INTEGRA®

DuraSorb^{365}™

Product Performance Pledge

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DuraSorb[365]™ is an innovative Product Performance Pledge from Integra LifeSciences Corporation – maker of DuraSorb® Monofilament Mesh.

DuraSorb is a fully resorbable knitted scaffold designed to address the limitations of existing soft tissue support products in surgery.[1,2]* DuraSorb Monofilament Mesh is intended for use in reinforcement of soft tissue where weakness exists.

Our Commitment

The DuraSorb family of products are backed by DuraSorb[365], a program dedicated to Integra's commitment to product quality and performance.

Integra will, subject to the terms and conditions below, provide the purchaser of the device ("Purchaser") with a replacement product of the same SKU at no cost if a Board-Certified Surgeon implants DuraSorb® Monofilament Mesh in a patient and either of the following occurs:

(i) between six months and one year from implantation, the patient has returned to the Board-Certified Surgeon and the device is palpable through the skin.

OR

(ii) an examination by the Board-Certified Surgeon reveals that the device has extruded through the patient's skin within one year from implantation.

Terms & Conditions

- The device must be implanted by a Board-Certified Surgeon for the reinforcement of soft tissue where weakness exists.
- The Purchaser or Board-Certified Surgeon must complete and execute the claim form and submit it to custsvcnj@integralife.com. Integra LifeSciences does not require, and should not receive, patient identifying information with the submission.
- The Purchaser must provide proof of purchase of the DuraSorb product.
- The Board-Certified Surgeon must certify as to the existence of one of the two conditions set forth in the Pledge as set forth in (i) and (ii) above.
- Integra LifeSciences will make reasonable efforts to respond to any claim within 30 days of receipt.
- The replacement device may be shipped only to the same account name and address that purchased the original device implanted.
- Replacement product provided by Integra related to the program shall only be utilized by the Purchaser.
- The Purchaser shall either, as applicable, (i) report receipt of replacement product as a credit for purposes of cost reporting to any third-party payor, including the Medicare program, and the cost of the replacement product shall be subtracted from the DRG payment, or (ii) apply the cost of the replacement product as a discount on the purchase of both the initial product and the replacement product for cost reporting purposes.
- This program does not supplant the Board-Certified Surgeon's exercise of discretion or otherwise interfere with his or her independent clinical judgment in the use of DuraSorb products. Neither this program nor any of Integra's actions hereunder shall be construed to be a substitute for professional medical advice, diagnosis, or treatment.
- Terms are subject to change or discontinuance without notice. Integra reserves the right to determine the sufficiency of any claim and compliance with program requirements.

References

*Pre-clinical results may not be indicative of clinical results.

1. Mlodinow AS, Yerneni K, Hasse ME, Cruickshank T, Kuzycz M, Ellis MF. Evaluation of a novel absorbable mesh in a porcine model of abdominal wall repair. Plas Reconstr Surg Glob Open. 2021 May 25;9(5):e3529.
2. SIA DuraSorb Registry Study Investigator Satisfaction Survey. Of 816 users surveyed, 568 rated DuraSorb as "much better" alternative compared to other products they would use for soft tissue support. Surgeon investigators completed the survey after implanting DuraSorb for soft tissue reinforcement. The responses reflect a variety of surgical procedures.

DuraSorb Claim Form Elements:

Name of Purchaser: _____

Address: _____ **City, State, Zip:**_____

Integra Account Number (if known): _____

Name of Person filing this claim on behalf of Purchaser: _____

Email Address: _____

Name of Surgeon Implanting Device: _____**Type of Surgery:** _____

Product Code for DuraSorb Product implanted: _____ **Lot Number:** _____

Date of Device Implantation: _____

Date of Examination forming basis of this claim: _____

Observation on which claim is based: _____

Choose One: **Device was palpable** **Device extruded through skin**

If Device extruded through skin, please attach photographic evidence.

Note: If all other terms and conditions of a palpability or extrusion claim are met, the surgeon will be required to certify to Integra in writing that the device was palpable on the date of examination before the claim can be approved.

- An Integra representative may contact you for REDACTED physician notes to confirm details of the claim.
- The replacement product can only be provided to the hospital or clinic that purchased the product.
- A copy of this claim form will be provided to the Integra Product Complaint Department.

Integra shall be solely responsible for determining whether a claim meets program requirements.

By signing below, I certify that to the best of my knowledge, the information provided in this claim form is complete and accurate:

Signed: _____

For more information or to place an order, please contact:

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