# **Vitrolife Labware**

For improved embryo culture conditions









## Challenges with plastic disposables

# Optimisation of the embryo culture system

The ability to culture viable embryos involves more than simply using appropriate culture media. There are many variables that can have an impact on the outcome of an IVF cycle, all of which need to be taken into account in order to optimise pregnancy rates<sup>1, 2</sup>. This is particularly critical during treatment of infertility since gametes and embryos are extremely sensitive. Precautions have to be taken at every step to prevent toxic or harmful components from entering the culture system.



### Plastic disposables and reprotoxicity

Plastic disposables are used throughout the IVF process, from oocyte aspiration to embryo transfer. However only a small percentage of the contact supplies and tissue cultureware used in IVF is suitably tested.

When plastic disposables are insufficiently quality controlled, they can contain components that are toxic to human reproductive cells such as gametes and embryos. This phenomenon can be referred to as reprotoxicity and is defined as a negative influence on the physiology and viability of human gametes and embryos. Reprotoxicity can result in reduced gamete and embryo viability with a subsequent reduction in implantation rate or ongoing pregnancy rates<sup>3</sup>.

### The importance of quality tested disposables

It has been reported that not all disposables on the market used for IVF fulfill the quality standard needed for safe procedures. Approximately 25% of all contact materials failed pre-screening with an accurate and sensitive Mouse Embryo Assay (MEA) and were

## Factors affecting gamete and embryo quality

Above are examples of components of a culture system that come into direct contact with gametes and embryos. No chain is stronger than the weakest link. In order to optimise the efficacy of a culture system, all components involved must be considered and controlled.

#### Definition

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Negative influence of components on the physiology and viability of human gametes and embryos

#### **Manifestations of reprotoxicity**

- Reduced fertilisation rate
- Impaired embryo development
- Reduced embryo implantation rate
- Reduced on-going pregnancy rates

#### How to discover reprotoxicity

- Mouse Embryo Assay
- Human Sperm Survival Assay

considered sub-optimal for IVF<sup>4</sup>. In a published study, Nijs et al. showed that several of the products used for gamete and embryo related procedures were reprotoxic; such as lids of sperm containers, dishes and Pasteur pipettes<sup>3</sup>. These findings are in accordance with data obtained by Vitrolife during quality testing of plastic disposables such as culture dishes, test tubes and pipettes. During the extensive quality control testing program at Vitrolife, it was revealed that approximately 20-25% of the contact materials used during a three year period (2008-2010) failed pre-screening with the MEA<sup>5</sup>.

#### How often do contact materials fail the MEA? 4,5

Plastics	1 in 4
Oil raw material	3 in 5
Chemicals	1 in 4
Transfer Catheters	1 out of 5

## Reprotoxicity can be minimised

Reprotoxicity can be minimized by exclusively using media and contact supplies that have been accurately tested with sensitive bioassays. The Mouse Embryo Assay (MEA) and Human Sperm Survival Assay (HSSA) have been reported to be effective in detecting sub-optimal and toxic conditions for IVF. However, it is important to highlight that the conditions of these assays have a profound effect on the outcome<sup>1, 6</sup>. These assays can be used to great effectiveness provided they are performed under conditions that maximise sensitivity.

# Vitrolife MEA can detect sub-optimal conditions

Vitrolife has developed the most sensitive MEA protocols. These assays are capable of detecting toxic and sub-optimal raw materials, media, and contact materials. The MEA from Vitrolife is sensitive enough to identify subtle problems that will also lead to impaired human embryo development.

Many steps have been taken by Vitrolife to maximise the sensitivity of the MEA. By assessing embryos at multiple time points during the preimplantation period (rather than simply determining blastocyst formation), together with key parameters such as blastocyst cell number, it is possible to identify the sub-optimal components of a plastic disposable<sup>6</sup>. Blastocyst development by itself is a poor indicator of embryo quality and does not reflect developmental potential. A more sensitive and quantitative parameter is blastocyst cell numbers<sup>7</sup>. Furthermore, a specially designed protein-free test medium has been developed with a more sensitive MEA in mind. To increase the sensitivity of the MEA, this medium does not contain amino acids, EDTA, vitamins or hyaluronan.

Vitrolife's approach on MEA is to use sequential assessment of embryos similar to that used to score embryos in human IVF. Using this approach, discrete time points are selected and embryos are assessed using multiple end-points of development.

#### The Mouse Embryo Assay performed on Vitrolife Labware

#### 1-cell MEA only

Embryos are most sensitive at the 1-cell stage. Using this starting point for the MEA makes the assay more sensitive.

#### Multiple end-points for assessment of embryo development

Discrete time points are selected for assessment and embryos are assessed using multiple end-points of development.

#### Blastocyst cell number on all MEAs

Determining cell number of blastocysts in the MEA is indicative of embryo viability.

### Specifically designed test medium

Specially designed protein-free test medium is used with a more sensitive MEA in mind. Albumin can chelate potential reprotoxic components. The presence of proteins would therefore hide the possible presence of toxins.

### Extensive product sampling and testing

Each LOT of raw material and final products is tested with a highly sensitive MEA to ensure high LOT-to-LOT consistency. Extensive sampling of each LOT is performed to ensure minimal variation within each LOT.

### Thorough exposure procedures

To ensure thorough MEA testing each product undergoes an exposure protocol that reflects its intended use.

### Strict acceptance and release criteria

Each raw material and final product shall pass, at every time point, the defined specifications for each stage. The raw material or final product is only released once all results comply with the defined specifications.

## Complete labware assortment dedicated for use in IVF

### Safe, efficient, and certified

Our focus on IVF techniques is based on experience and dedication. For more than 25 years Vitrolife has been an active partner in the development of products for the IVF community.

Vitrolife Labware has been developed in close collaboration with IVF clinics with the aim of simplifying and improving daily work in the lab. Each product is designed for a specific task and is manufactured from certified materials.

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Our labware improves the chances of success throughout the IVF procedure. The products offer a secure environment for your gametes and embryos to achieve the best possible results.





#### **Pure control**

As with all products from Vitrolife, our new range of labware is extensively tested and ready-to-use.

We have strict selection criteria. Only the very purest raw materials that pass the sensitive MEA are selected for production.

Multiple QC tests are performed both during the production process and on the final products. All finished products are MEA tested, using multiple endpoints, including 1-cell, expanded blastocyst ≥ 80% and cell count.

Products for handling semen are also tested using a Human Sperm Survival Assay (HSSA). Motility of control ≥ 80%.

#### Safe environment from aspiration to transfer

Vitrolife Labware gives you the possibility to use a high quality, extensively tested environment for your gametes and embryos through all the steps of an IVF procedure.

### **Designed for you**

Vitrolife Labware is designed to support you throughout the IVF workflow with products developed for each procedure. The improved design makes your way of working efficient and more reliable.

# Meeting regulatory requirements

The complete product line of Vitrolife Labware is CE-marked exclusively for IVF, which means that they are tested for and compliant for use in IVF procedures.

## Specialised dishes for IVF







# Temperature consistency

The absolute flat bottom, enables full contact with the heated stage. All dishes receive the same bottom temperature when placed on a heated stage.

# ID

### Labelling area

To secure patient identification, dishes have a dedicated area for labels or barcodes, separated from the handling area.



### α-numeric identification

The  $\alpha$ -numeric identification secures and facilitates embryo identification, both when viewed in and outside of the microscope. *Micro-droplet culture dish and ICSI dish.* 



Our dishes are specifically designed to support and facilitate the various procedures during the IVF process to make your way of working easier and more effective. Vitrolife dishes are manufactured with quality controlled and certified materials. The finished products are further tested to offer a secure environment for gametes and embryos.





### **Tapered edges**

 $\checkmark$ 

Tapered edges provide easier access to embryos as they are also clearly visible at the periphery of the well. *All dishes except ICSI dish*.

#### **Protective grid**

The protective grid between the micro-wells prevents mixing of droplets. *Micro-droplet culture dish.* 

### **Security ledge**

The culture dish has a security ledge on the rim to reduce the risk of overflow. *Culture dish 40 mm*.

### **Dishes enabling control**



# Temperature consistency between dishes

Embryos in culture are very sensitive to temperature fluctuations, therefore consistent temperature ensures embryo viability. This can be accomplished with Vitrolife Labware. All square dishes have an absolute flat bottom. When placed on a heated stage, all dishes receive the same bottom temperature. The picture shows four products from Vitrolife Labware on a heated stage calibrated to 37°C. Once you have calibrated the temperature of your heated stage you can feel confident that all dishes will have the same temperature.

# Labelling area secures patient identification

To secure patient identification, dishes have a dedicated area for labels or barcodes for convenient and safe ID-management. The label area is away from the handling area.





### **Convenient handling**

The square dishes are designed with an easy grip-feature, which enables stacking and makes for easy handling and optimised storage space. The format of the dishes also makes it possible to fully take advantage of microscopes with X/Y stages.

### **Dishes for every procedure**



## Micro-droplet culture dish

This unique innovation takes culture in micro-droplets to a higher level. The dish is equipped with 12 micro-wells optimised for  $25-35 \ \mu L$  droplets.



#### **5 Well culture dish**

The 5-well dish ensures embryo viability, as each well is surrounded by either air or media, resulting in a homogenous temperature.



#### **Centre well dish**

The centre well dish is a multipurpose dish for fertilisation, cryo-procedures, embryo culture and embryo transfer. The oval centre well allows for easy instrument access from the sides. The small diameter of the bottom facilitates easy embryo location.



#### **ICSI dish**

The square format and low profile ICSI dish allows for easy instrument access.



#### Culture dish 40 mm

Like the other dishes intended for culture, this dish has tapered edges. The ramp makes for easier access to embryos as they are clearly visible when at the periphery of the well. The dish has a security ledge.

#### Guaranteed embryo and gamete safe

- Sterility assurance level (irradiation) 10<sup>-6</sup>
- Less than 0.25 endotoxin units/device
- CE-marked for IVF
- MEA using multiple endpoints, including 1-cell, expanded blastocyst within 96h ≥ 80% and cell count

## Embryo safe tubes & pipettes



#### **MEA-tested**

Multiple endpoints, including 1-cell, expanded blastocyst within 96h  $\geq$  80% and cell count. All products.

### **Two-position cap**

Atrolife

45ml

40

35

30

25

20

15

10

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The collection tubes have a two-position cap to enable venting.



#### **HSSA-tested**

Motility of control  $\ge$  80%. Products for sperm handling.



Vitrolife Labware includes a wide variety of high-quality tubes and pipettes in different sizes to suit your needs. Our labware is certified and quality tested at all stages of manufacture from the raw materials to the finished product to secure the right conditions for gametes and embryos.

#### Guaranteed embryo and gamete safe

- Sterility assurance level (irradiation) 10<sup>-6</sup>
- Less than 0.25 endotoxin units/device
- CE-marked for IVF
- MEA using multiple endpoints, including 1-cell, expanded blastocyst within 96h ≥ 80% and cell count.
- Motility of control ≥ 80%\*.

# Pasteur and serological pipettes

0 10 ml × 0.1 Vitrolife A

Our plastic pasteur and serological pipettes meet the safety required for IVF tasks, so you no longer need to wash and sterilise glass pipettes.

# **Working together**

The Vitrolife media is designed to meet the embryo's needs and to protect its development in vitro. Using the our media together with the non-toxic environment of Vitrolife Labware will further protect the embryo and its development.



## Dishes

Dishes specifically designed for IVF to make your work easier and more effective. For a certified, quality tested and safe environment for gametes and embryos.

Product	REF	Description
Culture dish 40 mm	16001	For oocyte pickup, fertilisation and culture
Micro-droplet culture dish	16003	For embryo culture
5 Well culture dish	16004	For denudation before ICSI, culture and cryo procedures
Centre well dish	16005	For fertilisation, culture, cryo procedures and transfer
ICSI dish	16006	For ICSI
Culture dish 60 mm	16002	For oocyte pickup, fertilisation and culture
Collection dish 90 mm	16007	For oocyte pickup













Culture dish 40 mm





Culture dish 60 mm

Collection dish 90 mm

### Product information

### **Temperature management**

For accurate, easy and consistent temperature measurements of media during operations outside the incubator.

Product	REF	Description
VitroTemp™	16210	Digital readout instrument and probe kit (5 Well + 40 mm)
VitroTemp <sup>™</sup> probe kit	16211	Separate probe kit (5 Well + 40 mm dishes with built-in sensor)



VitroTemp™

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VitroTemp<sup>™</sup> probe kit

### **Tubes**

A wide range of high quality tubes meeting the requirements of IVF. For a certified, quality tested and safe environment for gametes.

Product	REF	Cap type	Base shape	Material	Recommended max RCF x g
Oocyte collection tube 14 mL	16101	Two position cap (PE)	Round	PS	n/a
Centrifuge tube 15 mL	16105	Screw cap (PE)	Conical	PP	3800
Centrifuge tube 50 mL	16106	Screw cap (PE)	Conical	PP	9200
Sample tube 5 mL	16103	Two position cap (PE)	Round	PS	n/a
Sperm collection container	16102	Snap lid (PE)	Tapered/flat	PP	n/a

PP = Polypropylene, PS = Polystyrene, PE = Polyethylene











Sample tube 5 mL

Sperm collection container

Oocyte collection tube 14 mL

Centrifuge tube 15 mL

Centrifuge tube 50 mL

## **Pipettes**

High-quality pasteur and serological pipettes meeting the requirements of IVF. For a certified, quality tested and safe environment for gametes and embryos.

Product	REF	Material	Negative graduations [mL]
Pasteur pipette 1 mL	16201	PE	n/a
Pasteur pipette 3 mL	16202	PE	n/a
Serological pipette 1 mL	16203	PS, plugged	-0.2
Serological pipette 2 mL	16204	PS, plugged	-0.3
Serological pipette 5 mL	16205	PS, plugged	-2.0
Serological pipette 10 mL	16206	PS, plugged	-3.0

PS = Polystyrene, PE = Polyethylene





Pasteur pipette 3 mL





Serological pipette 1 mL

Serological pipette 2 mL

Serological pipette 5 mL



Serological pipette 10 mL

#### Orders & customer support

Contact your local sales representative for prices and availability. Orders can be placed through our website at www.vitrolife.com. You can also contact us by email and phone:

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NOTE. All products shown in this brochure might not be available on all markets.

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PATENT NUMBERS Culture Dish 40 mm REF 16001, Micro-droplet Culture Dish REF 16003, 5 Well Culture Dish REF 16004, Centre Well Dish REF 16005, ICSI Dish REF 16006, Container for culturing US-2020-0248115-A1, EP262989 and US10,550,359 approved. US16/717,124 pending, other patent applications pending.

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