FSN Ref: **RKL-7048 and RKL-7079**

Leonhard Lang

Date: 2026 – 07 - 30

Urgent Field Safety Notice

For defibrillation electrodes:
50116 - REF DF28N SKINTACT DF28N Adult
50518: REF DF30G SKINTACT DF30G Pediatric

For Attention of*: Users of the affected lots of REF DF28N SKINTACT adult electrodes and REF DF30G SKINTACT pediatric electrodes

Contact details of local representative (name, e-mail, telephone, address etc.)*
Manufacturer: Leonhard Lang GmbH: Thomas Recheis (Head of Quality), vigilance@leonhardlang.at, Tel. +43 512 33425, Archenweg 56, 6020 Innsbruck, Austria

Figure 1 Identification of potentially affected product based on REF, Lot number and expiry date on the label.

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Electrodes for defibrillation
1.	2. Commercial name(s)*
	SKINTACT DF28N Adult (Zoll) / SKINTACT DF30G Pediatric (Zoll)
1.	3. Unique Device Identifier(s) (UDI-DI)
	19005531501161 / 19005531505183
1.	4. Primary clinical purpose of device(s)*
	Defibrillation, Pacing, Monitoring, Cardioversion
1.	5. Device Model/Catalogue/part number(s)*
	REF DF28N / REF DF30G
1.	6. Software version
	Not applicable.
1.	7. Affected serial or lot number range
	REF DF28N: 250722-4045, 260227-4044, 260319-5482, 260430-5489, 260528-5484 REF DF30G: 260202-4047, 260408-4045
1.	8. Associated devices

	Zoll M-, E-, R-, and X Series with adapter cable 8000-0308-01/02, 8009-0749, 8300-0783, 8300-000676

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	The connector cannot be fully inserted into the compatible adapter cable using the usual amount of force. The locking tab does not engage and the audible "click" is absent (see Figure 2).
2.	2. Hazard giving rise to the FSCA*
	Electrical contact and retention force meet the requirements; safety and performance are not impaired, and intended use remains possible. However, the locking tab not engaging may confuse users and delay treatment.
2.	3. Probability of problem arising
	Depending on the adapter cable used, a high incidence is possible.
2.	4. Predicted risk to patient/users
	No hazard to patients or users has been identified in connection with this deviation.
2.	5. Further information to help characterise the problem
	The deviation is detected when the cable is inserted into the adapter cable.
2.	6. Background on Issue
	Error in the connector manufacturing process.
2.	7. Other information relevant to FSCA
	Not applicable.

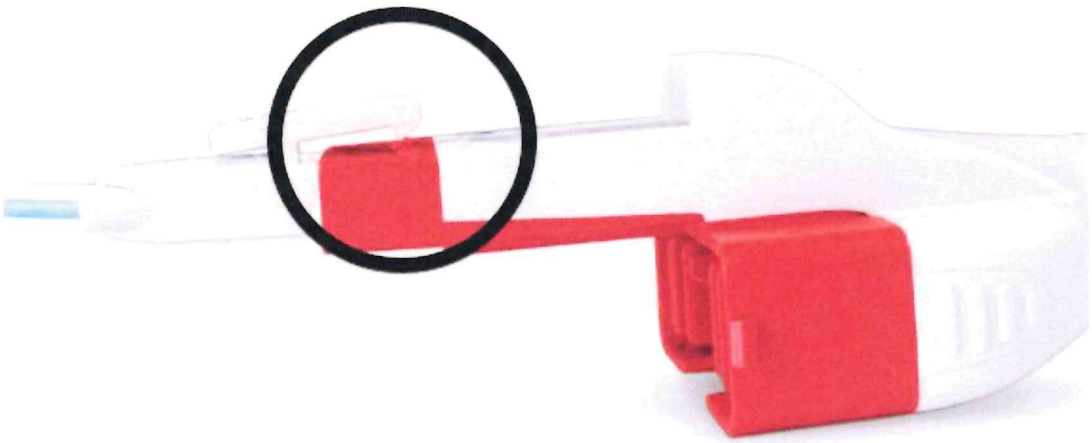
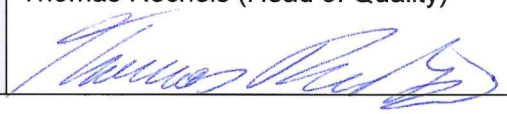


Figure 2. Locking mechanism that does not fully engage

3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User*** Electrodes can be used without restrictions.

3.	2. By when should the action be completed?	Not applicable
3.	**3. Action Being Taken by the Manufacturer*** Correction of the manufacturing process and implementation of a reliable detection method (100% inspection) for this deviation.	
3.	4. By when should the action be completed?	The detection method was implemented in July 2026.
3.	5. Is the FSN required to be communicated to the patient /lay user?	No
	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	Leonhard Lang GmbH
	b. Address	Archenweg 56, 6020 Innsbruck, Austria
	c. Website address	www.leonhardlang.at
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * **Yes**	
4.	5. List of attachments/appendices:	Not applicable
4.	6. Name/Signature	Thomas Recheis (Head of Quality) 

	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.