

FIELD SAFETY NOTICE № MI-01-2022-FSN
Mobile patient lift Diana II ELA, Diana II MLA, Lifteo ELA, Lifteo MLA
FSCA-identifier: MI-01-2022- FSCA
Type of FSCA: Replacement of a component by an authorized service center

2022-07-15

Attention: clients of Meden-Inmed according to the distribution list

The notice concerns the Diana II ELA, Diana II MLA, Lifteo ELA and Lifteo MLA mobile patient lifts with factory-installed type 2P45 two-point slings.

The lifts subject to sling replacement have the following serial numbers:

Lift type	Serial number
Diana II ELA	SN-03072-2020
	SN-03071-2020
	SN-03075-2020
	SN-03076-2020
	SN-03077-2020
	SN-03078-2020
	SN-03079-2020
	SN-03080-2020
	SN-03081-2020
	SN-03082-2020
	SN-03083-2020
	SN-03084-2020
	SN-00266-2021
	SN-00267-2021
	SN-00268-2021
	SN-00269-2021
	SN-00278-2021
	SN-00265-2021
Diana II MLA	SN-03056-2020
	SN-03055-2020
	SN-03057-2020
	SN-03058-2020
	SN-03743-2021
	SN-03059-2020
	SN-03744-2021
	SN-03745-2021
	SN-03746-2021
	SN-03747-2021
	SN-03748-2021
	SN-03061-2020
	SN-03749-2021
	SN-03752-2021
	SN-03750-2021
SN-03751-2021	

Lift type	Serial number
LIFTEO ELA	SN-03217-2022
	SN-03209-2022
	SN-03211-2022
	SN-03212-2022
	SN-03213-2022
	SN-03214-2022
SN-03215-2022	
LIFTEO MLA	SN-03223-2021
	SN-03220-2021
	SN-03224-2021
	SN-06221-2022
	SN-06220-2022
	SN-02157-2021
	SN-03217-2021
SN-03102-2022	

1. Description of the problem:

An analysis of the causes of the recently reported incident revealed that when the two-point sling type 2P45 is asymmetrically and frequently loaded with the patient's weight, fatigue of the attachment pin material can occur, resulting in a gradual loss of attachment integrity and rupture, involving a patient fall.

In an effort to ensure the maximum possible safety in the use of the Diana II ELA, Diana II MLA, Lifteo ELA and Lifteo MLA mobile patient lifts, the manufacturer has decided to replace the type 2P45 slings with the type 2P45 slings with a reinforced mandrel with additional protection against rotation of the head of the bolt securing the mandrel.

2. Advise on action to be taken by the user:

The manufacturer's authorized service will carry out the replacement of the type 2P45 two-point slings in the lifts with the above listed serial numbers with the type 2P45 slings of reinforced construction which will be delivered free of charge on the dates agreed with the users.

Upon receipt of type 2P45 slings with reinforced construction, the replacement should be carried out as soon as possible (delivery date is expected at the 31st week of 2022), but no later than within 4 weeks of receipt.

3. 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 lifts with the serial numbers listed above have been distributed.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

4. Contact reference person:

Meden-Inmed, ul. Wenedów 2a, 75-847, Koszalin, Polska

Karol Wojciechowski, e-mail: kwojciechowski@meden.com.pl

Marek Urbanowicz, e-mail: murbanowicz@meden.com.pl

Please confirm receipt of this notice and completion of the above-described replacement of the 2P45 slings in the Diana II ELA, Diana II MLA, Lifteo ELA and Lifteo MLA lifts with the serial numbers listed above on the attached form.

The undersigned confirms that this notice has been notified the appropriate Regulatory Agency.

Signed: Mariusz Drewniak

