

2023-05-22

**URGENT: VOLUNTARY MEDICAL DEVICE RECALL**

**SurgiMend® PRS / SurgiMend® PRS Meshed  
 SurgiMend®/ SurgiMend® MP  
 Revize™ / Revize™-X  
 PriMatrix® Dermal Repair Scaffold  
 PriMatrix® Ag Antimicrobial Dermal Repair Scaffold**

Dear Valued Customer/Distributor:

Integra LifeSciences is issuing this Voluntary Medical Device Recall Notice for the PriMatrix®, SurgiMend®, and Revize™ products listed in Appendix 1, distributed from March 1, 2018 to May 22, 2023.

**Reason for Recall (Removal):**

Based on an internal investigation, Integra LifeSciences has identified issues with in-process and finished goods endotoxin testing that may result in out of specification endotoxin results. Accordingly, we are recalling those products per the instructions below. Our records indicate you have purchased at least one of those products.

Eighty-two (82) complaints have been received for which endotoxin could not completely be eliminated as a possible contributor to patient signs and symptoms (see Risk to Health section below for the harms), 53 of which were deemed reportable to the FDA.

**Risk to Health:**

Per the Health Hazard Evaluation conducted for this issue, the potential harms due to high levels of endotoxins may include low-grade fever, inflammation, and/or inflammatory response leading to fever (pyrexia), and/or surgical intervention/revision surgery. Per the conclusion of this evaluation, there is a remote possibility of these adverse health consequences occurring.

If you have already implanted or used the products affected by this recall, we recommend you monitor the patient for a fever in the immediate postoperative period according to the standard hospital or clinician protocol. If these harms do occur, they would most likely begin to present themselves after the first few days to within a few weeks post-operative care.

**Summary of Actions Required:**

Our goal at Integra LifeSciences is to provide you with the best quality products and services to ensure the highest level of patient safety. We are therefore asking you do the following:

1. **Verify if you have any lots of the product on the next page and if so, STOP using that product.**
2. **Remove that product from service.**
3. **Complete the Return Acknowledgment Form on the next page. Send it to Integra as directed on the form.**
4. **See “Actions Required” below for more details.**

This voluntary recall is limited to the product scope specified in this communication as outlined in Appendix 1.

Our records indicate that you may have received product from these lots.

**Actions to be Taken by Customers:**

1. If you **do** have units of the affected product listed in Appendix 1, **remove them immediately from service.**
2. If you **do** have affected product, check the box on the enclosed form “I **do** have affected product.” Record the total quantity of the affected product that you have.
3. If you **do not** have affected product, check the box, “I **do not** have affected product.”

4. Complete the attached "Acknowledgement Form" and return in one of the following ways:
  - a. Email: [Integralife6562@sedgwick.com](mailto:Integralife6562@sedgwick.com)
  - b. Fax: 888-229-0320
  - c. Questions via Phone: 888-656-6375
5. Keep a copy of the form for your records.
6. If you have affected product, please use the enclosed return shipping label and instructions for returning product.
7. A credit will be issued for eligible product. Should you require a refund, please indicate in the "special instructions" section of the product acknowledgement form.
8. If you have already implanted or used products affected by this recall, monitor the patient for a fever in the immediate postoperative period according to the standard hospital or clinician protocol. (See Risk to Health above for details.)

PLEASE NOTE THAT REGARDLESS OF WHETHER YOU HAVE THE AFFECTED PRODUCT OR NOT – A COMPLETED ACKNOWLEDGEMENT IS REQUIRED

**Actions to be Taken by Integra Sales Representatives, Authorized Dealers and/or Distributors:**

1. If you do have the affected product listed in Appendix 1, **remove the product from further distribution.**
2. If you do have affected product, check the box on the enclosed form "I do have affected product." Record the total quantity of the Integra owned (consignment) product only.
3. If you do not have affected product, check the box, "I do not have affected product."
4. Complete the attached "Acknowledgement Form" and return in one of the following ways:
  - a. Email: [Integralife6562@sedgwick.com](mailto:Integralife6562@sedgwick.com)
  - b. Fax: 888-229-0320
  - c. Questions via Phone: 888-656-6375
5. Keep a copy of the form for your records.
6. If you have affected product, please use the enclosed return shipping label and instructions for returning product.
7. Should any affected product be Integra owned (consigned) on the shelves of customers you are to collect the affected product and return using the provided shipping information. Do not return any customer owned product.
8. A direct replacement for affected product is not available at this time, but similar products may be available that you should review with your customers.

PLEASE NOTE THAT REGARDLESS OF WHETHER YOU HAVE THE AFFECTED PRODUCT OR NOT – A COMPLETED ACKNOWLEDGEMENT IS REQUIRED

Receipt of this form ensures that Integra has achieved a level of effectiveness in communicating this information. We recommend you also maintain a copy of this notification and signed copy of the acknowledgement form for your records. Regulatory agencies such as the FDA perform audits of field actions of this nature to verify that customers have been notified and understand the nature of the field action.

Should you have any questions regarding these instructions, please contact your Integra Sales Representative or Customer Service from Monday to Friday 8:00 a.m. – 8:00 p.m. EST at 1-800-654-2873 or [custsvcnj@integralife.com](mailto:custsvcnj@integralife.com).

In addition, adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax:

Online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)

Mail:

Medwatch, Food and Drug Administration

5600 Fishers Lane

Rockville, MD 20852

Fax: 800-332-0178 (toll-free)

Integra is dedicated to patient safety and manufacturing excellence, and has made numerous quality improvements and investments in our facilities around the world. In addition, we are improving our processes in accordance with applicable regulations. We sincerely apologize for any inconvenience this voluntary recall may cause and thank you for your cooperation in this effort.

Sincerely,

*Lacey Gigante*

SignNow e-signature ID: 54faa1ba69...  
06/21/2023 14:48:02 UTC  
Lacey Gigante (Signer)

Lacey Gigante,  
Corporate Global Quality Assurance, Post-Market Surveillance

**URGENT: VOLUNTARY MEDICAL DEVICE RECALL**

**SurgiMend® PRS / SurgiMend® PRS Meshed  
SurgiMend®/ SurgiMend® MP  
Revize™ / Revize™-X  
PriMatrix® Dermal Repair Scaffold  
PriMatrix® Ag Antimicrobial Dermal Repair Scaffold**

**FOR CUSTOMERS ONLY Response is Required: Please Complete and Return Promptly**

**Please fill out this form and return to:  
Integralife6562@sedgwick.com or FAX to 888-229-0320**

**Customers:**

I have received, read, and understand the information provided in the Voluntary Medical Device Recall Notice. I have/will comply with the Voluntary Medical Device Recall Notice and return the completed acknowledgement form. **Yes**

Any adverse events associated with recalled product? Yes  No

If yes, please explain:

---

---

**I do not have affected product**

**I do have affected product:**

| <b>SKUs Representing Products on the list below from all lots: Distributed between: 03/01/2018 to 5/22/2023</b> |   |                                |   |
|---|---|--------------------------------|---|
| <b>Manufacturer's Product Number (SKU)</b>  | <b>Product Name/Catalog Description</b> | <b>Customer Owned Quantity</b> | <b>Integra Owned (Consigned) Quantity</b> |
| 606-001-002   | SurgiMend 1.0 5x6 cm                    |                                |   |
| 606-001-004   | SurgiMend 1.0 6x12 cm                   |                                |   |
| 606-001-005   | SurgiMend 1.0 10x10 cm                  |                                |   |
| 606-001-006   | SurgiMend 1.0 10x15 cm                  |                                |   |
| 606-001-007   | SurgiMend 1.0 10x20 cm                  |                                |   |
| 606-001-008   | SurgiMend 1.0 16x20 cm                  |                                |   |
| 606-001-009   | SurgiMend 1.0 13x25 cm                  |                                |   |
| 606-001-010   | SurgiMend 1.0 4x16 cm                   |                                |   |
| 606-001-012   | SurgiMend 1.0 3x3 cm                    |                                |   |
| 606-001-013   | SurgiMend 1.0 4x7 cm                    |                                |   |
| 606-001-014   | SurgiMend 1.0 4x12 cm                   |                                |   |
| 606-001-015   | SurgiMend 1.0 6x16 cm                   |                                |   |
| 606-001-016   | SurgiMend 1.0 25x40 cm                  |                                |   |
| 606-001-017   | SurgiMend 1.0 20 x 30 cm                |                                |   |
| 606-001-018   | SurgiMend 1.0 8x16 cm                   |                                |   |
| 606-002-002   | SurgiMend 1.0 4x7 cm Thin               |                                |   |
| 606-002-003   | SurgiMend 1.0 5x6 cm Thin               |                                |   |

**SKUs Representing Products on the list below from all lots:Distributed between: 03/01/2018 to 5/22/2023**

| Manufacturer's Product Number (SKU) | Product Name/Catalog Description         | Customer Owned Quantity | Integra Owned (Consigned) Quantity |
|-------------------------------------|--|-------------------------|------------------------------------|
| 606-002-005                         | SurgiMend 1.0 3x3 cm Thin                |                         |                                    |
| 606-003-001                         | SurgiMend 1.0 0.3x25 cm                  |                         |                                    |
| 606-003-002                         | SurgiMend 1.0 0.6x25 cm                  |                         |                                    |
| 606-003-003                         | SurgiMend 1.0 1x25 cm                    |                         |                                    |
| 606-004-100                         | SurgiMend PRS 10x15 cm Semi-Oval         |                         |                                    |
| 606-004-101                         | SurgiMend PRS 7x17 cm Fenestrated        |                         |                                    |
| 606-004-102                         | SurgiMend PRS 10x20 cm Fenestrated       |                         |                                    |
| 606-004-103                         | SurgiMend PRS 8x16 cm Semi-Oval          |                         |                                    |
| 606-004-104                         | SurgiMend PRS 15x15 cm Semi-Oval         |                         |                                    |
| 606-004-105                         | SurgiMend PRS 8x20 cm Fenestrated        |                         |                                    |
| 606-004-106                         | SurgiMend PRS 10x15 cm Slant Fenestrated |                         |                                    |
| 606-004-107                         | SurgiMend PRS 7x17 cm Semi-Oval          |                         |                                    |
| 606-004-108                         | SurgiMend PRS 8x16 cm Thin Semi-Oval     |                         |                                    |
| 606-004-109                         | SurgiMend PRS 10x20 cm Thin Semi-Oval    |                         |                                    |
| 606-004-110                         | SurgiMend PRS 6x16 cm Semi-Oval          |                         |                                    |
| 606-005-001                         | SurgiMend PRS Thin Oval 8x12 cm          |                         |                                    |
| 606-005-002                         | SurgiMend PRS Thin Oval 10x15 cm         |                         |                                    |
| 606-005-003                         | SurgiMend 1.0 8x12 cm Thin               |                         |                                    |
| 606-005-004                         | SurgiMend 1.0 10x15 cm Thin              |                         |                                    |
| 606-007-001                         | SurgiMend PRS Meshed 20cm x 10 cm        |                         |                                    |
| 606-200-002                         | SurgiMend 2.0 5x6 cm                     |                         |                                    |
| 606-200-004                         | SurgiMend 2.0 6x12 cm                    |                         |                                    |
| 606-200-006                         | SurgiMend 2.0 10x15 cm                   |                         |                                    |
| 606-200-008                         | SurgiMend 2.0 16x20 cm                   |                         |                                    |
| 606-200-009                         | SurgiMend 2.0 13x25 cm                   |                         |                                    |
| 606-200-016                         | SurgiMend 2.0 25x40 cm                   |                         |                                    |
| 606-200-017                         | SurgiMend 2.0 20x30 cm                   |                         |                                    |
| 606-200-019                         | SurgiMend 2.0 20x20 cm                   |                         |                                    |
| 606-200-020                         | SurgiMend 2.0 20x25cm                    |                         |                                    |
| 606-204-100                         | SurgiMend 2.0 10x15cm Semi-Oval          |                         |                                    |
| 606-206-001                         | SurgiMend MP 10x15 cm                    |                         |                                    |
| 606-206-002                         | SurgiMend MP 20x20 cm                    |                         |                                    |
| 606-206-003                         | SurgiMend MP 13x25 cm                    |                         |                                    |
| 606-206-004                         | SurgiMend MP 16x20 cm                    |                         |                                    |
| 606-206-005                         | SurgiMend MP 20x25cm                     |                         |                                    |
| 606-206-006                         | SurgiMend MP 20x30 cm                    |                         |                                    |
| 606-206-007                         | SurgiMend MP 25x40 cm                    |                         |                                    |
| 606-300-002                         | SurgiMend 3.0 5x6 cm                     |                         |                                    |
| 606-300-004                         | SurgiMend 3.0 6x12 cm                    |                         |                                    |
| 606-300-006                         | SurgiMend 3.0 10x15 cm                   |                         |                                    |
| 606-300-008                         | SurgiMend 3.0 16x20 cm                   |                         |                                    |
| 606-300-009                         | SurgiMend 3.0 13x25 cm                   |                         |                                    |

**SKUs Representing Products on the list below from all lots:Distributed between: 03/01/2018 to 5/22/2023**

| Manufacturer's Product Number (SKU) | Product Name/Catalog Description    | Customer Owned Quantity | Integra Owned (Consigned) Quantity |
|-------------------------------------|-------------------------------------|-------------------------|------------------------------------|
| 606-300-016                         | SurgiMend 3.0 25x40 cm              |                         |                                    |
| 606-300-017                         | SurgiMend 3.0 20x30 cm              |                         |                                    |
| 606-300-019                         | SurgiMend 3.0 20x20 cm              |                         |                                    |
| 606-300-020                         | SurgiMend 3.0 20x25 cm              |                         |                                    |
| 606-300-021                         | SurgiMend 3.0 1x5 cm                |                         |                                    |
| 606-300-022                         | SurgiMend e3.0 10x25 cm             |                         |                                    |
| 606-304-001                         | SurgiMend 3.0 4x7cm Fenestrated     |                         |                                    |
| 606-304-002                         | SurgiMend e3.0 10x25 cm Fenestrated |                         |                                    |
| 606-400-002                         | SurgiMend 4.0 5x6 cm                |                         |                                    |
| 606-400-004                         | SurgiMend 4.0 6x12 cm               |                         |                                    |
| 606-400-006                         | SurgiMend 4.0 10x15 cm              |                         |                                    |
| 606-400-009                         | SurgiMend 4.0 13x25 cm              |                         |                                    |
| 606-400-016                         | SurgiMend 4.0 25x40 cm              |                         |                                    |
| 606-400-017                         | SurgiMend 4.0 20x30 cm              |                         |                                    |
| 606-400-018                         | SurgiMend e4.0 10x25 cm             |                         |                                    |
| 606-403-001                         | SurgiMend 4.0 20x0.5 cm             |                         |                                    |
| 606-404-001                         | SurgiMend e4.0 10x25 cm Fenestrated |                         |                                    |
| 606-907-001                         | SurgiMend PRS Meshed 10cm x 20 cm   |                         |                                    |
| 607-001-009                         | PriMatrix 0.2x26.5cm, 3 Pack        |                         |                                    |
| 607-001-112                         | PriMatrix 10x12cm                   |                         |                                    |
| 607-001-125                         | PriMatrix 10x25 cm                  |                         |                                    |
| 607-001-225                         | PriMatrix 20x25 cm                  |                         |                                    |
| 607-001-440                         | PriMatrix 4x4 cm                    |                         |                                    |
| 607-001-660                         | PriMatrix 6x6 cm                    |                         |                                    |
| 607-001-812                         | PriMatrix 8x12 cm                   |                         |                                    |
| 607-001-880                         | PriMatrix 8x8 cm                    |                         |                                    |
| 607-004-440                         | PriMatrix Fenestrated 4x4 cm        |                         |                                    |
| 607-004-660                         | PriMatrix Fenestrated 6x6 cm        |                         |                                    |
| 607-004-880                         | PriMatrix Fenestrated 8x8 cm        |                         |                                    |
| 607-005-014                         | PriMatrix 14mm Meshed* Disc         |                         |                                    |
| 607-005-018                         | PriMatrix 18mm Meshed* Disc         |                         |                                    |
| 607-005-125                         | PriMatrix Meshed 2:1 10x25 cm       |                         |                                    |
| 607-005-220                         | PriMatrix Meshed* 2x2 cm            |                         |                                    |
| 607-005-225                         | PriMatrix Meshed 1:1 20x25 cm       |                         |                                    |
| 607-005-330                         | PriMatrix Meshed 2:1 3x3 cm         |                         |                                    |
| 607-005-440                         | PriMatrix Meshed 2:1 4x4 cm         |                         |                                    |
| 607-005-550                         | PriMatrix Meshed 2:1 5x5 cm         |                         |                                    |
| 607-005-660                         | PriMatrix Meshed 2:1 6x6 cm         |                         |                                    |
| 607-005-812                         | PriMatrix Meshed 2:1 8x12 cm        |                         |                                    |
| 607-005-880                         | PriMatrix Meshed 2:1 8x8 cm         |                         |                                    |
| 607-101-112                         | PriMatrix Ag 10x12 cm               |                         |                                    |
| 607-101-125                         | PriMatrix Ag 10x25 cm               |                         |                                    |

| <b>SKUs Representing Products on the list below from all lots:Distributed between: 03/01/2018 to 5/22/2023</b> |                                  |                         |                                    |
|--|----------------------------------|-------------------------|------------------------------------|
| Manufacturer's Product Number (SKU)  | Product Name/Catalog Description | Customer Owned Quantity | Integra Owned (Consigned) Quantity |
| 607-101-225  | PriMatrix Ag 20x25 cm            |                         |                                    |
| 607-101-440  | PriMatrix Ag 4x4 cm              |                         |                                    |
| 607-101-660  | PriMatrix Ag 6x6 cm              |                         |                                    |
| 607-101-812  | PriMatrix Ag 8x12 cm             |                         |                                    |
| 607-101-880  | PriMatrix Ag 8x8 cm              |                         |                                    |
| 607-104-125  | PriMatrix Ag Fenestrated 10x25   |                         |                                    |
| 607-104-225  | PriMatrix Ag Fenestrated 20x25   |                         |                                    |
| 607-104-440  | PriMatrix Ag Fenestrated 4x4 cm  |                         |                                    |
| 607-104-660  | PriMatrix Ag Fenestrated 6x6 cm  |                         |                                    |
| 607-104-812  | PriMatrix Ag Fenestrated 8x12 cm |                         |                                    |
| 607-104-880  | PriMatrix Ag Fenestrated 8x8 cm  |                         |                                    |
| 607-105-112  | PriMatrix Ag Meshed 2:1 10x12 cm |                         |                                    |
| 607-105-125  | PriMatrix Ag Meshed 2:1 10x25 cm |                         |                                    |
| 607-105-225  | PriMatrix Ag Meshed 1:1 20x25 cm |                         |                                    |
| 607-105-440  | PriMatrix Ag Meshed 2:1 4x4 cm   |                         |                                    |
| 607-105-660  | PriMatrix Ag Meshed 2:1 6x6 cm   |                         |                                    |
| 607-105-812  | Primatrix Ag Meshed 2:1 8x12 cm  |                         |                                    |
| 607-105-880  | PriMatrix Ag Meshed 2:1 8x8 cm   |                         |                                    |
| 611-001-001  | Revize 10x10 cm                  |                         |                                    |
| 611-001-002  | Revize 4x12 cm                   |                         |                                    |
| 611-001-003  | Revize 4x16 cm                   |                         |                                    |
| 611-005-001  | Revize-X 12x6 cm                 |                         |                                    |
| 611-005-002  | Revize-X 10x9 cm                 |                         |                                    |

\*The following description was corrected for SKU# 607-005-220, 607-005-014, and 607-005-018: from "fenestrated" or "fenest." to "meshed"

\_\_\_\_\_  
Company / Hospital

\_\_\_\_\_  
Street Address

\_\_\_\_\_  
City, Postal Code

\_\_\_\_\_  
Telephone

\_\_\_\_\_  
Email

\_\_\_\_\_  
Customer Name

\_\_\_\_\_  
Customer Title

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

**URGENT: VOLUNTARY MEDICAL DEVICE RECALL**

**SurgiMend® PRS / SurgiMend® PRS Meshed  
SurgiMend®/ SurgiMend MP  
Revize™ / Revize™-X  
PriMatrix® Dermal Repair Scaffold  
PriMatrix® Ag Antimicrobial Dermal Repair Scaffold**

**FOR SALES ONLY Response is Required: Please Complete and Return Promptly**

**Please fill out this form and return to:  
Integralife6562@sedgwick.com or FAX to 888-229-0320**

**Integra Sales Representatives, Authorized Dealers and/or Distributors:**

I have received, read, and understand the information provided in the Voluntary Medical Device Recall Notice. I have/will comply with the Voluntary Medical Device Recall Notice and return the completed acknowledgement form. **Yes**

**I do have affected product:**

**I do not have affected product**

| <b>SKUs Representing Products on the list below from all lots:<br/>Distributed between: 03/01/2018 to 5/22/2023</b> |   |   |
|---|---|---|
| <b>Manufacturer's Product Number (SKU)</b>  | <b>Product Name/Catalog Description</b> | <b>Integra Owned (Consigned) Quantity</b> |
| 606-001-002   | SurgiMend 1.0 5x6 cm                    |   |
| 606-001-004   | SurgiMend 1.0 6x12 cm                   |   |
| 606-001-005   | SurgiMend 1.0 10x10 cm                  |   |
| 606-001-006   | SurgiMend 1.0 10x15 cm                  |   |
| 606-001-007   | SurgiMend 1.0 10x20 cm                  |   |
| 606-001-008   | SurgiMend 1.0 16x20 cm                  |   |
| 606-001-009   | SurgiMend 1.0 13x25 cm                  |   |
| 606-001-010   | SurgiMend 1.0 4x16 cm                   |   |
| 606-001-012   | SurgiMend 1.0 3x3 cm                    |   |
| 606-001-013   | SurgiMend 1.0 4x7 cm                    |   |
| 606-001-014   | SurgiMend 1.0 4x12 cm                   |   |
| 606-001-015   | SurgiMend 1.0 6x16 cm                   |   |



**SKUs Representing Products on the list below from all lots:  
Distributed between: 03/01/2018 to 5/22/2023**

| Manufacturer's Product Number (SKU) | Product Name/Catalog Description         | Integra Owned (Consigned) Quantity |
|-------------------------------------|--|------------------------------------|
| 606-001-016                         | SurgiMend 1.0 25x40 cm                   |                                    |
| 606-001-017                         | SurgiMend 1.0 20 x 30 cm                 |                                    |
| 606-001-018                         | SurgiMend 1.0 8x16 cm                    |                                    |
| 606-002-002                         | SurgiMend 1.0 4x7 cm Thin                |                                    |
| 606-002-003                         | SurgiMend 1.0 5x6 cm Thin                |                                    |
| 606-002-005                         | SurgiMend 1.0 3x3 cm Thin                |                                    |
| 606-003-001                         | SurgiMend 1.0 0.3x25 cm                  |                                    |
| 606-003-002                         | SurgiMend 1.0 0.6x25 cm                  |                                    |
| 606-003-003                         | SurgiMend 1.0 1x25 cm                    |                                    |
| 606-004-100                         | SurgiMend PRS 10x15 cm Semi-Oval         |                                    |
| 606-004-101                         | SurgiMend PRS 7x17 cm Fenestrated        |                                    |
| 606-004-102                         | SurgiMend PRS 10x20 cm Fenestrated       |                                    |
| 606-004-103                         | SurgiMend PRS 8x16 cm Semi-Oval          |                                    |
| 606-004-104                         | SurgiMend PRS 15x15 cm Semi-Oval         |                                    |
| 606-004-105                         | SurgiMend PRS 8x20 cm Fenestrated        |                                    |
| 606-004-106                         | SurgiMend PRS 10x15 cm Slant Fenestrated |                                    |
| 606-004-107                         | SurgiMend PRS 7x17 cm Semi-Oval          |                                    |
| 606-004-108                         | SurgiMend PRS 8x16 cm Thin Semi-Oval     |                                    |
| 606-004-109                         | SurgiMend PRS 10x20 cm Thin Semi-Oval    |                                    |
| 606-004-110                         | SurgiMend PRS 6x16 cm Semi-Oval          |                                    |
| 606-005-001                         | SurgiMend PRS Thin Oval 8x12 cm          |                                    |
| 606-005-002                         | SurgiMend PRS Thin Oval 10x15 cm         |                                    |
| 606-005-003                         | SurgiMend 1.0 8x12 cm Thin               |                                    |
| 606-005-004                         | SurgiMend 1.0 10x15 cm Thin              |                                    |
| 606-007-001                         | SurgiMend PRS Meshed 20cm x 10 cm        |                                    |
| 606-200-002                         | SurgiMend 2.0 5x6 cm                     |                                    |
| 606-200-004                         | SurgiMend 2.0 6x12 cm                    |                                    |
| 606-200-006                         | SurgiMend 2.0 10x15 cm                   |                                    |
| 606-200-008                         | SurgiMend 2.0 16x20 cm                   |                                    |
| 606-200-009                         | SurgiMend 2.0 13x25 cm                   |                                    |
| 606-200-016                         | SurgiMend 2.0 25x40 cm                   |                                    |
| 606-200-017                         | SurgiMend 2.0 20x30 cm                   |                                    |
| 606-200-019                         | SurgiMend 2.0 20x20 cm                   |                                    |
| 606-200-020                         | SurgiMend 2.0 20x25cm                    |                                    |
| 606-204-100                         | SurgiMend 2.0 10x15cm Semi-Oval          |                                    |
| 606-206-001                         | SurgiMend MP 10x15 cm                    |                                    |
| 606-206-002                         | SurgiMend MP 20x20 cm                    |                                    |
| 606-206-003                         | SurgiMend MP 13x25 cm                    |                                    |
| 606-206-004                         | SurgiMend MP 16x20 cm                    |                                    |

**SKUs Representing Products on the list below from all lots:  
Distributed between: 03/01/2018 to 5/22/2023**

| Manufacturer's Product Number (SKU) | Product Name/Catalog Description    | Integra Owned (Consigned) Quantity |
|-------------------------------------|-------------------------------------|------------------------------------|
| 606-206-005                         | SurgiMend MP 20x25cm                |                                    |
| 606-206-006                         | SurgiMend MP 20x30 cm               |                                    |
| 606-206-007                         | SurgiMend MP 25x40 cm               |                                    |
| 606-300-002                         | SurgiMend 3.0 5x6 cm                |                                    |
| 606-300-004                         | SurgiMend 3.0 6x12 cm               |                                    |
| 606-300-006                         | SurgiMend 3.0 10x15 cm              |                                    |
| 606-300-008                         | SurgiMend 3.0 16x20 cm              |                                    |
| 606-300-009                         | SurgiMend 3.0 13x25 cm              |                                    |
| 606-300-016                         | SurgiMend 3.0 25x40 cm              |                                    |
| 606-300-017                         | SurgiMend 3.0 20x30 cm              |                                    |
| 606-300-019                         | SurgiMend 3.0 20x20 cm              |                                    |
| 606-300-020                         | SurgiMend 3.0 20x25 cm              |                                    |
| 606-300-021                         | SurgiMend 3.0 1x5 cm                |                                    |
| 606-300-022                         | SurgiMend e3.0 10x25 cm             |                                    |
| 606-304-001                         | SurgiMend 3.0 4x7cm Fenestrated     |                                    |
| 606-304-002                         | SurgiMend e3.0 10x25 cm Fenestrated |                                    |
| 606-400-002                         | SurgiMend 4.0 5x6 cm                |                                    |
| 606-400-004                         | SurgiMend 4.0 6x12 cm               |                                    |
| 606-400-006                         | SurgiMend 4.0 10x15 cm              |                                    |
| 606-400-009                         | SurgiMend 4.0 13x25 cm              |                                    |
| 606-400-016                         | SurgiMend 4.0 25x40 cm              |                                    |
| 606-400-017                         | SurgiMend 4.0 20x30 cm              |                                    |
| 606-400-018                         | SurgiMend e4.0 10x25 cm             |                                    |
| 606-403-001                         | SurgiMend 4.0 20x0.5 cm             |                                    |
| 606-404-001                         | SurgiMend e4.0 10x25 cm Fenestrated |                                    |
| 606-907-001                         | SurgiMend PRS Meshed 10cm x 20 cm   |                                    |
| 607-001-009                         | PriMatrix 0.2x26.5cm, 3 Pack        |                                    |
| 607-001-112                         | PriMatrix 10x12cm                   |                                    |
| 607-001-125                         | PriMatrix 10x25 cm                  |                                    |
| 607-001-225                         | PriMatrix 20x25 cm                  |                                    |
| 607-001-440                         | PriMatrix 4x4 cm                    |                                    |
| 607-001-660                         | PriMatrix 6x6 cm                    |                                    |
| 607-001-812                         | PriMatrix 8x12 cm                   |                                    |
| 607-001-880                         | PriMatrix 8x8 cm                    |                                    |
| 607-004-440                         | PriMatrix Fenestrated 4x4 cm        |                                    |
| 607-004-660                         | PriMatrix Fenestrated 6x6 cm        |                                    |
| 607-004-880                         | PriMatrix Fenestrated 8x8 cm        |                                    |
| 607-005-014                         | PriMatrix 14mm Meshed* Disc         |                                    |
| 607-005-018                         | PriMatrix 18mm Meshed* Disc         |                                    |
| 607-005-125                         | PriMatrix Meshed 2:1 10x25 cm       |                                    |
| 607-005-220                         | PriMatrix Meshed* 2x2 cm            |                                    |
| 607-005-225                         | PriMatrix Meshed 1:1 20x25 cm       |                                    |

**SKUs Representing Products on the list below from all lots:  
Distributed between: 03/01/2018 to 5/22/2023**

| Manufacturer's Product Number (SKU) | Product Name/Catalog Description | Integra Owned (Consigned) Quantity |
|-------------------------------------|----------------------------------|------------------------------------|
| 607-005-330                         | PriMatrix Meshed 2:1 3x3 cm      |                                    |
| 607-005-440                         | PriMatrix Meshed 2:1 4x4 cm      |                                    |
| 607-005-550                         | PriMatrix Meshed 2:1 5x5 cm      |                                    |
| 607-005-660                         | PriMatrix Meshed 2:1 6x6 cm      |                                    |
| 607-005-812                         | PriMatrix Meshed 2:1 8x12 cm     |                                    |
| 607-005-880                         | PriMatrix Meshed 2:1 8x8 cm      |                                    |
| 607-101-112                         | PriMatrix Ag 10x12 cm            |                                    |
| 607-101-125                         | PriMatrix Ag 10x25 cm            |                                    |
| 607-101-225                         | PriMatrix Ag 20x25 cm            |                                    |
| 607-101-440                         | PriMatrix Ag 4x4 cm              |                                    |
| 607-101-660                         | PriMatrix Ag 6x6 cm              |                                    |
| 607-101-812                         | PriMatrix Ag 8x12 cm             |                                    |
| 607-101-880                         | PriMatrix Ag 8x8 cm              |                                    |
| 607-104-125                         | PriMatrix Ag Fenestrated 10x25   |                                    |
| 607-104-225                         | PriMatrix Ag Fenestrated 20x25   |                                    |
| 607-104-440                         | PriMatrix Ag Fenestrated 4x4 cm  |                                    |
| 607-104-660                         | PriMatrix Ag Fenestrated 6x6 cm  |                                    |
| 607-104-812                         | PriMatrix Ag Fenestrated 8x12 cm |                                    |
| 607-104-880                         | PriMatrix Ag Fenestrated 8x8 cm  |                                    |
| 607-105-112                         | PriMatrix Ag Meshed 2:1 10x12 cm |                                    |
| 607-105-125                         | PriMatrix Ag Meshed 2:1 10x25 cm |                                    |
| 607-105-225                         | PriMatrix Ag Meshed 1:1 20x25 cm |                                    |
| 607-105-440                         | PriMatrix Ag Meshed 2:1 4x4 cm   |                                    |
| 607-105-660                         | PriMatrix Ag Meshed 2:1 6x6 cm   |                                    |
| 607-105-812                         | Primatrix Ag Meshed 2:1 8x12 cm  |                                    |
| 607-105-880                         | PriMatrix Ag Meshed 2:1 8x8 cm   |                                    |
| 611-001-001                         | Revize 10x10 cm                  |                                    |
| 611-001-002                         | Revize 4x12 cm                   |                                    |
| 611-001-003                         | Revize 4x16 cm                   |                                    |
| 611-005-001                         | Revize-X 12x6 cm                 |                                    |
| 611-005-002                         | Revize-X 10x9 cm                 |                                    |

\*The following description was corrected for SKU# 607-005-220, 607-005-014, and 607-005-018: from "fenestrated" or "fenest." to "meshed"

| No. | Instructions   | Yes                      | No                       |
|-----|--|--------------------------|--------------------------|
| 1   | I have identified and notified my customers that were shipped or may have been shipped this product          | <input type="checkbox"/> | <input type="checkbox"/> |
| 2   | Or, attached is a list of customers who received/may have received this product. Please notify my customers. | <input type="checkbox"/> | <input type="checkbox"/> |

**Special Instructions:**

---



---

Integra Sales Representative, Authorized Dealer, and/or Distributor Name

Street Address

City, Postal Code

Telephone

Email

Customer Name

Customer Title

Signature

Date

**Appendix 1: Product and Distribution Information Table**

SKUs representing Products on the list below from all lots:

- Manufactured between (MM/DD/YYYY): 09/10/2015 and 1/11/2023
- Expiring between (MM/DD/YYYY): 5/16/2023 and 6/30/2027
- Distributed between (MM/DD/YYYY): 03/01/2018 to 5/22/2023

| Manufacturer's Product Number (SKU) | Product Name/Catalog Description   | Unique Device Identifier (UDI) Number |
|-------------------------------------|------------------------------------|---------------------------------------|
| 606-001-002                         | SurgiMend 1.0 5x6 cm               | 10381780112617                        |
| 606-001-004                         | SurgiMend 1.0 6x12 cm              | 10381780112624                        |
| 606-001-005                         | SurgiMend 1.0 10x10 cm             | 10381780112631                        |
| 606-001-006                         | SurgiMend 1.0 10x15 cm             | 10381780112648                        |
| 606-001-007                         | SurgiMend 1.0 10x20 cm             | 10381780112655                        |
| 606-001-008                         | SurgiMend 1.0 16x20 cm             | 10381780112662                        |
| 606-001-009                         | SurgiMend 1.0 13x25 cm             | 10381780112679                        |
| 606-001-010                         | SurgiMend 1.0 4x16 cm              | 10381780112686                        |
| 606-001-012                         | SurgiMend 1.0 3x3 cm               | 10381780112693                        |
| 606-001-013                         | SurgiMend 1.0 4x7 cm               | 10381780112709                        |
| 606-001-014                         | SurgiMend 1.0 4x12 cm              | 10381780112716                        |
| 606-001-015                         | SurgiMend 1.0 6x16 cm              | 10381780112723                        |
| 606-001-016                         | SurgiMend 1.0 25x40 cm             | 10381780112730                        |
| 606-001-017                         | SurgiMend 1.0 20 x 30 cm           | 10381780112747                        |
| 606-001-018                         | SurgiMend 1.0 8x16 cm              | 10381780112754                        |
| 606-002-002                         | SurgiMend 1.0 4x7 cm Thin          | 10381780112761                        |
| 606-002-003                         | SurgiMend 1.0 5x6 cm Thin          | 10381780112778                        |
| 606-002-005                         | SurgiMend 1.0 3x3 cm Thin          | 10381780112785                        |
| 606-003-001                         | SurgiMend 1.0 0.3x25 cm            | 10381780112792                        |
| 606-003-002                         | SurgiMend 1.0 0.6x25 cm            | 10381780112808                        |
| 606-003-003                         | SurgiMend 1.0 1x25 cm              | 10381780112815                        |
| 606-004-100                         | SurgiMend PRS 10x15 cm Semi-Oval   | 10381780112822                        |
| 606-004-101                         | SurgiMend PRS 7x17 cm Fenestrated  | 10381780112839                        |
| 606-004-102                         | SurgiMend PRS 10x20 cm Fenestrated | 10381780112846                        |

| <b>Manufacturer's Product Number (SKU)</b> | <b>Product Name/Catalog Description</b>  | <b>Unique Device Identifier (UDI) Number</b> |
|--|--|--|
| 606-004-103                                | SurgiMend PRS 8x16 cm Semi-Oval          | 10381780112853                               |
| 606-004-104                                | SurgiMend PRS 15x15 cm Semi-Oval         | 10381780112860                               |
| 606-004-105                                | SurgiMend PRS 8x20 cm Fenestrated        | 10381780112877                               |
| 606-004-106                                | SurgiMend PRS 10x15 cm Slant Fenestrated | 10381780112884                               |
| 606-004-107                                | SurgiMend PRS 7x17 cm Semi-Oval          | 10381780112891                               |
| 606-004-108                                | SurgiMend PRS 8x16 cm Thin Semi-Oval     | 10381780112907                               |
| 606-004-109                                | SurgiMend PRS 10x20 cm Thin Semi-Oval    | 10381780112914                               |
| 606-004-110                                | SurgiMend PRS 6x16 cm Semi-Oval          | 10381780112921                               |
| 606-005-001                                | SurgiMend PRS Thin Oval 8x12 cm          | 10381780112938                               |
| 606-005-002                                | SurgiMend PRS Thin Oval 10x15 cm         | 10381780112945                               |
| 606-005-003                                | SurgiMend 1.0 8x12 cm Thin               | 10381780112952                               |
| 606-005-004                                | SurgiMend 1.0 10x15 cm Thin              | 10381780112969                               |
| 606-007-001                                | SurgiMend PRS Meshed 20cm x 10 cm        | 10381780357322                               |
| 606-200-002                                | SurgiMend 2.0 5x6 cm                     | 10381780112976                               |
| 606-200-004                                | SurgiMend 2.0 6x12 cm                    | 10381780112983                               |
| 606-200-006                                | SurgiMend 2.0 10x15 cm                   | 10381780112990                               |
| 606-200-008                                | SurgiMend 2.0 16x20 cm                   | 10381780113003                               |
| 606-200-009                                | SurgiMend 2.0 13x25 cm                   | 10381780113010                               |
| 606-200-016                                | SurgiMend 2.0 25x40 cm                   | 10381780113027                               |
| 606-200-017                                | SurgiMend 2.0 20x30 cm                   | 10381780113034                               |
| 606-200-019                                | SurgiMend 2.0 20x20 cm                   | 10381780113041                               |
| 606-200-020                                | SurgiMend 2.0 20x25cm                    | 10381780113058                               |
| 606-204-100                                | SurgiMend 2.0 10x15cm Semi-Oval          | 10381780113065                               |
| 606-206-001                                | SurgiMend MP 10x15 cm                    | 10381780357339                               |
| 606-206-002                                | SurgiMend MP 20x20 cm                    | 10381780357360                               |
| 606-206-003                                | SurgiMend MP 13x25 cm                    | 10381780357346                               |
| 606-206-004                                | SurgiMend MP 16x20 cm                    | 10381780357353                               |
| 606-206-005                                | SurgiMend MP 20x25cm                     | 10381780357377                               |
| 606-206-006                                | SurgiMend MP 20x30 cm                    | 10381780357384                               |
| 606-206-007                                | SurgiMend MP 25x40 cm                    | 10381780357391                               |
| 606-300-002                                | SurgiMend 3.0 5x6 cm                     | 10381780113072                               |
| 606-300-004                                | SurgiMend 3.0 6x12 cm                    | 10381780113089                               |
| 606-300-006                                | SurgiMend 3.0 10x15 cm                   | 10381780113096                               |
| 606-300-008                                | SurgiMend 3.0 16x20 cm                   | 10381780113102                               |
| 606-300-009                                | SurgiMend 3.0 13x25 cm                   | 10381780113119                               |
| 606-300-016                                | SurgiMend 3.0 25x40 cm                   | 10381780113126                               |
| 606-300-017                                | SurgiMend 3.0 20x30 cm                   | 10381780113133                               |
| 606-300-019                                | SurgiMend 3.0 20x20 cm                   | 10381780113140                               |
| 606-300-020                                | SurgiMend 3.0 20x25 cm                   | 10381780113157                               |
| 606-300-021                                | SurgiMend 3.0 1x5 cm                     | 10381780113164                               |
| 606-300-022                                | SurgiMend e3.0 10x25 cm                  | 10381780113171                               |
| 606-304-001                                | SurgiMend 3.0 4x7cm Fenestrated          | 10381780113188                               |
| 606-304-002                                | SurgiMend e3.0 10x25 cm Fenestrated      | 10381780113195                               |

| <b>Manufacturer's Product Number (SKU)</b> | <b>Product Name/Catalog Description</b> | <b>Unique Device Identifier (UDI) Number</b> |
|--|---|--|
| 606-400-002                                | SurgiMend 4.0 5x6 cm                    | 10381780113201                               |
| 606-400-004                                | SurgiMend 4.0 6x12 cm                   | 10381780113218                               |
| 606-400-006                                | SurgiMend 4.0 10x15 cm                  | 10381780113225                               |
| 606-400-009                                | SurgiMend 4.0 13x25 cm                  | 10381780113232                               |
| 606-400-016                                | SurgiMend 4.0 25x40 cm                  | 10381780113249                               |
| 606-400-017                                | SurgiMend 4.0 20x30 cm                  | 10381780113256                               |
| 606-400-018                                | SurgiMend e4.0 10x25 cm                 | 10381780113263                               |
| 606-403-001                                | SurgiMend 4.0 20x0.5 cm                 | 10381780113270                               |
| 606-404-001                                | SurgiMend e4.0 10x25 cm Fenestrated     | 10381780113287                               |
| 606-907-001                                | SurgiMend PRS Meshed 10cm x 20 cm       | N/A  |
| 607-001-009                                | PriMatrix 0.2x26.5cm, 3 Pack            | 10381780113294                               |
| 607-001-112                                | PriMatrix 10x12cm                       | 10381780113300                               |
| 607-001-125                                | PriMatrix 10x25 cm                      | 10381780113317                               |
| 607-001-225                                | PriMatrix 20x25 cm                      | 10381780113324                               |
| 607-001-440                                | PriMatrix 4x4 cm                        | 10381780113331                               |
| 607-001-660                                | PriMatrix 6x6 cm                        | 10381780113348                               |
| 607-001-812                                | PriMatrix 8x12 cm                       | 10381780113355                               |
| 607-001-880                                | PriMatrix 8x8 cm                        | 10381780113362                               |
| 607-004-440                                | PriMatrix Fenestrated 4x4 cm            | 10381780113379                               |
| 607-004-660                                | PriMatrix Fenestrated 6x6 cm            | 10381780113386                               |
| 607-004-880                                | PriMatrix Fenestrated 8x8 cm            | 10381780113393                               |
| 607-005-014                                | PriMatrix 14mm Meshed* Disc             | 10381780357414                               |
| 607-005-018                                | PriMatrix 18mm Meshed* Disc             | 10381780357421                               |
| 607-005-125                                | PriMatrix Meshed 2:1 10x25 cm           | 10381780113409                               |
| 607-005-220                                | PriMatrix Meshed* 2x2 cm                | 10381780357407                               |
| 607-005-225                                | PriMatrix Meshed 1:1 20x25 cm           | 10381780113423                               |
| 607-005-330                                | PriMatrix Meshed 2:1 3x3 cm             | 10381780113430                               |
| 607-005-440                                | PriMatrix Meshed 2:1 4x4 cm             | 10381780113447                               |
| 607-005-550                                | PriMatrix Meshed 2:1 5x5 cm             | 10381780113454                               |
| 607-005-660                                | PriMatrix Meshed 2:1 6x6 cm             | 10381780113461                               |
| 607-005-812                                | PriMatrix Meshed 2:1 8x12 cm            | 10381780113478                               |
| 607-005-880                                | PriMatrix Meshed 2:1 8x8 cm             | 10381780113485                               |
| 607-101-112                                | PriMatrix Ag 10x12 cm                   | 10381780113492                               |
| 607-101-125                                | PriMatrix Ag 10x25 cm                   | 10381780113508                               |
| 607-101-225                                | PriMatrix Ag 20x25 cm                   | 10381780113515                               |
| 607-101-440                                | PriMatrix Ag 4x4 cm                     | 10381780113522                               |
| 607-101-660                                | PriMatrix Ag 6x6 cm                     | 10381780113539                               |
| 607-101-812                                | PriMatrix Ag 8x12 cm                    | 10381780113546                               |
| 607-101-880                                | PriMatrix Ag 8x8 cm                     | 10381780113553                               |
| 607-104-125                                | PriMatrix Ag Fenestrated 10x25          | 10381780113775                               |
| 607-104-225                                | PriMatrix Ag Fenestrated 20x25          | 10381780113782                               |
| 607-104-440                                | PriMatrix Ag Fenestrated 4x4 cm         | 10381780113560                               |
| 607-104-660                                | PriMatrix Ag Fenestrated 6x6 cm         | 10381780113577                               |

| <b>Manufacturer's Product Number (SKU)</b> | <b>Product Name/Catalog Description</b> | <b>Unique Device Identifier (UDI) Number</b> |
|--|---|--|
| 607-104-812                                | PriMatrix Ag Fenestrated 8x12 cm        | 10381780113768                               |
| 607-104-880                                | PriMatrix Ag Fenestrated 8x8 cm         | 10381780113584                               |
| 607-105-112                                | PriMatrix Ag Meshed 2:1 10x12 cm        | 10381780177685                               |
| 607-105-125                                | PriMatrix Ag Meshed 2:1 10x25 cm        | 10381780113591                               |
| 607-105-225                                | PriMatrix Ag Meshed 1:1 20x25 cm        | 10381780113607                               |
| 607-105-440                                | PriMatrix Ag Meshed 2:1 4x4 cm          | 10381780113614                               |
| 607-105-660                                | PriMatrix Ag Meshed 2:1 6x6 cm          | 10381780177715                               |
| 607-105-812                                | Primatrix Ag Meshed 2:1 8x12 cm         | 10381780177739                               |
| 607-105-880                                | PriMatrix Ag Meshed 2:1 8x8 cm          | 10381780177722                               |
| 611-001-001                                | Revize 10x10 cm                         | 10381780357292                               |
| 611-001-002                                | Revize 4x12 cm                          | 10381780357278                               |
| 611-001-003                                | Revize 4x16 cm                          | 10381780357285                               |
| 611-005-001                                | Revize-X 12x6 cm                        | 10381780357308                               |
| 611-005-002                                | Revize-X 10x9 cm                        | 10381780357315                               |

\*The following description was corrected for SKU# 607-005-220, 607-005-014, and 607-005-018: from "fenestrated" or "fenest." to "meshed"

3507197-2-EN