Date: 10.Aug.2026

Urgent Field Safety Notice
DermaV

For Attention of*:Cynosure Lutronic Technology's Customer

Contact details of local representative (name, e-mail, telephone, address etc.)*
Please refer to the email sender.

Rev 1: September 2018

FSN Ref: CLT-FSN-2026-001 FSCA Ref: CLT-FSCA-2026-001

Urgent Field Safety Notice (FSN)
DermaV
Potential occurrence of spark or loud noise at high fluence treatment

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	The DermaV laser system contains a Nd:YAG (Neodymium-doped Yttrium Aluminum Garnet) resonator which generate pulsed laser energy at the nominal wavelength 1064 nm and also generate pulsed laser energy at the nominal wavelength 532 nm using KTP. The outputs of each laser generator and the aiming beam (635 nm) are optically combined on the laser rail so that their beam paths areidentical as they exit the laser system. This allows the use of a single delivery system for either the 532 nm or 1064 nm wavelength.
1.	2. Commercial name(s)
	DermaV
1.	3. Unique Device Identifier(s) (UDI-DI)
	08800291820194
1.	4. Primary clinical purpose of device(s)*
	DermaV is intended for use in the medical specialty of dermatology requiring selective photothermolysis of target chromophores in soft tissue. The 532 nm wavelength is intended to be used by a trained physician as treatment of the following: - Benign vascular lesions,including spider veins of the lower extremities - Benign cutaneous lesions, including erythematous scars The 1064 nm wavelength is intended to be used by a trained physician as treatment of the following: - Benign vascular lesions, including port wine stains
1.	5. Device Model/Catalogue/part number(s)*
	DermaV
1.	6. Software version
	The software version is irrelevant.
1.	7. Affected serial or lot number range
	All DermaV systems configured to use the specified ICD gas type

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	No device malfunction, manufacturing defect, or hardware failure has been identified. Following the review of post-market surveillance data and field complaints, Cynosure Lutronic Technology identified that Spark or localized ignition may occur during certain high-fluence 1064 nm vascular treatments when cryogen timing settings allow excessive residual cryogen vapor to remain on the skin immediately before laser irradiation. This FSCA is intended to reinforce updated guidance for ICD timing parameters to further reduce this potential risk
	2. Hazard giving rise to the FSCA*

2.	Under certain treatment conditions involving: • 1064 nm wavelength • High fluence vascular treatments • ICD cooling using HFO-1234ze • Longer Delay settings Residual cryogen vapor may remain on the skin surface at the moment of laser emission. This may increase the likelihood of: • Spark • Localized ignition (small flame) • Loud popping sound In rare cases, localized superficial skin burns may occur. No permanent injury has been identified.
2.	3. Probability of problem arising
	The occurrence is infrequent and limited to specific treatment conditions involving high-fluence vascular procedures.
2.	4. Predicted risk to patient/users
	Based on the Health Hazard Evaluation (HHE): Severity -Low to Moderate Probability -Low Overall Risk -Low
2.	5. Further information to help characterise the problem
	The phenomenon is associated with treatment parameter configuration rather than device malfunction. No hardware defect has been identified. No manufacturing issue has been identified.
2.	6. Background on Issue
	Internal engineering evaluations demonstrated that reducing the Delay parameter decreases the amount of residual cryogen vapor present immediately before laser irradiation. Following cross-functional review by R&D, Clinical, Quality, it was concluded that changing the recommended ICD timing parameters is an appropriate risk mitigation measure.

	3. Type of Action to mitigate the risk*

3. 1. Action To Be Taken by the User*

☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device

☐ On-site device modification/inspection

☐ Follow patient management recommendations

☐ Take note of amendment/reinforcement of Instructions For Use (IFU)

☒ Other ☐ None

*Take note of new safety information

For 1064 nm vascular treatments, users should set:
ICD gas setting : Delay = Pre-5ms

For example

As-Is		To-Be	
Pre	Delay	Pre	Delay
15	15	15	10
20	20	20	15

Users should also:

*Inform all clinical operators.
*Update internal ICD setting parameter.
*Retain this notice with the Operator Manual.

3.	2. By when should the action be completed?	Immediately upon receipt.
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes

3. 4. Action Being Taken by the Manufacturer

☐ Product Removal ☐ On-site device modification/inspection
☐ Software upgrade ☒ IFU or labelling change
☐ Other ☐ None

The Instructions for Use (IFU) will be updated to include a warning regarding the potential occurrence of spark, localized ignition, or loud popping sound during certain 1064 nm vascular treatments using the Intelligent Cooling Device (ICD), and to instruct users to configure the ICD Delay setting lower than the Pre setting.

3	5. By when should the action be completed?	Until September 15, 2026

	4. General Information*	
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN? *	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Cynosure Lutronic Technology**
	b. Address	**55, Samwon-ro, Deogyang-gu, Goyang-si, Gyeonggi-do, 10550, Republic of Korea**
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	5. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	6. Name/Signature	**CEO Jaehoon Yoo** Jaehoon Yoo

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations 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, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.