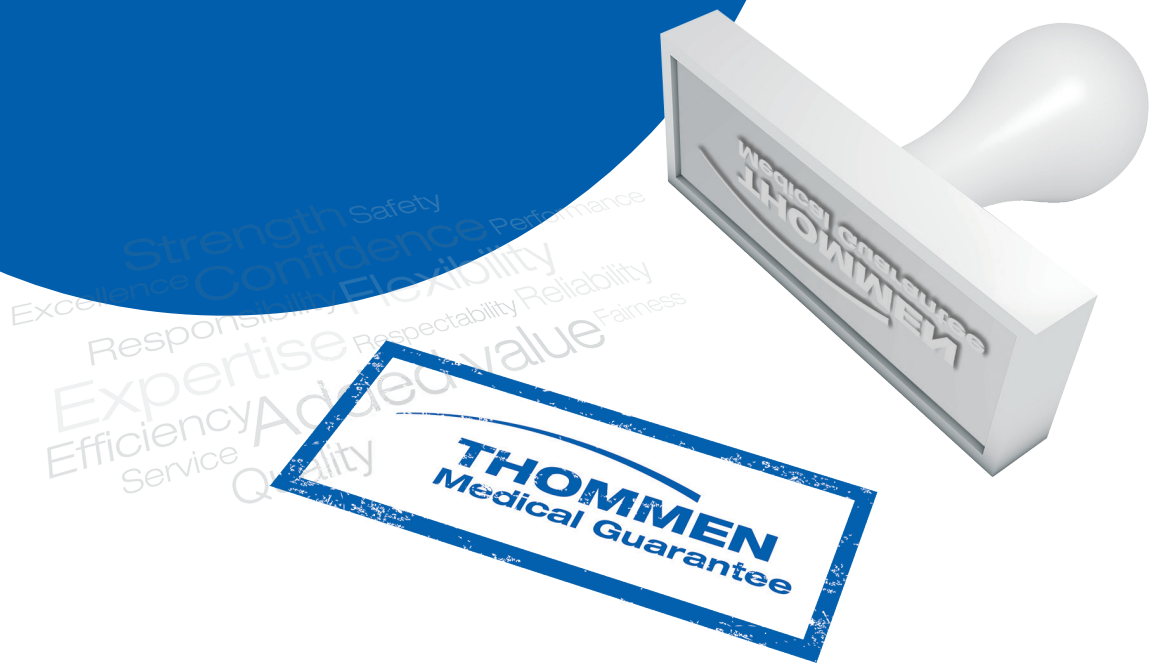
THOMMEN
Medical

Thommen Medical Guarantee.



Thommen Medical Guarantee

1. Guarantee beneficiary and scope

This guarantee ("Thommen Medical Guarantee as defined below") by Thommen Medical AG, Grenchen, Switzerland ("Thommen Medical" below) applies exclusively to the products specified below and in favor of the attending physician/dentist ("users" below). Third parties, in particular, patients or intermediate suppliers cannot derive any rights from it. The Thommen Medical Guarantee covers Thommen Implant System product ("Thommen Medical Products" below) replacement according to paragraph 2. The Thommen Medical Guarantee only covers the replacement of Thommen Medical products and no other costs, particularly costs for technical dental work and continuing treatments.

2. Thommen Medical products included within the scope of the Thommen Medical Guarantee

2.1. 3rd party products

Since the Thommen Implant System is a comprehensive infrastructure of original Thommen parts all working together for the life of the patient, the use of any 3rd party products outside of those approved and/or distributed by Thommen Medical in the place of Thommen products voids the Thommen Medical warranty.

2.2 Lifelong guarantee for implants with INICELL®

Thommen Medical Guarantees that an implant with INICELL® surface which does not remain in the bone after its implantation will be replaced by an identical or equivalent implant free of charge. Thommen Medical replaces the implant and the Thommen Medical prosthetic components which were attached to the implant at the time of its loss.

2.3 Lifelong guarantee for prosthetic components

If any Thommen Medical prosthetic component fails, Thommen Medical Guarantees to replace it with a corresponding prosthetic component free of charge. Provisional components are exempt. The lifelong guarantee only applies to original Thommen Medical parts.

2.4 Guarantee for instruments

Thommen Medical shall replace all Thommen Medical instruments which fail in the purpose for which they were designed and no longer function properly due to wear. Cutting instruments are exempt.

3. Guarantee conditions

Thommen Medical hereby guarantees that a Thommen Medical product deemed to be defective due to inadequate material strength and stability will be replaced with an identical or largely equivalent product as described in paragraph 2 within the guarantee periods specified in paragraph 2.

The guarantee periods indicated above begin at the time of treatment with a Thommen Medical product by the user. A requirement, however, is that the following guarantee terms are cumulatively in evidence and are proven:

3.1 Return of the offending Thommen Medical product in a sterilized state (or disinfected, if supplied as such);
3.2 Observance and implementation of Thommen Medical's directions available at the time of treatment (including the instructions for use) and the recognized dental procedures prior to, during and after treatment;
3.3 The cause of damage or failure is not the result of an accident, a trauma or any other damage caused by the patient or a third party;
3.4 The cause of damage or failure resulted from the use of parts manufactured by a 3rd party (products outside of those approved and/or distributed by Thommen Medical).
3.5 Filing of a completed and signed guarantee form not later than three months after a Guarantee Case arises.

⚠ **4. Limits and limitations**

Thommen Medical hereby disclaims any other warranties, express or implied, and Thommen Medical hereby excludes any liability for lost earnings and direct or indirect damages as well as collateral and consequential damages, directly or indirectly related to Thommen Medical products, services or information.

5. Guarantee territory

This Thommen Medical Guarantee has worldwide validity for Thommen Medical products that are sold by companies affiliated to Thommen Medical or official sales partners.

6. Adjustment or termination

Thommen Medical can adjust or terminate this guarantee completely or partly at any time. An adjustment or a termination of the Thommen Medical Guarantee, however, does not have any impact on the guarantees for Thommen Medical products granted within this Thommen Medical Guarantee which was used before the date of such an adjustment or termination.

7. Reporting requirement

Thommen Medical stipulates that events subject to a reporting requirement must be submitted either directly to the manufacturer and/or to the responsible authority in accordance with the locally applicable regulations.

8. Data protection

Thommen Medical stipulates that all applicable data protection regulations (e.g. Regulation (EU) 2016/679 (General Data Protection Regulation)) must be complied with. All patient data must be anonymized. This means that no personal names or initials of patients may be submitted, neither on x-rays nor on patient reports. A patient ID number, which does not allow any conclusions to be drawn about patient data, must be used for each patient.

Guarantee form

As specified in paragraph 8 of the Thommen Medical Guarantee, all applicable data protection regulations must be complied with and all patient data must be anonymized. A patient ID number, which does not allow any conclusions to be drawn about patient data, must be used for each patient.

1. CUSTOMER INFORMATION

Attending physician's name and address (use capital letters or stamp)

_____ Telephone _____

_____ Country _____

_____ Contact at the practice _____

_____

_____

2. PRODUCT INFORMATION (please list all Thommen Medical products involved)

Art. no.	Lot no.	Placement Date (D/M/Y)	Removal Date (D/M/Y)	Region
___ . _____ . _____	_____	_____ / _____ / _____	_____ / _____ / _____	_____
___ . _____ . _____	_____	_____ / _____ / _____	_____ / _____ / _____	_____
___ . _____ . _____	_____	_____ / _____ / _____	_____ / _____ / _____	_____
___ . _____ . _____	_____	_____ / _____ / _____	_____ / _____ / _____	_____

Date of the event: _____ / _____ / _____

3. GENERAL PATIENT INFORMATION (complete this section only if returning implants)

Patient ID no. _____ Age: _____ ☐ Female ☐ Male

Medical Record

☐ Radiation Tx-head/neck area
☐ Bisphosphonate treatment
☐ Illness requiring steroids
☐ Chemotherapy around time of implant placement
☐ Blood coagulation disorder
☐ Compromised immune resistance
☐ Diabetes mellitus
☐ Uncontrolled endocrine illness
☐ Psychological disorder
☐ Drug or alcohol abuse
☐ Xerostomia
Smoker: ☐ Yes ☐ No

Other local or systemic diseases which may be significant: _____

Allergies: _____ ☐ No significant findings

4. INFORMATION (complete this section only if returning implants)

☐ Manual placement ☐ Mechanical insertion

Comments (use capital letters): _____

If implant was placed and removed the same day, was another implant successfully placed in the site during surgery? ☐ Yes ☐ No

At the time of surgery, were any of the following present:

☐ Periodontal disease
☐ Diseased mucous membrane
☐ Local infection/ subacute chronic osteitis
☐ Complication in site preparation
Whichever: _____

Bone quality ☐ Type I ☐ Type II ☐ Type III ☐ Type IV
Use thread tap? ☐ Yes ☐ No
Was primary stability achieved? ☐ Yes ☐ No
Did implant achieve osseointegration? ☐ Yes ☐ No
Was the implant surface completely covered with bone? ☐ Yes ☐ No

Was augmentation performed at the time of surgery?

☐ No ☐ Sinus ☐ Ridge Material used: _____

Was GTR membrane used?

☐ No ☐ Yes ☐ Resorbable ☐ Non-resorbable Material used: _____

5. EVENT INFORMATION (complete this section only if returning implants)

Hygiene around implant ☐ Excellent ☐ Good ☐ Fair ☐ Poor

Were any of the following involved in the event?

☐ Trauma/Accident
☐ Biomechanical overload
☐ Bruxism
☐ Implant fracture
☐ Immediate implantation
☐ Undersized implant bed
☐ Overheating of bone
☐ Nerve encroachment
☐ Sinus perforation
☐ Inadequate bone quality/quantity
☐ Preceding/simultaneous bone augmentation
☐ Bone resorption
☐ Peri-Implantitis
☐ Infection

Other (please write in capital letters): _____

At the time of implant failure, there was (check all that apply):

☐ Pain ☐ Swelling ☐ Bleeding ☐ Mobility
☐ Numbness ☐ Fistula ☐ Inflammation Other: _____
☐ Increased sensitivity ☐ Abscess ☐ Asymptomatic

Was the prosthesis fitted? ☐ Yes ☐ No **If yes, please complete section 6.**

Please comment on why you think the implant failed/was removed (please write in capital letters):

_____

_____

6. PROSTHESIS INFORMATION (complete this section only if returning abutments and restorations)

☐ Model ☐ Insertion ☐ In use

Type of restoration? ☐ Crown ☐ Bridge RPD: ☐ Upper ☐ Lower
Full: ☐ Upper ☐ Lower

Date abutment was installed? ____ / ____ / _____ (D/M/Y)
Date of abutment removal: ____ / ____ / _____ (D/M/Y)

Was the MONO torque ratchet used? ☐ Yes ☐ No ☐ Unknown Torque applied: ____ Ncm

Date of temporary restoration installation: ____ / ____ / _____ (D/M/Y)
Date of final restoration installation: ____ / ____ / _____ (D/M/Y)

Was a check-up performed? ☐ Yes ☐ No

Description of event (please write in capital letters):

_____

_____

7. INSTRUMENTS (complete this section only if returning instruments)

Which drills were used: ☐ VECTOdrill steel ☐ VECTOdrill ceramic

☐ Other Whichever: _____

Approximate number of uses (cutting instruments only): ☐ Initial use ☐ 2-5 x ☐ 6-10 x ☐ 10-20 x ☐ More than 20 x

Type of cleaning method used: ☐ Manual ☐ Ultrasonic ☐ Thermodesinfection Other: _____

Type of sterilization method used: ☐ Autoclave ☐ Dry heat ☐ Chemiclave

Short description of incident (please write in capital letters):

_____

_____

Please return questionnaire, autoclaved product and include X-rays (as appropriate) to your distribution partner.
Use a padded pouch to return items – failure to do so could result in items lost during shipment and void guarantee program.
Autoclave all products (do not clean) and lable them as **sterile.**

Based on the Thommen Medical Guarantee Terms and Conditions, please consider replacing the above listed products.

Doctor's Signature: _____ Date: _____

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HEADQUARTERS

Thommen Medical AG
Neckarsulmstrasse 28
2540 Grenchen | Switzerland
Tel. +41 61 965 90 20
Fax +41 61 965 90 21
info@thommenmedical.com

SUBSIDIARIES/NATIONAL DISTRIBUTORS

AUSTRIA
Thommen Medical Austria GmbH
Mühlgasse 3
2322 Zwölfaxing | Austria
Tel. +43 660 2011953
info@thommenmedical.at

BENELUX
Thommen Medical Benelux B.V.
Dierenriem 1
3738 TP Maartensdijk | Netherlands
Tel. +31 30 68 68 468
Info.benelux@thommenmedical.nl

CHINA
Shanghai Yujing Trading Co., Ltd.
Room G | Floor 15th | Plaza JiaFa | No.1
Lane 129 | DaTian Road | JingAn District
Shanghai | China
Tel. +86 21 62723077
Fax +86 21 62175264

CZECH REPUBLIC
C. Witt Dental spol. s r.o.
Cihlárská 643/19
602 00 Brno
Tel. +420 739 043 449
helena.novak@cwittdental.cz

FINLAND
Vector Laboratories Oy
Engelinaukio 8 B
00150 Helsinki | Finland
Tel. +358 400 940 700
labs@vektor.fi

FRANCE
Thommen Medical France
10 avenue Gabriel Pierné
77680 Roissy-en-Brie | France
Tel. +33 1 83 64 06 35
Fax +33 3 89 33 52 53
infos@thommenmedical.fr

GERMANY
Thommen Medical Deutschland GmbH
Am Rathaus 2
79576 Weil am Rhein | Germany
Tel. +49 7621 422 58 30
Fax +49 7621 422 58 41
info@thommenmedical.de

HONG KONG
Shengyuan (Hong Kong) Int. Trade Co. Ltd.
Level 13, 68 Yee Wo Street
Causeway Bay | Hong Kong
Tel. +852 530 876 41

ITALY
Dental Trey S.r.l.
Via Partisani, 3
47016 Fiumana | Predappio (FC) | Italy
Tel. +39 0543 929111
Fax +39 0543 940659
implantologia@dentaltrey.it
www.dentaltrey.it

JAPAN
J. Morita Corporation
3-33-18, Tarumi-cho
Suita | Osaka 564-8650 | Japan
Tel. +81 6 6384 6921
Fax +81 6 6384 6746
www.morita.com

LITHUANIA/LATVIA
ČERNIKIS MEDICAL PROJECTS, UAB
Šiaurės prospektas 5B, Kaunas
Lithuania LT-49191
Tel. +370 37 201072
Mobile +370 65 771550
info@cmp.lt
www.cmp.lt

MIDDLE EAST
Star Science International GmbH
Jupiterstrasse 57
3015 Bern | Switzerland
Tel. +41 31 941 07 31
Fax +41 31 941 07 33
star.science@bluewin.ch

NORWAY
Novus Dental AS
Johannes Bruns gate 5
0452 Oslo | Norway
Tel. +47 951 07 007
post@novusdental.no
www.novusdental.no

POLAND
C.WITT DENTAL Sp. z o. o.
Ul. Granitowa 10
87-100 Toruń | NIP 951-15-08-371 | Poland
Tel. +48 56 623 61 23
biuro@cwittdental.pl
www.cwittdental.pl

REPUBLIC OF CROATIA
Futura Dental d.o.o.
Kralja Zvonimira 108
10 000 Zagreb | Republic of Croatia
Tel. +385 91 6814 860
info@futura-dental.hr
www.futura-dental.hr

RUSSIAN FEDERATION
CIS – JSC Geosoft
Build. 14, Ap. 16, 3-ya Mytishchinskaya ul.
Moscow, 129626 | Russian Federation
Tel. +7 495 663 22 11
thommenmedical@geosoft.ru

SINGAPORE
FONDACO Pte Ltd
7 Kaki Bukit Road 1, #03-06
Eunos Techno Link
Singapore 415937 | Singapore
Tel. +65 6392 2806
Fax +65 6392 1296
fondaco@fondacosg.com

SOUTH KOREA
KMbio
02 Ho, 129, Dongseo-daero
Seobuk-gu, Cheonan-si
Chungcheonnam-do
Republic of Korea
Tel. +82 070 3141 2875
kmbio149@naver.com

SPAIN/PORTUGAL
Thommen Medical Ibérica
C/Los quintos n 1
03350 Cox (Alicante) | Spain
Tel. +34 96 536 10 20
Mobile +34 606 99 78 34
info@thommeniberica.com

SWITZERLAND
Thommen Medical AG
Neckarsulmstrasse 28
2540 Grenchen | Switzerland
Tel. +41 32 644 30 20
Fax +41 32 644 30 25
info@thommenmedical.ch

TAIWAN
En-Jye International Co., Ltd.
No. 18 | Lane 177 | Sec 3 | Chengde Rd.
Taipei, 103 Taiwan
Tel. +886 2 2585 1669
Fax +886 2 2585 0892
enjye168@gmail.com

TURKEY
Bioport Biyolojik Maddeler A.Ş.
Büyükdere cd. Subay evleri 9. Blok D1 Esentepe
Şişli 34394 Istanbul | Turkey
Tel. +90 212 2727577
Fax +90 212 2727628
info@bioport.com.tr
www.bioport.com.tr

USA/CANADA
Thommen Medical USA L.L.C.
1375 Euclid Avenue | Suite 450
Cleveland OH 44115 | USA
Tel. +1 866 319 9800 (toll free)
Fax +1 216 583 9801
info.us@thommenmedical.com
orders.us@thommenmedical.com

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