



Pursuing Good Results

# Lifetime Implant Warranty Program



 **ZimVie**

ZimVie DENTAL SOLUTIONS

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This document describes the global limited warranty program for ZimVie Dental. This limited warranty comprises lifetime product replacement for eligible ZimVie Dental products described below and applies automatically to such products implanted on or after January 1, 2016. This document supersedes any other product warranties or guarantees previously issued by either Biomet 3i, LLC or Zimmer Dental, Inc.

**1. PRODUCTS COVERED:** This warranty covers only ZimVie Dental Implants manufactured by Biomet 3i, LLC and Zimmer Dental, Inc. that have been surgically placed but not restored or which have been placed and restored exclusively with ZimVie restorative devices manufactured by Zimmer Dental, Inc. or Biomet 3i, LLC, or the GenTek™ line of components manufactured by Zfx GmbH ("Covered Implants"). For direct customers purchasing from a ZimVie affiliate only, this warranty covers additional ZimVie Dental restorative components as described in Section 4 below. Except for Covered Products and the restorative components explicitly referenced in Section 4 below, other products distributed by ZimVie Dental and its affiliates (including but not limited to products manufactured by third parties) are explicitly excluded.

**2. SCOPE AND TERMS:** Subject to the limitations and exceptions described below, if a product covered by this warranty program fails to remain in the intraoral site into which it was originally placed, ZimVie Dental will provide the warranty benefits outlined herein.

**3. SURGICAL WARRANTY BENEFITS:** Subject to review and approval by ZimVie Dental, the clinician or distributor submitting a warranty claim will receive replacement implants equivalent or comparable to the devices originally installed in the surgical implant site(s). All replacement devices will be ZimVie Dental devices comparable to those used in the original "surgical procedure" (as defined below). Any requested product or service substitutions shall be at ZimVie Dental's discretion only. ZimVie Dental reserves the right to deny warranty coverage if it cannot determine whether the affected product is a ZimVie Dental product, or if the implant was restored with third-party restorative components. It is in the clinician's best interest to keep proper patient records, including patient file stickers, to record product lot numbers and other relevant product information. For purposes of this warranty program, "surgical procedure" means the clinical procedure (a) of preparing an osteotomy and inserting a dental implant(s) and cover screw(s) or, in place of a cover screw(s), temporary healing or restorative components/devices or (b) to reopen the osteotomy after implant(s) healing to place temporary or permanent components onto properly healed and integrated dental implants.

**4. RESTORATIVE WARRANTY BENEFITS - NON-DISTRIBUTOR CUSTOMERS ONLY:** Subject to review and approval by ZimVie Dental, a direct purchaser submitting a warranty claim will receive replacement restorative components equivalent or comparable to the components originally affixed to a failed ZimVie Dental surgical implant. These devices may include an impression coping, analog, retaining screws, and/or provisional, stock or BellaTek abutment. All replacement devices will be ZimVie Dental devices comparable to those used in the original "restorative procedure" (as defined below). Zfx products other than GenTek™ restorative components are excluded from this warranty policy. Restorative warranty coverage does not extend to distributors or other customers who purchase products for resale. For purposes of this warranty program a "restorative procedure" means the clinical procedure to affix to an implant(s) a provisional or permanent restorative appliance.

**5. ELIGIBILITY:** To receive warranty benefits, the treating clinician(s) or distributor must:

- Submit a properly completed ZimVie Product Experience Report Form ("Report") immediately upon being made aware of the product complaint and in no event later than 120 calendar days thereafter; AND return the pre-sterilized device(s) as indicated on the Report within 60 calendar days following submission of the Report. Returned products submitted in connection with complaint reports must be packaged such to prevent loss from damage throughout shipment. Distributors must notify and require their end-customers to submit complaints and failed products to the distributor sufficiently in advance to enable the distributor to meet the above timelines;
- Be current in all financial account activities with ZimVie Dental; and
- Have installed all devices covered by this Warranty Program in accordance with (i) ZimVie Dental prescribed procedures and manuals, including the device's Instructions for Use (IFU), (ii) approved (on-label) product uses, and (iii) accepted medical/dental practices.

**6. WARRANTY MODIFICATION OR TERMINATION:** ZimVie Dental reserves the right to modify or terminate this warranty program at any time, and will endeavor to provide notice of any material change by sending customer communications by mail or e-mail and/or by posting a notice of the modification or update on this site: <https://www.zimvie.com/en/customer-service/dental.html#Return-and-Exchange-Policies-&-Warranties>

**7. TERMINATION OF INDIVIDUAL ELIGIBILITY:** ZimVie Dental may, in its sole discretion, terminate the eligibility of any participant from this warranty program, including in the event of suspected abuse or fraud. Such termination shall not affect benefits accruing to the participant prior to the effective termination date, provided all aspects of the previous claim(s) are in full compliance with this warranty program

**8. NO OTHER WARRANTIES:** AS MANUFACTURER, ZIMVIE DENTAL WARRANTS THAT ITS PRODUCTS ARE FREE FROM DEFECTS IN MATERIALS AND/OR WORKMANSHIP. SUBJECT TO APPLICABLE LAWS, EXCEPT FOR THIS MANUFACTURERS WARRANTY AND THE TERMS OF THIS WARRANTY PROGRAM, NEITHER ZIMVIE DENTAL NOR ANY AFFILIATED ENTITY THAT MAY MANUFACTURE, DISTRIBUTE OR ACT IN ANY WAY AS AN AGENT TO ZIMVIE DENTAL, MAKES ANY OTHER WARRANTY WITH RESPECT TO THE ZIMVIE DENTAL PRODUCTS, EXPRESS OR IMPLIED, WRITTEN OR ORAL, INCLUDING, WITHOUT LIMITATION, OTHER AGREEMENTS OR ANY IMPLIED WARRANTIES, INCLUDING, WITHOUT LIMITATION, IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. TO THE EXTENT PERMITTED BY APPLICABLE LAWS, ZIMVIE DENTAL AND ALL AFFILIATES DISCLAIM LIABILITY TO ANY CUSTOMER, DISTRIBUTOR OR TREATING CLINICIAN FOR (A) LOST EARNINGS, INCOME OR PROFITS, (B) ALL LOSSES OR DAMAGES ARISING, DIRECTLY OR INDIRECTLY, IN WHOLE OR PART FROM THE TREATING CLINICIAN'S FAILURE TO CONFORM TO GENERALLY ACCEPTED STANDARDS OF DENTAL PRACTICES AND (C) ALL INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM DESIGN, COMPOSITION, CONDITION, USE OR PERFORMANCE OF ANY OF THE ZIMVIE DENTAL PRODUCTS.

**9. OFFSETS:** If a treating clinician is eligible for insurance coverage providing benefits for the failure of any covered product or if a covered product is covered by another warranty, all benefits under this warranty program by ZimVie Dental to the treating clinician with respect to the product shall be reduced by the amount of the insurance and/or other warranty benefits applicable to the product.

**10. LICENSES AND PERMITS:** The timely securing of permits, licenses, or other local state or federal governmental approvals required in connection with Purchaser's use of any products hereunder shall be the sole responsibility of Purchaser and Purchaser shall bear the cost thereof. Unless otherwise agreed between ZimVie Dental and Purchaser, products sold hereunder are only for use in the United States.

**11. APPLICATION OF WARRANTY; COMPLIANCE:** Warranty benefits under this warranty program are exclusively for the benefit of the eligible treating clinician(s) only. Patients and other third parties must contact their clinician for coverage. Clinicians and distributors must not charge their customers or patients for in-kind replacement products supplied pursuant to this warranty policy.

**12. EXCEPTIONS:** ZimVie Dental benefits under this warranty program shall not apply to 1) implants placed in patients with contraindicating conditions related to alcoholism, prolonged corticosteroid use, blood dyscrasia, collagen diseases, uncontrolled diabetes, chronic contraindicating drug dependency, recent history of chemotherapy, osteoporosis, endocrine disease, or osteomyelitis; and (2) implants that are not placed in accordance with the product's IFU or the guidelines for Patient Evaluation and Selection contained in ZimVie Dental's surgical manual. This warranty program does not apply to any products that are manufactured or modified from an original device design unless the device is specifically designed for such modification.

**13. SOLE REMEDY:** This warranty program document contains ZimVie Dental's sole obligations and the sole remedies available to any clinician, distributor, or patient with respect to the products manufactured by the ZimVie Dental division.

**14. ENTIRE AGREEMENT:** Except as set forth in this warranty program, neither ZimVie Dental nor any affiliate or representative of ZimVie Dental makes any representation, warranty, covenant, or other undertaking relating to the ZimVie Dental products referenced herein. This warranty program sets forth the entire understanding between ZimVie Dental and its customers and supersedes all prior agreements relating to warranties, guarantees, or product replacement. This warranty program is governed by the laws of Florida without regard to conflicts of law principles.

**Note:** ZimVie Product Experience Report forms are available from ZimVie's website <https://www.zimvie.com/en/customer-service/dental.html#eper> or you may contact your Customer Service representative. When possible, all warranty claim submissions must include the catalog and lot number of the actual device(s) covered by this warranty program. Failure to provide this information or any other required information, or failure to return original devices, may void warranty benefits.

For more information, visit [ZimVie.com](https://www.zimvie.com)

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