

Levion™ Cervical Collar Return Policy

At Outcome-Based Technologies, LLC, each Levion™ Cervical Collar is custom fabricated specifically for the individual patient using a patient-specific digital workflow and custom fabrication process. Due to the personalized medical nature of the device, all Levion™ Cervical Collars are considered custom medical devices intended for repeated use by the same patient only.

As a result, **all sales are final.**

Returns & Refunds

- No returns, exchanges, or refunds are accepted on Levion™ Cervical Collars.
- Each collar is custom fabricated for a specific patient and cannot be restocked, reused by another patient, or resold.
- Once fabrication has begun, orders cannot be canceled.

Manufacturing Defects

If you believe your Levion™ Cervical Collar has a manufacturing defect, please contact Outcome-Based Technologies, LLC immediately for evaluation.

If the issue is determined to be related to manufacturing or fabrication, Outcome-Based Technologies, LLC may repair or replace the device at its discretion.

Examples of potential manufacturing defects may include:

- Structural cracking or failure under normal prescribed use
- Defective latch, hinge, dial, or locking mechanism
- Improper fabrication resulting in significant fitment issues
- Material defects
- Damage present upon arrival

Fitment & Adjustment Notice

The Levion™ Cervical Collar is fabricated from patient scan data and may require minor adjustments by a qualified healthcare provider to optimize fit and comfort.

Minor pressure areas, comfort adjustments, pad break-in, or provider-directed fitting modifications are not considered manufacturing defects.

Exclusions

This policy does not cover:

- Normal wear and tear
- Improper use or failure to follow Instructions for Use (IFU)
- Unauthorized modifications or repairs

- Damage caused by accidents, misuse, excessive force, or improper cleaning
- Cosmetic variations inherent to custom fabrication or additive manufacturing processes
- Issues resulting from inaccurate scans, patient movement during scanning, or changes in patient anatomy after scanning
- Damage caused during shipping after delivery confirmation

Defect Claims

To submit a defect claim, please provide:

- Patient or order information
- Product serial number
- Description of the issue
- Clear photographs of the collar and affected area
- Any relevant provider notes regarding the issue

Outcome-Based Technologies, LLC may request return inspection of the product before approving repair or replacement.

Shipping

Outcome-Based Technologies, LLC will make reasonable efforts to fabricate and ship devices within estimated lead times. Expedited fabrication and shipping services may be available for an additional charge.

Shipping timelines may vary based on production schedules, material availability, scan quality, provider communication, and carrier delays.

Intended Use

The Levion™ Cervical Collar is intended for repeated use by the same patient only and should not be transferred, shared, or reused by another individual.

Levion™ Custom Replacement BamDex™ Pad Set Return Policy

At Outcome-Based Technologies, LLC, all Levion™ Custom Replacement BamDex™ Pad Sets are custom fabricated for the individual patient and are considered single-patient-use medical products. Due to the custom nature of these products, **all sales are final.**

Returns & Refunds

- No returns, exchanges, or refunds are accepted on Levion™ Custom Replacement BamDex™ Pad Sets.
- Replacement pad sets are custom fabricated specifically for the patient's Levion™ cervical collar and cannot be restocked or reused.

Manufacturing Defects

If you believe your replacement pad set has a manufacturing defect, please contact Outcome-Based Technologies, LLC as soon as possible for review.

If the issue is determined to be a manufacturing defect, a replacement item will be provided at no additional charge.

Examples of potential manufacturing defects may include:

- Material separation or delamination
- Improper fabrication or sizing
- Defective stitching or attachment areas
- Damage present upon arrival

Exclusions

This policy does not cover:

- Normal wear and tear
- Damage caused by misuse, improper installation, or improper cleaning
- Alterations or modifications to the product
- Damage caused by excessive force, chemicals, or improper storage
- Cosmetic variations associated with custom fabrication

Defect Claims

To submit a defect claim, please provide:

- Patient or order information
- Product serial number (located underneath the pads on both the front and back pieces of the collar)
- Description of the issue
- Clear photographs of the product

Outcome-Based Technologies, LLC may request additional information or inspection of the product before approving a replacement.

Shipping

We do our best to fabricate and ship replacement pad sets within 24–48 business hours. Expedited shipping services may be available for an additional charge.

Shipping delays caused by carriers, weather, or other circumstances outside of our control are not covered under this policy.

Contact Information

For questions regarding replacement pads or defect claims, please contact:



RECOVERY BUILT AROUND YOU

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