FSCA Ref: **200051316 - NL**

Date: 20.06.2023

Urgent Field Safety Notice

SmartOne Vac

Contact details of the legal manufacturer
KLS Martin GmbH + Co. KG Am Flugplatz 18 79108 Freiburg Mail: complaint.fr@klsmartin.com **Quality Management** Frank Paschke Person Responsible for Regulatory Compliance (PRRC) Phone/Telefon: +49 761 557997-174 Mail: frank.paschke@klsmartin.com **Product Management** Leon Binkele Junior Product Manager Phone/Telefon: +49 7461 706-530 Mail: leon.binkele@klsmartin.com

Dear customer,

With this FSN we would like to inform you about a possible security risk with our smartOne VAC single-use electrode handles and how you should deal with it.

Thank you for your immediate attention and cooperation. We apologise for any inconvenience this matter may cause.

KLS Martin GmbH + Co. KG

Am Flughafen 18 · D-79108 Freiburg im Breisgau
Tel. +49 761 557 997-0 · Fax +49 761 557 997-137
info@klsmartin.com · www.klsmartin.com

Registergericht: Freiburg im Breisgau
Handelsregister: HRA 4044
USt.-Id.-Nr.: DE 237467280

Persönlich haftende Gesellschafterin:
KLS Martin Verwaltungsgesellschaft mbH
Registergericht: Stuttgart
Handelsregister: HRB 451316
Sitz der Gesellschaft:
Mühlheim/Donau

Geschäftsführer:
Michael Martin, Karl Leibinger, Christian Leibinger

Kreissparkasse Tuttlingen:
IBAN DE 29 6435 0070 0008 5027 20 · BIC SOLADE S1 TUT
Deutsche Bank Tuttlingen:
IBAN DE 04 6537 0075 0218 5775 00 · BIC DEUT DE SS 653
Sparkasse Freiburg:
IBAN DE 95 6805 0101 0013 3634 80 · BIC FRSPDE66XXX

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1	**Information on Affected Devices**
1.1	**Clinical purpose of the product**
	This smartOne Vac single-use electrode handle with active electrode is designed to conduct and activate electrical energy for monopolar cutting, coagulation and for simultaneous smoke evacuation.  The smartOne Vac handles with electrodes can be used for all surgical procedures for which the clinical benefit of monopolar application (cutting tissue and/or hemostasis) has been established.
1.2	**Article number**

Article number	Article name	UDI-DI
80-701-20-04	SO telesc. smoke evac. handle, NSTC, 4.5m	04057607002568

1.3	**Batches**
	120150522 120150622
1.4	**EUDAMED-DI**
	B-80-701-20-04VL

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2	**Reason for Field Safety Corrective Action (FSCA)**
2.1	**Description of the product problem**
	Feedback from our Dutch sales subsidiary that during an operation it was found that plastic parts may be in the bag and on the products. These plastic parts or pieces of foil are die-cut parts of the sterilized packaging bag. The cut-outs are needed for EO sterilization.
2.2	**Hazards giving rise of the FSCA**
	These plastic parts could fall unnoticed into the surgical field and enter the patient's body.
2.3	**Probability of problem arising**
	So far, the problem has been identified in one batch from 2022. However, only a few products within this batch have been affected.
2.4	**Further information to help characterise the problem**
	The problem was identified for the first time in 2023 in a batch that has already been sold since 2022. So far, only one feedback has been received.

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3	**Type of action to mitigate the risk**	
3.1	**Action to be taken by the User** ☒ Identify Device ☒ On-site device inspection ☒ Other: Take note of the information, that the products must be checked for die-cut plastic parts before use and remove them if necessary.	
3.2	**Is customer Reply required?** (If yes, form attached specifying deadline for return)?	**No**
3.3	**Action to be taken by the Manufacturer** ☒ Other: Affixing an information to the packaging units of the potentially affected LOTs/products still in stock.	

4	**Transmission of this Field Notice**
4.1	Please pass on this notice immediately to all departments who might use the concerned products. Forwarding of the Filed notice is the responsibility of the distributors. In addition, ensure that the information is provided to any organisation where the concerned products potentially have been distributed.

[redacted]

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