

Field Safety Notice

Please forward this notice to all relevant staff and potential users of the device!

Preventive Corrective Action

concerning

OTESUS OR table column 116001C0 und 116001D0

Dear customer,

with this letter we would like to inform you about a potential issue concerning the OTESUS OR table column 116001C0 and 116001D0.

The OTESUS operating table system (116001XX) is intended for the support and positioning of patients directly before, during or after surgery as well as for examination and treatment purposes.

The OTESUS operating table system (116001XX) is designed for use with a maximum overall load on the table top of 155kg without any limitations with regard to the positioning and adjustment functions.

Depending on the column and the table top being used, an overall load of up to a maximum of 380 kg is possible but with limitations with regard to the positioning and adjustment functions.

The product may only be operated by medically trained staff within the OR environment.

The OTESUS operating table system (116001XX) may not be used under the following conditions:

- With an overall load on the table top of more than 380 kg in conjunction with the columns (116001A0/B0/C0)
- with an overall load of the table top that exceeds 250 kg in conjunction with the independently maneuverable column (116001D0),
- if the overall load exceeds 155 kg, without taking restrictions into account
- with accessories which are not approved by Maquet.
- In rooms in which a magnetic resonance tomograph is deployed within the 0.5 mT line

Description of the problem including the determined cause:

As part of our Post Market Surveillance three (3) cases have been reported to MAQUET in which the column was out of service due to a battery malfunction. The root cause of the failure was in all cases ingress of liquids most likely during cleaning or during procedure. Ingress of liquids may result in a potential hazard due to smoke rising from the column, hot surfaces and/or due to suspension of the operating table.

In these three registered cases only in two patients were involved. During transfer of the table top to the column the clinic staff noticed white smoke rising from the column. The patient was transferred to another table top in both cases.

In no case serious injury of a patient or user was reported to MAQUET.

Identification of the affected medical devices:

Potentially affected by this issue are OTESUS OR table column

- 116001C0 SN: 1 until 552 and
- 116001D0 SN: 1 until 34.

The serial number is on the type plate which is to be found at side of the lower column casing (refer to Fig. 1 unterhalb)

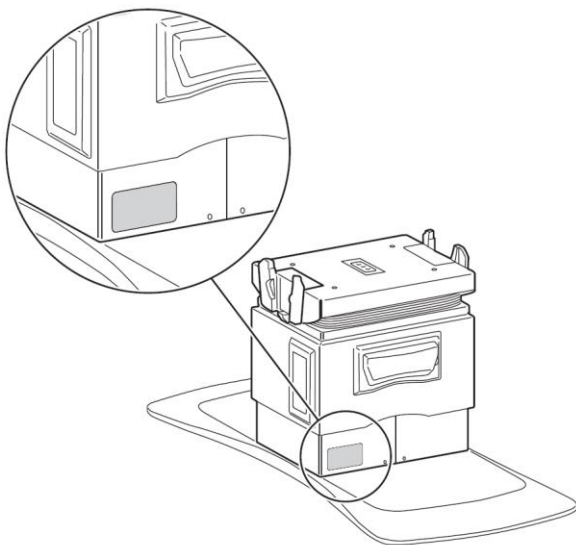


Fig. 1 Position of type plate / label

Which measures are to be taken by the user?

Our sales records indicate that you own one or several of the potentially affected products.

As a battery malfunction due to ingress of liquids in the course of excessive cleaning or during use cannot be ruled out with certainty, all affected OTESUS OR table column 116001C0 and 116001D0 within the listed serial number ranges will be overhauled.

Therefore MAQUET service will be contacting you to arrange an appointment to carry out the service.

Until all actions have been accomplished, a visual and functional check shall be performed by a trained person before operation.

However please observe the recommendations within the instruction for use concerning cleaning and disinfecting.

Passing on the information described here:

Please ensure that all persons within your organization who use the above-mentioned devices and anybody else who needs to know receive this field safety notice. If you have passed the product on to third parties, please forward a copy of this notice or inform the MAQUET contact you are aware of.

Please keep this notice together with the instructions for use of the device at least until the corrective measure has been performed.

Contact person:

For further queries please do not hesitate to contact your MAQUET contact person. Should more information being required please contact our safety officer for medical devices during normal business hours (refer to contact data on the first page).

This is a voluntary corrective action. Thus far no incident has been reported in which a person has been injured.

The competent authorities concerned have received a copy of this field safety notice.

We apologize for any inconvenience, however, consider this action as a preventive action to increase quality.

With kind regards

MAQUET GmbH

Holger Ullrich

Director Product Compliance SW

Mario Mühe

Safety Officer for medical devices