

EmbryoSlide+ ic8 dishes

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EN (US)

Intended use

The EmbryoSlide+ ic8 dish is an accessory for embryo storage.

Indications for use

The EmbryoSlide+ ic8 dish is intended for culturing, handling and preparation for transfer of human embryos. The EmbryoSlide+ ic8 dish must be used together with the EmbryoScope+ incubator.

Restrictions on use

The EmbryoSlide+ ic8 dish must be handled by trained personnel according to the instructions in this insert.

The EmbryoSlide+ ic8 dishes and lids are sterile. The pouches must only be opened in a sterile laminar flow hood, and the dish must be covered by the lid when in use.

Storage conditions

The EmbryoSlide+ ic8 dish must be stored at room temperature.

Warnings and precautions

WARNINGS:

The EmbryoSlide+ ic8 dish is intended for single use only and MAY NOT be re-used. Any attempt by the user to clean and re-sterilize the dish may result in contamination with microorganisms or other risks of device failure.

To avoid contamination with microorganisms, always place the dish in a sterile laminar flow hood while loading and generally handling the dish.

Always label the dish appropriately and validate the label when the embryo is transferred either to a new device or to the patient.

PRECAUTIONS:

Federal law restricts this device to sale by or on the order of a physician or a practitioner trained in its use.

Do not use the rinsing wells for incubating embryos as no images are acquired from these wells.

The reservoir and rinsing wells MUST always be covered by a confluent oil layer of 1.6 ml of IVF-grade oil. This prevents the medium from evaporating during incubation.

Evaporation of the medium can change osmolality, which may affect embryo development.

Always place the dish in a sterile laminar flow hood while loading it. Take care while loading and handling the dish to reduce the risk of spilling any oil or medium.

If ANY oil or medium is accidentally spilled from the dish while it is loaded or handled, the embryos MUST be transferred to a new dish to prevent them from being adversely affected by the spillage.

In case any oil is spilled on the dish outside of the reservoir, gently wipe off the oil by using a lint-free tissue paper. If any oil is present on the lid, the lid must be replaced.

If any bubbles are present in the well or oil layer after preparation, they may block the camera light and compromise image quality. In rare cases, bubbles may dislodge the embryo from the bottom of the microwell.

Any bubbles must be removed carefully and relatively quickly to avoid evaporation of medium.

Take care not to remove any medium when removing the bubbles.













Preparing the dish

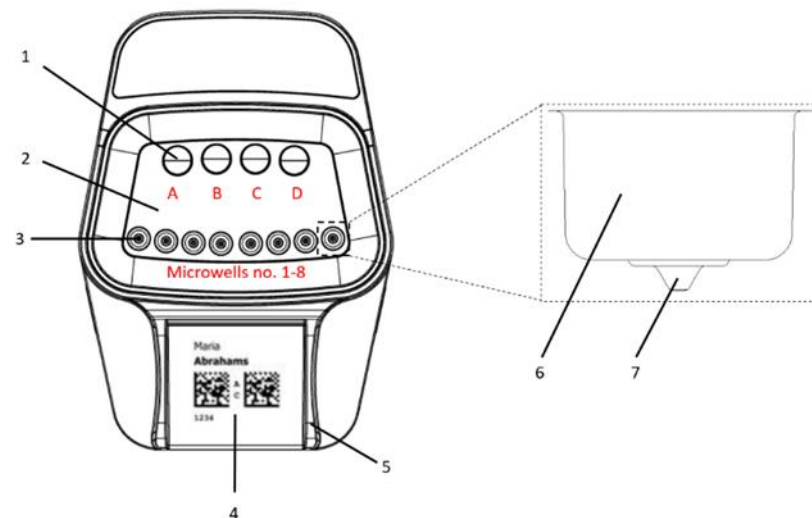
Prepare one dish at a time to minimize handling time. Work on a non-heated workbench and use cold medium and oil.

1. Remove the dish from the pouch in a sterile laminar flow hood.
2. Fill all microwells with medium using a micropipette (max. diameter: 200 µm). One filling of the tip will suffice to completely fill all microwells. The tip of the pipette must touch the side of the microwell during filling. Slightly overfill each microwell.
3. Use a standard pipette to immediately fill an additional 20 µl of medium into each well (160 µl in total to fill all eight wells).
4. Fill each rinsing well with max. 30 µl and min. 25 µl of medium.
5. Load 1.6 ml of oil certified for IVF into the reservoir. Make sure that all culture wells and rinsing wells are covered with a confluent oil layer. Add an additional amount of oil for each well or reservoir not filled with medium.
6. Push up any large bubbles with a micropipette and then remove them.
7. Cover the dish with the lid and equilibrate it overnight.
8. Identify and remove any bubbles under a stereo microscope.
9. Place the barcode label on the dedicated label tab on the dish. The barcode must be placed so that it is possible to read the text on the label when the dish is correctly inserted into the incubator. Make sure that the label is smoothed out as best as possible to avoid

wrinkles in the paper. If the barcode is in any way damaged or not smoothly applied, the label can not be read. In this case, print a new label from the EmbryoViewer software.

10. Load embryos into the center of the microwells using a micropipette.
11. Place the dish in the EmbryoScope+ incubator. See the EmbryoScope+ user manual for information on how to use the dish with the EmbryoScope+ incubator.

Symbol	Title	Description
	Catalog number ISO 15223-1:2016 5.1.6	Indicates the manufacturer's catalog number so that the medical device can be identified.
	Batch code ISO 15223-1:2016 5.1.5	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Use by date ISO 15223-1:2016 5.1.4	Indicates the date after which the medical device is not to be used.
	Do not re-use ISO 15223-1:2016 5.4.2	Indicates a medical device that is intended for one use or for use on a single patient during a single procedure.
	Do not use if packaging is damaged ISO 15223-1:2016 5.2.8	Indicates a device that should not be used if the package has been damaged or opened.
	Sterilized using irradiation ISO 15223-1:2016 5.2.4	Indicates a medical device that has been sterilized using irradiation.
	Consult the instructions for use ISO 15223-1:2016 5.4.3	Indicates the need for the user to consult the instructions for use.
	Temperature limit ISO 15223-1:2016 5.3.7	Indicates the temperature limits to which the medical device can be safely exposed.
	Manufacturer ISO 15223-1:2016 5.1.1	Indicates the medical device manufacturer.
	Date of manufacture ISO 15223-1:2016 5.1.3	Indicates the date when the medical device was manufactured.
	Medical device	Indicates that the device is a medical device.
	Unique device identifier	Indicates a carrier that contains unique device identifier information.



1	2	3	4	5	6	7
Rinsing wells	Oil reservoir	Culture wells	Barcode label tab	Handling fins	Well	Microwell

Technical support

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