Rev 1: September 2018

FSN Ref: FSN-AG191103 FSCA Ref: FSCA-AG191103

Date: 15/01/2020

Urgent Field Safety Notice
STERNAL RETRACTOR IMA – REF DC30200-00

For Attention of*: UniversitatsSpital Zurick – Ramistrasse 100 -8091 ZURICH - SCHWEIZ

Contact details of local representative (name, e-mail, telephone, address etc.)*
MCM Medsys AG – Cassandra Somma - Glutz-Blotzheim-Str.3 – 4500 Solothurm Switzerland.

LANDANGER

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In worst case, parts could fall unnoticed into the patient during surgical operation./
Dans le pire des cas, des parties métalliques pourraient passer inaperçues dans le patient pendant l'opération chirurgicale.

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Non sterile sternal retractor, made of stainless steel. / Ecarteur sternal non stérile, fait d'acier inoxydable 
1.	2. Commercial name(s)
	STERNAL RETRACTOR IMA (COUETIL) L:180MM MAX OPENING :205 MM U SHAPED INCLUDED DC30210-20 AND DC30220-28 AND DC30221-32. / ECARTEUR STERNAL IMA (DR COUETIL - ORIGINAL) L:180MM OUVERTURE MAX:205MM AVEC DC30210-20 ET DC30220-28 ET DC30221-32
1.	3. Unique Device Identifier(s) (UDI-DI)
	NA
1.	4. Primary clinical purpose of device(s)*
	The device is used to retract the patient's sternal walls during the operation to provide access to the surgical site. / Le dispositif est utilisé pour écarter les parois sternales du patient au cours de l'opération, pour donner accès au site chirurgical.
1.	5. Device Model/Catalogue/part number(s)*
	DC30200-00
1.	6. Software version
	NA
1.	7. Affected serial or lot number range
	Serial number 00837436 – 00837435 – Delivery MCM MEDSYS – Lieferschein 2174282 date 11.12.2017
1.	8. Associated devices
	NA

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Damage of the device and burr formation during use due to a lack of lubrication. / Endommagement du dispositif et formation de bavures lors de l'utilisation par manque de lubrification
2.	2. Hazard giving rise to the FSCA*
	Risk for the patient : In worst case, parts could fall unnoticed into the patient during

	surgical operation. / Risque pour le patient : Dans le pire des cas, des parties métalliques pourraient tomber inaperçues dans le patient pendant l'opération chirurgicale.
2.	3. Probability of problem arising
	Very low. / Très faible.
2.	4. Predicted risk to patient/users
	In worst case, there is a risk of serious deterioration in state of health of the patient / Dans le pire des cas, il existe un risque de détérioration grave de l'état de santé du patient
2.	5. Further information to help characterise the problem
	No real case of deterioration of state of health of a patient has been reported formerly. / Aucun cas réel de détérioration de l'état de santé d'un patient n'a été signalé auparavant.
2.	6. Background on Issue
	Manufacturer became aware following an e-mail from Swissmedic. The root cause is a lack of lubrication before using the device. The incriminated device was manufactured in April 2017. Since May 25th, 2018, all new devices are laser marked with the indication that the lubrication is necessary. / Le fabricant a été alerté suite à un e-mail de Swissmedic. La cause est un manque de lubrification avant l'utilisation du dispositif. Le dispositif incriminé avait été fabriqué en Avril 2017. Depuis le 25 Mai 2018, tous les nouveaux dispositifs sont marqués avec l'indication de lubrification.
2.	7. Other information relevant to FSCA
	NO / NON

	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 Information already transmitted on November 12th, 2019 to the distributor as part of the expert report and the compliance of the incriminated MD. Information déja transmise le 12 novembre 2019 au distributeur dans le cadre du rapport d'expertise et de la mise en conformité du DM incriminé.	
3.	2. By when should the action be completed?	Laser marking on the new devices already applied since May 25th, 2018. Update of the instructions for use I AQ 008-20191220-FR-EN-DE-IT-v4 realised on December 12th, 2019. / Marquage sur les dispositifs neufs déjà en place depuis le 25/05/2018. Mise à jour de la notice IAQ 008-20191220-FR-EN-DE-IT-v4 réalisée le 20/12/2019.

3.	3. Particular considerations for: NA Is follow-up of patients or review of patients' previous results recommended? NA	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No / Non
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☒ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☐ Other ☐ None 1/ In connection with the treatment of the medical device in question, add lubrication information on the device manufactured in April 2017 so that the user is aware when he/she holds it. Laser marking of the new devices is applied since May 25th, 2018. 2/Update of the general instructions for use IAQ 008 : precision that the user must lubricate the instrument before each use, and translation of the instructions for use into the 3 languages spoken in Switzerland. 1/ Dans le cadre du traitement de DM incriminé, ajout de l'information de lubrification sur le dispositif fabriqué en 04/2017 pour que l'utilisateur en soit informé lors de la prise en main. Marquage des dispositifs neufs en place depuis le 25/05/2018. 2/ Mise à jour de la notice générale IAQ 008 : Précision que l'utilisateur doit lubrifier l'instrument avant chaque utilisation, et traduction de la notice dans les trois langues parlées en Suisse.	
3	6. By when should the action be completed?	Information already transmitted on November 12th, 2019 to the distributor as part of the expert report and the compliance of the incriminated MD. / Information déja transmise le 12 novembre 2019 au distributeur dans le cadre du rapport d'expertise et de la mise en conformité du DM incriminé.
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	NA	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	NA
4.	**3.** For Updated FSN, key new information as follows:	
	NA	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	NA	
4	6. Anticipated timescale for follow-up FSN	NA
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**LANDANGER**
	b. Address	**ZI LA VENDUE – 52906 CHAUMONT - FRANCE**
	c. Website address	**landanger@landanger.com – aguillaumot@landanger.com**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	NA
4.	10. Name/Signature	**Alain GUILLAUMOT, quality manager**
		

	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.