

PRODUCT DISRUPTION BRIEF

Biologic surgical mesh (reviewed Oct. 24)

Resolution for backorders on product codes impacted by Integra's voluntary medical device recall for PriMatrix®, SurgiMend®, and Revize™ has been pushed to 2026.

Current conditions

On May 22, 2023, Integra LifeSciences issued a **voluntary medical device recall** for PriMatrix®, SurgiMend®, and Revize™ products distributed from March 1, 2018 to May 22, 2023 due to issues with in-process and finished goods endotoxin testing that may result in out of specification endotoxin results. The potential harms due to high levels of endotoxins may include lowgrade fever, inflammation, and/or inflammatory response leading to fever (pyrexia), and/or surgical intervention/revision surgery.

In May 2024, Integra completed a third-party inspection resulting in unexpected findings. As a result, **affected product codes** are anticipated to be on backorder through 2026 while Integra responds to the findings.

Call to action

If you do have units of affected products:

- Immediately remove that product from service.
- Follow the return instructions in the **voluntary medical device recall notice** and complete Return Acknowledgment Form and return to Integralife6562@sedgwick.com. Integra is asking all providers to complete an acknowledgement even if you do not have affected products.
- A direct replacement for affected product is not available at this time, but similar Integra alternative products may be available that can be reviewed.

If you have already implanted or used the products affected by this recall, Integra recommends 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.

Potentially impacted procedures

As a result of this disruption, there may be potential impact to the following procedures. Based on **Vizient's Procedural Analytics**, these are the top 5 procedures, based on product utilization. This is not an exhaustive list of potentially impacted procedures.

- Skin graft procedures
- Mastectomy
- Open Abdominal Wall Hernia
- Open Small Bowel Resection
- Partial Gastrectomy

Questions about Procedural Analytics? Contact askproceduralanalytics@vizientinc.com

Alternatives

Click [here](#) for a list of available cross-references. Vizient will continue to monitor the situation and add additional cross references as they are validated.

Contracted Suppliers:

	Allergan (MS8991)	Davol (MS8992 &	RTI (MS8994)	MTF (MS8993)	Gore (MS9004)
Contact:	Robin Madrigal 480-435-6477 Robin.Madrigal@allergan.com	John Perrotto 908-216-7239 John_Perrotto@bd.com	Matt Meyer 760-405-7235 wmeyer@rtix.com	Amy Seip 602-758-0667 Amy_seip@mtf.com	Cress Whitfield 886-686-4673 cwhitfield@wlgore.com

Non-Contracted Suppliers:

	Tela-Bio
Contact:	Lisa Ponssa 813-928-0414 lponssa@telabio.com

 To learn more, please contact:
Corey Girard, Sr. Category Manager,
corey.girard@vizientinc.com.

As the nation's largest member-driven health care performance improvement company, Vizient provides solutions and services that empower health care providers to deliver high-value care by aligning cost, quality and market performance. With analytics, advisory services and a robust sourcing portfolio, we help members improve patient outcomes and lower costs.

Impacted products distributed from March 1, 2018 to May 22, 2023

- 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
- 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
- 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 Fenest. Disc
- 607-005-018 PriMatrix 18mm Fenest. Disc
- 607-005-125 PriMatrix Meshed 2:1 10x25 cm
- 607-005-220 PriMatrix Fenestrated 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
- 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

Impacted products distributed from March 1, 2018 to May 22, 2023 (continued)

- 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

Additional resources

Supply assurance webpage; Vizient Newsroom



Want to receive weekly Supply Assurance updates?

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Questions? Contact disasterresponse@vizientinc.com, pharmacyquestions@vizientinc.com, novaplus@vizientinc.com.