

**Urolift™ Deployment Warranty**

Notwithstanding anything to the contrary in Teleflex's Standard Terms and Conditions of Sale or any other agreement between Customer and Teleflex with respect to the subject matter of this warranty, if during an outpatient prostatic urethral lift procedure performed for a purpose cleared by the United States Food and Drug Administration and using Teleflex's Urolift™ System ("Procedure"), which consists of a Urolift™ Delivery Device and Urolift™ Implants, a Urolift™ Implant's capsular tab fails to fully deploy and seat on the capsular surface of the prostate ("Non-Deployment") as a result of (a) contact with the pelvic bone ("Bone Strike") or (b) pulling through the adenoma towards the delivery device ("Pull Through"), due to anatomical variations, Teleflex will provide to Customer a new, single Urolift™ Implant at no additional charge (the "Replacement Urolift™ Implant"). This Urolift™ Deployment Warranty ("Warranty") is subject to the following conditions:

- 1) Customer must fully and accurately report any price reduction of the items received as part of this Warranty in its applicable cost reports and must also provide, upon request by federal or state government, information provided by Teleflex as specified in 42 C.F.R. § 1001.952(g)(3).
- 2) Patients whose care is subject to this Warranty must have received a Procedure as prescribed by their physician. The Urolift™ System, which includes the Urolift™ Delivery Device and Urolift™ Implant, must have been used in a manner consistent with all labeling and instructions for use, with all indications for use present and no contraindications present prior to the Procedure.
- 3) The Non-Deployment must result from a Bone Strike or Pull Through due to anatomical variation.
- 4) Teleflex must receive Customer's completed Urolift™ Deployment Warranty Form (form attached) for each claim made under this Warranty within ten business (10) days of the date of the Procedure. If requested, Customer will allow Teleflex reasonable access to, or furnish Teleflex with copies of, Customer's books and records, sufficient to enable Teleflex to confirm that Customer's claim satisfies all conditions of this Warranty.
- 5) Following a determination by Teleflex of a valid Warranty claim, Teleflex will issue a Replacement Urolift™ Implant to Customer. Teleflex's determinations as to eligibility and satisfaction of Warranty conditions will be conclusive absent manifest error.
- 6) The following limitations apply to the Warranty Program:
  - a. Claims by a Customer for any physician with more than twelve (12) months of experience with the Urolift™ System may not exceed 2.5% of that physician's prior year annualized deployments.
  - b. Claims by a Customer for any physician with less than six (6) months of experience with the Urolift™ System may not exceed four (4) Implants in the calendar year for that physician. New Urolift™ System physicians who are still within the New Start Training Period are not eligible for this Warranty.

- c. Claims by a Customer for any physician with six (6) to twelve (12) months of experience with the Urolift<sup>TM</sup> System may not exceed the greater of four (4) Implants or 2.5% of that physician's annualized deployments in the calendar year.
- 7) Customer must certify that it has not and will not submit for reimbursement nor charge the patient for the Urolift<sup>TM</sup> Implant(s) with the capsular tab that did not fully deploy due to a Bone Strike or Pull Through.
- 8) Customer must certify that physicians performing Procedures at Customer's facility(ies) will, at all times, remain responsible for determining whether specific medical devices, including the Urolift<sup>TM</sup> System as well as the Urolift<sup>TM</sup> Delivery Device and Urolift<sup>TM</sup> Implant, are medically necessary and clinically appropriate for a particular patient.

This Warranty program is not contingent upon or in any way related to purchasing quotas, minimums, or any other eligibility criteria tied to volume, value, or exclusivity.

This Warranty program does not apply to any Urolift<sup>TM</sup> Implant that was not purchased directly from Teleflex by the Customer Facility at which the Procedure was performed.

Teleflex may terminate the Warranty program at any time for any reason upon written notice. Warranty claims for a Urolift<sup>TM</sup> Implant used in a Procedure prior to termination of the Warranty program will continue to be accepted and (if all conditions of this Warranty are satisfied) honored by Teleflex, to the extent legally permissible.

This Warranty program is intended to comply with all applicable laws and regulations. Customer will report Warranty price reductions and provide other information about this Warranty program as required or as requested to third parties (including the U.S. Department of Health and Human Services or state agencies) under laws and regulations that apply to Customer



**Urolift™ Deployment Warranty Claim Form**

Please complete all fields below. An incomplete Deployment Warranty Claim Form may delay receipt of a replacement implant or result in the rejection of a claim. All capitalized terms not otherwise defined herein shall have the same definition as specified in the Urolift™ Deployment Warranty. Submit one form per patient case to ULWarranty@Teleflex.com

**Customer Account Name:**<sup>1</sup> \_\_\_\_\_

**Teleflex Account #:** \_\_\_\_\_ **Procedure Date:** \_\_\_\_\_

1. Facility where Procedure took place (if part of a health system, please indicate name of health system): \_\_\_\_\_

2. Lot #(s) of Urolift™ Implant(s) used in Procedure that did not deploy due to anatomical variations. List Lot #, Qty & Model Type:  
\_\_\_\_\_  
\_\_\_\_\_

3. Physician performing Procedure: \_\_\_\_\_

4. Physician NPI No: \_\_\_\_\_

**Initial next to each statement below, indicating agreement with each of the following:**

5. \_\_\_\_\_ Urolift™ Implant’s capsular tab did not fully deploy and seat on the capsular surface of the prostate as a result of a Bone Strike or Pull Through due to anatomical variation.

6. \_\_\_\_\_ The use of the Urolift™ System, which includes the Urolift™ Delivery Device and Urolift™ Implant, was consistent with all labeling and instructions for use, with all indications for use present and no contraindications present prior to the Procedure.

7. \_\_\_\_\_ Physicians performing Procedures at the Facility remain responsible for determining whether specific medical devices, including the Urolift™ System as well as the Urolift™ Delivery Device and Urolift™ Implant, are medically necessary and clinically appropriate for a particular patient.

<sup>1</sup> “Customer” should be the name of the entity that purchased the Urolift™ Implant used in the Procedure.

8. \_\_\_\_\_ A claim for reimbursement has not been nor will be submitted for the Urolift<sup>TM</sup> Implant with the capsular tab that did not fully deploy and seat on the capsular surface of the prostate.
9. \_\_\_\_\_ The patient will not be billed for the Urolift<sup>TM</sup> Implant with the capsular tab that did not fully deploy and seat on the capsular surface of the prostate.
10. \_\_\_\_\_ Customer does not believe a device malfunction occurred with the Urolift<sup>TM</sup> System used in the Procedure, including the Urolift<sup>TM</sup> Delivery Device and Urolift<sup>TM</sup> Implant.<sup>2</sup>
11. \_\_\_\_\_ Customer has discarded the Urolift<sup>TM</sup> Implant with the capsular tab that did not fully deploy and seat on the capsular surface of the prostate OR Customer has returned the Urolift<sup>TM</sup> Implant as a suspected device malfunction, and upon closure of the investigation, was notified by the Urolift<sup>TM</sup> Warranty Team they may be eligible for a replacement under this program.

***By signing below, Customer certifies that all information provided above is true and correct, and further certifies that the Deployment identified in this Deployment Warranty Claim Form satisfies all of the conditions of the Urolift<sup>TM</sup> Implant Deployment Warranty Program.***

Customer Account Name: \_\_\_\_\_

Signature: \_\_\_\_\_ Date Signed: \_\_\_\_\_

Name (Printed): \_\_\_\_\_

Title: \_\_\_\_\_

Contact Name (if different): \_\_\_\_\_

Phone: \_\_\_\_\_ Email: \_\_\_\_\_

**Please remit complete, executed Deployment Warranty Claim Form to:**

**Urolift<sup>TM</sup> Warranty Team**

**E: [ULWarranty@Teleflex.com](mailto:ULWarranty@Teleflex.com)**

<sup>2</sup> Should the Customer believe a device malfunction has occurred; he/she should contact the Teleflex Quality Department at [USPLE-Complaints@Teleflex.com](mailto:USPLE-Complaints@Teleflex.com)