

Safety Communication

رسالة سلامة

Broken circlip on Hanaulux sterilizable handle hub

Device/ Product Description:	sterilizable handle hub		
Brand:	Hanaulux		
Part Number:	Lot/Serial	Item	ITEM DESCRIPTION
	20047	ARD568357999	HLED500DF LIGHTHEAD V FITTING K4
	30000	ARD568303903	HLED700DF LIGHTHEAD V FITTING K4 W
	30001	ARD568303903	HLED700DF LIGHTHEAD V FITTING K4 W
	40037	ARD568357999	HLED500DF LIGHTHEAD V FITTING K4
	1006	ARD568334999	HLD300SF LEUCHTENKÖRPER - K4
	20001	ARD568310999	HLED700SF VIDEO LEUCHT H BEFEST K4
	20001	ARD568311999	HLED700SF LEUCHTENKÖRPER H BEFES K4
	20002	ARD568310999	HLED700SF VIDEO LEUCHT H BEFEST K4
	20002	ARD568311999	HLED700SF LEUCHTENKÖRPER H BEFES K4
	20046	ARD568357999	HLED500DF LIGHTHEAD V FITTING K4
Manufacturer:	MAQUET Inc.		
Problem:	<p>Under certain conditions, the manufacturer has identified that the circlip, which is part of the locking system, may break. As a result, when the user unlocks the sterilizable handle, the circlip or other components of the locking mechanism may fall. If during surgery the handle is removed for potential aseptic reasons, the circlip or other components may fall on the surgical field.</p> <p>The manufacturer conducted investigations, which established that some cleaning products and cleaning protocols more aggressive than those mentioned in the product labeling might be used. This results in altering the circlip, notably causing its oxidation resulting in a breakage.</p> <p>This issue may result in preventing the usage of the device causing delays in planned surgery. It may also create a contamination issue if the circlip falls on the surgical field.</p>		

<p>Recommendation/ Actions:</p>	<ol style="list-style-type: none"> 1. Review this notice and ensure that affected personnel are aware of the contents. 2. Verify that the locking mechanism works correctly before use. 3. If you have affected product at your facility, or if the mechanism does not work or lock correctly, contact the authorized representative to arrange for the correction of your device. 4. Only use the recommended cleaning materials and cleaning protocols <p>For more information, Please click here.</p>	
<p>Devices/Products photo:</p>	 <p style="text-align: center;">Hanaulux Hub</p>	 <p style="text-align: center;">Hub with sterilizable Handle</p>
<p>Authorized Representative Details</p>	<p>AR name:</p>	<p>Gulf Medical Co.</p>
	<p>Assigned Contact Person:</p>	<p>Mohammed Al Ghamdi</p>
	<p>Mobile/Phone:</p>	<p>0551417735</p>
	<p>Email:</p>	<p>regulatory@gulfmedical.com</p>