# Field Safety Notice

2019-12-20 | REF-MSA-2019-002-IU |

**Please forward this information to all relevant users, [biomedical staff for capital equipment, materials management and/or purchasing for consumables] and to the risk management department of your facility**

## Subject: Broken circlip on Hanaulux sterilizable handle hub

### Products affected:

| Product | Article No. | S/N or Batch No. |
|---|---|---|
| The complete list of potentially affected devices (with product name, articles numbers, serial numbers…) for your market are listed in a separate document (consignee list) | | |

Dear Customer,

The purpose of this letter is to inform you about a potential issue found on the Hanaulux sterilizable handle hub (please see picture below):

Hanaulux Hub

Hub with sterilizable Handle

Our records indicate that your facility has received one or more of these devices.

### Normal use and Indications

Under normal circumstances, this hub is used to mount the sterilizable handle, which is secured by a locking system. In order to detect any potential damage, the IFUs recommend users to perform daily checks prior to use and the maintenance staff to perform an annual verification that the locking mechanism of the sterilizable handle is in good conditions.

### The following has been discovered

Under certain conditions, Maquet SAS 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.



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Maquet SAS conducted investigations which established that some cleaning products and cleaning protocols more aggressive than those mentioned in the product labeling may be used. This results in altering the circlip, notably causing its oxidation resulting in a breakage.

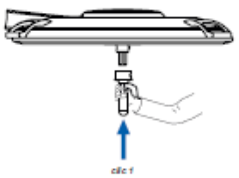
## Potential hazards

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.

## Precautions

Maquet SAS is asking you to strictly follow the provided Instructions for Use, paying special attention to:

1. Verify that the locking mechanism works correctly before use



- Check that the sterilisable handle clicks and locks in place correctly; replace it if not.

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2. If the mechanism does not work or lock correctly, please contact a Getinge representative or Maquet SAS' International Technical Service

3. Only use the recommended cleaning materials and cleaning protocols as follow:



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## 9 Cleaning / Disinfection / Sterilisation

**WARNING!**

As cleaning and sterilisation procedures vary considerably in individual healthcare facilities and depending on local regulations, it is impossible for Maquet to specify a single procedure that would correspond to all requirements.

Users must contact their hospital's sanitary specialists. The recommended products and procedures must be applied. Should there be any doubt concerning the compatibility of active agents to be used, contact the local Maquet customer service department.

### 9.1 Cleaning and disinfecting the system

**RECOMMENDATION**

Check that the power is switched off and the light has cooled down before starting cleaning.

#### General instructions concerning cleaning, disinfection and safety

In standard use, the level of treatment required for cleaning and disinfection of the H LED system is low-level disinfection. The device is classified as non-critical with a low infectious risk. However, depending on the infectious risk, intermediate or high level disinfection may be envisaged.

#### Cleaning the device

- Remove the sterilisable handles.
- Use a slightly alkaline universal cleaner (soap solution) containing active substances such as detergents and phosphates. Do not use abrasive products which could damage the surfaces.
- Wipe the equipment with a cloth moistened with a surface cleaner. Follow the manufacturer's dilution, application time and temperature recommendations.
- Rinse the unit with a cloth and clean water. Wipe with a dry cloth.

#### Disinfecting the device

- Wipe evenly with a cloth soaked in disinfectant. Follow the manufacturer's recommendations.

**WARNING!**

Never spray a solution directly onto the unit.

#### Disinfectant to be used

- Disinfectants are not sterilising agents. They result in a qualitative and quantitative reduction in the microorganisms present.
- Use only surface disinfectants containing combinations of the following active substances:
  - quaternary ammonium (bacteriostatic for Gram - and bactericidal for Gram +, variable activity on enveloped viruses, no action on non-enveloped viruses, fungistatic, no sporicidal action)
  - guanidine compounds or
  - alcohols

#### List of active substances that can be used for disinfection of the device

| Class | Active substances |
|---|---|
| **Low level of disinfection** | |
| Quaternary ammonium | Didecyl dimethyl ammonium chloride, Alkyl dimethyl benzyl ammonium chloride, Dioctyl dimethyl ammonium chloride |
| Biguanides | Polyhexamethylene biguanide hydrochloride |
| **Intermediate level of disinfection** | |
| Alcohols | Propan-2-ol |
| **High level of disinfection** | |
| Acids | Sulfamic acid (5%), malic acid (10%), ethylenediaminetetraacetic acid (2.5%) |

#### Examples of commercially available products tested

- ANIOS product: Surfa'Safe
- Pharmacal Research product: Virkon, 1% dilution
- ECOLAB product: Incidin Plus, 2% dilution
- Other products: 20% or 45% isopropyl alcohol

#### Examples of prohibited products

**WARNING!**

Disinfectants containing glutaraldehyde, phenol or iodine must not be used. Fumigation methods are unsuitable for disinfecting the unit and must not be used.



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Please complete and return the attached acknowledgement of receipt form and maintain awareness on this notice to ensure effectiveness of the preventive action.

We apologize for any inconvenience this may cause.

Should you have questions or require additional information, please contact your local Getinge representative or Maquet SAS' International Technical Service.

Sincerely,

| | |
|---|---|
| … | … |
| Technical Service Director | Local Quality Manager |



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# Customer Response Form

## MSA-2019-002-IU

***Reference: Field Safety Notice MSA-2019-002-IU.***

***Broken circlip on Hanaulux sterilizable handle hub***

Our records indicate that the *<Device Name>* device shown below was delivered to your location. Please verify if you have any of the listed devices that are potentially affected and complete the information below.

| GETINGE ORDER NO. | ITEM NO. | SERIAL NO. | MANUFACTURING DATE |
|---|---|---|---|
| X | 1 | XXXX | <Date> |
| Y | | YYYY | <Date> |

**Record the total number of affected device currently located at your facility here please ➔ ____.**

Please check the appropriate boxes below:

☐ We have read the *Hanaulux sterilizable handle* Field Safety Notice and we understand the communication and the required actions.

**If checked : please provide information where the affected devices are physically located.**

**Field Safety Notice Receipt and Customer Response Form Completion and Certification**

| | | | |
|---|---|---|---|
| **Current Facility Name** | | | |
| **Contact Name / Title** | | | |
| **Address (no PO boxes)** | | | |
| **City, State, Zip** | | | |
| **Phone Number** | | **Fax:** | |
| **E-Mail Address:** | | | |

☐ We have sold/moved our *Hanaulux sterilizable handle* to another facility.

**If checked : please provide new facility information below.**

| | | | |
|---|---|---|---|
| **New Facility Name** | | | |
| **Contact Name / Title** | | | |
| **Address*** | | | |
| **City, State, Zip** | | | |
| **Phone Number** | | **Fax:** | |
| **E-Mail Address:** | | | |

**PLEASE RETURN YOUR COMPLETED FORM TO:**

**MAIL**

*<local SSU address line 1>*
*<local SSU address line 2>*
*<local SSU address line 3>*

**CONTACT**

*<contact ddress>*@getinge.com
Tel: *<SSU contact phone number>*
Fax: *<SSU contact fax number>*



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