Legal Manufacturer:
Eclipse Medical Co. Ltd
88/62 Moo1, 345 Road, Pakkret
Nonthaburi-11120, Thailand

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Eclipse Medical Co. Ltd Reference: EM-FSN-24002

18 December 2024

Field Safety Notice
URGENT Medical Device Recall
ChekFLO Vascular Plug (CVP) Device

Dear Account Contact,

Eclipse Medical is commencing an immediate and URGENT RECALL of the **ChekFLO** Vascular Plug (CVP) 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 **ChekFLO** Vascular Plug (CVP) devices are vascular plugs which are made of self-expandable Nitinol mesh occlusion devices. The device has a screw attachment for a delivery cable. It is coated with platinum for better radiopacity. It is attached to a 135 cm delivery cable with a stainless steel screw.

The ChekFLO™ vascular plugs are self-expandable Nitinol mesh occlusion devices.
The device has a screw attachment for a delivery cable. It is coated with platinum for better radiopacity. It is attached to a 135 cm delivery cable with a stainless steel screw.
The ChekFLO vascular plugs are available in two variants, and indicated for use in the peripheral vasculature.

- The multi-layered, 3-lobe ChekFLO vascular plug II (CVP-II) is designed to significantly reduce the time to occlusion for transcatheter embolization procedures while maintaining complete control during positioning and delivery. It is available in multiple sizes to treat a wide range of vessels (4 to 22 mm).
- The bi-lobed low-profile ChekFLO vascular plug IV (CVP-IV) is designed to access more distal vasculature. Its flexible shape allows the device to occlude more tortuous target vessels. It is available in 3 diameters (4, 6 and 8 mm).
- The ChekFLO vascular plugs are indicated for arterial and venous embolizations in the peripheral vasculature.

The ChekFLO vascular plug was initially released to the market in August 2020, and in accordance with all applicable regulations and testing in effect at the time. The ChekFLO Vascular Plug is not available in the EU and US markets and has not been distributed within the US markets.
Subsequent to this market release, EMT decided to pursue a transition from MDD to MDR in the EU for a similar product design's continued CE certification. To support this activity, additional performance testing was conducted on the similar product that was not originally required prior to initial market release. The additional testing was performed to meet the MDR regulations and state of the art requirements of standards released since the original testing was performed. Compliance to the new ISO

Standard 22679 released in 2021 took into account any associated transition timeline for companies currently with MDD CE marks.

Note: All testing information contained within HHE2024-002 for the ChekFLO Vascular Plug (CVP) is leveraged and identical to the testing performed and documented within the OMEGA LAA Occluder HHE2024-001. After assessment by Eclipse Medical, it was determined that testing performed on the OMEGA product was identical to that required for the ChekFLO device due to the product similarities, and did not require any additional testing. The two products utilize the same materials, specifically, Platinum-coated Nitinol in a similar woven design, and are manufactured following the same internal processes at the Legal Manufacturer, EMT, and are both utilized in the circulatory system, albeit different anatomical locations. To date, zero (0) complaints have been received from the field since market release in August 2020.

Eclipse Medical is initiating a voluntary URGENT RECALL of ALL **ChekFLO** Vascular Plug (CVP) devices, as well as voluntary Medical Device Removal of all non- implanted **ChekFLO** Vascular Plug (CVP) 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 **ChekFLO** Vascular Plug (CVP) devices listed below. All **ChekFLO** Vascular Plug (CVP) devices distributed to the field since initial release in August 2020 are included within this Field Safety Notice, inclusive of all Device Sizes and Catalogue Numbers, as listed below.

Product Name	Catalog Number	Device Diameter (D)	Device Length (L)	Minimum Delivery Catheter ID	Maximum Delivery Catheter Length	UDI-DI
ChekFLO Vascular Plug (CVP)	CVP04-II	4 mm	6 mm	1.33 mm	100 cm	08857127156149
	CVP06-II	6 mm	6 mm	1.33 mm	100 cm	08857127156156
	CVP08-II	8 mm	7 mm	1.67 mm	100 cm	08857127156163
	CVP10-II	10 mm	7 mm	1.67 mm	100 cm	08857127156170
	CVP12-II	12 mm	9 mm	2.00 mm	100 cm	08857127156187
	CVP14-II	14 mm	10 mm	2.00 mm	100 cm	08857127156194
	CVP16-II	16 mm	12 mm	2.00 mm	100 cm	08857127156200
	CVP18-II	18 mm	14 mm	2.33 mm	100 cm	08857127156217
	CVP20-II	20 mm	16 mm	2.33 mm	100 cm	08857127156224
	CVP22-II	22 mm	18 mm	2.33 mm	100 cm	08857127156231
	CVP04-IV	4 mm	10 mm	1.33 mm	100 cm	08857127156248
	CVP06-IV	6 mm	11 mm	1.33 mm	100 cm	08857127156255
	CVP08-IV	8 mm	13 mm	1.33 mm	100 cm	08857127156262

Information below is included for the customers awareness, and includes all ChekFLO Vascular Plug (CVP) devices distributed to the field since initial product release in August 2020. All ChekFLO Vascular Plug (CVP) devices distributed to the field are included within this Field Safety Notice, inclusive of the Lot #s listed below.

Product Description	Catalogue #	Device Diameter (D)	Device Length (L)	Minimum Delivery Catheter ID	Maximum Delivery Catheter Length	Lot #	Manufacturing Date	Expiration Date
ChekFLO Vascular Plug (CVP)	CVP04-II	4 mm	6 mm	1.33 mm	100 cm	19064	2019-02-22	2022-01-31
						20098	2020-03-02	2023-02-28
						22047	2022-08-05	2025-07-31
						23006	2023-01-23	2025-12-31
						23011	2023-02-13	2026-01-31
						23053	2023-09-19	2026-08-31
						24006	2024-05-13	2027-04-30
						24020	2024-08-09	2027-07-31
	CVP04-IV	4 mm	10 mm	1.33 mm	100 cm	20095	2020-03-02	2023-02-28
						22014	2022-02-21	2024-12-31
						22048	2022-09-06	2025-08-31
						23055	2023-09-19	2026-08-31
	CVP06-II	6 mm	6 mm	1.33 mm	100 cm	19065	2019-02-22	2022-01-31
						20099	2020-03-02	2023-02-28
						22033	2022-05-27	2025-04-30
						23007	2023-01-23	2025-12-31
						23012	2023-02-13	2026-01-31
						23054	2023-09-19	2026-08-31
						24007	2024-05-13	2027-04-30
						24008	2024-05-13	2027-04-30
						24021	2024-08-09	2027-07-31
						24022	2024-08-09	2027-07-31
	CVP06-IV	6 mm	11 mm	1.33 mm	100 cm	20096	2020-03-02	2023-02-28
						22015	2022-01-21	2024-12-31
						22049	2022-09-06	2025-08-31
						23056	2023-09-19	2026-08-31
	CVP08-II	8 mm	7 mm	1.67 mm	100 cm	19525	2019-10-18	2022-09-30
						21004	2021-06-30	2024-05-31
						23008	2023-01-23	2025-12-31
						23013	2023-02-13	2026-01-31
						23078	2023-11-09	2026-10-31
						24009	2024-05-13	2027-04-30
						24023	2024-08-09	2027-07-31
						24024	2024-08-09	2027-07-31
	CVP08-IV	8 mm	13 mm	1.33 mm	100 cm	20097	2020-03-02	2023-02-28
						22016	2022-01-21	2024-12-31
						23079	2023-11-09	2026-10-31
	CVP10-II	10 mm	7 mm	1.67 mm	100 cm	19288	2019-06-25	2022-05-31
						21005	2021-06-30	2024-05-31
						23009	2023-01-23	2025-12-31
						23014	2023-02-13	2026-01-31
						24010	2024-05-13	2024-04-30
						24025	2024-08-09	2027-07-31

Product Description	Catalogue #	Device Diameter (D)	Device Length (L)	Minimum Delivery Catheter ID	Maximum Delivery Catheter Length	Lot #	Manufacturing Date	Expiration Date
ChekFLO Vascular Plug (CVP)	CVP12-II	12 mm	9 mm	2.00 mm	100 cm	19289	2019-06-25	2022-05-31
						21006	2021-06-30	2024-05-31
						22034	2022-05-27	2025-04-30
						23015	2023-02-13	2026-01-31
						24011	2024-05-13	2027-04-30
						24026	2024-08-09	2027-07-31
	CVP14-II	14 mm	10 mm	2.00 mm	100 cm	19290	2019-06-25	2022-05-31
						23010	2023-01-23	2025-12-31
						24012	2024-05-13	2027-04-30
						20100	2020-03-32	2023-02-28
	CVP16-II	16 mm	12 mm	2.00 mm	100 cm	19291	2019-06-25	2022-05-31
						22035	2022-05-27	2025-04-30
						24027	2024-08-09	2027-07-31
	CVP18-II	18 mm	14 mm	2.33 mm	100 cm	19292	2019-06-25	2022-05-31
						20101	2020-03-02	2023-02-28
						24028	2024-08-09	2027-07-31
	CVP20-II	20 mm	16 mm	2.33 mm	100 cm	19293	2019-06-25	2022-05-31
						20102	2020-03-02	2023-02-28
	CVP22-II	22 mm	18 mm	2.33 mm	100 cm	19294	2019-06-25	2022-05-31
						20103	2020-03-02	2023-02-28
						22050	2022-09-06	2025-08-31

INSTRUCTIONS:

1) Immediately cease implantation of ALL unused **ChekFLO** Vascular Plug (CVP) devices. Provide a copy of this URGENT Field Safety Notice to all distributors, importers, hospitals, clinics, and clinicians who have received any ChekFLO Vascular Plug (CVP) devices.

2) **Complete the attached** URGENT Field Safety Notice – Recall Acknowledgement Form. A Recall Acknowledgement Form must be completed for all ChekFLO Vascular Plug (CVP) 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 27 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 **ChekFLO** Vascular Plug (CVP) 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,

Supansa Sangsumlee
Quality Assurance Manager
18 December 2024

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
ChekFLO Vascular Plug (CVP) Device

I acknowledge receipt of the Eclipse Medical Urgent Field Safety Notice dated 18 December 2024
for the ChekFLO Vascular Plug (CVP) 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
ChekFLO Vascular Plug (CVP) Device

I have reviewed the **URGENT Field Safety Notice** for the **ChekFLO Vascular Plug (CVP)** 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

ChekFLO Vascular Plug (CVP) 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, Brazil, Uruguay	+66 21473445	supansa@eclipsemedical.biz	Supansa Sangsumlee