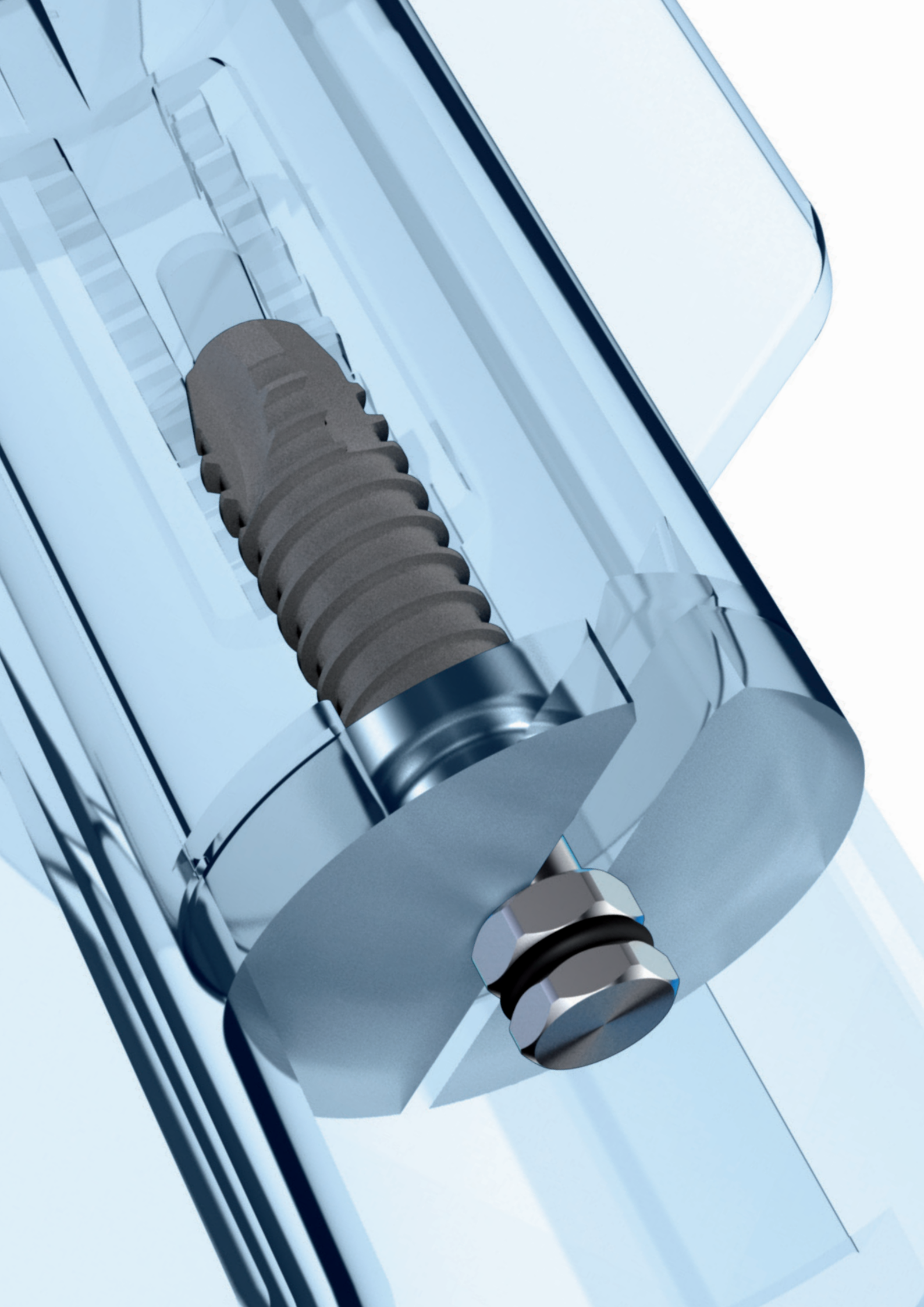
- Restoration of posterior teeth in the upper or lower jaw.
- Single-tooth restoration of canines and central incisors in the upper jaw.
- Any applications involving the use of retentive anchors.
- Applications in areas where pronounced rotation and translation movements occur, causing the implants to be subjected to large bending moments (e.g. use of single implants for the restoration of canines).

SPI®ELEMENT implants with length 6.5 mm

Because of reduced mechanical anchorage in bone, these short implants must only be used for the following indications:

- As an additional implant in combination with longer implants to support implant-borne reconstructions.
- As auxiliary implant for implant-borne bar constructions supporting full dentures in a seriously atrophied mandible.

Remark: The complete information and general contraindications of the packaging leaflet (Fo_50d527) must be respected.



Notes

THOMMEN IMPLANT SYSTEM

THOMMEN Medical

Manufacturer: Thommen Medical AG
Neckarsulmstrasse 28
2540 Grenchen, Switzerland
www.thommenmedical.com

LOT	Batch code
	Use by date
	Date of manufacture
STERILE R	Sterilized using irradiation
EC REP	Authorized representative
	Temperature limitation
	Do not re-use
NON STERILE	Non-sterile
	Caution
REF	Article number
CE	Conformity symbol as specified by EU Directive MDD 93/42/EEC
	Consult instructions for use
STERILIZE	Do not resterilize
	Do not use if package is damaged
	Atmospheric pressure limitation
	Manufacturer
	Keep away from sunlight
Rx Only	May only be sold to and prescribed by physicians (USA)
MD	Medical device
UDI	Single product code

COLORED WARNING STICKER

Application was changed – follow the directions in the corresponding instructions for use.

NEW HANDLING

New design – the application has not been changed.

NEW DESIGN

PRODUCT INFORMATION The information in this document describes the application of the Thommen Medical implant system. This information is available in electronic form online at: www.ifu-tm.com. The responsible country representative or distributor for Thommen Medical AG is available to provide technical advice.

COLOR CODE Each implant platform diameter has a color code, which can be found on all implant packagings, on the impression items and on most diameter-specific instruments.

TRACEABILITY

In order to ensure the traceability of the implantable products as well as the manufacturer, product type and product dimensions for a later prosthetic re-restoration, each product package comes with three patient labels. These labels should be used in the practice for documentation and for the implant passport.

Brown	=	PF 3.0
Yellow	=	PF 3.5
Green	=	PF 4.0
Blue	=	PF 4.5
Grey	=	PF 5.0
Purple	=	PF 6.0

AVAILABILITY Not all of the Thommen Medical products mentioned in these instructions for use are available in all countries. The responsible country representative or distributor of Thommen Medical AG informs about availability of Thommen Medical products for the country in question.

GENERAL RESTRICTIONS OF USE Restorations with cantilevers to individual implants are not recommended. Individual restorations with angled abutments should not be used in regions with high mechanical stress. For implants with a small diameter (PF 3.0 and 3.5), the prosthetic restoration should be constructed in such a way that large bending moment does not occur.

CONTRAINDICATION The Thommen Medical products may not be used on patients who are known to have allergies to the corresponding materials.

POSSIBLE COMPLICATIONS A stressed loading of the implant or abutment over and above its functional capacity can lead to excessive bone loss or fracture of the implant or restoration. The clinician must supervise the occlusion and functional loading of the prosthetic supraconstruction very carefully.

SIDE EFFECTS The patient should be informed about the possible side effects, interactions, precautionary measures and complications associated with Thommen Medical products.
Potential complications can occur immediately after insertion of dental implants:
Temporary symptoms: swelling, difficulties with speaking, gum inflammations, pain.
Longer lasting symptoms: chronic pain connected with the dental implant, localized or systemic infections, dysesthesia, loss of alveolar ridge (upper and lower jaw), oroantral or oronasal fistulas, irreversible damage to neighboring teeth, esthetic problems, nerve damage, hyperplasia.

WARNINGS All Thommen Medical products that come into effect inside the oral cavity must be protected against aspiration. Thommen Medical products have not been tested for safety and compatibility in an MR environment. Thommen Medical products have not been tested for heating or migration in the MR environment. The safety of Thommen Medical products in the MR environment is unknown. Magnetic resonance tomographic examinations of patients, who have been treated with Thommen Medical products, may result in patient injuries.

RESPONSIBILITY/LIABILITY As a part of an overall scheme, Thommen Medical products may be used only with the related original components and instruments in accordance with the instructions for use provided by Thommen Medical. The use of non-system parts may compromise the performance of Thommen Medical products and lead to failures. Users must have appropriate knowledge and information about the handling of Thommen Medical products in order to use the products safely and correctly. The user is obliged to use the Thommen Medical products according to the instructions for use and to check whether the product is suitable for the individual patient situation. The use of Thommen Medical products is the responsibility of the user, as such, beyond the control of Thommen Medical AG. We refuse to accept any responsibility or liability for any damage due to incorrect utilization of the product. Products labeled «Do not re-use» may not be refurbished and/or reused. The refurbishment and/or reuse of these products can affect their function (e.g. fitting and/ or cutting properties) as well as their safe use (e.g. risk of infection, disease transmission, fading of the laser or color marks, corrosion). Detailed information about the possible consequences, which may result from incorrect use, is available from the responsible country representative or distributor of Thommen Medical AG. All serious incidents which have occurred in connection with the product must be reported to the manufacturer and the competent authority of the Member State, in which the user is resident.

GUARANTEE The comprehensive guarantees can be found in the country-specific guarantee leaflets.

TRANSPORT AND STORAGE Please note the specifications on the labels and instructions for use regarding transportation, storage and handling. If the packaging is damaged, the products must not be used; a visual inspection is necessary. Under no circumstances may Thommen Medical products be used beyond the expiry date, as proper functioning or sterility of sterile packaged products cannot be guaranteed by the manufacturer.

APPLICATION The following descriptions are not intended as comprehensive for the. immediate use of the Thommen Medical Implant System. Training by a specialist experienced in the use of this system is recommended

GUARANTEE OF STERILITY In general, products of the Thommen Implant System supplied in sterile packaging must not be re-sterilized Sterile-packed products, whose packaging is damaged, must not be used under any circumstances. Sterile-supplied products, which have not been used for the surgical operation, whose packaging has been opened are considered as having been used and must not be used thereafter. In the event of resterilization, proper function and the sterility cannot be guaranteed by the manufacturer. The products intended for single use must never be reprocessed, sterilized or reused and must be disposed of safely and properly after use in compliance with all applicable legal and regulatory requirements. Reusable products must be reprocessed according to the instructions for use and, if used on patients, sterilized. They must be checked for their integrity before each use. Any damage (for example, scratches, cracks, nicks, dents), as well as bent parts, means that they must not be used any longer. The number of reprocessing cycles is limited and must be monitored. If the number of cycles is exceeded, proper function and sterility of the product are not guaranteed by the manufacturer anymore.

DISPOSALIn the case of cutting products, there is always a risk of injury, therefore the products must be disposed of safely and properly after use, observing all applicable legal and regulatory requirements. For products and their accessories, which have been used on a patient, there is a risk of an infection. Our products are designed and produced so that they can be disposed of safely and correctly after use in compliance with all valid legal and regulatory requirements.

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