THOMMEN
Medical

Thommen Medical Guarantee.

Thommen Medical USA, LLC.

Thommen Medical Guarantee

1. Scope and Beneficiary

This Guarantee ("Thommen Medical guarantee") by Thommen Medical USA, LLC ("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, and are not third party beneficiaries. The Thommen Medical guarantee covers Thommen Medical 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, including but not limited to required treatments. The parties agree that the transactions covered herein are for commercial purposes only.

2. Covered Products

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 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.

2.3 Guarantee for instruments

Thommen Medical shall replace all Thommen Medical instruments which fail in the purpose envisaged for them and/or no longer function properly due to wear. Cutting instruments are exempt.

3. 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. As a mandatory precondition to coverage under this guarantee, User must also fulfill these conditions precedent:

3.1 Return of the damaged or defective 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 No Guarantee Case resulting from 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 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.

3.6 **Except as provided herein, Thommen disclaims any warranty, express or implied, or as to fitness for any particular purpose, regarding the goods covered herein, and expressly limits its liability to the provisions contained herein.**

4. 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.

5. 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. Thommen expressly reserves the right to terminate this program at any time in its sole discretion.

6. 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.

7. Miscellaneous

7.1 **Disputes**. In the event that any dispute arises under the terms of this agreement, the parties agree that it will be resolved, solely and exclusively, through arbitration, conducted under the laws of the state of Ohio, using the American Arbitration Association to conduct the same, with a designated location at Thommen's corporate offices in Cleveland, Ohio.

7.2 **Modifications.** No alterations or modifications of this agreement shall be recognized unless they are in writing, and agreed to by both parties.

7.3 **Notices.** All notices under this Agreement shall be sent to:
Thommen Medical USA, LLC
1375 Euclid Avenue, Suite 450
Cleveland, Ohio 44115

By their signatures below, and in consideration of the promises contained herein, the parties agree to be bound by the terms of this Agreement.

_____

_____

Thommen Medical USA, LLC

By: _____

Its Authorized Representative

Dated: _____

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: _____

HEADQUARTERS

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