December 5th 2018

URGENT – FIELD SAFETY NOTICE

Sonolith® i-sys – Arm rupture

1- Description and reason for the corrective action

Dear customer of Sonolith® i-sys,

EDAP TMS has been informed of the rupture of the fixing element of the monitor arm suspension which occurred on a Sonolith I-Sys device in Japan.

This rupture results from an overload applied to the mechanical component (screws) fixing the monitor arm suspension to the device structure due to a combination of inappropriate design and operator action on the monitor.

In a nominal situation, the suspension arm allows the positioning of the screens at about 1150 mm from the floor. The rupture of the 3 fixing screws of the suspension arm results in a lateral tilting of the arm of about 500 mm positioning the screen at 650 mm from the floor. The arm is retained in its fall by wedging against the steel cylinder on which the three screws are initially screwed.

2- Health risk

In case of rupture of the monitor arm fixing element, the system tilts laterally on a height of about 500 mm but remains retained to its support. The arm geometry does not allow a suspension above the patient and therefore, this incident can only affect the operator resulting in benign injury, possibly requiring a medical procedure. The probability of occurrence combined to the degree of severity result in a risk level classified as "low to medium". This risk level does not require a product recall.

3- Products concerned

Only some devices of the Sonolith i-Sys range (TMS 230793 / TMS 230795) are concerned by this safety information. The list of equipment concerned, identified by their serial number, is presented in **Appendix A**.

4- Measures to be taken by the user

Please take the following measures:

1. Transmit this letter to your local medical device vigilance correspondent, urologist, and biomedical engineering staff, and your medical personnel who perform therapeutic procedures with Sonolith® i-Sys devices.
2. Perform a visual inspection and a verification of the mobility of the monitor arm suspension on your system. In case of abnormality or unsmooth displacement, please advise your EDAP-TMS Technical Service local representative (fill the attached form and send it back to your local representative to schedule a specific maintenance).
3. In any case, you can continue to normally use your equipment until the visit of your EDAP-TMS Technical Service representative. Please keep a copy of this letter in your records.

5- Measures taken by EDAP TMS France

1. The root cause of this failure has been promptly investigated by EDAP-TMS technical services and a corrective action is currently designed and will be released after validation.
2. The devices concerned by this failure will be then upgraded by your EDAP-TMS Technical Service representative.
3. A copy of this Safety Information will be sent to customers with the relevant Sonolith® i-sys systems.

EDAP TMS France representatives will be available by phone to answer any questions related to this safety information.

6- Additional information and assistance

For additional information or assistance with this safety information, please contact your EDAP TMS France representative or the EDAP TMS France technical service at the following numbers:
Phone : +33 (0) 4.75.15.31.50 or Fax : +33 (0) 4.72.15.31.51 or Email : ccc@edap-tms.com

Please note that the relevant ANSM regulatory authority has been informed of this safety information.

Yours sincerely,

Emmanuel BLANC
Medical Device Vigilance Correspondent

EDAP TMS France
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4 Rue Du Dauphiné
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REQUEST FOR A SPECIFIC MAINTENANCE

Security information / Corrective action

Sonolith® i-sys – Arm rupture

PLEASE COMPLETE ALL INFORMATION REQUIRED AND RETURN THE FORM

1. I have received and consulted this notice.
2. I made the visual inspection and mobility verification required and noticed a malfunction.
3. I ask for specific maintenance:

Contact of your EDAP-TMS local representative
Phone :
Email :

Contact of EDAP-TMS Head quarter:
Phone : +33 (0) 4.75.15.31.50 / Fax : +33 (0) 4.72.15.31.51
Email : ccc@edap-tms.com

Name of the hospital : _____

Serial number : _____

Name & Function (in capitals) :_____

Signature : _____

Phone number : _____

e-mail : _____

Date : _____

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APPENDIX A

Country	Serial number	Country	Serial number	Country	Serial number
Algeria	SIS023	Indonesia	SIS034	Japan	SIS080
Germany	SIS018		SIS035		SIS082
	SIS030	Iran	SIS063	Jordania	SIS053
	SIS068	Japan	SIS039	Kuwait	SIS072
Bolivia	SIS042		SIS045	Malaysia	SIS069
Canada	SIS058		SIS047	Morocco	SIS040
Korea	SIS014		SIS048	Norway	SIS013
	SIS027		SIS052	Poland	SIS011
	SIS038R		SIS054	Portugal	SIS012
Ecuador	SIS019		SIS056		SIS029
	SIS020		SIS057	United Kingdom	SIS032
	SIS021		SIS060		SIS043
Spain	SIS033		SIS061		SIS046
	SIS037		SIS062		SIS049
	SIS041		SIS064		SIS065
	SIS055R		SIS066		SIS078
France	SIS016		SIS067	Russia	SIS031
	SIS022		SIS070		SIS059
	SIS028		SIS073		SIS074
	SIS036		SIS075		SIS081
Italy	SIS015		SIS076	Switzerland	SIS025
	SIS017		SIS077	Taiwan	SIS003R
	SIS051		SIS079		SIS071