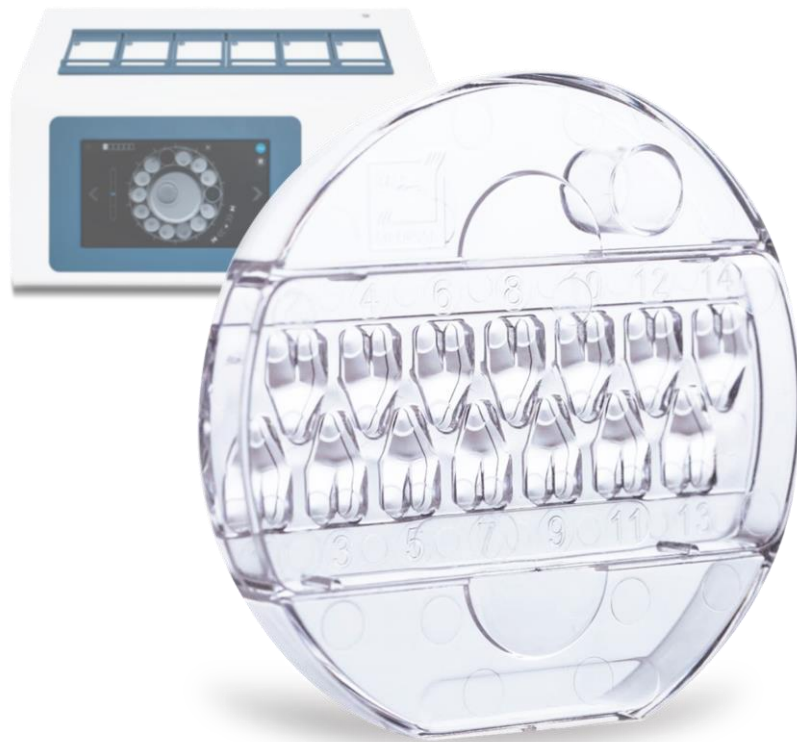


CE 0123



## USER MANUAL

# CultureCoin®

Rev. 7.1  
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Rx only



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## Copyright Information

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Esco reserves the right to make periodic minor design changes without obligation to notify any person or entity of such change.

Sentinel™ is a registered trademark of Esco.

Caution: Federal law restricts this device to sale by or on a licensed healthcare practitioner's order.

Only to be used by a trained and qualified professional. The device is sold under exemption 21 CFR 801 Subpart D.

*"Material in this manual is provided for informational purposes only. The contents and the product described in this manual (including any appendix, addendum, attachment or inclusion) are subject to change without notice. Esco makes no representations or warranties as to the accuracy of the information contained in this manual. In no event shall Esco be held liable for any damages, direct or consequential, arising out of or related to the use of this manual."*

## **Unpacking and Inspection**

Follow standard receiving practices upon receipt of the medical device. Check the shipping carton for damage. If the damage is found, stop unpacking the medical device. Notify the freight carrier and ask for an agent to be present while the medical device is unpacked. There are no special unpacking instructions, but be careful not to damage the medical device when unpacking it. Inspect the medical device for physical damage such as bent or broken parts, dents, or scratches.

## **Claims**

Our routine method of shipment is via common carrier. If physical damage is found, upon delivery, retain all packing materials in their original condition and immediately contact the carrier to file a claim.

If the medical device is delivered in good physical condition but does not operate within specifications, or if there are any other problems not caused by shipping damage, please contact your local sales representative or Esco Medical Technologies immediately.

## **Standard Terms and Conditions**

### **Refunds & Credits**

Please note only sterilized products (products labeled with a distinct serial number) and accessories are eligible for a partial refund and/or credit. The *Return Procedure* must be followed.

### **Return Procedure**

Every product returned for refund/credit must be accompanied by a Return Material Authorization (RMA) number, obtained from Esco Medical Technologies Customer Service. All items being returned must be sent *prepaid* (freight, duty, brokerage and taxes) to our factory location.

### **Restocking Charges**

Products returned within 30 days of original purchase are subject to a minimum restocking fee of 20% of the list price. Additional charges for damage and/or missing parts and accessories will be applied to all returns. Products that are not in “as new” and resalable condition are not eligible for credit return and will be returned to the customer at their own expense.

### **Certification**

This medical device has been thoroughly tested/inspected and found to meet Esco Medical Technologies’ manufacturing specifications when shipped from the factory.

### **Warranty and Product Support**

Esco Medical Technologies warrants this medical device to be free from defects in materials and workmanship under regular use and service until the date “Use by” provided on the label. During the warranty period, Esco Medical Technologies will replace a product that proves to be defective at no charge, provided you return the product (shipping, duty, brokerage and taxes prepaid) to Esco Medical Technologies. Any transportation charges incurred are the purchaser’s responsibility and are not included within this warranty. This warranty extends only to the original purchaser. It does not cover damage from abuse, neglect, accident or misuse, or as the result of service or modification by parties other than Esco Medical Technologies.

IN NO EVENT SHALL ESCO MEDICAL TECHNOLOGIES, UAB BE LIABLE FOR CONSEQUENTIAL DAMAGES.

No warranty shall apply when any of the following causes damage:

- Damage in transit or when moving the medical device
- Accident, alteration, abuse or misuse of the medical device
- Fire, water damage, theft, war, riot, hostility, acts of God such as hurricanes, floods, etc.

Only CultureCoin® is covered under this warranty if the package is not damaged during storage and transportation.

PHYSICAL DAMAGE CAUSED BY MISUSE OR PHYSICAL ABUSE IS NOT COVERED UNDER THE WARRANTY.

This warranty gives you specific legal rights and you may have other rights, which vary from province to province, state to state, or country to country. This warranty is limited to repairing the medical device per Esco Medical Technologies specifications.

When you return the medical device to Esco Medical Technologies for investigation, we recommend shipment using the original shipping foam and container. If the original packing materials are not available, we recommend the following guide for repackaging:

- Use a double-walled carton of sufficient strength for the weight being shipped. There cannot be spare space in the shipment box with the medical device; otherwise, it will move and can cause possible damage
- In the case of a single medical device is sent, an envelope with an adapted bubble envelope may be used

Esco Medical Technologies will not be responsible for lost shipments or medical devices received in damaged condition due to improper packaging or handling. All warranty claim shipments must be made on a prepaid basis (freight, duty, brokerage, and taxes). No returns will be accepted without a Return Materials Authorization ("RMA") number. Please contact Esco Medical Technologies to obtain an RMA number and receive help with shipping/customs documentation.

### **Warranty Disclaimer**

With CultureCoin® dishes could work only individuals with formal education in a relevant field of healthcare or medical discipline. If this medical device is used by other person, Esco Medical Technologies, UAB takes no responsibility for damage to users, patients and property.

If a primary package of CultureCoin® is damaged before opening it, Esco Medical Technologies, UAB takes no responsibility for damage to users, patients and property.

**WARNING**

Esco Medical Technologies will not be responsible for any possible injury and side effects sustained due to unauthorized equipment modifications.

ESCO MEDICAL TECHNOLOGIES, UAB DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION.

THIS PRODUCT CONTAINS NO USER-SERVICEABLE COMPONENTS.

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## 1 How to use this manual

The manual is intended to be read from start to finish.

## 2 Safety warning

- Anyone working with, on or around this equipment should read this manual. Failure to read, understand, and follow the instructions given in this documentation may result in damage to the unit, injury to operating personnel, and/or poor equipment performance.
- The use of any hazardous materials in this equipment must be monitored by an industrial hygienist, safety officer or other suitably qualified individuals.
- In this manual, important safety-related points will be marked with the following symbols:



### **NOTE**

It is used to direct attention to a specific item.



### **WARNING**

Use caution.

- If the equipment is used in a manner not specified by this manual, the protection provided by this equipment may be impaired.

## 3 Intended purpose

Preparing, storing and transferring human embryos. To be used only with the MIRI® TL device.

## 4 About the product

The Esco Medical Technologies CultureCoin® is a sterile, single-use culture vessel specifically developed for use in IVF. The dish holds up to 14 embryos in the centrally placed line of culture wells. The culture well features a 300 µm, optically clear area where the embryo is situated. The area is optimized for microscopy. A clear circle is present around the culture area for the purpose of making it easy for an automatic focus algorithm to find the area under microscopic image acquisition. The culture wells are numbered (1 – 14) for easy location of each well by the user. Each culture well has two washing wells for cell manipulations, washing media or replacement media.

The lid is mounted inside the circumference of the dish covering the culture area completely – the user will only grab the dish during handling and not risk losing the dish by holding on to the lid only – as can be the case on all traditionally designed dishes. A

large well is provided outside the culture for pH measuring without affecting the cultured samples. The dish has a flat bottom, so it is ideal for heat transfer from below.

Principles of operation of the device and its mode of action: CultureCoin® is designed to culture cells only in Esco Medical Technologies MIRI® TL family's multiroom IVF incubators for a period of up to 6 days. The capacity of droplets in incubation wells is 25µl. Such an amount of media is sufficient for cell development during such a period. A high wall surrounds the droplet area to ensure enough space for an oil overlay to secure media from evaporation. Incubation wells are situated in one line, at the same height and across the exact distance between well centers. It perfectly fits the design of the MIRI® TL family's multiroom IVF incubators, which camera moves under CultureCoin® along incubation wells.

Model Code: MRI-CC.

With CultureCoin® dishes could work only individuals with formal education in a relevant field of healthcare or medical discipline.

The CultureCoin®'s intended target groups are IVF patients. Patients are women in their reproductive years who have fertility health issues. The intended target group indication is IVF treatment. There are no intended target group contraindications.

CultureCoin® is a medical device intended for use on one patient during a single procedure. It is not intended to be reprocessed (cleaned, disinfected/sterilized) and used on another patient.

CultureCoin® can be used only with the MIRI® TL family's multiroom IVF incubators and sequential media specifically designed for IVF treatment. CultureCoin® cannot be used with non-medical devices and other non-IVF treatment-designed media.

The device is manufactured under a full EU certified 13485 ISO quality management system.

This product conforms to the requirements of the Regulation (EU) 2017/745 concerning medical devices and is classified as a Class IIa device under rule II.

Personal Protective Equipment (89/686/EEC) and Machine Directive (2006/42/EC) is not applicable for the CultureCoin®. Also, the CultureCoin® do not contain or incorporates: a medical substance, including a human blood or plasma derivate; tissues or cells, or their derivates, of human origin; or tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) NO. 722/2012.



## 5 Safety symbols and labels

There are several user labels on the surfaces of the CultureCoin® to guide the user. User labels are shown below.

**Table 5.1** Packing bag and box labels

Description	Image
<b>Packaging bag label:</b> 1. Logo 2. Model 3. Catalogue number 4. Batch code 5. Temperature limit 6. Rx only 7. Consult instructions for use 8. Do not use if package is damaged 9. Keep away from direct sunlight 10. Manufacturer 11. UDI code 12. CE mark 13. Use-by date 14. Sterilized using irradiation 15. Sterile barrier system 16. Keep dry 17. Medical device 18. Do not re-use 19. Non-pyrogenic 20. Do not re-sterilize 21. WEEE	
<b>Packing box label:</b> 1. Logo 2. Model 3. Catalogue number 4. Batch code 5. Consult instructions for use 6. Do not use if package is damaged 7. Keep away from direct sunlight 8. Manufacturer 9. UDI code 10. CE mark 11. Use-by date 12. Keep dry 13. Temperature limit 14. Medical device 15. Sterilized using irradiation 16. Amount of dishes	

## 6 Important safety instructions and warnings

### 6.1 Pre-use

1. Do not use the product if the package is damaged. Contact Esco Medical Technologies or the local representative.
2. Read the user manual thoroughly before use.
3. Always keep these instructions at hand.



**With CultureCoin® dishes could work only individuals with formal education in a relevant field of healthcare or medical discipline.**

Basic training on how to use CultureCoin® with MIRI® TL family's multiroom IVF incubators is provided along with the installation of MIRI® TL family's multiroom IVF incubators.

### 6.2 During use

1. Use only for the purpose listed under intended use.
2. The dishes are single-use only. Please do not attempt to clean and reuse them.
3. Only for the use of water-based culture media and mineral oil.
4. Do not use this product at temperatures exceeding 40 °C.

Functions related to SAFETY:

- Identifying the correct dish
- Avoiding cross-contamination
- Placing the embryo correctly



**Please refer to sections 9 – 14 in this manual for more information on how to properly use CultureCoin®.**

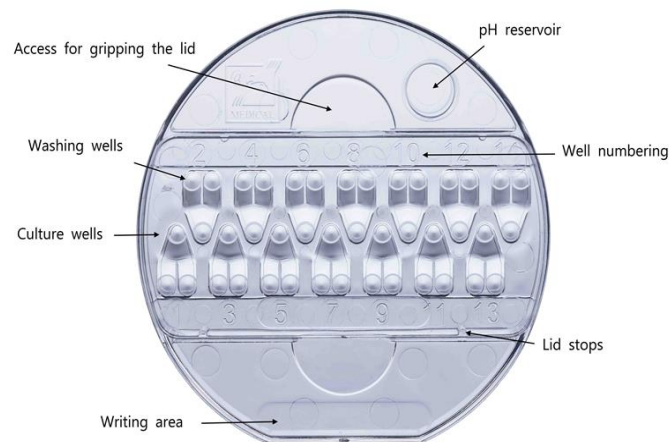
### 6.3 Post use

If the dish was used to store/incubate biological samples, it should be discarded as biohazardous waste according to laws and procedures valid in the user's country.

## 7 The Culture mode

The CultureCoin® can be used only for culturing with culture media filled into the wells and oil overlay. They cannot be used for open culture.

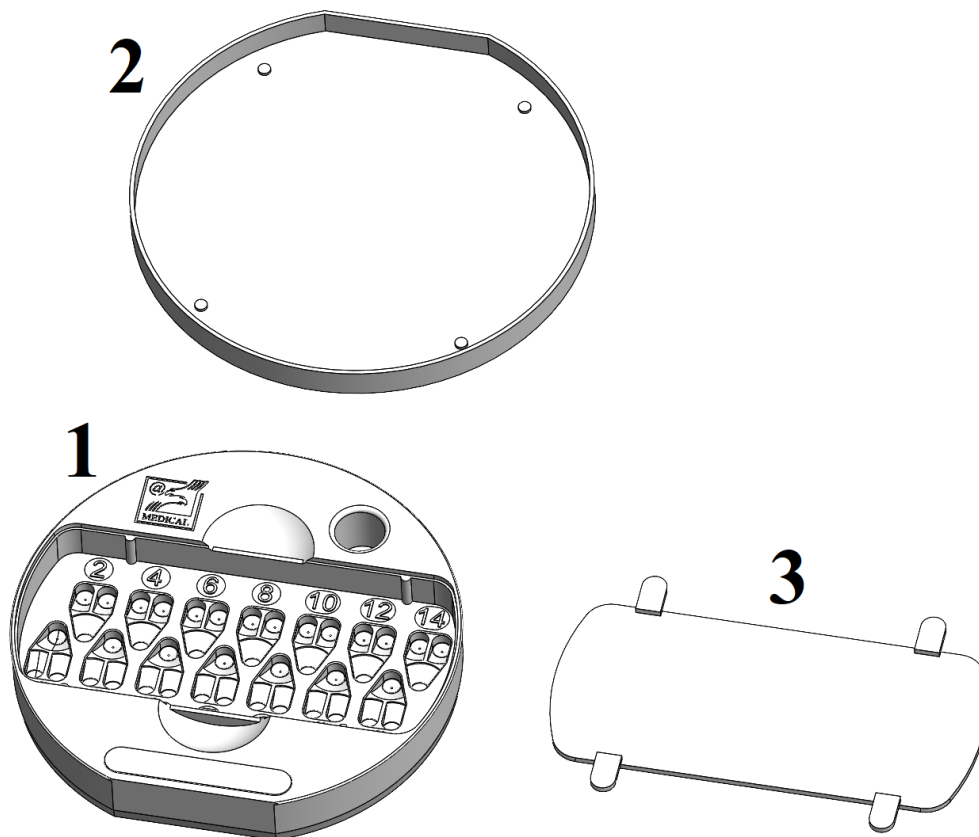
## 8 Overview



**Figure 8.1** CultureCoin®

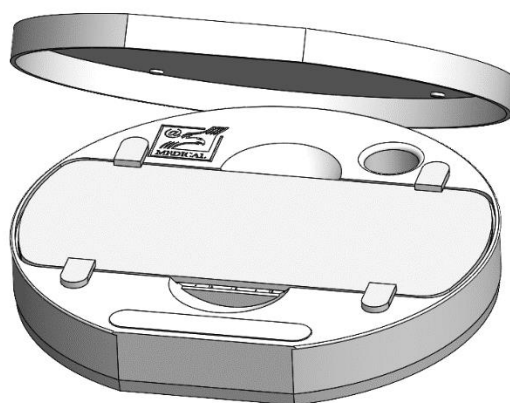
The CultureCoin® dish consists of 3 parts:

- CultureCoin® dish (1).
- Lid (2) that covers the entire CultureCoin® area.
- A small lid (3) that covers only the middle part of the CultureCoin® area.



**Figure 8.2** CultureCoin® dish parts

The correct way to assemble the CultureCoin® dish using both lids:



**Figure 8.3** Assembled CultureCoin® dish

**👉 The smaller lid is put on the CultureCoin® dish facing the 4 handles up. If the lid is put upside down, it will be loose and not fit correctly.**

The lid (2) is used to protect liquid content until the CultureCoin® dish is placed in MIRI® TL multiroom IVF incubator. Before putting CultureCoin® into MIRI® TL multiroom IVF incubator, this lid should be removed.

The small lid (3) can optionally be used to maintain stable conditions if the CultureCoin® dish is removed from the MIRI® TL family's multiroom IVF incubator several times during the incubation cycle.

The small lid (3) is not used if the CultureCoin® dish is not removed from the MIRI® TL family's multiroom IVF incubator during the entire incubation cycle.

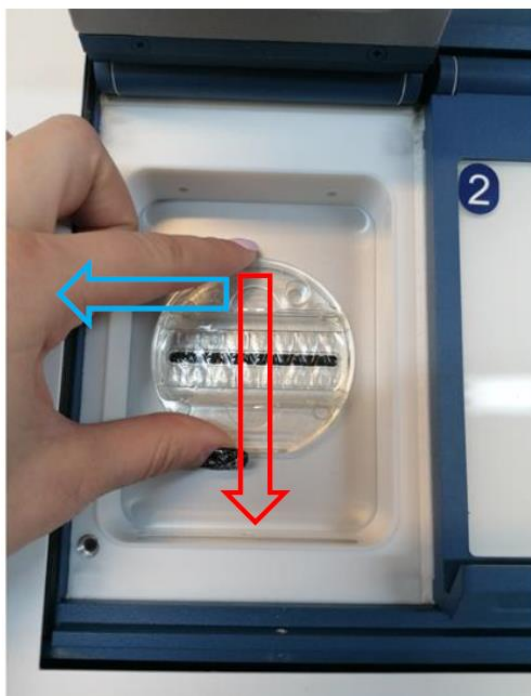
## 9 Use

1. Unpack both the lid and dish in an aseptic environment.
2. Leave the dishes with the lids on for off-gassing in the aseptic environment for 12 hours.
3. Warm the dishes on a heated stage or an incubator before filling them with media.
4. Fill all the wells with the app. 25 µl of precultured equilibrated culture media in an aseptic environment. Filling of the washing wells is optional. They can contain approximately 23 µl each.
5. Check under a microscope for any visible air bubbles and remove them with a stripper tip.
6. Fill the oil area with a confluent layer of suitable mineral or paraffin oil to cover the culture media. The recommended amount is 5 ml. Do not overfill.
7. Put the lid on the dish and leave it for 4 hours of equilibration in the CO<sub>2</sub> incubator.

8. Check for air bubbles in the culture wells after the equilibration. Remove any bubbles with a stripper tip.
9. Load the embryos in the wells. Make sure the embryos are located very precisely in the center of the culturing well and not on the side slope.
10. Optionally fill the pH reservoir and insert the silicone plug.
11. Incubate the CultureCoin® in the MIRI® TL.

## 10 CultureCoin® placement in the compartment

Before starting the time-lapse, it is essential to place the CultureCoin® in the compartment properly. To ensure the correct position of the CultureCoin® (so that the camera can identify all the wells), place the CultureCoin® in its place and secure its position by pushing it **downwards and towards you**, then to the **left edge**.

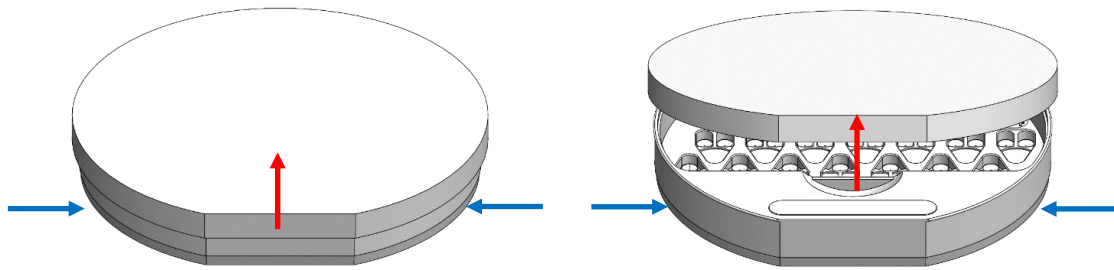


**Figure 10.1** Positioning CultureCoin® in the compartment

## 11 Removing the CultureCoin® lid

CultureCoin® lid does not have a lot of free movement on the dish while it is closed, but the lid may move slightly during transportation. The lid can rotate a bit on the CultureCoin® and get stuck on the dish edges. As a result, it may be harder to open it.

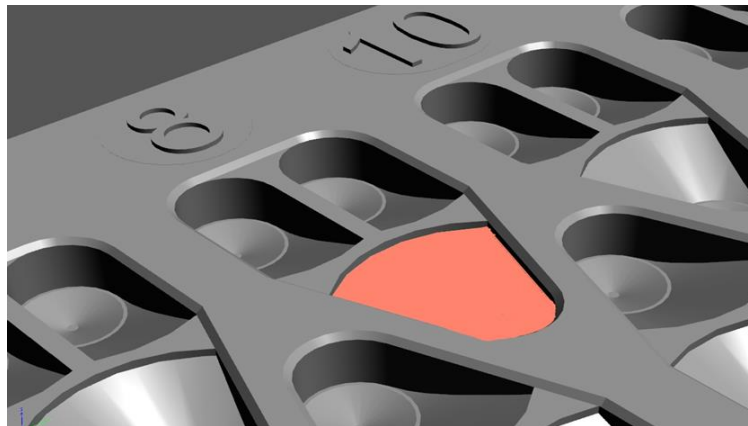
In such a case, there is a specific technique for the CultureCoin® lid opening. **Hold the dish** and **lift the lid from the cut edge**.



**Figure 11.1** CultureCoin® lid opening

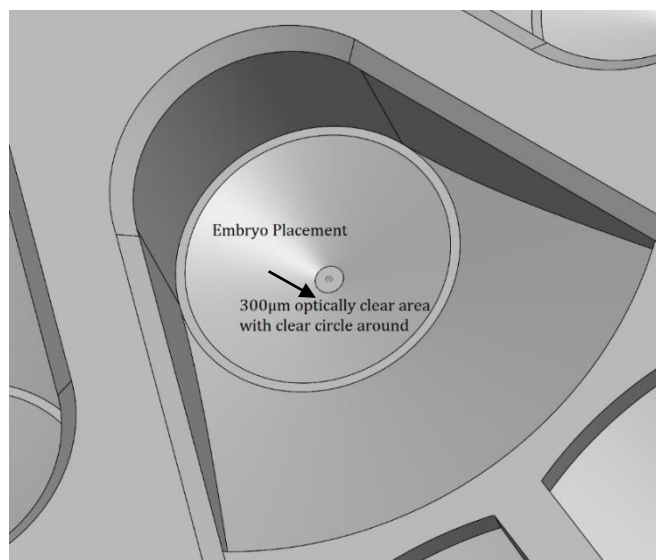
👉 Please do not twist the lid of the CultureCoin®, because it will be locked, and it will be even harder to open it.

## 12 The use illustrated

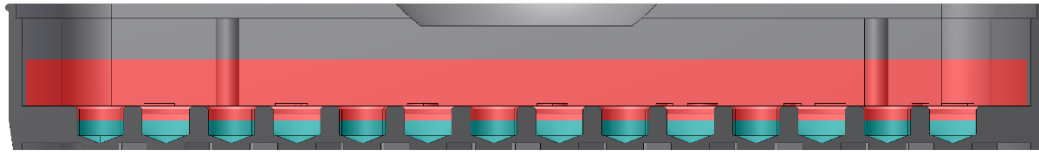


**Figure 12.1** The wells

Each of the 14 wells is filled with approximately 25  $\mu$ l culture medium. The washing wells can also be filled, but it is not a requirement. The embryo is placed at the bottom of the culturing area.



**Figure 12.2** Embryo Placement in detail on the 300 $\mu$ m optically clear area



**Figure 12.3** The culture wells are covered with a mineral oil layer and the lid is put on

## 13 pH measuring

Validating the pH of the culture media should be a standard procedure. The CultureCoin® is equipped with a reservoir that is located outside the culturing area. It makes it possible to safely and conveniently make spot checks on the pH level.

Remove the silicone plug and measure with a calibrated pH probe in the reservoir. Adjust the CO<sub>2</sub> level if necessary.

When choosing an electrode (probe), it is necessary to consider the probe's size, as measurements will be made on either a 4-well dish or a droplet.

## 14 Writing area on the CultureCoin® and lid



**Figure 14.1** Always mark both the lid and the dish

## 15 User troubleshooting

**Table 15.1** Heating system

Symptom	Cause	Action
Embryos drift to the side of the well.	The placement of the embryo is not done with enough accuracy.	Practice correct placement.
Air bubbles appear during culturing.	Temperature differences during loading or incorrect procedure for bubble removal.	Avoid temperature differences and follow the correct procedure. Practice proper bubble removal.
Oil overflows during the handling of the dish.	Too much oil in the reservoir.	Decrease the oil volume.

## 16 Specifications

**Table 16.1** CultureCoin® specifications

Technical specifications	CultureCoin®
Overall dimensions (Diameter x Height)	Ø 71 x 10 mm
Weight empty	0.5 gram
Material	Polystyrene
Temperature range	25.0 – 40.0 °C
CO <sub>2</sub> range	1.9 – 10.0%
O <sub>2</sub> range	4.9 – 20.0%
Sterilization method	Gamma beam
Lifetime	2 years
Toxicity tested	Embryotoxicity tested with thawed 1 cell mouse embryos. Expanded Blastocyst rate after 96 hours > 80 % (n=150), 0.6 bar (8.70 PSI)