

ZIMMER BIOMET BONE CEMENT WARRANTY TERMS AND CONDITIONS

March 11, 2019

THIS ZIMMER BIOMET BONE CEMENT WARRANTY (HEREINAFTER "WARRANTY") TERMS & CONDITIONS COVER THE ZIMMER BIOMET BONE CEMENT AND ASSOCIATED PARTIAL AND PRIMARY KNEE REPLACEMENT IMPLANTS USED IN THE PRIMARY (INITIAL) SURGERY ("PRODUCT") MANUFACTURED AND DISTRIBUTED BY ZIMMER BIOMET, INC. OR ANY OF ITS SUBSIDIARIES OR AFFILIATES (COLLECTIVELY, "ZIMMER BIOMET") ONLY.

THE WARRANTY OUTLINED IN THESE TERMS AND CONDITIONS IS EXCLUSIVELY FOR THE BENEFIT OF ELIGIBLE PATIENTS WHO HAVE THE PRODUCT IMPLANTED IN THE UNITED STATES OF AMERICA AT HOSPITALS AND FACILITIES THAT HAVE ENROLLED IN THE WARRANTY PROGRAM, WHO PURCHASE OR IMPLANT REPLACEMENTS FOR THE PRODUCTS WHICH WERE ORIGINALLY IMPLANTED IN THE UNITED STATES OF AMERICA (COLLECTIVELY "PURCHASER(S)") CONSISTENT WITH THE TERMS HEREIN ONLY AND IS NOT FOR THE BENEFIT OF ANY OTHER PERSON OR ENTITY, INCLUDING, BUT NOT LIMITED TO, ANY OTHER PHYSICIANS, HOSPITALS, LABORATORIES, CLINICS, INSURANCE COMPANIES AND INTERMEDIATE SUPPLIERS OR DISTRIBUTORS.

1. WARRANTY PERIOD

THE WARRANTY SET OUT IN THESE TERMS AND CONDITIONS IS GRANTED FOR THE FOLLOWING PERIODS:

- As more fully set forth herein, for the one-time free replacement of the PRODUCT manufactured or distributed by ZIMMER BIOMET, in the event a revision surgery is required within ten years of primary implantation due to the aseptic loosening of the ZIMMER BIOMET Partial or Primary Knee Replacement Implant and/or ZIMMER BIOMET Bone Cement where the ZIMMER BIOMET Bone Cement used in the primary implantation was not infused with antibiotics (hereinafter referred to "ASEPTIC LOOSENING"). The free replacement is limited to one replacement.
- In order to qualify under this WARRANTY, the PRODUCT(s) must be implanted before the expiration date set forth in any PRODUCT's packaging.

2. SCOPE OF WARRANTY

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

- The subject revision surgery must be the result of ASEPTIC LOOSENING.
- ZIMMER BIOMET'S WARRANTY extends to the replacement of the PRODUCT(s) that was used in the primary or initial surgery and that are necessary for completion of a revision surgery. To the extent that the subject knee system or other PRODUCT that was implanted in the initial surgery is no longer marketed or otherwise commercially available, PURCHASER shall be provided, as applicable, with replacement ZIMMER BIOMET Bone Cement, and a Knee Replacement Implant comparable in use and value as determined by ZIMMER BIOMET ("REPLACEMENT PRODUCT").
- When the revision surgery is required due to ASEPTIC LOOSENING, and otherwise qualifies as set forth herein, then ZIMMER BIOMET will promptly replace the PRODUCT(s) with REPLACEMENT PRODUCT or, in the sole discretion of ZIMMER BIOMET, comparable versions thereof. The benefits set out above constitute ZIMMER BIOMET'S sole liability and obligation, and the PURCHASER'S sole and exclusive remedies, with respect to the PRODUCT and the subject matter of these Terms and Conditions. No other replacement components or products are included within the scope of this WARRANTY.

If eligible, ZIMMER BIOMET'S WARRANTY extends to a single, free replacement of the PRODUCT(s) only and such free replacement does not extend to any guides, products, instruments, systems, devices, surgical or professional costs/fees or any services.

This WARRANTY cannot be varied or extended in any manner by any employee or agent of ZIMMER BIOMET.

3. ELIGIBILITY AND CLAIM PROCEDURE

In order to receive the WARRANTY benefits under these Terms and Conditions, the respective hospital or facility must be enrolled in the WARRANTY program and the following must be complied with:

- Subject to Section 1, to remain eligible, notification of a forthcoming replacement claim must be reported to ZIMMER BIOMET in writing at least five (5) business days prior to the date of the revision surgery. The Surgeon shall notify the ZIMMER BIOMET sales representative; and
- Within thirty (30) days following the revision surgery wherein the REPLACEMENT PRODUCT was implanted in accordance with the provisions herein, the surgeon must complete and return the claim form along with the revised PRODUCT in question. The returned PRODUCT must be decontaminated by the surgeon and maintained in a safe, “nondestructive” manner prior to being returned to ZIMMER BIOMET; and
- Unless already on file at ZIMMER BIOMET, the surgeon submitting a claim form for a REPLACEMENT PRODUCT that is eligible under this WARRANTY, must provide:
 - the surgical notes associated with the primary (initial) surgery and revision surgery;
 - certification that the reason for the revision surgery is ASEPTIC LOOSENING;
 - certification that the PRODUCT was used in accordance with the PRODUCT’s Indications for Use and Instructions for Use (hereinafter “on-label”), specifically as follows:
 - ZIMMER BIOMET antibiotic-infused Bone Cement was NOT used in the primary surgery; and/or
 - Non-antibiotic-infused ZIMMER BIOMET Bone Cement was not infused, mixed or otherwise manipulated with antibiotic prior to or during the primary surgery; and
 - a receipt/invoice or sticker sheets for PRODUCT for which replacement is sought.

The cost of return shipment shall be borne by ZIMMER BIOMET in cases covered by the WARRANTY under these Terms and Conditions.

4. DISCLAIMER AND GENERAL LIMITATIONS OF THE WARRANTY

Except for the provisions specified in these Terms and Conditions, ZIMMER BIOMET hereby expressly disclaims and excludes, and PURCHASER hereby expressly waives, any representation, warranty, contract, covenant or other undertaking, whether express or implied or otherwise, written or oral, with respect to the PRODUCT, or its quality, condition, safety or effectiveness, 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, ZIMMER BIOMET disclaims (on behalf of itself and any of its representatives or other third parties which manufacture or distribute the PRODUCT) and PURCHASER releases and waives any and all liability with respect to pain and suffering, medical expenses, lost earnings, incomes or profits, or other direct or indirect, special, contingent, incidental or consequential damages for (1) failure of the PURCHASER to conform to generally accepted standards of care, surgical procedures, techniques and practice, (2) failure of the surgeon to use the PRODUCT in an “on-label” manner, and (3) any other claim resulting or arising from the design, manufacture, composition, condition, use or performance of the PRODUCT or ZIMMER BIOMET, including without limitation any claim or lawsuit based on a cause of action for negligence, tort, strict liability, or statutory violation.

Notwithstanding anything to the contrary, if applicable, the total liability of ZIMMER BIOMET, if any, under or in connection with the PRODUCT, including for any breach of contractual obligations, breach of duty, breach of warranty, misrepresentations, misstatements or tortious act or omissions (including without limitation, strict liability, tort, negligence, statutory violation and liability for infringement of any third party intellectual property rights) shall be limited to damages in an amount equal to the amount paid by the PURCHASER for the PRODUCT.

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, equipment supply charges.

5. MODIFICATION OR WITHDRAWAL OF THE WARRANTY

ZIMMER BIOMET 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 fully paid by the PURCHASER to ZIMMER BIOMET, prior to the date thereof.

6. GENERAL CONDITIONS OF SALE

The provisions 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 PURCHASER, if any.

7. SAFE HARBOR

Any replacement PRODUCT(s) provided by ZIMMER BIOMET under this WARRANTY represent a price reduction that PURCHASER must fully and accurately report in applicable cost reports or claims for payment filed with federal or state health care programs in accordance with the warranty safe harbor provisions of the federal anti-kickback statute at 42 C.F.R. § 1001.952(g). PURCHASER must provide information upon request to Medicare, Medicaid and other federal health care programs on price reductions (including free items) obtained as part of this WARRANTY.

8. PRIVACY AND INFORMATION SECURITY

Under this WARRANTY, the surgeon may provide information relating to patients that have had the PRODUCT implanted. ZIMMER BIOMET may use this information in order to provide the WARRANTY benefits, and for related activities such as monitoring the quality, safety, or effectiveness of the PRODUCT. The surgeon is responsible for ensuring that any disclosure of information to ZIMMER BIOMET in connection with the WARRANTY is in compliance with applicable privacy and information security laws and requirements, including, to the extent applicable, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").

9. GOVERNING LAW AND VENUE

Any action relating to or hereunder shall be governed by the laws of the State of Indiana exclusive of any choice of law principles. The parties agree that the exclusive venue for such action shall lie in a court located in Kosciusko County, Indiana or in the United States District Court of the Northern District of Indiana.

10. EFFECTIVE DATE

THIS WARRANTY AND ITS TERMS AND CONDITIONS SHALL ONLY APPLY TO PROCEDURES WHEREIN THE PRODUCT WAS IMPLANTED ON OR AFTER THE RESPECTIVE HOSPITAL'S OR FACILITY'S ENROLLMENT DATE.