To the attention of Quality Assurance Dpt or Regulatory Affairs Dpt or Management

Saint Priest, May 30th, 2023

Subject: URGENT - FIELD SAFETY NOTICE – INTEGRA – RECALL SurgiMend® PRS / SurgiMend® PRS Meshed / SurgiMend®/ SurgiMend® MP / PriMatrix® / PriMatrix® Ag

Legal manufacturer:
TEI Biosciences Inc. – 7 Elkins Street, Boston, MA, 02127, USA. SRN: US-MF-000012766

EC Representative:
INTEGRA LIFESCIENCES (France) SAS – Immeuble Séquoia 2 – 97 Allée Alexandre Borodine – 69800 SAINT PRIEST, France – SRN : FR-AR-000002474

Medical devices and Primary clinical purpose of device:
SurgiMend® PRS
SurgiMend® PRS Meshed
SurgiMend®
SurgiMend® MP
PriMatrix®
PriMatrix® Ag
The description and primary clinical purpose of the medical devices are available in Appendix 1

Concerned references and lot numbers:
References are available in the Reply form in Appendix 2.
All non-expired lot numbers are concerned.

Dear Valued Integra Customer,

Integra LifeSciences is voluntarily issuing this Field Safety Notice for SurgiMend® PRS, SurgiMend® PRS Meshed, SurgiMend®, SurgiMend® MP, PriMatrix®, PriMatrix® Ag products listed in Appendix 2, distributed from March 1, 2018, to date.

Reason for Recall:
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 received at least one of those products, including products in consignment.

Fifty-three (53) complaints have been received worldwide 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). These fifty-three (53) complaints were deemed reportable to FDA. Eleven (11) complaints occurred in Europe and were reported to the European National Authorities.

Risks 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.

The risks have been assessed based on the International Standards for Medical Devices (ISO 14971) and other applicable regulations.

Actions to be Taken by Distributor

1. Please review and understand the information provided in this letter.
2. If **you do have** affected units of the affected products in your warehouse:
    a. Remove the units from further distribution
    b. Check the box “I do have affected units” in the enclosed reply form
    c. Record on the form the total quantity and lot numbers of affected units you have.
3. If **you do not have** affected product**,** check the box, “I do not have affected units”.
4. Please check **your customer traceability records** for shipments of affected products.
5. **Forward a copy of the enclosed Field Safety Notice** to any of your customers that have purchased the affected products.
6. Please return the completed Reply form by email to IntegraLifeEMEA@sedgwick.com or Fax to +44 20 7660 1560. By filling this form, you confirm that you have received this Safety Notice and you intend to fully comply with this notification. **We expect a response within 3 weeks.** You also confirm that this notification has been forwarded to every concerned person in your organization.
7. At receipt of the reply form, and if it is noted that you or your customers have affected products, our logistic partner will contact you and provide an RMA number and directions to return the products.
8. We recommend that you retain a copy of the form for your records.

The receipt of this form ensures that Integra has achieved a level of effectiveness in communicating this information.

National Competent Authorities may perform audits of field actions of this nature to verify that our customers have been notified and understand the nature of the field action being taken.

The National Competent Authority of your country has been alerted of this Field Safety Corrective Action.

Thank you for your cooperation with this Field Safety Corrective Action and for returning the attached Reply Form.

Should you have any questions regarding these instructions, please contact our logistic partner IntegraLifeEMEA@sedgwick.com for any additional questions. Your cooperation is appreciated, and we thank you for your continued collaboration.

Yours Sincerely,

Angélique AUBERT
Materiovigilance correspondent

Appendix 1 : Medical devices and primary clinical purpose
Appendix 2: Field Safety Notice Distributor Reply Form (2 pages)

APPENDIX 1 : Medical devices and primary clinical purpose

SurgiMend® PRS / SurgiMend® PRS Meshed, Collagen Matrix for Soft Tissue Reconstruction

Description:

SurgiMend® PRS / SurgiMend® PRS Meshed is an acellular dermal tissue matrix derived from bovine dermis. The device is available in fenestrated (SurgiMend PRS) and meshed (SurgiMend PRS Meshed) configurations, and is supplied sterile in various sizes, shapes, and thicknesses. The meshed device is designed to expand at a 2:1 ratio when hydrated with 0.9% saline.

Primary clinical purpose of device:

SurgiMend PRS/ SurgiMend PRS Meshed is intended for implantation to reinforce soft tissue where weakness exists and for surgical repair of damaged or ruptured soft tissue membranes. SurgiMend PRS/ SurgiMend PRS Meshed is specifically indicated for plastic and reconstructive surgery, including breast reconstruction.

SurgiMend®/ SurgiMend MP, Collagen Matrix for Soft Tissue Reconstruction

Description:

SurgiMend® is an acellular dermal tissue derived from bovine dermis. The device is available in solid, fenestrated, and perforated configurations. The device is supplied sterile in a variety of sizes, shapes, and thicknesses. SurgiMend® is intended for implantation to reinforce soft tissue where weakness exists and for surgical repair of damaged or ruptured soft tissue membranes.

Primary clinical purpose of device:

SurgiMend® is specifically indicated for:

- Plastic and reconstructive surgery
- Muscle flap reinforcement
- Hernia repair including abdominal, inguinal, femoral, diaphragmatic, scrotal, umbilical, and incisional hernias.

PriMatrix®: Dermal Repair Scaffold

Description:

PriMatrix® is an acellular dermal tissue matrix derived from fetal bovine dermis. The device is supplied sterile in a variety of sizes to be trimmed by the surgeon to meet the individual patient's needs.

Primary clinical purpose of device:

PriMatrix® is intended for the management of wounds that include:

- Partial and full thickness wounds
- Pressure, diabetic, and venous ulcers
- Second-degree burns
- Surgical wounds—donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence
- Trauma wounds —abrasions, lacerations and skin tears
- Tunneled/undermined wounds
- Draining wounds

PriMatrix® Ag Antimicrobial : Dermal Repair Scaffold

Description:

PriMatrix® Ag Antimicrobial is an acellular dermal tissue matrix derived from fetal bovine dermis. The device is supplied sterile in a variety of sizes to be trimmed by the surgeon to meet the individual patient's needs. The Ionic Silver content is intended to prevent microbial colonization of the device. Ionic silver is a broad spectrum antimicrobial. PriMatrix® Ag Antimicrobial has been shown in CLSI Disc Susceptibility testing to be effective against a range of bacteria, including: Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Methicillin-Resistant Staphylococcus aureus (MRSA), Enterococcus faecium, Klebsiella pneumoniae, Listeria monocytogenes, Vancomycin-Resistant Enterococcus faecalis (VRE), Acinetobacter baumanni, and Streptococcus pyrogenes (Group A).

Primary clinical purpose of device:

PriMatrix® Ag Antimicrobial is intended for the management of wounds that include:

- Partial and full thickness wounds
- Pressure, diabetic, and venous ulcers
- Second-degree burns
- Surgical wounds—donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence
- Trauma wounds —abrasions, lacerations, and skin tears
- Tunneled/undermined wounds
- Draining wounds

APPENDIX 2: DISTRIBUTOR REPLY FORM

1. Field Safety Notice (FSN) information	
FSN Reference number	**FSN 2023-HHE-005**
FSN Date	**30/05/2023**
Devices names	**See list in Table 1 below**
Products Codes	**See list in Table 1 below**
Lots	**All unexpired lots**

2. Distributor/Importer Details	
SRN Number	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Distributors/Importers (Tick all that apply)		
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.*	
☐	I have checked my inventory and I do have affected units and I have quarantined them.	*If yes, please indicate quantity and lot numbers in Table 1*
☐	I have checked my inventory and I do not have affected unit	
☐	I have identified customers that received affected units and informed them of this Field Safety Notice *	**Date of communication:**
☐	I have attached customer list	
☐	I have received confirmation of reply for all identified customers	
☐	All units have been received back from end customers	*If yes, please indicate quantity and lot numbers in Table 1*
☐	My customers have not received any affected units, or all the received units were already consumed	
Print Name*		*Distributor print name here*
Signature*		*Distributor sign Here*
Date *		

Table 1: List of product references concerned by the recall

Unique Device Identification	Product reference	Product designation	Quantity + lot number(s)
10381780112617	606-001-002	SurgiMend 1.0 5x6 cm	
10381780112624	606-001-004	SurgiMend 1.0 6x12 cm	
10381780112631	606-001-005	SurgiMend 1.0 10x10 cm	
10381780112648	606-001-006	SurgiMend 1.0 10x15 cm	
10381780112655	606-001-007	SurgiMend 1.0 10x20 cm	
10381780112662	606-001-008	SurgiMend 1.0 16x20 cm	
10381780112679	606-001-009	SurgiMend 1.0 13x25 cm	
10381780112686	606-001-010	SurgiMend 1.0 4x16 cm	
10381780112693	606-001-012	SurgiMend 1.0 3x3 cm	
10381780112709	606-001-013	SurgiMend 1.0 4x7 cm	
10381780112716	606-001-014	SurgiMend 1.0 4x12 cm	
10381780112723	606-001-015	SurgiMend 1.0 6x16 cm	
10381780112730	606-001-016	SurgiMend 1.0 25x40 cm	
10381780112747	606-001-017	SurgiMend 1.0 20 x 30 cm	
10381780112754	606-001-018	SurgiMend 1.0 8x16 cm	
10381780112761	606-002-002	SurgiMend 1.0 4x7 cm Thin	
10381780112778	606-002-003	SurgiMend 1.0 5x6 cm Thin	
10381780112785	606-002-005	SurgiMend 1.0 3x3 cm Thin	
10381780112792	606-003-001	SurgiMend 1.0 0.3x25 cm	
10381780112808	606-003-002	SurgiMend 1.0 0.6x25 cm	
10381780112815	606-003-003	SurgiMend 1.0 1x25 cm	
10381780112822	606-004-100	SurgiMend PRS 10x15 cm Semi-Oval	
10381780112839	606-004-101	SurgiMend PRS 7x17 cm Fenestrated	
10381780112846	606-004-102	SurgiMend PRS 10x20 cm Fenestrated	
10381780112853	606-004-103	SurgiMend PRS 8x16 cm Semi-Oval	
10381780112860	606-004-104	SurgiMend PRS 15x15 cm Semi-Oval	
10381780112877	606-004-105	SurgiMend PRS 8x20 cm Fenestrated	
10381780112884	606-004-106	SurgiMend PRS 10x15 cm Slant Fenestrated	
10381780112891	606-004-107	SurgiMend PRS 7x17 cm Semi-Oval	
10381780112907	606-004-108	SurgiMend PRS 8x16 cm Thin Semi-Oval	
10381780112914	606-004-109	SurgiMend PRS 10x20 cm Thin Semi-Oval	
10381780112921	606-004-110	SurgiMend PRS 6x16 cm Semi-Oval	
10381780112938	606-005-001	SurgiMend PRS Thin Oval 8x12 cm	
10381780112945	606-005-002	SurgiMend PRS Thin Oval 10x15 cm	
10381780112952	606-005-003	SurgiMend 1.0 8x12 cm Thin	
10381780112969	606-005-004	SurgiMend 1.0 10x15 cm Thin	
10381780357322	606-007-001	SurgiMend PRS Meshed 20cm x 10 cm	
10381780112976	606-200-002	SurgiMend 2.0 5x6 cm	
10381780112983	606-200-004	SurgiMend 2.0 6x12 cm	

Unique Device Identification	Product reference	Product designation	Quantity + lot number(s)
10381780112990	606-200-006	SurgiMend 2.0 10x15 cm	
10381780113003	606-200-008	SurgiMend 2.0 16x20 cm	
10381780113010	606-200-009	SurgiMend 2.0 13x25 cm	
10381780113027	606-200-016	SurgiMend 2.0 25x40 cm	
10381780113034	606-200-017	SurgiMend 2.0 20x30 cm	
10381780113041	606-200-019	SurgiMend 2.0 20x20 cm	
10381780113058	606-200-020	SurgiMend 2.0 20x25cm	
10381780113065	606-204-100	SurgiMend 2.0 10x15cm Semi-Oval	
10381780357339	606-206-001	SurgiMend MP 10x15 cm	
10381780357360	606-206-002	SurgiMend MP 20x20 cm	
10381780357346	606-206-003	SurgiMend MP 13x25 cm	
10381780357353	606-206-004	SurgiMend MP 16x20 cm	
10381780357377	606-206-005	SurgiMend MP 20x25cm	
10381780357384	606-206-006	SurgiMend MP 20x30 cm	
10381780357391	606-206-007	SurgiMend MP 25x40 cm	
10381780113072	606-300-002	SurgiMend 3.0 5x6 cm	
10381780113089	606-300-004	SurgiMend 3.0 6x12 cm	
10381780113096	606-300-006	SurgiMend 3.0 10x15 cm	
10381780113102	606-300-008	SurgiMend 3.0 16x20 cm	
10381780113119	606-300-009	SurgiMend 3.0 13x25 cm	
10381780113126	606-300-016	SurgiMend 3.0 25x40 cm	
10381780113133	606-300-017	SurgiMend 3.0 20x30 cm	
10381780113140	606-300-019	SurgiMend 3.0 20x20 cm	
10381780113157	606-300-020	SurgiMend 3.0 20x25 cm	
10381780113164	606-300-021	SurgiMend 3.0 1x5 cm	
10381780113171	606-300-022	SurgiMend e3.0 10x25 cm	
10381780113188	606-304-001	SurgiMend 3.0 4x7cm Fenestrated	
10381780113195	606-304-002	SurgiMend e3.0 10x25 cm Fenestrated	
10381780113201	606-400-002	SurgiMend 4.0 5x6 cm	
10381780113218	606-400-004	SurgiMend 4.0 6x12 cm	
10381780113225	606-400-006	SurgiMend 4.0 10x15 cm	
10381780113232	606-400-009	SurgiMend 4.0 13x25 cm	
10381780113249	606-400-016	SurgiMend 4.0 25x40 cm	
10381780113256	606-400-017	SurgiMend 4.0 20x30 cm	
10381780113263	606-400-018	SurgiMend e4.0 10x25 cm	
10381780113270	606-403-001	SurgiMend 4.0 20x0.5 cm	
10381780113287	606-404-001	SurgiMend e4.0 10x25 cm Fenestrated	
10381780357155	606-907-001	SurgiMend PRS Meshed 10cm x 20 cm	
10381780113294	607-001-009	PriMatrix 0.2x26.5cm, 3 Pack	
10381780113300	607-001-112	PriMatrix 10x12cm	
10381780113317	607-001-125	PriMatrix 10x25 cm	
10381780113324	607-001-225	PriMatrix 20x25 cm	
10381780113331	607-001-440	PriMatrix 4x4 cm	

Unique Device Identification	Product reference	Product designation	Quantity + lot number(s)
10381780113348	607-001-660	PriMatrix 6x6 cm	
10381780113355	607-001-812	PriMatrix 8x12 cm	
10381780113362	607-001-880	PriMatrix 8x8 cm	
10381780113379	607-004-440	PriMatrix Fenestrated 4x4 cm	
10381780113386	607-004-660	PriMatrix Fenestrated 6x6 cm	
10381780113393	607-004-880	PriMatrix Fenestrated 8x8 cm	
10381780357414	607-005-014	PriMatrix 14mm Fenest. Disc	
10381780357421	607-005-018	PriMatrix 18mm Fenest. Disc	
10381780113409	607-005-125	PriMatrix Meshed 2:1 10x25 cm	
10381780357407	607-005-220	PriMatrix Meshed 2x2 cm	
10381780113423	607-005-225	PriMatrix Meshed 1:1 20x25 cm	
10381780113430	607-005-330	PriMatrix Meshed 2:1 3x3 cm	
10381780113447	607-005-440	PriMatrix Meshed 2:1 4x4 cm	
10381780113454	607-005-550	PriMatrix Meshed 2:1 5x5 cm	
10381780113461	607-005-660	PriMatrix Meshed 2:1 6x6 cm	
10381780113478	607-005-812	PriMatrix Meshed 2:1 8x12 cm	
10381780113485	607-005-880	PriMatrix Meshed 2:1 8x8 cm	
10381780113492	607-101-112	PriMatrix Ag 10x12 cm	
10381780113508	607-101-125	PriMatrix Ag 10x25 cm	
10381780113515	607-101-225	PriMatrix Ag 20x25 cm	
10381780113522	607-101-440	PriMatrix Ag 4x4 cm	
10381780113539	607-101-660	PriMatrix Ag 6x6 cm	
10381780113546	607-101-812	PriMatrix Ag 8x12 cm	
10381780113553	607-101-880	PriMatrix Ag 8x8 cm	
10381780113775	607-104-125	PriMatrix Ag Fenestrated 10x25	
10381780113782	607-104-225	PriMatrix Ag Fenestrated 20x25	
10381780113560	607-104-440	PriMatrix Ag Fenestrated 4x4 cm	
10381780113577	607-104-660	PriMatrix Ag Fenestrated 6x6 cm	
10381780113768	607-104-812	PriMatrix Ag Fenestrated 8x12 cm	
10381780113584	607-104-880	PriMatrix Ag Fenestrated 8x8 cm	
10381780177685	607-105-112	PriMatrix Ag Meshed 2:1 10x12 cm	
10381780113591	607-105-125	PriMatrix Ag Meshed 2:1 10x25 cm	
10381780113607	607-105-225	PriMatrix Ag Meshed 1:1 20x25 cm	
10381780113614	607-105-440	PriMatrix Ag Meshed 2:1 4x4 cm	
10381780177715	607-105-660	PriMatrix Ag Meshed 2:1 6x6 cm	
10381780177739	607-105-812	Primatrix Ag Meshed 2:1 8x12 cm	
10381780177722	607-105-880	PriMatrix Ag Meshed 2:1 8x8 cm	

4. Return acknowledgement to Sender	
Email	IntegraLifeEMEA@sedgwick.com
Distributor Helpline	+33 (0) 6 38 15 85 03
Postal Address	Post Market Surveillance Department Integra Immeuble Séquoia 2, 97 allée Alexandre Borodine Parc technologique de la Porte des Alpes 69800 Saint Priest, France
Web Portal	https://integralife.eu/
Fax	+44 20 7660 1560
Deadline for returning the reply form*	23/06/2023

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

To the attention of Medical Device Vigilance responsible / Central Pharmacy

Saint Priest, May 30th, 2023

Subject: URGENT - FIELD SAFETY NOTICE – INTEGRA – RECALL SurgiMend® PRS / SurgiMend® PRS Meshed / SurgiMend®/ SurgiMend® MP / PriMatrix® / PriMatrix® Ag

Legal manufacturer:
TEI Biosciences Inc. – 7 Elkins Street, Boston, MA, 02127, USA. SRN: US-MF-000012766

EC Representative:
INTEGRA LIFESCIENCES (France) SAS – Immeuble Séquoia 2 – 97 Allée Alexandre Borodine – 69800 SAINT PRIEST, France – SRN : FR-AR-000002474

Medical devices and Primary clinical purpose of device:
SurgiMend® PRS
SurgiMend® PRS Meshed
SurgiMend®
SurgiMend® MP
PriMatrix®
PriMatrix® Ag
The description and primary clinical purpose of the medical devices are available in Appendix 1

Concerned references and lot numbers:
References are available in the Reply form in Appendix 2.
All non-expired lot numbers are concerned.

Dear Valued Integra Customer,

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Risks to Health

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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.

The risks have been assessed based on the International Standards for Medical Devices (ISO 14971) and other applicable regulations.

Actions to be Taken by Customer

1. Please **review and understand** the information provided in this letter.
2. If **you do have** units of the affected products:
    a. Remove the units immediately from service.
    b. Check the box on the enclosed form "I do have affected units."
    c. Record on the form the total quantity and lot numbers of the affected product that you have.
3. If **you do not have** units of the affected products, check the box, "I do not have affected products."
4. Please return the completed reply form by email to IntegraLifeEMEA@sedgwick.com or Fax to +44 20 7660 1560. By filling this form, you confirm that you have received this Safety Notice and you intend to fully comply with this notification. **We expect a response within 3 weeks.** You also confirm that this notification has been forwarded to every concerned person in your organization.
5. At receipt of your form, and if it is noted that you have affected products, our logistic partner will contact you and provide a Return Material Authorization (RMA) number and directions to return the affected products.
6. We recommend that you retain a copy of the form for your records.

The receipt of this form ensures that Integra has achieved a level of effectiveness in communicating this information.

National Competent Authorities may perform audits of field actions of this nature to verify that our customers have been notified and understand the nature of the field action being taken.

The National Competent Authority of your country has been alerted of this Field Safety Corrective Action.

Thank you for your cooperation with this Field Safety Corrective Action and for returning the attached Reply Form.

Should you have any questions regarding these instructions, please contact our logistic partner IntegraLifeEMEA@sedgwick.com for any additional questions. Your cooperation is appreciated, and we thank you for your continued collaboration.

Yours Sincerely,

Angélique AUBERT
Materiovigilance correspondent

Appendix 1 : Medical devices and primary clinical purpose
Appendix 2: Field Safety Notice Customer Reply Form (2 pages)

APPENDIX 1 : Medical devices and primary clinical purpose

SurgiMend® PRS / SurgiMend® PRS Meshed, Collagen Matrix for Soft Tissue Reconstruction

Description:

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Primary clinical purpose of device:

SurgiMend PRS/ SurgiMend PRS Meshed is intended for implantation to reinforce soft tissue where weakness exists and for surgical repair of damaged or ruptured soft tissue membranes. SurgiMend PRS/ SurgiMend PRS Meshed is specifically indicated for plastic and reconstructive surgery, including breast reconstruction.

SurgiMend®/ SurgiMend MP, Collagen Matrix for Soft Tissue Reconstruction

Description:

SurgiMend® is an acellular dermal tissue derived from bovine dermis. The device is available in solid, fenestrated, and perforated configurations. The device is supplied sterile in a variety of sizes, shapes, and thicknesses. SurgiMend® is intended for implantation to reinforce soft tissue where weakness exists and for surgical repair of damaged or ruptured soft tissue membranes.

Primary clinical purpose of device:

SurgiMend® is specifically indicated for:

- Plastic and reconstructive surgery
- Muscle flap reinforcement
- Hernia repair including abdominal, inguinal, femoral, diaphragmatic, scrotal, umbilical, and incisional hernias.

PriMatrix®: Dermal Repair Scaffold

Description:

PriMatrix® is an acellular dermal tissue matrix derived from fetal bovine dermis. The device is supplied sterile in a variety of sizes to be trimmed by the surgeon to meet the individual patient's needs.

Primary clinical purpose of device:

PriMatrix® is intended for the management of wounds that include:

- Partial and full thickness wounds
- Pressure, diabetic, and venous ulcers
- Second-degree burns
- Surgical wounds—donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence
- Trauma wounds —abrasions, lacerations and skin tears
- Tunneled/undermined wounds
- Draining wounds

PriMatrix® Ag Antimicrobial : Dermal Repair Scaffold

Description:

PriMatrix® Ag Antimicrobial is an acellular dermal tissue matrix derived from fetal bovine dermis. The device is supplied sterile in a variety of sizes to be trimmed by the surgeon to meet the individual patient's needs. The Ionic Silver content is intended to prevent microbial colonization of the device. Ionic silver is a broad spectrum antimicrobial. PriMatrix® Ag Antimicrobial has been shown in CLSI Disc Susceptibility testing to be effective against a range of bacteria, including: Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Methicillin-Resistant Staphylococcus aureus (MRSA), Enterococcus faecium, Klebsiella pneumoniae, Listeria monocytogenes, Vancomycin-Resistant Enterococcus faecalis (VRE), Acinetobacter baumanni, and Streptococcus pyrogenes (Group A).

Primary clinical purpose of device:

PriMatrix® Ag Antimicrobial is intended for the management of wounds that include:

- Partial and full thickness wounds
- Pressure, diabetic, and venous ulcers
- Second-degree burns
- Surgical wounds—donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence
- Trauma wounds —abrasions, lacerations, and skin tears
- Tunneled/undermined wounds
- Draining wounds

APPENDIX 2: CUSTOMER REPLY FORM

1. Field Safety Notice (FSN) information	
FSN Reference number	**FSN 2023-HHE-005**
FSN Date	**30/05/2023**
Devices names	**See list in Table 1 below**
Products Codes	**See list in Table 1 below**
Lots	**All unexpired lots**

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation		
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content. *	
☐	I performed all actions requested by the FSN *	
☐	The information and required actions have been brought to the attention of all relevant users and executed.*	
☐	I have checked my inventory*	
☐	I do have affected units and I have quarantined them.*	*If yes, please indicate quantity and lot numbers in Table 1*
☐	I do not have any affected units	
☐	I have a query please contact me	*Customer to enter contact details if different from above and brief description of query*
Print Name*		*Customer print name here*
Signature*		*Customer sign here*
Date*		

Table 1: List of product references concerned by the recall

Unique Device Identification	Product reference	Product designation	Quantity + lot number(s)
10381780112617	606-001-002	SurgiMend 1.0 5x6 cm	
10381780112624	606-001-004	SurgiMend 1.0 6x12 cm	
10381780112631	606-001-005	SurgiMend 1.0 10x10 cm	
10381780112648	606-001-006	SurgiMend 1.0 10x15 cm	
10381780112655	606-001-007	SurgiMend 1.0 10x20 cm	
10381780112662	606-001-008	SurgiMend 1.0 16x20 cm	
10381780112679	606-001-009	SurgiMend 1.0 13x25 cm	
10381780112686	606-001-010	SurgiMend 1.0 4x16 cm	
10381780112693	606-001-012	SurgiMend 1.0 3x3 cm	
10381780112709	606-001-013	SurgiMend 1.0 4x7 cm	
10381780112716	606-001-014	SurgiMend 1.0 4x12 cm	
10381780112723	606-001-015	SurgiMend 1.0 6x16 cm	
10381780112730	606-001-016	SurgiMend 1.0 25x40 cm	
10381780112747	606-001-017	SurgiMend 1.0 20 x 30 cm	
10381780112754	606-001-018	SurgiMend 1.0 8x16 cm	
10381780112761	606-002-002	SurgiMend 1.0 4x7 cm Thin	
10381780112778	606-002-003	SurgiMend 1.0 5x6 cm Thin	
10381780112785	606-002-005	SurgiMend 1.0 3x3 cm Thin	
10381780112792	606-003-001	SurgiMend 1.0 0.3x25 cm	
10381780112808	606-003-002	SurgiMend 1.0 0.6x25 cm	
10381780112815	606-003-003	SurgiMend 1.0 1x25 cm	
10381780112822	606-004-100	SurgiMend PRS 10x15 cm Semi-Oval	
10381780112839	606-004-101	SurgiMend PRS 7x17 cm Fenestrated	
10381780112846	606-004-102	SurgiMend PRS 10x20 cm Fenestrated	
10381780112853	606-004-103	SurgiMend PRS 8x16 cm Semi-Oval	
10381780112860	606-004-104	SurgiMend PRS 15x15 cm Semi-Oval	
10381780112877	606-004-105	SurgiMend PRS 8x20 cm Fenestrated	
10381780112884	606-004-106	SurgiMend PRS 10x15 cm Slant Fenestrated	
10381780112891	606-004-107	SurgiMend PRS 7x17 cm Semi-Oval	
10381780112907	606-004-108	SurgiMend PRS 8x16 cm Thin Semi-Oval	
10381780112914	606-004-109	SurgiMend PRS 10x20 cm Thin Semi-Oval	
10381780112921	606-004-110	SurgiMend PRS 6x16 cm Semi-Oval	
10381780112938	606-005-001	SurgiMend PRS Thin Oval 8x12 cm	
10381780112945	606-005-002	SurgiMend PRS Thin Oval 10x15 cm	
10381780112952	606-005-003	SurgiMend 1.0 8x12 cm Thin	
10381780112969	606-005-004	SurgiMend 1.0 10x15 cm Thin	
10381780357322	606-007-001	SurgiMend PRS Meshed 20cm x 10 cm	
10381780112976	606-200-002	SurgiMend 2.0 5x6 cm	
10381780112983	606-200-004	SurgiMend 2.0 6x12 cm	

Unique Device Identification	Product reference	Product designation	Quantity + lot number(s)
10381780112990	606-200-006	SurgiMend 2.0 10x15 cm	
10381780113003	606-200-008	SurgiMend 2.0 16x20 cm	
10381780113010	606-200-009	SurgiMend 2.0 13x25 cm	
10381780113027	606-200-016	SurgiMend 2.0 25x40 cm	
10381780113034	606-200-017	SurgiMend 2.0 20x30 cm	
10381780113041	606-200-019	SurgiMend 2.0 20x20 cm	
10381780113058	606-200-020	SurgiMend 2.0 20x25cm	
10381780113065	606-204-100	SurgiMend 2.0 10x15cm Semi-Oval	
10381780357339	606-206-001	SurgiMend MP 10x15 cm	
10381780357360	606-206-002	SurgiMend MP 20x20 cm	
10381780357346	606-206-003	SurgiMend MP 13x25 cm	
10381780357353	606-206-004	SurgiMend MP 16x20 cm	
10381780357377	606-206-005	SurgiMend MP 20x25cm	
10381780357384	606-206-006	SurgiMend MP 20x30 cm	
10381780357391	606-206-007	SurgiMend MP 25x40 cm	
10381780113072	606-300-002	SurgiMend 3.0 5x6 cm	
10381780113089	606-300-004	SurgiMend 3.0 6x12 cm	
10381780113096	606-300-006	SurgiMend 3.0 10x15 cm	
10381780113102	606-300-008	SurgiMend 3.0 16x20 cm	
10381780113119	606-300-009	SurgiMend 3.0 13x25 cm	
10381780113126	606-300-016	SurgiMend 3.0 25x40 cm	
10381780113133	606-300-017	SurgiMend 3.0 20x30 cm	
10381780113140	606-300-019	SurgiMend 3.0 20x20 cm	
10381780113157	606-300-020	SurgiMend 3.0 20x25 cm	
10381780113164	606-300-021	SurgiMend 3.0 1x5 cm	
10381780113171	606-300-022	SurgiMend e3.0 10x25 cm	
10381780113188	606-304-001	SurgiMend 3.0 4x7cm Fenestrated	
10381780113195	606-304-002	SurgiMend e3.0 10x25 cm Fenestrated	
10381780113201	606-400-002	SurgiMend 4.0 5x6 cm	
10381780113218	606-400-004	SurgiMend 4.0 6x12 cm	
10381780113225	606-400-006	SurgiMend 4.0 10x15 cm	
10381780113232	606-400-009	SurgiMend 4.0 13x25 cm	
10381780113249	606-400-016	SurgiMend 4.0 25x40 cm	
10381780113256	606-400-017	SurgiMend 4.0 20x30 cm	
10381780113263	606-400-018	SurgiMend e4.0 10x25 cm	
10381780113270	606-403-001	SurgiMend 4.0 20x0.5 cm	
10381780113287	606-404-001	SurgiMend e4.0 10x25 cm Fenestrated	
10381780357155	606-907-001	SurgiMend PRS Meshed 10cm x 20 cm	
10381780113294	607-001-009	PriMatrix 0.2x26.5cm, 3 Pack	
10381780113300	607-001-112	PriMatrix 10x12cm	
10381780113317	607-001-125	PriMatrix 10x25 cm	
10381780113324	607-001-225	PriMatrix 20x25 cm	
10381780113331	607-001-440	PriMatrix 4x4 cm	

Unique Device Identification	Product reference	Product designation	Quantity + lot number(s)
10381780113348	607-001-660	PriMatrix 6x6 cm	
10381780113355	607-001-812	PriMatrix 8x12 cm	
10381780113362	607-001-880	PriMatrix 8x8 cm	
10381780113379	607-004-440	PriMatrix Fenestrated 4x4 cm	
10381780113386	607-004-660	PriMatrix Fenestrated 6x6 cm	
10381780113393	607-004-880	PriMatrix Fenestrated 8x8 cm	
10381780357414	607-005-014	PriMatrix 14mm Fenest. Disc	
10381780357421	607-005-018	PriMatrix 18mm Fenest. Disc	
10381780113409	607-005-125	PriMatrix Meshed 2:1 10x25 cm	
10381780357407	607-005-220	PriMatrix Meshed 2x2 cm	
10381780113423	607-005-225	PriMatrix Meshed 1:1 20x25 cm	
10381780113430	607-005-330	PriMatrix Meshed 2:1 3x3 cm	
10381780113447	607-005-440	PriMatrix Meshed 2:1 4x4 cm	
10381780113454	607-005-550	PriMatrix Meshed 2:1 5x5 cm	
10381780113461	607-005-660	PriMatrix Meshed 2:1 6x6 cm	
10381780113478	607-005-812	PriMatrix Meshed 2:1 8x12 cm	
10381780113485	607-005-880	PriMatrix Meshed 2:1 8x8 cm	
10381780113492	607-101-112	PriMatrix Ag 10x12 cm	
10381780113508	607-101-125	PriMatrix Ag 10x25 cm	
10381780113515	607-101-225	PriMatrix Ag 20x25 cm	
10381780113522	607-101-440	PriMatrix Ag 4x4 cm	
10381780113539	607-101-660	PriMatrix Ag 6x6 cm	
10381780113546	607-101-812	PriMatrix Ag 8x12 cm	
10381780113553	607-101-880	PriMatrix Ag 8x8 cm	
10381780113775	607-104-125	PriMatrix Ag Fenestrated 10x25	
10381780113782	607-104-225	PriMatrix Ag Fenestrated 20x25	
10381780113560	607-104-440	PriMatrix Ag Fenestrated 4x4 cm	
10381780113577	607-104-660	PriMatrix Ag Fenestrated 6x6 cm	
10381780113768	607-104-812	PriMatrix Ag Fenestrated 8x12 cm	
10381780113584	607-104-880	PriMatrix Ag Fenestrated 8x8 cm	
10381780177685	607-105-112	PriMatrix Ag Meshed 2:1 10x12 cm	
10381780113591	607-105-125	PriMatrix Ag Meshed 2:1 10x25 cm	
10381780113607	607-105-225	PriMatrix Ag Meshed 1:1 20x25 cm	
10381780113614	607-105-440	PriMatrix Ag Meshed 2:1 4x4 cm	
10381780177715	607-105-660	PriMatrix Ag Meshed 2:1 6x6 cm	
10381780177739	607-105-812	Primatrix Ag Meshed 2:1 8x12 cm	
10381780177722	607-105-880	PriMatrix Ag Meshed 2:1 8x8 cm	

4. Return acknowledgement to Sender	
Email	IntegraLifeEMEA@sedgwick.com
Customer Helpline	+33 (0) 6 38 15 85 03
Postal Address	Post Market Surveillance Department Integra Immeuble Séquoia 2, 97 allée Alexandre Borodine Parc technologique de la Porte des Alpes 69800 Saint Priest, France
Web Portal	https://integralife.eu/
Fax	+44 20 7660 1560
Deadline for returning the customer reply form*	23/06/2023

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective action.