



MoRe[®] Promise

MoRe[®] Rod Lifetime Limited Warranty Terms and Conditions

MiRus warrants the MoRe[®] Rods against breakage for as long as the rods remain implanted and pursuant to the terms and conditions set forth in this Limited Warranty. This Limited Warranty is not a guarantee against structural failure and does not replace the information contained in the Instructions for Use, including the Possible Adverse Effects identified in the instructions.

1. SCOPE OF WARRANTY

This Limited Warranty applies to MoRe[®] Rods (the "Product") implanted as part of the EUROPA[™] Pedicle Screw System supplied by MiRus. Use of MoRe[®] Rods with pedicle screws or other components not supplied by MiRus voids this Limited Warranty. This Limited Warranty is exclusively for the benefit of health care providers who were original purchasers of the Product and applies only to Products implanted in the United States. Provided the terms and conditions of this Limited Warranty are met, MiRus will, at its sole option and for the original purchaser, replace the Product if it experiences breakage at any time after implantation. If MiRus chooses to provide replacement Product, it will provide MiRus screws, connectors, set screws, and implants required to implant the replacement Product.

2. ELIGIBILITY

In order to qualify for replacement under this Limited Warranty, Purchaser must submit evidence at least 30 days prior to the scheduled revision surgery that the Product experienced breakage and that the Product was: (1) used for an approved indication of use; (2) implanted with pedicle screws and other components supplied by MiRus; (3) implanted before the expiration date set forth in the Product's packaging; and (4) the first spinal rod implanted in the patient and not used in a revision surgery to replace any previous rod.

3. CLAIM PROCEDURE

- a. To file a claim under this Limited Warranty, the purchaser must submit a claim form available at www.mirusmed.com/more-promise with the following information: date of original surgery, case usage form, attending surgeon, pre-planning for surgery and a full description of the patient prior to original surgery including previous correction for spinal disease.
- b. Diagnostic image(s) (i.e. X-Rays) showing breakage of the Product.
- c. Surgeon validation in form of a signature on the claim form.
- d. The claim form must be returned prior to the revision surgery using either of the following options:
 - i. Mail: MiRus MoRe Rod Lifetime Warranty Program, 1755 W. Oak Parkway, Suite 100, Marietta, Georgia 30062.
 - ii. E-mail: MoRerodwarranty@mirusmed.com

4. DISCLAIMER AND GENERAL LIMITATIONS OF THE LIMITED WARRANTY

This Limited Warranty is the sole warranty provided in connection with the Product, and **MIRUS HEREBY EXPRESSLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY WITH RESPECT TO THE PRODUCT, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT, OR FITNESS FOR A PARTICULAR USE OR PURPOSE.**

In addition, MiRus 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 purchaser or healthcare provider 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.

This repair or replacement Limited Warranty is the exclusive remedy with respect to the Product, and shall exclude any other rights, benefits, or remedies, such as, for example, reimbursement or payment of any clinical treatment, costs, services, charges or fees incurred by the purchaser, including without limitation any charges related to explanting the Product.

5. MODIFICATION OR WITHDRAWAL OF THE WARRANTY

MiRus reserves the right to modify or withdraw the Limited Warranty at any time without notice. Products purchased between the initial effective date and withdrawal of the Limited Warranty will continue to be covered under the Limited Warranty.

6. GENERAL CONDITIONS OF SALE

The Limited Warranty 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 or components provided by MiRus under this Limited Warranty represent a price reduction that Purchasers 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). Purchasers 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 Limited Warranty.

8. GOVERNING LAW AND VENUE

This Limited Warranty shall be governed by the laws of the State of Georgia exclusive of any choice or conflict of law principles.

9. EFFECTIVE DATE

This Limited Warranty applies to Products sold on or after March 1, 2021.