

cc to Chairman Medical Board and relevant Head of Departments

URGENT - FIELD SAFETY NOTICE

**MAQUET VOLISTA
Field Action MSA/2017/006/IU**

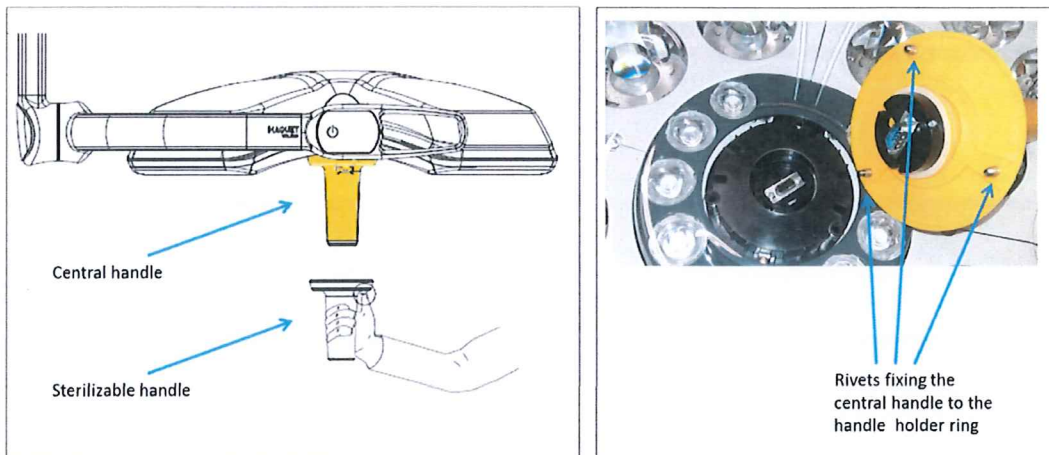
Date:	December 26, 2017
Product Issue:	Detachment of the central handle holder from the VOLISTA surgical light
Affected Product:	5214 MAQUET VOLISTA StanOP, Triop and Access cupolas. All potentially affected devices in your market are listed in the attached list of products.
Resolution:	Maquet proposes to replace the central holder ring of your VOLISTA surgical light to make sure all devices present in the market are working effectively and safely.
Affected Serial Nos.:	All potentially affected devices in your market are listed in the attached list of products.
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Dear Customer,

Our records indicate that you bought one or more VOLISTA surgical lights manufactured before July 2016.

This letter is to inform you of a corrective action that will be performed on these units to prevent a possible hazard to persons and equipment. This action consists in the replacement of the central handle holder ring.

We received complaints indicating that the central handle holder detaches easily from the cupola during use. We determined that the root cause of this malfunction is excessive tightening of the screws during mounting of the handle holder, resulting in the rivets loosening and detaching from the central handle holder ring.



During manipulation, the handle holder may completely detach from the light head, if all three rivets loosen simultaneously. In this case, although the handle remains in the user's hand, small quantities of particles may be generated from the plastic holder ring. From our clinical evaluation, it was concluded that there is a remote chance that this issue may cause post-operative infection, foreign body granuloma or allergic reactions, if the particles fall into the patient's wound or on sterile equipment.

The issue was solved in production by a design change of the rivets (modification of shape and overmolding with the handle holder ring). For units manufactured before application of the modification in production, we see the issue as a potential long term hazard and want to prevent any related event from occurring with our customers. This action consists in the replacement of the existing central holder rings with the new design.

Next Steps

1. Please make sure that all users of the VOLISTA surgical lights are made aware of this Field Notice and all listed devices at your facility are accessible during the MAQUET service technician visit.
2. Complete and sign the enclosed Customer Response Form and return this form to the local MAQUET office.
Note: A MAQUET Sales or Service person will contact the person you listed on the Customer Response Form to schedule service to replace your device, free of charge.

Transmission of this Field Notice:

This MAQUET VOLISTA Field Notice needs to be distributed to those individuals who need to be aware within your organization - or to any organization where the potentially affected devices have been transferred.

Please maintain awareness of this notice and resulting action for the use period of the device to ensure effectiveness of the corrective action.

In cases where you as customer choose not to proceed with completion of the corrective action requirements described above, MAQUET cannot accept any responsibility for safety related issues or legal liabilities caused by the failure to respond to this Field Safety Notice.

Additional Comment

We deeply regret this inconvenience, but we greatly appreciate your understanding as we take actions to ensure correct product performance. If you have any further questions or require assistance completing the Customer Response Form, please contact MAQUET.

Volista Standop range

Light head Part Number	Light head Description	Up to Serial Number (indicated serial number not involved)
ARD568811900	VLT600SF STP	500000
ARD568811901	VLT600SF AIM STP	500000
ARD568811902	VLT600SF TK STP	500000
ARD568811903	VLT600SF TK AIM STP	500000
ARD568811910	VLT600SF STP	500005
ARD568811911	VLT600SF AIM STP	500006
ARD568811912	VLT600SF TK STP	500004
ARD568811913	VLT600SF TK AIM STP	500013
ARD568811950	VLT600DF STP	500000
ARD568811951	VLT600DF AIM STP	500000
ARD568811952	VLT600DF TK STP	500000
ARD568811953	VLT600DF TK AIM STP	500000
ARD568811960	VLT600DF STP	500063
ARD568811961	VLT600DF AIM STP	500003
ARD568811962	VLT600DF TK STP	500030
ARD568811963	VLT600DF TK AIM STP	500017
ARD568812900	VLT400SF STP	500000
ARD568812902	VLT400SF TK STP	500000

Maquet SAS

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France

Light head Part Number	Light head Description	Up to Serial Number (indicated serial number not involved)
ARD568812903	VLT400SF TK AIM STP	500000
ARD568812910	VLT400SF STP	500004
ARD568812911	VLT400SF AIM STP	500000
ARD568812912	VLT400SF TK STP	500002
ARD568812913	VLT400SF TK AIM STP	500000
ARD568812950	VLT400DF STP	500000
ARD568812951	VLT400DF AIM STP	500000
ARD568812952	VLT400DF TK STP	500000
ARD568812953	VLT400DF TK AIM STP	500000
ARD568812960	VLT400DF STP	500046
ARD568812961	VLT400DF AIM STP	500000
ARD568812962	VLT400DF TK STP	500007
ARD568812963	VLT400DF TK AIM STP	500002
ARD568821910	VLT600SF STP QL	500030
ARD568821911	VLT600SF AIM STP QL	500008
ARD568821912	VLT600SF TK STP QL	500001
ARD568821913	VLT600SF TK AIM STP QL	500018
ARD568821960	VLT600DF STP QL	500047

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Light head Part Number	Light head Description	Up to Serial Number (indicated serial number not involved)
ARD568821961	VLT600DF AIM STP QL	500039
ARD568821962	VLT600DF TK STP QL	500016
ARD568821963	VLT600DF TK AIM STP QL	500030
ARD568822910	VLT400SF STP QL	500034
ARD568822911	VLT400SF AIM STP QL	500005
ARD568822912	VLT400SF TK STP QLCS	500005
ARD568822913	VLT400SF TK AIM STP QL	500001
ARD568822960	VLT400DF STP QL	500249
ARD568822961	VLT400DF AIM STP QL	500015
ARD568822962	VLT400DF TK STP QL	500016
ARD568822963	VLT400DF TK AIM STP QL	500010

Volista Access range

Light head Part Number	Light head Description	Up to Serial Number (indicated serial number not involved)
ARD568805900	VLT400SF ACE	500015
ARD568805901	VLT400DF ACE	500006
ARD568805905	VLT600SF ACE	500003
ARD568805906	VLT600DF ACE	500008

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Volista Triop range

Light head Part Number	Light head Description	Up to Serial Number (indicated serial number not involved)
ARD568801913	VLT 600 SF TK AIM TRP	500000
ARD568801960	VLT 600 DF TRP	500000
ARD568802960	VLT 400 DF TRP	500000
ARD568801910	VLT 600 SF TRP	500000
ARD568801963	VLT 600 DF TK AIM TRP	500000
ARD568802910	VLT 400 SF TRP	500000
ARD568802963	VLT 400 DF TK AIM TRP	500000
ARD568802951	VLT400DF HD AIM TRP	500000
ARD568801900	VLT600SF HD TRP	500000
ARD568801901	VLT600SF HD AIM TRP	500000
ARD568801902	VLT600SF HD TK TRP	500000
ARD568801903	VLT600SF HD TK AIM TRP	500000
ARD568801910	VLT600SF HD TRP	500000
ARD568801912	VLT600SF HD TK TRP	500001
ARD568801950	VLT600DF HD TRP	500000
ARD568801953	VLT600DF HD TK AIM TRP	500000
ARD568801961	VLT600DF HD AIM TRP	500000
ARD568802900	VLT400SF HD TRP	500000
ARD568802902	VLT400SF HD TK TRP	500000
ARD568802903	VLT400SF HD TK AIM TRP	500000
ARD568802912	VLT400SF HD TK TRP	500000
ARD568802950	VLT400DF HD TRP	500000

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ARD568802952	VLT400DF HD TK TRP	500000
ARD568802953	VLT400DF HD TK AIM TRP	500000
ARD568802961	VLT400DF HD AIM TRP	500000
ARD568802962	VLT400DF HD TK TRP	500000

Ordering Information

Locate and identify the quantity of light heads installed and provide this information through a MAGIC report titled **"Field Action # MSA/2017/006/IU"**.

Then order the necessary Central Holder Ring kit according to the Volista range (see table below).

Credit note will be granted as per confirmation of completion within the MAGIC report.

Volista Range	Central Handle Holder kit P/N	Description
All Standop and Access lighthouse	ARD368823998	VLT4/6>25000-ACE4/6 - CENTRAL HOLDER V2
All Triop lighthouse	ARD368708998	VLT 4-6 TRIOP -CENTRAL HOLDER KIT>25000

Given the large quantities, the Central Holder Ring kit shipment will be phased over several cycles upon request. Thank you for your kind understanding.

Refund

Maquet SAS will refund 50 €, as a compensation, for each central handle holder that has been replaced, up on receipt of duly filled tracking records forms.

Contents

The package contains a Central Holder Ring kit.



Maquet SAS

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