Reprocessing

# Polaris Multimedia

**WARNING**

**To properly use this medical device, read and comply with the instructions for use and this supplement.**

## Handles

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# Supplement to the instructions for use

**WARNING**

**To properly use this medical device, read and comply with the instructions for use and this supplement.**

| Instructions for use | Part number | Edition |
|---|---|---|
| Polaris Multimedia | 1571949 | 1 – 2021-08 and higher |

- Keep this supplement with the instructions for use.

This supplement updates the "Reprocessing" chapter in the instructions for use.

# Reprocessing

## Safety instructions

**WARNING**

**Risk due to inappropriately reprocessed products**

**Reusable products must be reprocessed, otherwise there is an increased risk of infection.**

- **Follow the infection prevention policies and reprocessing regulations of the health-care facility.**
- **Follow the national infection prevention policies and reprocessing regulations.**
- **Use validated procedures for reprocessing.**
- **Reprocess reusable products after every use.**
- **Follow the manufacturer's instructions for cleaning agents, disinfectants, and reprocessing devices.**

**WARNING**

**Risk of infection or danger of a falling handle**

**After reprocessing, the sterilizable handle must be checked for signs of wear, e.g., cracks, deformation, discoloration or peeling.**

**If there are signs of wear, a new handle must be used.**

**WARNING**

**Risk of damage to the device**

**The device consists in part of materials that are not resistant to certain components of surface disinfectants.**

**It is essential to follow the instructions in this chapter.**

## Information on reprocessing

Follow the national infection prevention policies and reprocessing regulations.

Follow the infection prevention policies and reprocessing regulations of the health-care facility (e.g., concerning the reprocessing cycles).

# Classifications for reprocessing

## Classification of medical devices

The classification depends on the intended use of the medical device. The risk of infection transmission through the application of the product to the patient without proper reprocessing is the basis of the Spaulding classification.

| **Classification** | **Explanation** |
|---|---|
| Non-critical | Components that come into contact only with skin that is intact |
| Semi-critical | Components that carry breathing gas or come into contact with mucous membranes or pathologically altered skin |
| Critical | Components that penetrate skin or mucous membranes or come into contact with blood |

## Classification of device-specific components

The following classification is a recommendation from Dräger.

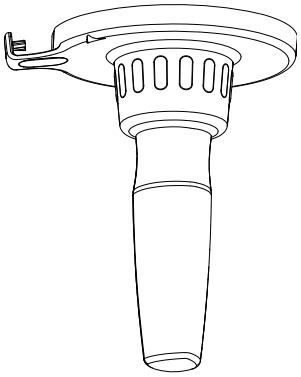
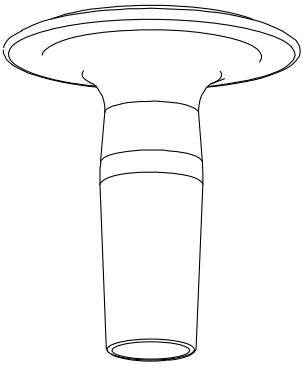
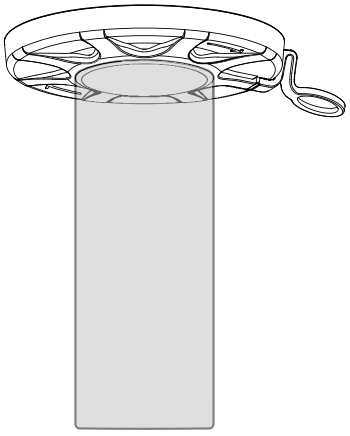
**Non-critical**

– Device surface

**Critical**

– Sterilizable handle E
– Sterilizable handle

**Component overview (handles)**

| Accessories | Classification | Order no. | Part no. | |
|---|---|---|---|---|
| Sterilizable handle E | Critical | G36993 | G29662 |  |
| Sterilizable handle (with button) | Critical | G92099 | G95413 |  |
| Dräger Polaris disposable handle, Duo | Critical | MP05700 | - |  |
| Dräger Polaris disposable handle, Solo | Critical | MP05701 | - | |

## Before reprocessing

**Observe before disassembly**

1 Switch off the device and all devices connected to it.

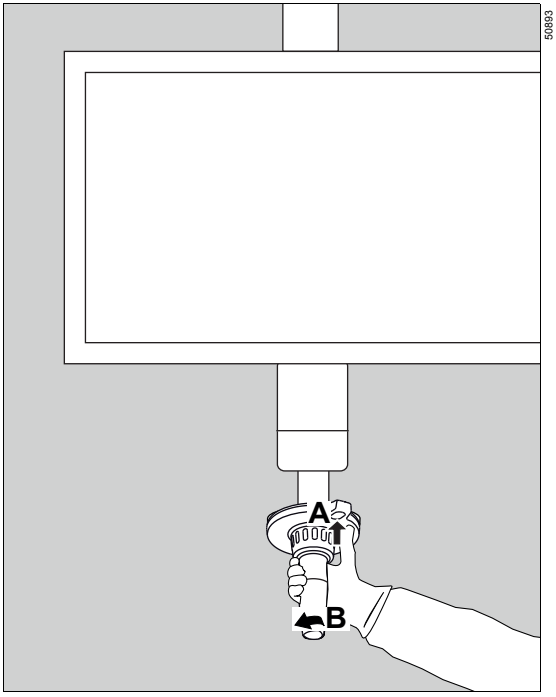
2 For the Polaris Mobil version: Disconnect all power plugs.

### Device-specific components

The device-specific components must be removed from the device and, if necessary, disassembled.

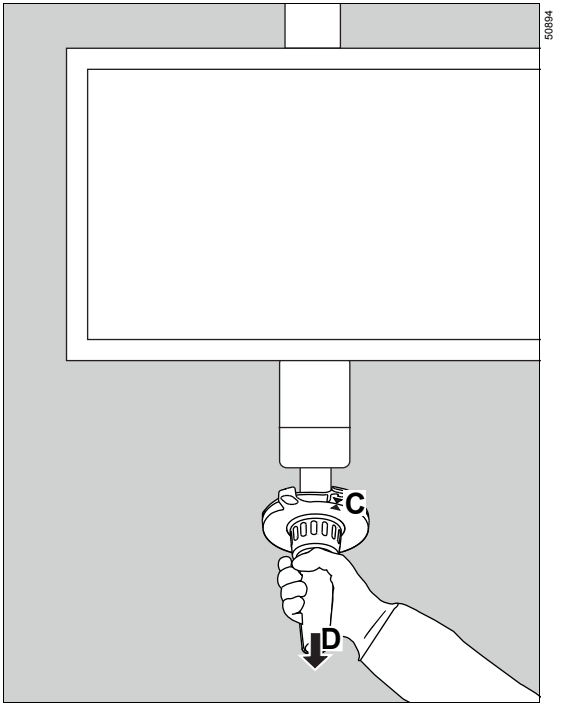
**Removing the sterilizable handle E on the display mount**

The handle is located below the display mount and is removed from the inner handle by pulling.




1 Take hold of the handle section and press the locking mechanism (A).

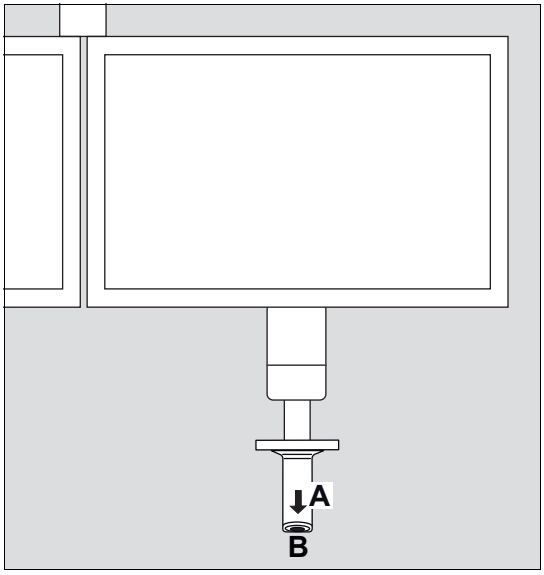
2 Keep the locking mechanism pressed and turn the handle counterclockwise (B) until the markers (C) line up.




3 Pull the handle (D) down to remove it.

**Removing the sterilizable handle on the display mount**

The handle is located below the display mount and is removed from the inner handle by pulling.



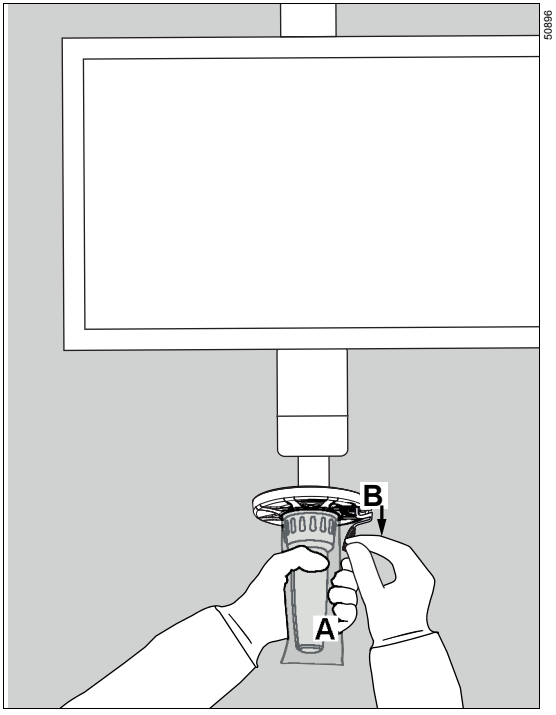

- Hold the housing of the display mount.

**1** Take hold of the handle (A).

**2** Push and hold down the button (B) at the lower end of the handle and pull off the handle.

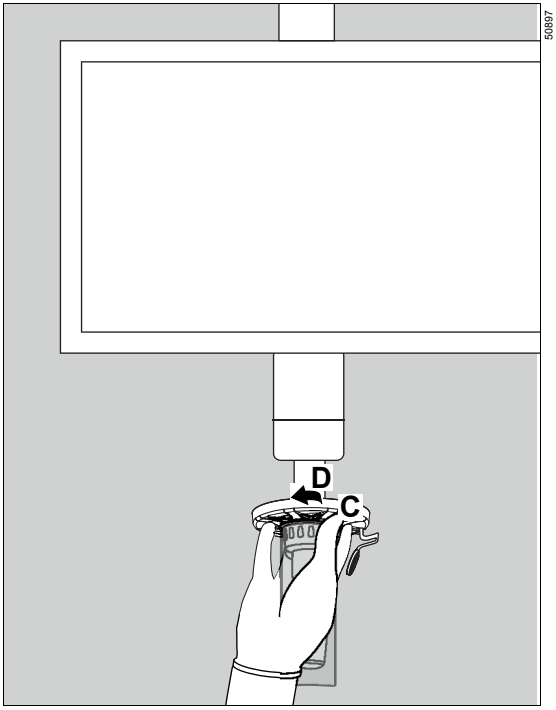
**Removing the Dräger disposable handle on the display mount**

The disposable handle is located below the display mount and is removed from the inner handle by pulling.

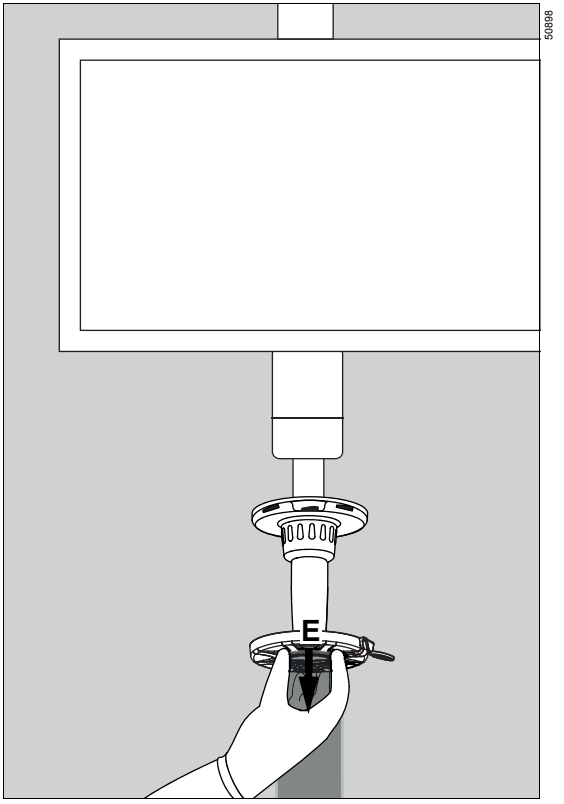



**1** Take hold of the disposable handle (A).

**2** Pull the locking mechanism (B) on the disposable handle until the entire perforation on the locking mechanism is ripped open. The locking mechanism is intended to ensure single use of the disposable handle and is unusable after pulling.




**3** Hold the disposable handle by the recessed grips (C) and turn it counterclockwise (D).




**4** Pull the disposable handle (D) down to remove it.

- Dispose of the disposable handle in accordance with the applicable infection prevention policy and disposal regulations of the hospital.

# Validated reprocessing procedures

## Overview of the reprocessing procedures of the components

| Components | Surface disinfection with cleaning | Manual cleaning followed by disinfection by immersion | Machine cleaning with thermal disinfection | Steam sterilization |
|---|---|---|---|---|
| Device surfaces | Yes, see page 11 | No | No | No |
| Sterilizable handle E | No | Yes, see page 12 | Yes, see page 14 | Yes, see page 15 |
| Sterilizable handle | No | Yes, see page 12 | Yes, see page 14 | Yes, see page 15 |

# Surface disinfection with cleaning

| Surface disinfectant | Manufacturer | Concentration | Contact time |
|---|---|---|---|
| Dismozon pur/ plus | BODE Chemie | 1.6 % | 15 min |

**Prerequisites:**

– The surface disinfectant has been prepared in accordance with the manufacturer's instructions.

– Observe the manufacturer's instructions, e.g., regarding shelf life or application conditions.

– An uncontaminated, lint-free cloth soaked in disinfectant is used for the cleansing surface disinfection.

**WARNING**

**Risk due to penetrating liquid**

**Penetrating liquid may cause the following:**

**– Damage to the device**

**– Electric shock**

**– Device malfunctions**

**Ensure that no liquid penetrates the device.**

**Cleaning**

**Procedure:**

**1** Wipe off obvious soiling using a disposable cloth (or a similar cloth) soaked in disinfectant solution and dispose of this.

**2** Wipe all areas. After that, there must no longer be any soiling visible.

**Surface disinfection**

**3** Wipe cleaned surfaces again to visibly wet all surfaces to be disinfected with disinfectant solution.

4 Wait for the contact time of the disinfectant.

5 At the end of the contact time, moisten a new germ-free and lint-free cloth with water (at least drinking water quality).

6 Wipe all surfaces until no remains of the surface disinfectant, such as foam residues or streaks, are visible.

7 Wait until the surfaces are dry.

8 Check the surfaces for visible damage and replace the product if necessary.

## Manual cleaning followed by disinfection by immersion

**Components:**

– Sterilizable handle E

| | **Manufacturer** | **Concentration** | **Contact time** |
|---|---|---|---|
| **Cleaning agent:** | | | |
| Neodisher LM 2 | Dr. Weigert | 2 % | 10 min |
| **Disinfectant:** | | | |
| Korsolex extra | BODE Chemie | 3 % | 15 min |

– Sterilizable handle

| | **Manufacturer** | **Concentration** | **Contact time** |
|---|---|---|---|
| **Cleaning agent:** | | | |
| Neodisher LM 2 | Dr. Weigert | 2 % | 20 min |
| **Disinfectant:** | | | |
| Korsolex extra | BODE Chemie | 4 % | 60 min |

**Manual cleaning**

**Prerequisites:**

– The cleaning agent has been prepared according to the manufacturer's instructions.

**Procedure:**

**1** Place the components in the cleaning agent.

**2** Swish the components back and forth. Make sure the cleaning agent reaches all surfaces and interior spaces.

**3** Remove the components from the cleaning agent and brush thoroughly.

**4** Only applies to the "sterilizable handle (with push button)" component: Thoroughly flush the interior of the handle with a disposable syringe, especially in the area of the push button.

**5** Then return the components to the cleaning agent. Observe the contact time.

**6** At the end of the contact time, brush the components thoroughly again.

**7** After the contact time, rinse the components with water (at least drinking water quality) until no residues of the cleaning agent are visible.

**8** Shake out residual water thoroughly. Allow the components to dry completely.

**9** Check the components for visible soiling and repeat steps 1 through 8 if necessary.

**10** Check the components for visible damage and replace if necessary.

**Disinfection by immersion**

**Prerequisites:**

– The disinfectant has been prepared according to the manufacturer's instructions.

**Procedure:**

**11** Place the components in the disinfectant.

**12** Swish the components back and forth at the beginning of the contact time. Make sure the disinfectant reaches all surfaces and interiors.

**13** Only applies to the "sterilizable handle (with push button)" component: Thoroughly flush the interior of the handle with a disposable syringe, especially in the area of the push button.

**14** Observe the contact time.

**15** After the contact time, rinse the components with water (at least drinking water quality) until no residues of the disinfectant are visible.

**16** Check the components for visible damage and replace if necessary.

**17** Shake out residual water thoroughly. Allow the components to dry completely.

## Machine cleaning with thermal disinfection

Use a washer-disinfector that meets the requirements of the standard ISO 15883. Follow the manufacturer's instructions for the washer-disinfector.

**Components:**

– Sterilizable handle E

– Sterilizable handle

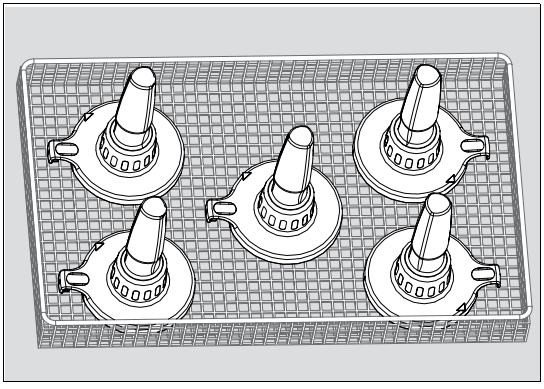
| Step | Agent | Manufacturer | Concentration | Temperature | Contact time |
|---|---|---|---|---|---|
| Cleaning | Neodisher MediClean | Dr. Weigert | According to the manufacturer's instructions | 55 °C (131 °F) | 10 min |
| | Neodisher MediClean Forte | Dr. Weigert | According to the manufacturer's instructions | 55 °C (131 °F) | 10 min |
| Disinfecting | – | – | – | 90 °C (194 °F) | at least 5 min |
| Drying | – | – | – | – | Drying time depends on the load |

**Prerequisites:**

– The washer-disinfector has been prepared according to the manufacturer's instructions.

**Positioning the components (handles) in the load carrier**

**Procedure:**




**1** Position the components so that they are stable.

**2** Ensure the following:

– All surfaces and interiors can be completely rinsed.

– The water can drain off freely.

**Performing reprocessing**

**Procedure:**

**1** Select a cycle.

**2** When the cycle has ended, check the components for visible soiling and repeat the cycle if necessary.

**3** Check the components for visible damage and replace if necessary.

## Steam sterilization

**Components:**

– Sterilizable handle E
– Sterilizable handle

**Prerequisites:**

– The components are cleaned, disinfected, and dry, and have been provided with a suitable sterile barrier system.
– Use a steam sterilizer that meets the requirements of the standard ISO 17665. Dräger recommends steam sterilization with fractionated vacuum.

**Procedure:**

**1** Sterilize the components (minimum 132 °C (269.6 °F), 4 min).
**2** Check the components for visible damage and replace if necessary.

## Storage and transport

After reprocessing, there are no special requirements for storage and transport of the product. However, the following must be observed:

– Store dry and free of dust
– Avoid recontamination and damage during transport

All further information on storage and transport included in the accompanying documents must be observed.

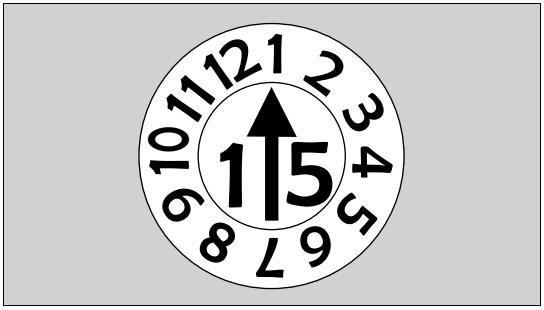
## Service life of the handle

**Components:**

– Sterilizable handle E

– Sterilizable handle

There is an identification mark on the upper side of the handle which shows the year and month of manufacture of the handle.




The identification mark here shows January 2015 as an example of the date of manufacture.

The number in the inner circle corresponds to the year of manufacture.

15 = 2015

The arrow points to the month of manufacture.

1 = January

The date of manufacture has no effect on the service life of the handle.

The handle can undergo up to 300 reprocessing cycles. After that, it must be disposed of.

**NOTE**

Cleaning methods based on alkaline agents (pH values >10) can increase material wear to the handle and thus shorten its service life.

**NOTE**

Use and frequent sterilization cause wear to the handle. In the event of material fatigue such as cracking and/or discoloration, the handle must be replaced.

# Other agents and reprocessing procedures

## Disinfectants

Use nationally approved disinfectants suitable for the respective reprocessing procedure and field of application.

### Surface disinfectants

The manufacturers of the surface disinfectants have verified at least the following spectra of activity:

– Bactericidal
– Yeasticidal
– Virucidal or virucidal against enveloped viruses

Follow the manufacturer's instructions for surface disinfectants.

The following surface disinfectants were compatible with the material at the time of testing:

| **Class of active ingredient** | **Surface disinfectant** | **Manufacturer** | **Listing** |
|---|---|---|---|
| Chlorine-releasing agents | Clorox Professional Disinfecting Bleach Cleaner | Clorox | EPA[1)] |
| | Dispatch Hospital Cleaner Disinfectant Towels with Bleach | | |
| | Actichlor plus | Ecolab | – |
| | Chlor-Clean Tablets | helix Solution | ARTG[2)] |

| **Class of active ingredient** | **Surface disinfectant** | **Manufacturer** | **Listing** |
|---|---|---|---|
| Oxygen-releasing agents | Descogen Liquid | Antiseptica | CE |
| | Descogen Liquid r.f.u. | | |
| | Oxygenon Liquid r.f.u. | | |
| | Dismozon plus | BODE Chemie | CE |
| | Oxycide | Ecolab USA | EPA |
| | Perform | Schülke & Mayr | CE |
| | SteriMax Wipes | Aseptix | CE |
| | Incidin OxyWipes | Ecolab USA | CE |
| | Rubysta | Kyorin (Japan) | – |
| | Rely+On Virkon | LANXESS Corporation | EPA |

| Class of active ingredient | Surface disinfectant | Manufacturer | Listing |
|---|---|---|---|
| Quaternary ammonium compounds | acryl-des[3] | Schülke & Mayr | CE |
| | Mikrozid alcohol free liquid[3] | | |
| | Mikrozid alcohol free wipes[3] | | |
| | Mikrozid sensitive liquid[3] | | |
| | Mikrozid sensitive wipes[3] | | |
| | Cleanisept Wipes Maxi | Dr. Schumacher | CE |
| | Surfa'Safe Premium | ANIOS Laboratories | CE |
| | Wip'Anios Excel | | |
| | Tuffie 5 | Vernacare | ARTG |

1) United States Environmental Protection Agency
2) Australian Register of Therapeutic Goods
3) Virucidal against enveloped viruses

Dräger states that oxygen-releasing agents and chlorine-releasing agents may cause color change in some materials. Color change does not indicate that the product is not functioning correctly.

Other surface disinfectants are used at one's own risk.

## After reprocessing

### Preparation before next use of device

#### Fitting the sterilizable handle E to the display mount

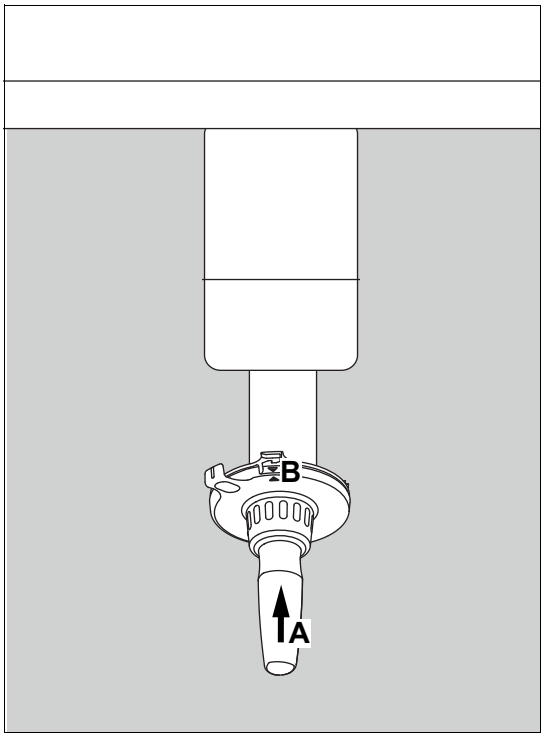
**WARNING**

**Risk of infection**

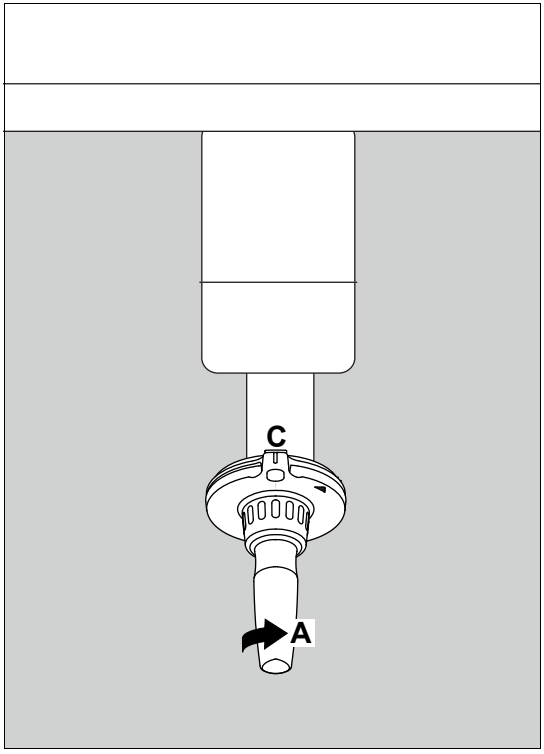
**Personnel and patient may become infected by a non-sterile handle.**

**Use only sterile handles.**

Immediately before surgery, fit the handle under sterile conditions as follows:




**1** Fit the handle (A) on the inner handle so that the markers (B) line up.




**2** Turn the handle (A) clockwise until the locking mechanism (C) engages audibly.

**3** Check that the handle is securely attached. Turn the handle counterclockwise to do this.

**WARNING**

**Risk of patient injury**

**The sterilizable handle E can fall down into the operating field if it is not engaged properly.**

**The handle must be checked for secure attachment after it has been fitted to the inner handle.**

**Fitting the sterilizable handle to the display mount**

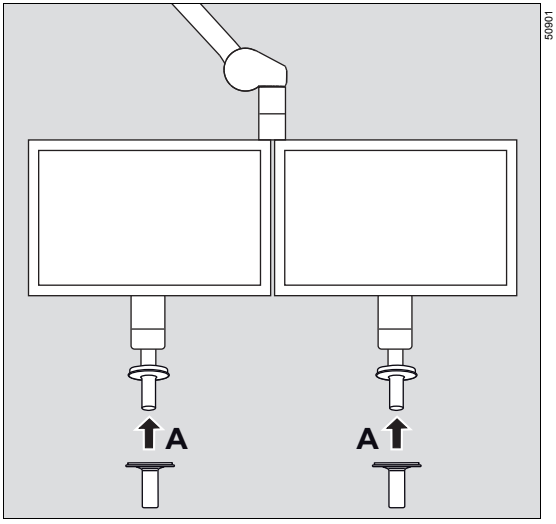
**WARNING**

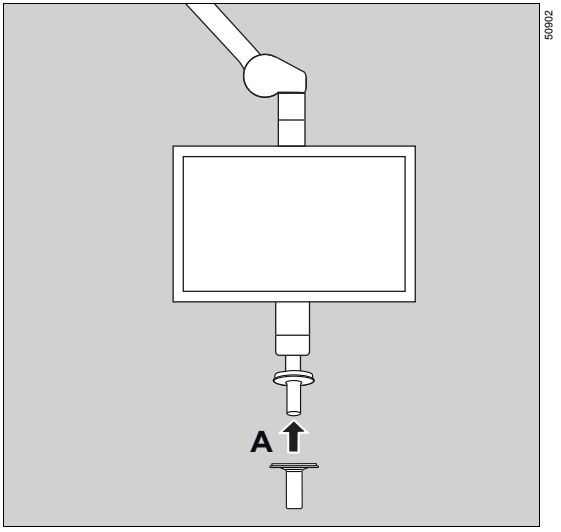
**Risk of infection**

**Personnel and patient may become infected by a non-sterile handle.**

**Use only sterile handles.**

Immediately before surgery, fit the handle under sterile conditions as follows:




**1** Push the handle (A) onto the inner handle. The handle must engage audibly. If necessary, turn the handle slightly to the right or left.

**2** Check that the handle is securely attached. To do so, pull in the direction opposite to that used to attach it.

**WARNING**

**Risk of patient injury**

**The sterilizable handle can fall down into the operating field if it is not engaged properly.**

**The handle must be checked for secure attachment after it has been fitted to the inner handle.**

**Fitting the Dräger disposable handle to the display mount**

Safety information

– The disposable handle is intended solely for single use. The disposable handle must not be reused, reprocessed, or sterilized.

– The membrane on the disposable handle must not exhibit any cracks, holes, or other damage.

– The inner handle must be free from damage.

– To prevent soiling of the disposable handle, do not unpack it until immediately before surgery.

– Do not use the disposable handle if the packaging is damaged.
– Do not use a knife to open the packaging for the disposable handle.

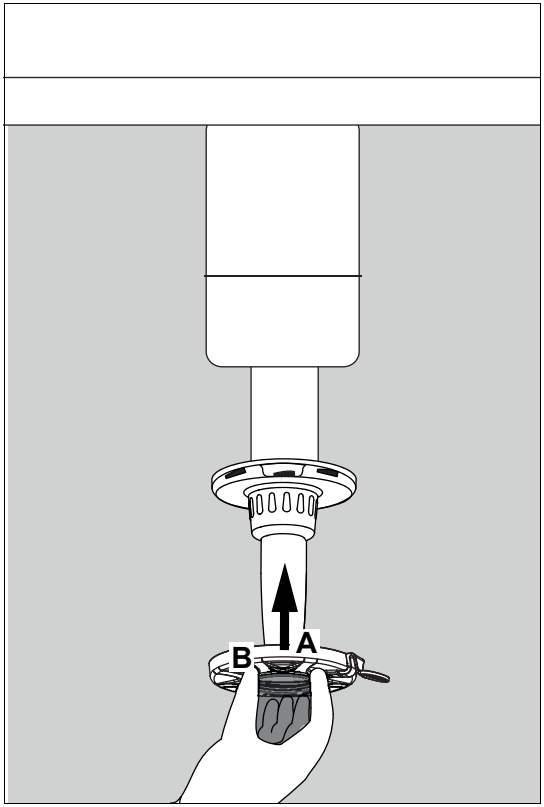
**WARNING**

**Risk of infection**

**Reuse of the disposable handle can lead to cross-infection.**

**The disposable handle is intended solely for single use. The disposable handle must not be reused.**

Immediately before surgery, fit the disposable handle under sterile conditions as follows:




**1** Remove the disposable handle from its packaging. Do not separate the membrane from the disposable handle after unpacking.

**2** Hold the disposable handle (A) by the recessed grips (B) and fit it onto the inner handle. When doing this, avoid trapping any air between the disposable handle and the inner handle.

**WARNING**

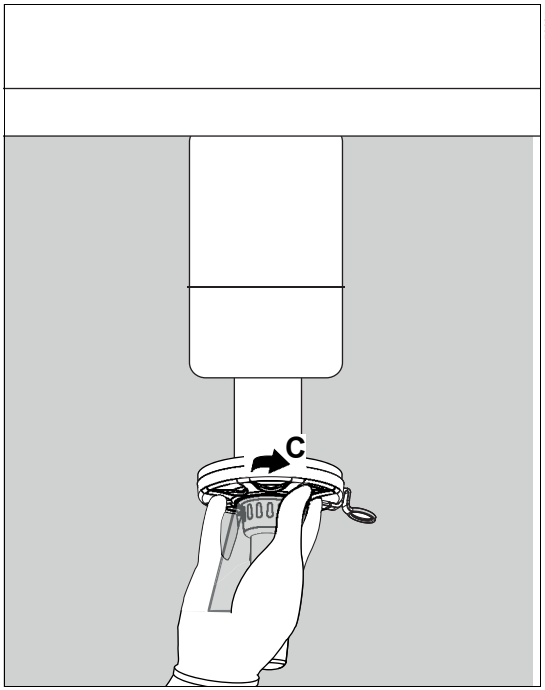
**Risk of infection**

**If the inner handle is not free from damage, it may damage the disposable handle.**

**The inner handle must be free from damage.**

**NOTE**

To facilitate fitting the disposable handle, non-sterile OR personnel may hold the light steady.




**3** Turn the disposable handle clockwise (C) until it can be felt to engage.

**4** Check that the disposable handle is securely attached. To do this, hold the disposable handle by the recessed grips and turn it counterclockwise.

**WARNING**

**Risk of patient injury**

**The disposable handle can fall down into the operating field if it is not engaged properly.**

**The disposable handle must be checked for secure attachment after it has been fitted to the inner handle.**

**5** If necessary, remove any air trapped in the membrane by moderate squeezing of the membrane.

**Checking the operational readiness**

**Prerequisites:**

– The device has been assembled and prepared so that it is ready for operation.

**Procedure:**

**1** Check the operational readiness, see instructions for use, chapter "Assembly and preparation".

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Manufacturer

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