



## CONFORMIS Limited Warranty for iTotal® Identity Implants

### Terms and Conditions

These LIMITED WARRANTY TERMS AND CONDITIONS cover the Patient-Specific Conformis iTotal® Identity Knee Implant ("Product"). The warranty outlined in these terms and conditions is exclusively for the benefit of eligible patients who have purchased Conformis' PLATINUM SERVICES and have had the product implanted in the United States of America ("Patient"). Consistent in the terms herein, the warranty is not for the benefit of any other person or entity, including, but not limited to, any physician, hospital, laboratory, ambulatory surgical center, clinic, insurance company, and intermediate contractor, supplier, or distributor, and cannot be assigned or transferred.

### 1. Warranty Period

The warranty set out in these Terms and Conditions is granted to the Patient for five (5) years from the date of his or her index surgery when the Product is implanted ("Warranty Period").

### 2. Scope of Warranty

Subject to the limitations and exceptions described in these Terms and Conditions, Conformis will provide the following benefits to the Patient:

If the Patient is required, for any reason, to undergo a revision surgery resulting in the explanation of the Product and otherwise qualifies as set forth herein, then Conformis will refund to the Patient his or her total out-of-pocket expense, up to \$3,000, paid by the Patient for Conformis' Platinum Services. Such out-of-pocket expense does not include any copayment or deductible amounts owed under the Patient's insurance plan(s), or amounts otherwise reimbursable by any applicable healthcare plan. The benefits set out above constitute Conformis' sole liability and obligation, and the Patient's sole and exclusive remedies, with respect to the Product and the subject matter of these Terms and Conditions.

This warranty cannot be varied or extended in any manner by any employee or agent of Conformis.

### 3. Eligibility and Claim Procedure

In order to receive the warranty benefits under these Terms and Conditions, and subject to Section 1, the following must be complied with:

- A. The Patient must require, upon the recommendation and advice of his or her treating surgeon ("Healthcare Provider" or "HCP"), a replacement or revision surgery within the Warranty Period; and
- B. Within thirty (30) business days of the revision surgery wherein the Product, or a component thereof, was revised or replaced in accordance with the provisions herein, the Patient must complete and return the warranty claim form (available through Conformis' website, [www.Conformis.com](http://www.Conformis.com)) endorsed by his or her HCP. If the claim form is not received within 30 business days of the revision surgery, the claim must be approved by the product manager responsible for the Product; and
- C. In connection with submitting a completed warranty claim form, the Patient must provide a receipt or invoice as evidence of the out-of-pocket expense paid by the Patient for Conformis' Platinum Services.

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## 4. Disclaimer and General Limitations of the Warranty

Except for the warranty specified in these Terms and Conditions, Conformis hereby expressly disclaims and excludes, and Patient hereby expressly waives, any representation, warranty, contract, covenant or other undertaking, negligence, tort, strict liability, statutory, express or implied or otherwise, written or oral, with respect to the Product, quality, condition, results, claims and descriptions, including, without limitation, any warranties of merchantability, non-infringement (except for implied warranty of title), durability, or fitness for a particular use or purpose.

In addition, Conformis disclaims (on behalf of itself and any of its representatives or other third parties which manufacture or distribute the Product) any and all liability with respect to pain and suffering, medical expenses, lost earnings, incomes or profits, failure of the HCP to conform to generally accepted standards of care, surgical procedures, techniques and practice, and any other direct or indirect, special, contingent, incidental, or consequential damages resulting or arising from the design, composition, condition, use or performance of the Product.

Notwithstanding anything to the contrary, the total liability of Conformis, if any, under or in connection with the Patient or caused in whole or in part by Conformis, including for any breach of contractual obligations, breach of duty, breach of warranty, misrepresentations, misstatements, or tortious acts or omissions (including, without limitation, strict liability, negligence, and liability for infringement of any third-party intellectual property rights) shall be limited to damages not to exceed the \$3,000 provided for under the Terms and Conditions of this warranty.

For the avoidance of doubt, these Terms and Conditions, and the benefits and remedies set out herein, shall be exhaustive with respect to the Product and the subject matter of these Terms and Conditions, and shall exclude any other rights, benefits, and/or remedies, such as, for example, reimbursement or payment of physicians, therapists, surgical, laboratory, radiological, hospital, rehabilitation, and clinical treatment, costs, services, charges, or fees; and/or travel, instrument, bone cement, product, device, and equipment supply charges.

## 5. Modification or Withdrawal of the Warranty

Conformis reserves the right to modify or withdraw the warranty and/or these Terms and Conditions at any time without notice. Any such modification or withdrawal will not affect Product already implanted in a Patient, and for which the Patient has already paid for Conformis' Platinum Services, prior to the date thereof.

## 6. General Conditions of Sale

The warranty provided for under these Terms and Conditions above shall apply alongside, and in addition to, any other terms and conditions set out in the agreement with the hospital, ambulatory surgical center, or other medical facility to which the Product was sold ("Medical Facilities"), if any.

## 7. Safe Harbor

To the extent applicable, if any benefit provided by Conformis under this warranty represents a price reduction that Medical Facilities must fully and accurately report in applicable cost reports or claims for payment filed with federal or state healthcare programs in accordance with the warranty safe harbor provisions of the federal anti-kickback statute at 42 C.F.R. § 1001.952(g), Medical Facilities take responsibility for fully and accurately reporting same. Patients and Medical Facilities must provide information upon request to Medicare, Medicaid, and other federal healthcare programs on price reductions (including free items), if any, obtained as part of this warranty.

## 8. Governing Law and Venue

Any action relating to or hereunder shall be governed by the laws of the Commonwealth of Massachusetts exclusive of any choice of law principles. The parties agree that the exclusive venue for such action shall lie in federal or state court with applicable jurisdiction located in Middlesex County, Massachusetts.

## 9. Effective Date

This warranty, effective as of [insert surgery date for Conformis iTotal® Identity implant] ("Effective Date"), and its Terms and Conditions shall only apply to Product implanted following a Patient's purchase of Conformis' Platinum Services. This warranty and its Terms and Conditions shall not apply to any procedures that occurred prior to the Effective Date under any circumstance.

