URGENT SAFETY INFORMATION
CAPA 22-037

Product: SEDECAL X URS
Serial Numbers Affected: INSTALLED BASE
Action to be applied: **SYSTEMS CHECK**

This document contains important information to ensure the correct use of your equipment. Please read it carefully.

Date: July 2022

Dear Customer,

The purpose of this letter is to inform you that SEDECAL, the manufacturer of this equipment, has detected a potential safety problem that may pose a risk to patients, users or third parties. Due to a problem that occurred in an equipment that has been installed for more than 7 years, where the screws that hold the trolley to the column have loosened but the user has continued using the system until finally the trolley has separated from the column, and some parts of the equipment has fallen to the ground. Containment measures have already been taken on the affected equipment's and corrective actions are being taken to definitively resolve this issue on systems affected.

The purpose of this security information is to inform you of:

- Systems affected.
- Nature of the problem and the circumstances under which it may occur.
- Measures to be taken to prevent risks for patients, users and third parties.
- Measures taken by SEDECAL to solve the problem.

You will find details related to this problem in Annex 1.
We kindly ask you to distribute this information to all staff involved.
The problem has been reported to the Authorities.

We kindly ask you to send us the attached signed document (ANNEX 2) as acknowledgement of receipt of this notification, understanding the described problem and its importance.
We also provide instruction to perform the mandatory field checks or upgrade to the affected units (SIN 22-05-14 CHECK THE CENTRAL GEAR IN URS), and we ask to send back the confirmation when checks are performed (ANNEX 3).

We thank you for your understanding and cooperation.
Yours sincerely,

[redacted]

Quality and Regulation Manager/ Technician Responsible SEDECAL, S.A

Central Offices: C/. Pelaya, 9 - 13
Pol. Ind. "Río de Janeiro"
28110 Algete (Madrid)
Tel: (+34) 916 280 544
Fax: (+34) 902 190 385
Email: quest@sedecal.com

ANEXX 1

AFECTED PRODUCT	SEDECAL X URS
MODEL	URS
SERIAL NUMBER	INSTALLED BASE
PROBLEM DESCRIPTION	Some equipment parts have fallen to the floor.
ORIGIN OF THE PROBLEM	This unit has been working in the field for 7 years, it was manufactured in October 2013. System is installed in USA. The system arm trolley is hold by 8 screws to the system column. If those 8 screws are partially loosened, the play and noise coming from the arm when it is being moved should be evident for the technologist much earlier than having falling risk, but the unit, in this deficient state, continued in use till the arm fell to the ground. The root cause of this event is an improper maintenance, as user was working with the system in bad conditions.
CORRECTION ACTION	The whole equipment affected will be replaced by new one.
CORRECTIVE ACTION	Systems visual checks, measuring the distance from the trolley to the column will be performed to verify that no screws are loosened. If it would be needed the screws and trolley will be replaced. Follow field instruction SIN 22-05-14 CHECK TEH CENTRAL GEAR IN URS. And if would be needed SIN 22-07-17 REPLACE CENTRAL GEAR FIXATION SCREWS IN URS o JOB CARD 1.10 CARRIAGE REPLACEMENT IN URS.
AUTHORYTIES	The FDA has been informed as this problem has occurred in USA. The Spanish Authorities have been informed by SEDECAL, the manufacturer of the equipment.

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28110 Algete (Madrid)
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Fax: (+34) 902 190 385
Email: guest@sedecal.com

ANNEX 2

RECEIPT ACKNOWLEDGMENT

Please return this document signed by email to calidad-clientes@sedecal.com, in the shortest time possible to file this acknowledgment.

Thanks in advance for your collaboration.

Company Name: _____

Address: _____

_____

_____

Manufacturer Reference: **CAPA 22-037**

Affected Product: **SEDECAL X URS**

I confirm that I have received and understand this Urgent Safety Information.

DATE:

SIGN:

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28110 Algete (Madrid)
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ANNEX 3
ACKNOWLEDGEMENT OF CORRECTIVE ACTION IMPLEMENTED

Please return this document signed by email to calidad-clientes@sedecal.com, in the shortest time possible to file this acknowledgment in our registers once you have implemented the corrective action in the affected systems.

Thanks in advance for your collaboration.

DISTRIBUTOR: _____

HOSPITAL: _____

_____

_____

Manufacturer Reference: **CAPA 22-037**

Affected Product: **SEDECAL X URS**

Serial number: _____

I confirm that this corrective action has been applied in the system describe above.

SYSTEM IS OK: ☐ **SYSTEM AFFECTED:** ☐ **CARRIAGE REPLACED:** ☐

DATE:

SIGN:

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