STIHLERELECTRONIC
A GENTHERM Company

Tel. +49 (0) 711-72067 0
Fax +49 (0) 711-7206757
E-Mail: info.ste@gentherm.com
www.stihlerelectronic.de

FSN Ref. #2023-11_en FSCA Ref. #2024-01_en

EU-SRN: DE-MF-000006188
Datum: 2023-11-29

URGENT FIELD SAFETY NOTICE

ASTOPAD

Dear valued customer,

We are writing to inform you of a potential issue with your ASTOPAD COV and SOF applied parts (blankets / pads) and corrective action to be taken. The COV and SOF applied parts, when used with the ASTOPAD control unit, are intended to prevent or treat hypothermia and to provide warmth to patients.

Please observe the following notes and instructions carefully! According to our records, you have received one or more of the affected products. This safety information is intended for users, operators, distributors, and sales partners.

COV applied parts (blanket)

SOF applied parts (pad)

Identification of the medical devices concerned

SOF2	COV105 SOF4	COV150 SOF5	COV155	COV070	COV180
2-230602-xxx	4-220416-xxx	5-221013-xxx	6-220921-xxx	7-220706-xxx	8-220809-xxx
	4-221208-xxx	5-221021-xxx	6-220929-xxx		
	4-230411-xxx	5-221110-xxx			
		5-230202-xxx			
		5-230301-xxx			
		5-230512-xxx			
		5-230608-xxx			
		5-230729-xxx			

xxx stands for the consecutive numbering (001 to 999) of a batch and means that all serial numbers of the batch named in the overview are affected.

FSN Ref. # 2023- I I _en FSCA Ref. # 2024- 0I _en j

Reason for FSCA - Description of the product problem

SOF and COV applied parts manufactured from May 2022 to October 2023 may potentially have internal (not visible from outside) damaged electrical insulation at a few distinct locations. The root cause is an error in the manufacturing process of the heating element. The damage could lead to localized overheating. This was identified during internal investigation after a single reported adverse event in which a patient received a burn approx. 3 cm in diameter.

Probability of problem arising

Local overheating requires all 5 of the following conditions to be met.

Damage must be present and severe enough to expose the conductor.
Location of damage must be aligned to make resistive contact with the device's mesh patterned heating element.
Contact between the exposed conductor and the heating element must have a high enough conductivity to cause overheating.
The patient must be in contact with this point of the applied part.
Depending on the position of the contact resistance, a delayed alarm can occur and thus cause different degrees of overheating.

999 potentially affected applied parts have been delivered and are in service worldwide. It is estimated that those parts have been used in 400560 use cases and only a single incident has been reported. Given this low occurrence and the cascade of 5 conditions that must be met, we have determined that the risk of recurrence is unlikely and the incident that occurred is an outlier. Although risk of recurrence is unlikely, as the manufacturer of ASTOPAD we are committed to ensuring maximum safety for patients and users, therefore we are issuing this FSN as an overly conservative risk measure.

Hazard giving rise to the FSCA

In the worst case, the localized overheating can result in a small and deep burn on the patient.

Manufacturer Actions

The manufacturer will provide an adapter for all affected applied parts. To supplement the existing circuit protection in the control unit, the adapter contains an additional fuse that opens when the electrical contact conditions described above are met. Instructions to connect the adapter to the affected applied parts will be included. Once properly connected per the instructions, the adapter must not be removed.

Adapters will be delivered to the customers/distributors for each affected applied part (FSCA Ref. #2024-01_ en) as they are available starting in January 2024. Distributors will immediately forward the adapter to the affected customers. Users (end customers) must then follow the detailed instructions to connect the adapter to the affected applied part. A list of the affected serial numbers is enclosed with the adapter delivery for each customer. Affected applied parts may then only be used together with the adapter.

User Actions

Until the manufacturer implements the measure described above, users must observe the following instructions:

- All applied parts that are connected to the control unit must be actively warming (i.e., it must be turned on which is recognizable by the control unit display).
- Disconnect any applied part that is not in use from the control unit.
- Follow the direction in the instructions for use, in particular:
  - Conduct a visual inspection of the applied part before each use. Do not use the applied part if it is damaged or discoloured.
  - Do not attempt to restart the ASTOPAD if it switches to alarm mode during operation.
  - Conduct the prescribed annual inspection of ASTOPAD.
- Start ASTOPAD before using it on the patient.
- Forward this FSN immediately to all relevant users and device owners.

- Send the reply form back to vigilance.ste@gentherm .com by **2023-12-22.**

Distributor Actions

Until the manufacturer implements the measure described above, please take the following measures:

- Identify the customers who have received affected applied parts.
- Forward this FSN to these customers immediately.
- Send the reply form back to vigilance.ste@gentherm .com by **2023-12-22.**

Transmission of this Field Safety Notice

This notice must be distributed to all potential users of the Astopad COV or SOF applied parts identified within this notice, or to any organisation where the affected applied parts have been transferred.

Please observe the following with respect to this FSN:

- Keep this information at least until the measure has been completed and maintain awareness for an appropriate period to ensure effectiveness of the FSCA.
- Report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority.
- The respective national Competent Authority has received a copy of this "Urgent Field Safety Notice".

Manufacturer Contact Information

If you have any questions, please contact:

Jens-Peter Weege
Tel. +49 711 72067-62
Fax +49 711 72067-57
E-Mail: vigilance.ste@gentherm.com

Patient safety is our top priority at Stihler Electronic. We apologize for any inconvenience.

ctor of Regulatory Affairs

Felix Stihler
Managing Director

Attachment
Reply form

::\ /fi

Reply Form

1. Information about the field safety notice (FSN)		
FSN Reference Number*	#2023-11	
FSN Date*	2023-11-29	
Product-/ Device name*	ASTOPAD	
Product Code(s) (REF)	COV SOF	
LOT/Serial number(s), which, according to our information, have been sent to your organization.	**SOF2**	2-230602-xxx to -xxx
	COV105 SOF4	4-220416-xxx to -xxx
		4-221208-xxx to -xxx
		4-230411-xxx to xxx
	COV150 SOF5	5-221013-xxx to -xxx
		5-221021-xxx to -xxx
		5-221110-xxx to -xxx
		5-230202-xxx to -xxx
		5-230301-xxx to -xxx
		5-230512-xxx to -xxx
		5-230608-xxx to -xxx
		5-230729-xxx to -xxx
	COV155	6-220921-xxx to -xxx
		6-220929-xxx to -xxx
	COV070	7-220706-xxx to -xxx
	COV180	8-220809-xxx to -xxx

2 . Details about the customer	
☐ User of the medical device *Please fill in table ,,2." and "3."*	☐ Distributor/ Importer/ Sales partner *Please fill in table "2." and "4."*
Name of the organisation*	
Address of the organisation*	
Department/unit	
Delivery address if different from above	
Contact name*	
Title or function	
Telephone number*	
E-mail*	

3. User action on behalf of the health organization

Please tick as annrooriate. If not annficable, olease tick "NIA

☐	I acknowledge receipt of the safety information and confirm that I have read and understood the contents*.	*Comment:* ☐		
☐	I have carried out all the measures required by the **FSN**.	☐ ***NIA***	*Comment:*	
☐ ☐	The information and necessary measures were brought to the attention of all relevant users and implemented	***NIA***	*Comment:*	
☐	The following affected products are within our organisation.	*Quantity:*	*Rf=f :*	*Serial number /from ... to ..., if applicable):*
		Quantity:	*REF:*	*Serial number /nnm ... to , . ,f appllcao fe;:*
		Quantity:	*REF:*	*Serial number /from •., to . , if applicabfe}:*
		Quantity:	*REF:*	*Sena/ numtler /n-om ... to ..., ,f appllcaofe;:*
		Quantity: ☐ ***NIA***	*REF.*	Serial *number /from . to . , if appiicabie):*
			Comment:	
	The following products were already taken out of operation before the FSN and destroyed for other reasons.	*Quantity:*	*REF :*	*Serial number /from .. to .. , if applicable):*
		Quantity:	*REF :*	*Serial number /*from *... to .. , if applicable):*
		Quantity:	*REF:*	*Serial number /from . to .. , if applicable):*
		Quantity: ☐ ***NIA***	*REF:*	*Serial number /from . to • , if applicable):*
		☐	*Comment:*	
☐	There are no affected products in our organisation.	**NIA**		
☐	Other action	*Description ofl he action:* ☐ **NIA**		
	I have a question, please contact me	*Please enter your contact details here fft hey are not the* same as *above, and* a tlnef descnption of your enquiry.		
	Name (first name and surname)*			
	Signature*			
	Date*			

FSN Ref. # 2023- II _en FSCA Ref. # 2024- 0I _en

4. Distributor/ importer action

Please tick as appropriate. If not applicable, please tick "NIA

☐	I acknowledge receipt of the safety information and confirm that I have read and understood the contents*.	
☐	I have checked our warehouse and quarantined the following affected products.	Quantity: / REF: / Sena / number (from .. to .., if applicable):
		Quantity: / REF: / Serial number (from .. to .., if applicable):
		Quantity: / REF: / Serial number (from .. to .., if applicable):
		Quantity: / REF: / Serial number (from .. to .., if applicable):
		Quantity: / REF: / Serial number (from .. to .., if applicable):
		☐ N/A
		Comment:
	I have identified customers/ users who have received or may have received affected applied parts.	D A separate list of delivered and affected products with details of the customer organisation, address and contact person is enclosed with this reply form.
		☐ N/A
		Comment:
☐	There are no affected products in our organisation.	NIA
☐	Other action	Description of the action:
		☐ N/A
	I have a question, please contact me	Please enter your contact details here if they are not the same as above. and a bnef description of your enquiry.
	Name (first name and surname)*	
	Signature*	
	Date*	

5. Return confirmation to the sender

E-Mail	vigilance.ste@gentherm.com
Phone	+49 (0)7111 72067 - 0
Postal address	Gaussstrasse 4 70771 Leinfelden-Echterdingen Germany
Web Portal	www.stihlerelectronic.de
Fax	+49 (0)7111 72067 - 57
Deadline for returning the customer response form*	**2023-12-22**

*Mandatory fields are marked with **

It is important that your organisation implements the actions described in the FSN and confirms receipt of the FSN.

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