

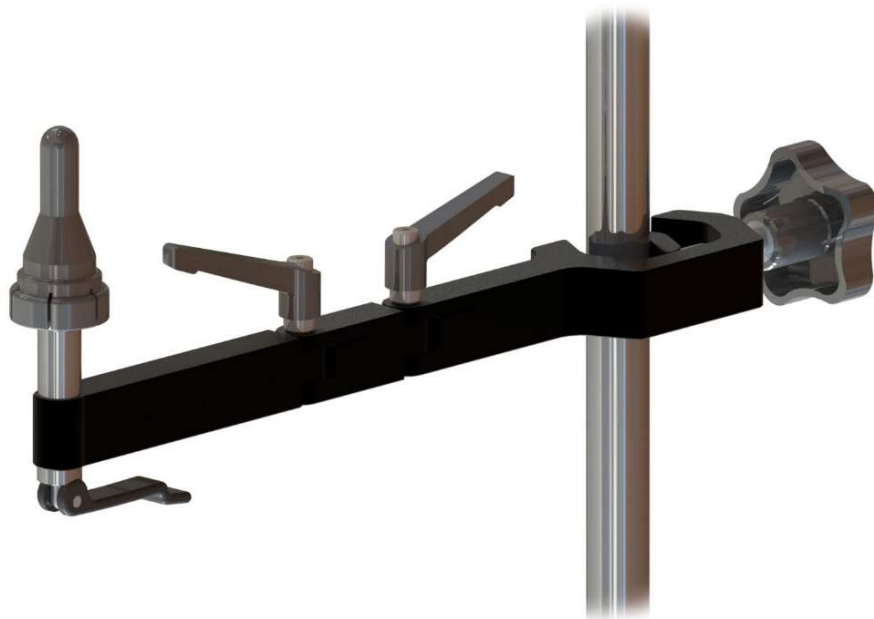


# Mechanical Holders for Medical Devices



## Instructions For Use

Read entire contents prior to using this device



English

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## **1 Holders**

### **1.1 Product Descriptions**

The medical device holders mentioned in this Instructions for Use have been designed and produced to securely hold medical devices in a user defined position during cardio-pulmonary bypass surgery or Extra Corporeal Membrane Oxygenation therapy.

### **1.2 Indications**

Medical device holders are intended for use with the compatible Chalice Medical Ltd devices, or those distributed by Chalice Medical Ltd, to aid safe use by securing the medical device to the appropriate medical equipment. Suitability with other devices has not been tested and therefore, is not authorised.

### **1.3 Contra-indications**

No contraindications have been raised to the present date with use as directed and by observing all indications and precautionary measures.

### **1.4 Duration of Use**

The intended use period of holders depends on the medical device being used. Please consult the individual medical device instructions for use for duration times. Medical device holders are re-usable providing cleaning and maintenance is carried out as per section 6.0.

### **1.5 Combination Products**

Holders are designed to be used with the specified medical device as identified in the product description (section 8.0).

### **1.6 Storage**

- Medical device holders are not to be stored in cupboards or worktops.
- Medical device holders must be stored on the drip stand/ fixed pole in a secure location to prevent damage.

## **2 Warnings**

**Read all warnings, precautions and instructions carefully prior to use.**

- Ensure the **medical device holder is secure** before attaching the relevant medical device.
- Ensure the **medical device is secure** in the holder before use.
- The products must only be used by appropriately trained and qualified personnel during clinical use.
- Discontinue use immediately if the device doesn't perform as intended. Chalice Medical Ltd are to be contacted and the device returned for investigation.

## **3 Handling**

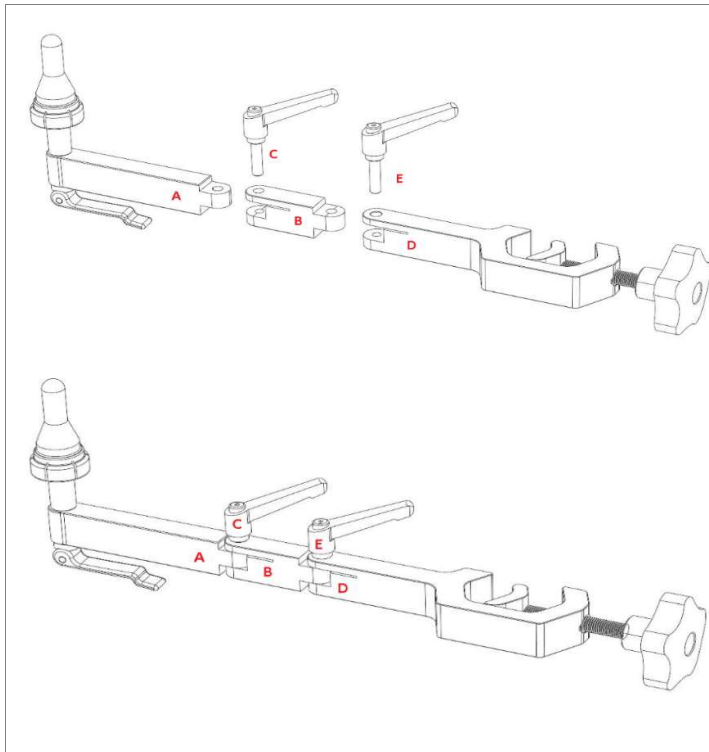
- When opening the packaging, ensure that the holder is not damaged.
- Ensure the device is cleaned as per section 6.0 before use.
- Ensure the device is not damaged or worn.

## **4 Application**

Holders are used as per section 7.0.

## 5 Assembly Instructions

Product code CMEH047 and CMEH049 will be provided unassembled. Refer to assembly diagrams below before attempting to use the product. Product code CMEH054 is also assembled following the process described below. **Once assembled, it is important that the cleaning and maintenance procedures detailed in section 6 are read carefully.**



### CMEH047: Holder for standalone Paragon Adult & Infant Oxygenator

Diagram 1 shows the holder in its component parts. Diagram 2 shows the holder as a fully assembled item.

Part A fits in to part B and is secured in place with part C. Part B fits in to Part D and is secured in place with Part E. Parts C and E and the star knob at the end of the assembly (opposite end to the oxygenator) can be tightened if required by turning them in a clockwise direction.

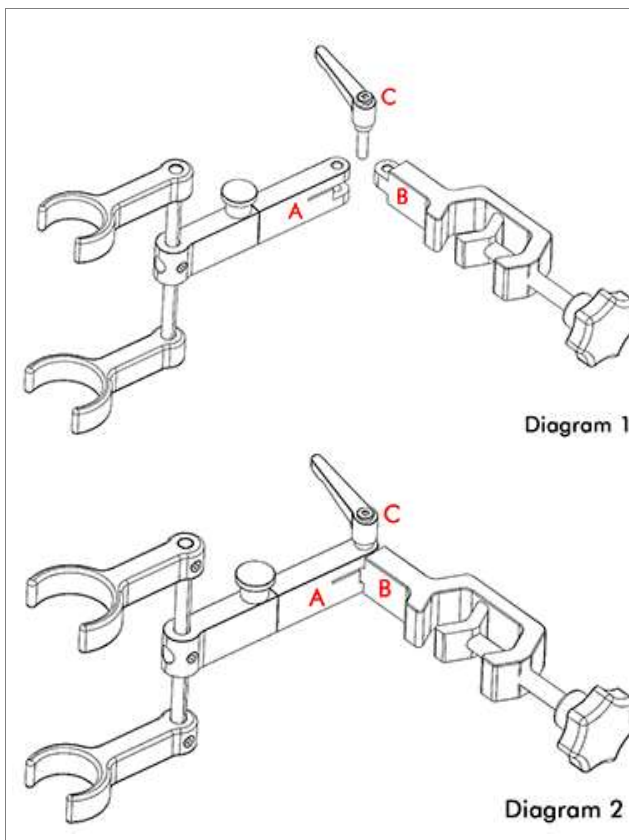


Diagram 1

Diagram 2

### CMEH049: Holder for Standalone Neonatal Paragon Oxygenator

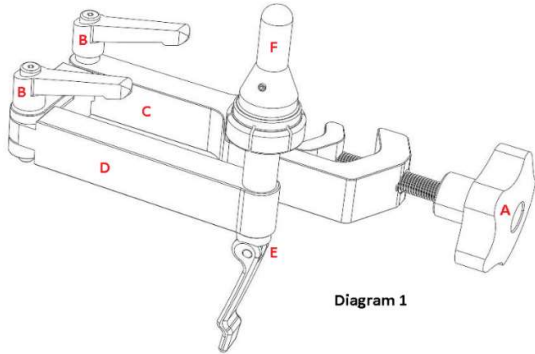
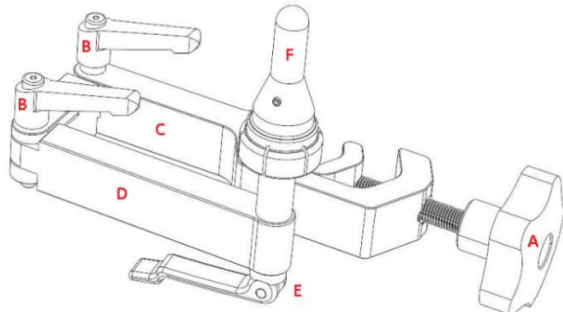
Diagram 1 shows the holder in its component parts. Diagram 2 shows the holder as a fully assembled item.

Part A fits in to part B and is secured in place with part C. Parts C and the star knob at the end of the assembly (opposite end to the oxygenator) can be tightened if required by turning them in a clockwise direction.

## 6 Cleaning and Maintenance

- Holders must be “damp dusted” daily as per the hospitals internal protocol, using the relevant cleansing wipe as per their internal infection control policy.
- Repeat this practice before each surgery, ensuring the holder is clean before any sterile product is opened.
- If the holder becomes contaminated with blood or other human bodily fluids, the hospitals’ infection control procedure is to be followed, involving a “deep clean” with a chlorine based cleaning agent.

## 7 Description of Use/Operation

|                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  <p>Diagram 1</p>   | <p><b>CMEH047: Paragon Oxygenator Holder</b></p> <p>Diagram 1 shows the Paragon Oxygenator holder in its “open” position. Diagram 2 shows the holder as a fully assembled item.</p> <p>The star knob at the end (part A) can be rotated to move the G-Clamp in or out to accommodate the size of the pole it is to be attached to. This holder can be used on poles with a diameter from 40 mm to 23 mm. To tighten the connection, rotate the star knob clockwise until it is locked in position.</p>                                                                                                                                                                                                                                                                                                                                                                                        |
|  <p>Diagram 2</p> | <p>The lever handles (part B) can be turned to release the mechanism that joins part C &amp; D. This will allow parts C &amp; D to pivot to the desired position. Once the desired location has been achieved, the lever handle (part B) is tightened by turning clockwise to lock the position.</p> <p>The lever (part E) is disengaged when it is in the position shown in diagram 1. This will allow a Paragon Oxygenator to be placed over the acetal spike (part F) and rotated to the desired orientation. Once the desired position has been achieved, the lever (part E) can be pushed up towards the main body of the holder (part D), locking the oxygenator and its position to the acetal spike (part F).</p> <p>The process is reversed to remove the oxygenator from the holder. Please note, this holder will not accommodate a Paragon neonatal oxygenator – use CMEH049.</p> |

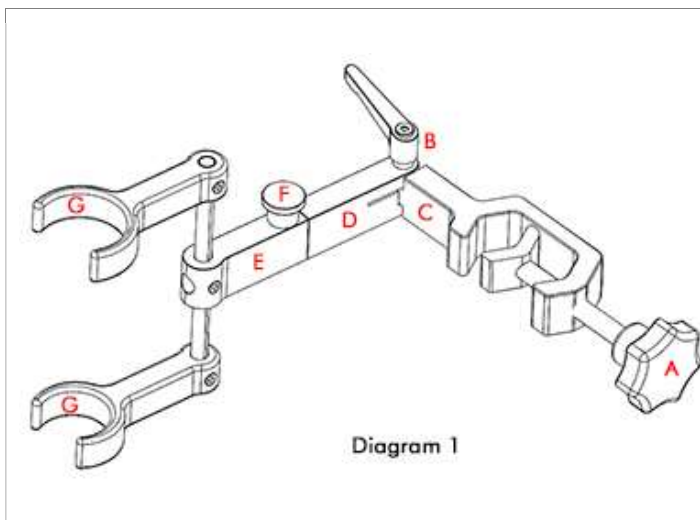


Diagram 1

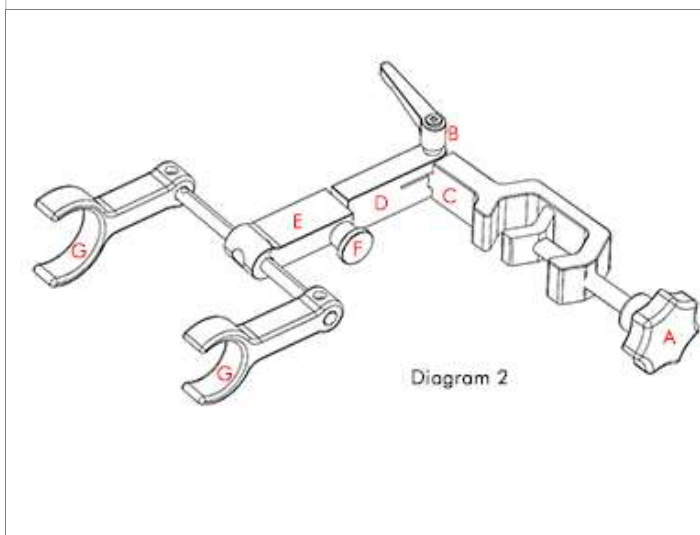


Diagram 2

#### CMEH049: Paragon Neonatal Oxygenator Holder

Diagram 1 shows the Paragon Neonatal Oxygenator holder in position 1. Diagram 2 shows the holder in Position 2.

The star knob at the end (part A) can be rotated to move the G-Clamp in or out to accommodate the size of the pole it is to be attached to. This holder can be used on poles with a diameter from 38 mm to 15 mm. To tighten the connection, rotate the star knob clockwise until it is locked in position.

The lever handle (part B) can be turned to release the mechanism that joins parts C & D. This will allow part D to pivot to the desired position. Once the desired position has been achieved, the lever handle (part B) is tightened by turning clockwise to lock the position.

The Paragon Neonatal Oxygenator can be pushed in to the actual C-Clamps (part G) to be held vertically throughout the procedure.

The Paragon Neonatal Oxygenator unit can be rotated during the priming process to aid de-airing. Pull the plunger (part F) up to release the body of the holder (part E) which will allow it to rotate through 90°. Once the Paragon Neonatal Oxygenator is fully de-aired, the body of the holder (part E) can be rotated back to the vertical position, where the plunger (part F) will lock back in place to secure the position.

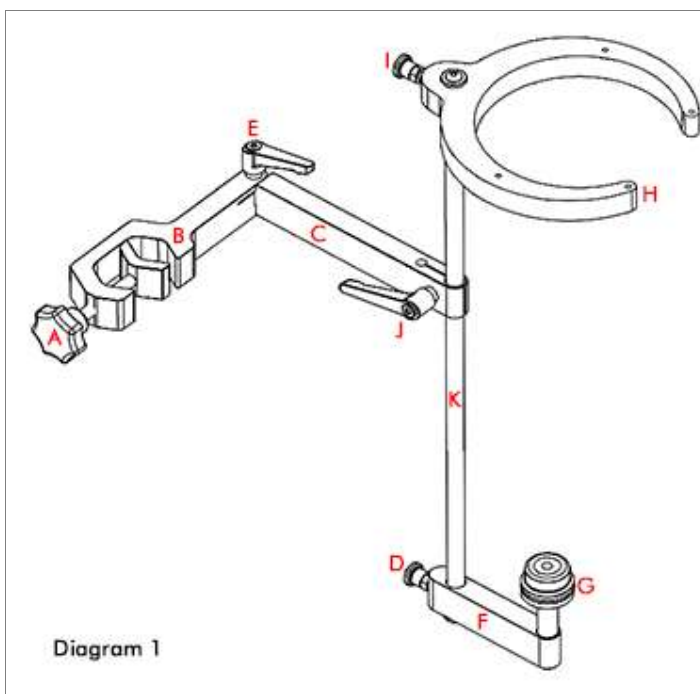


Diagram 1

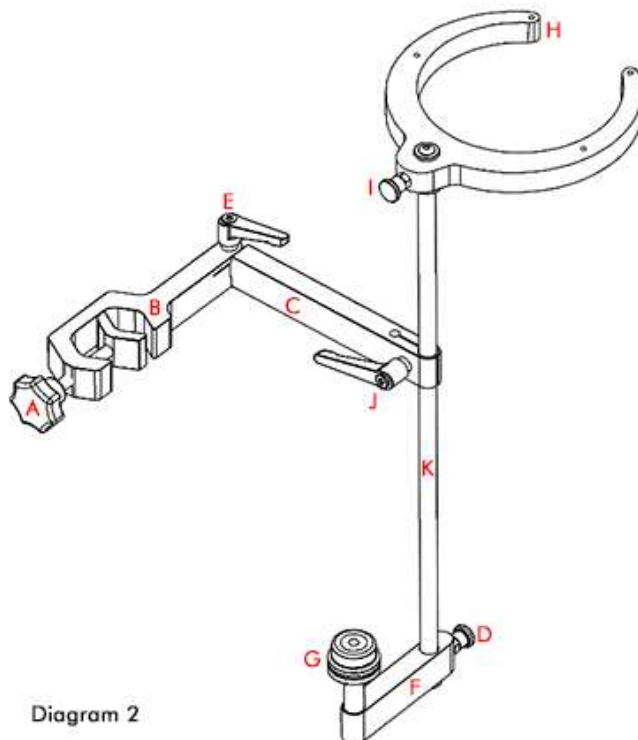
#### CMEH012: Holder for Integrated Paragon Oxy with 4000 mL Reservoir.

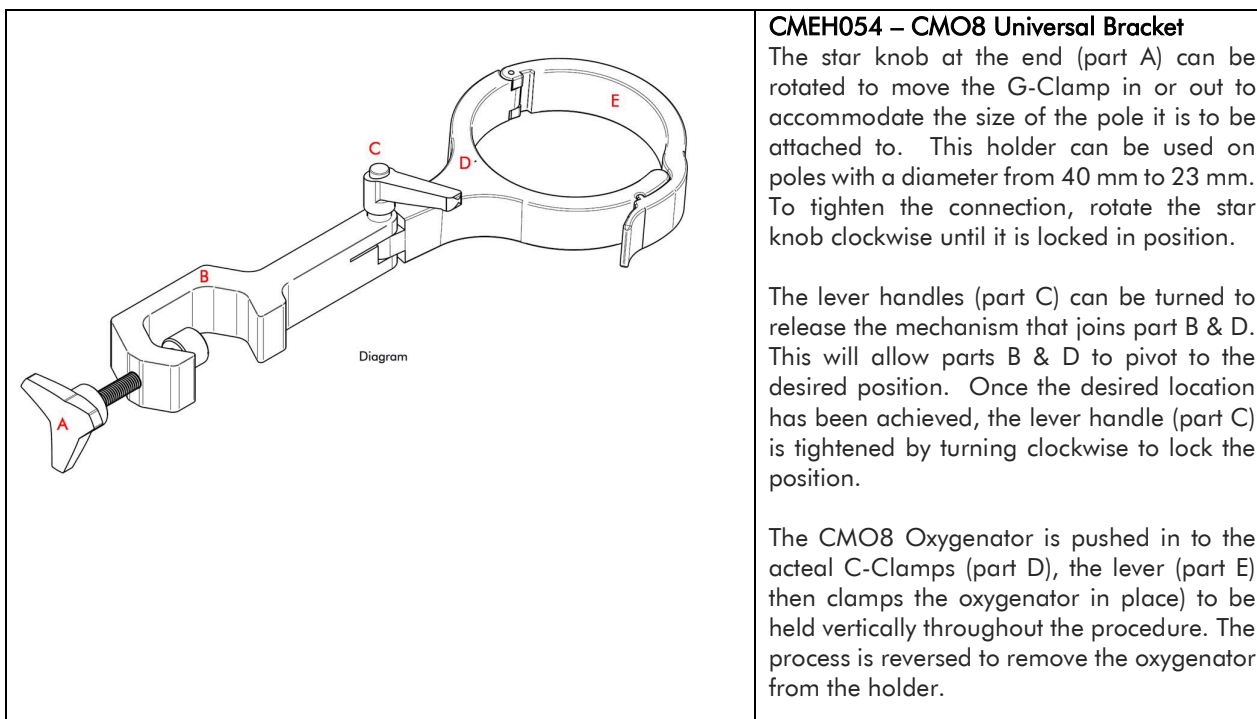
#### CMEH042: Holder for Integrated Paragon Oxy with 1800 mL Reservoir.

Diagram 1 shows the Paragon Oxygenator holder in position 1, and can be used when the Oxygenator and Reservoir are connected together.

The star knob at the end (part A) can be rotated to move the G-Clamp in or out to accommodate the size of the pole it is to be attached to. This holder can be used on poles with a diameter from 40 mm to 23 mm. To tighten the connection, rotate the star knob clockwise until it is locked in position.

The lever handle (part E) can be turned to release the mechanism that joins part B & C. This will allow part C to pivot to the desired position. Once the desired position has been

|                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                     | <p>achieved, the lever handle (part E) is tightened by turning clockwise to lock the position.</p> <p>The lever handle (part J) can be turned to release the mechanism that joins parts C &amp; K. This will allow part K to move up and down to the desired position. Once the desired position has been achieved, the lever handle (part J) is tightened by turning clockwise to lock the position.</p> <p>The Paragon Oxygenator with integrated Reservoir can then be lowered through the back acetal C (part H), until the bottom of the Oxygenator is located on to the aluminium stub (part G). At this point, the reservoir should also locate in the black acetal C (part H).</p>                                                                                                                                                                                                                                  |
|  <p>Diagram 2</p> | <p>Diagram 2 shows the Paragon Oxygenator holder in position 2, and can be used when the Oxygenator and Reservoir are separated from each other. The plunger (part D) located on the back of part F can be pulled to allow part F to rotate through 4 90° positions to the desired location. Once the desired location has been achieved, the plunger will snap back in place to secure the position. The Paragon Oxygenator can then be placed on to the aluminium stub (part G) to be held securely throughout the procedure.</p> <p>The plunger (part I) located on the back of part H can be pulled to allow part H to rotate through 4 90° positions to the desired location. . Once the desired location has been achieved, the plunger will snap back in place to secure the position. The Paragon Reservoir can then be securely placed in to the acetal C (part H) and held securely throughout the procedure.</p> |



## 8 Product Codes

These can be ordered from the manufacturer.

| Description                                              | Order Code |
|----------------------------------------------------------|------------|
| Holder for Stand-alone Paragon Adult & Infant Oxy        | CMEH047    |
| Holder for Stand-alone Paragon Neonatal Oxygenator       | CMEH049    |
| Holder for Integrated Paragon Oxy with 4000 mL Reservoir | CMEH012    |
| Holder for Integrated Paragon Oxy with 1800 mL Reservoir | CMEH042    |
| CMO8 Universal Bracket                                   | CMEH054    |

## 9 Explanation of Symbols

|                                        |  |                                                                         |  |
|----------------------------------------|--|-------------------------------------------------------------------------|--|
| Date of Manufacture                    |  | EC Authorised Representative                                            |  |
| Manufacturer                           |  | Importer                                                                |  |
| Language Symbol – assigned as required |  | CE Mark                                                                 |  |
| Consult Instructions for Use           |  | Keep away from sunlight                                                 |  |
| Lot Number/ Batch Code                 |  | Addition of number to determine how many products are in the packaging. |  |
| Catalogue Number                       |  | Fragile handle with care                                                |  |
| Keep dry                               |  | UKCA Mark                                                               |  |

## 10 Disposal

Dispose of the holder according to applicable clinical and local regulations.

## 11 Warranty and Liability Statement

The manufacturer guarantees that the products have been manufactured and packaged in accordance with the MDR Regulations 2017/745 and the UK regulations 2002. The manufacturer's obligation is to replace any products, which it determines were defective at the time of shipment. Faulty products must be returned for investigation. Because of factors that are out of the manufacturers control, i.e shipping, storage and handling by the user, the manufacturer cannot guarantee that a product is without faults. The manufacturer can not be made liable for damages, resulting from use or misuse of the product other than as intended. The manufacturer is not liable for any damages caused by off-label use of the product.

## 12 Further Information

All serious incidents relating to this product should be reported to Chalice Medical Ltd or Sales Representative and the Competent Authority of the Member State in which the User and/or patient is established. The report can be made by email to [quality@chalicemedical.com](mailto:quality@chalicemedical.com).

A product associated with an incident must not be disposed immediately after use. If the product is to be returned for any reason, please seek prior approval from Chalice Medical Ltd. If the product is contaminated, it is the responsibility of the User to adequately prepare and label the product for return shipment. The shipping address for returns is the Manufacturer's address.

It is encouraged to electronically record the Unique Device Identifier (UDI) of products that are supplied.

Along with a physical copy of the IFU, a QR code is provided on the product to allow to allow users to obtain a PDF version of the IFU.

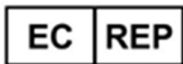
## 13 Economic Operator Contacts

### *Importer*



HSC-Medical GmbH  
Rugenranzel 4  
25373 Ellerhoop  
Deutschland

### *EC Authorised Representative*



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