Legal Manufacturer:
Eclipse Medical Co. Ltd
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HPRA Reference: CRN00FVZ7
Eclipse Medical Co. Ltd Reference: EM-FSN-24001

26 November 2024

Field Safety Notice

URGENT Medical Device Recall

OMEGA Left Atrial Appendage (LAA) Occluder Device

Dear Account Contact,

Eclipse Medical is commencing an immediate and URGENT RECALL of the **OMEGA** Left Atrial Appendage (LAA) Occluder device effectively immediately. Devices available in the field require immediate quarantine to prevent future implantation. Implantation of all unused devices should cease immediately. All unused devices are required to be returned following the instructions as contained within this Field Safety Notice.

The **OMEGA** LAA Occluder (OMEGA) is a permanent implant to the Left Atrial Appendage for percutaneous insertion. The OMEGA product is designed to function as a self-expandable, dual layer, cup and disc device made from a Nitinol wire mesh coated with platinum. The **OMEGA** device is intended to reduce the risk of thromboembolism from the left atrial appendage (LAA) in patients with non-valvular atrial fibrillation (AF) and who meet the criteria as listed within the OMEGA Instructions for Use.

The **OMEGA** LAA Occluder (OMEGA) device was initially released in 2019, with EU distribution beginning in December 2020. Subsequent to distribution into the European (EU) market, Eclipse Medical began testing to support initial EU MDR 2017/745 certification. Additional testing was conducted to verify fatigue and durability, as well as metallic ion release, which is required testing under EU MDR 2017/745.

Results of the additional testing demonstrated unsatisfactory results, specifically related to excessive Nickel leaching caused by corrosion, and wire breakage. To date, four (4) complaints have been received from the field, and determined to be unrelated to this issue. Three (3) events observed during the post market clinical study may possibly be related to the issue.

Eclipse Medical is initiating a voluntary URGENT RECALL of ALL **OMEGA** Left Atrial Appendage (LAA) Occluder devices, as well as voluntary Medical Device Removal of all non-implanted **OMEGA** Left Atrial Appendage (LAA) Occluder devices. In all cases, the instructions, as contained within the Instructions for Use should continue to be followed.

The root cause investigation of this issue is ongoing. Eclipse Medical is initiating this URGENT Field Safety Notice to cease future implants and patient exposures to this issue. For affected product that has been implanted, no extra action is currently necessary and patients should continue to be managed in accordance with the associated Instructions for Use, and your standard patient management protocol. If any further long-term risks and/or recommendations resulting from the ongoing investigations being carried out by the manufacturer are identified, they will be communicated to you in a future update as

soon as possible.

This URGENT Field Safety Notice affects all Catalogues and Lot Numbers of the OMEGA Left Atrial Appendage (LAA) Occluder devices listed below. All OMEGA devices distributed to the field since initial release in 2019 are included within this Field Safety Notice, inclusive of all Device Sizes and Catalogue Numbers, as listed below.

Occluder Catalogue Number	Device Size (mm)	UDI-DI	Product Name
OLAA14	14	08857127156026	OMEGA Left Atrial Appendage (LAA) Occluder
OLAA16	16	08857127156033	
OLAA18	18	08857127156040	
OLAA20	20	08857127156057	
OLAA22	22	08857127156064	
OLAA24	24	08857127156071	
OLAA26	26	08857127156088	
OLAA28	28	08857127156095	
OLAA30	30	08857127156101	

Information below is included for the customers awareness, and includes all OMEGA devices distributed to the field since initial product release in 2019. All OMEGA devices distributed to the field are included within this Field Safety Notice, inclusive of the Lot #s listed below.

Product Description	Catalogue #	Lot #	Manufacturing Date	Expiration Date
OMEGA Left Atrial Appendage (LAA) Occluder	OLAA14	20218	2020-06-23	2023-05-31
		22001	2022-01-21	2024-12-31
		22025	2022-04-19	2025-03-31
		23082	2023-12-08	2026-11-30
		23083	2023-12-08	2026-11-30
	OLAA16	20127	2020-03-23	2023-02-28
		22002	2022-01-21	2024-12-31
		22029	2022-05-27	2025-04-30
		23032	2023-05-08	2026-04-30
		23061	2023-10-06	2026-09-30
	OLAA18	20128	2020-03-23	2023-02-28
		22003	2022-01-21	2024-12-31
		22030	2022-05-27	2025-04-30
		22057	2022-10-07	2025-09-30
		23022	2023-03-14	2026-02-28
		23043	2023-06-02	2026-05-31
		23072	2023-11-09	2026-10-31
		24014	2024-05-13	2027-04-30
	OLAA20	19166	2019-03-11	2022-02-28
		20219	2020-06-23	2023-05-31
		22004	2022-01-21	2024-12-31
		22026	2022-04-19	2025-03-31
		22031	2022-05-27	2025-04-30
		22058	2022-10-07	2025-09-30
		23001	2023-01-23	2025-12-31
		23033	2023-05-08	2026-04-30

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Product Description	Catalogue #	Lot #	Manufacturing Date	Expiration Date
OMEGA Left Atrial Appendage (LAA) Occluder	OLAA20	23044	2023-06-02	2026-05-31
		23062	2023-10-06	2026-09-30
		23084	2023-12-08	2026-11-30
		23085	2023-12-08	2026-11-30
	OLAA22	19048	2019-01-15	2021-12-31
		22005	2022-01-21	2024-12-31
		22006	2022-01-21	2024-12-31
		22037	2022-07-05	2022-07-05
		22059	2022-10-07	2025-09-30
		23002	2023-01-23	2025-12-31
		23018	2023-03-14	2023-03-14
		23034	2023-05-08	2026-04-30
		23035	2023-05-08	2026-04-30
		23049	2023-09-19	2026-08-31
		23063	2023-10-06	2026-09-30
		23064	2023-10-06	2026-09-30
		23073	2023-11-09	2026-10-31
	OLAA24	19052	2019-02-22	2022-01-31
		20220	2020-06-23	2023-05-31
		22007	2022-01-21	2024-12-31
		22008	2022-01-21	2024-12-31
		22038	2022-07-05	2025-06-30
		22043	2022-08-05	2025-07-31
		22060	2022-10-21	2025-09-30
		22061	2022-10-21	2025-09-30
		23019	2023-03-14	2026-02-28
		23040	2023-05-08	2026-04-30
		23050	2023-09-19	2026-08-31
		23051	2023-09-19	2026-08-31
		23065	2023-10-06	2026-09-30
		23066	2023-10-06	2026-09-30
		23074	2023-11-09	2026-10-31
		23086	2023-12-08	2026-11-30
		24032	2024-08-09	2027-07-31
	OLAA26	19049	2019-01-15	2021-12-31
		21012	2021-06-30	2024-05-31
		22009	2022-01-21	2024-12-31
		22027	2022-04-19	2025-03-31
		22032	2022-05-27	2025-04-30
		22044	2022-08-05	2025-07-31
		22051	2022-09-06	2025-08-31
		22062	2022-10-21	2025-09-30
		23003	2023-01-23	2025-12-31
		23036	2023-05-08	2026-04-30
		23037	2023-05-08	2026-04-30
		23052	2023-09-19	2026-08-31
		23067	2023-10-06	2026-09-30
		23068	2023-10-06	2026-09-30
	OLAA28	19050	2019-01-15	2021-12-31
		19489	2019-09-23	2022-08-31
		22010	2022-01-21	2024-12-31
		22011	2022-01-21	2024-12-31
		22024	2022-04-19	2025-03-31

ECLIPSE
MEDICAL

Product Description	Catalogue #	Lot #	Manufacturing Date	Expiration Date
OMEGA Left Atrial Appendage (LAA) Occluder	OLAA28	22045	2022-08-05	2025-07-31
		22046	2022-08-05	2025-07-31
		22052	2022-09-06	2025-08-31
		23004	2023-01-23	2025-12-31
		23020	2023-03-14	2026-02-28
		23038	2023-05-08	2026-04-30
		23045	2023-06-02	2026-05-31
		23069	2023-10-06	2026-09-30
	OLAA30	19051	2019-01-15	2021-12-31
		19490	2019-09-23	2022-08-31
		22012	2022-01-21	2024-12-31
		22013	2022-01-21	2024-12-31
		22039	2022-07-05	2025-06-30
		22040	2022-07-05	2025-06-30
		22053	2022-09-06	2025-08-31
		23005	2023-01-23	2025-12-31
		23021	2023-03-14	2026-02-28
		23039	2023-05-08	2026-04-30
		23075	2023-11-09	2026-10-31
		23077	2023-11-09	2026-10-31

INSTRUCTIONS:

1) Immediately cease implantation of ALL unused **OMEGA** Left Atrial Appendage (LAA) Occluder devices. Provide a copy of this URGENT Field Safety Notice to all distributors, importers, hospitals, clinics, and clinicians who have received any OMEGA devices.

2) **Complete the attached** URGENT Field Safety Notice – Recall Acknowledgement Form. A Recall Acknowledgement Form must be completed for all OMEGA devices, even if there are no unused devices at your facility.

3) Return completed URGENT Field Safety Notice – Recall Acknowledgement Form to the email listed on the Contact Information no later than 04 December 2024. Any questions about completing this action should be directed to the Contact provided on the Contact Information attachment.

4) Communicate this Field Safety Notice to all who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (As appropriate). Please transfer this notice to other organizations on which this action has an impact. (As appropriate). Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative as this provides important feedback.

5) Please provide Eclipse Medical with details of any affected devices that have been transferred to other organizations.

As Eclipse Medical is physically recalling any unused **OMEGA** Left Atrial Appendage (LAA) Occluder devices, if you are a Distributor, you are required to notify your Competent Authority of this Field Safety Notice.

Eclipse Medical is committed to providing excellent service to our physicians and patients. We sincerely apologize for inconveniences resulting from this action, and appreciate your support in the continued focus on patient care.

If you have any questions or would like assistance with this Field Safety Notice, please contact the appropriate Contact as listed on the Contact Information attachment.

Sincerely,

Attachments Included:

1. Recall Acknowledgement Form
2. Customer Reply Form
3. Contact Information

Please complete the Recall Acknowledgement Form. Return completed forms to us @ <Insert contact information>.

Devices distributed to: <Insert facility name and address, Account Contact, Department, as available>

URGENT Field Safety Notice – Recall Acknowledgement Form

OMEGA™ Left Atrial Appendage (LAA) Occlude Device

I acknowledge receipt of the Eclipse Medical Urgent Field Safety Notice dated 26 November 2024
for the OMEGA Left Atrial Appendage (LAA) Occluder Device

Actions have been completed as per the Instructions contained within this Letter.

Printed Name:_____**Title**:_____

Telephone Number:_____

Email Address:_____

Signature:_____**Date**:_____
(dd/mm/yyyy)

Please complete the Customer Reply Form. Return completed forms to us @ <Insert contact information>.

Devices distributed to: <Insert facility name and address, Account Contact, Department, as available>

URGENT Field Safety Notice – Customer Reply Form
OMEGA Left Atrial Appendage (LAA) Occluder Device

I have reviewed the **URGENT Field Safety Notice** for the **OMEGA Left Atrial Appendance (LAA) Occluder** device, and confirm the following units are within my control and segregated to prevent unintended use. Devices will be returned as requested.

Product Lot #	# Units Sent to Account	# Units Returned from Account	# Units Consumed

(More rows may be inserted, delete if not needed)

Printed Name:_____**Title**:_____

Telephone Number:_____

Email Address:_____

Signature:_____**Date**:_____
(dd/mm/yyyy)

URGENT Field Safety Notice – CONTACT INFORMATION

OMEGA Left Atrial Appendage (LAA) Occluder Device

Refer to the below table identifying contact information for each distributed geography.

Geography	Telephone Number	Email Address	Contact Person
EU + UK & South Africa	+353 1 2885 000	aidan@eclipse-med.com	Aidan Mulloy
Argentina, Thailand, Philippines	+66 21473445	supansa@eclipsemedical.biz	Supansa Sangsumlee