

VITROLIFE LABWARE

For improved embryo culture conditions.

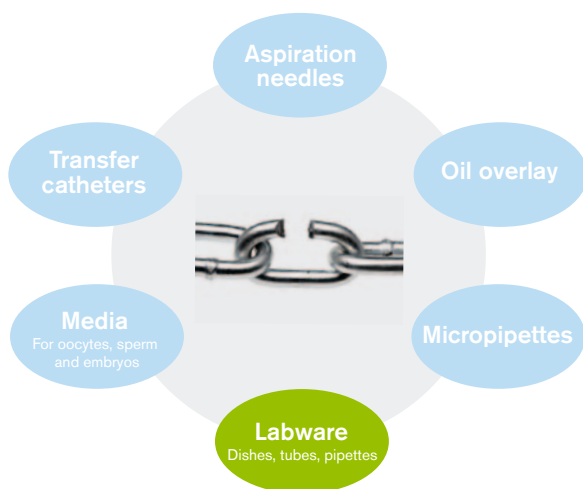


Vitrolife 

CHALLENGES WITH PLASTIC DISPOSABLES

Optimization 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 optimize pregnancy rates^{1,2}. 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.



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 optimize the efficacy of a culture system, all components involved must be considered and controlled.

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 rates³.

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

REPROTOXICITY

Definition

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

Manifestations of reprotoxicity

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

How to discover reprotoxicity

- Mouse Embryo Assay
- Sperm Survival Assay

materials failed pre-screening with an accurate and sensitive Mouse Embryo Assay (MEA) and were considered sub-optimal for IVF⁴. 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 pipettes³. 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 MEA⁵.

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 minimized

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^{1, 6}. These assays can be used to great effectiveness provided they are performed under conditions that maximize 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 maximize 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 disposable⁶. 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 numbers⁷. 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 are 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

Each product is thoroughly exposed during MEA, based on its intended use, to ensure accurate and sensitive testing.

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.

INTRODUCING A NEW STANDARD



Labware created and
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.

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 tested using a MEA using multiple endpoints, including 1-cell, expanded blastocysts $\geq 80\%$ and cell count.

Products for handling semen are also tested using a Human Sperm Survival Assay (HSSA). Motility $\geq 70\%$.

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.

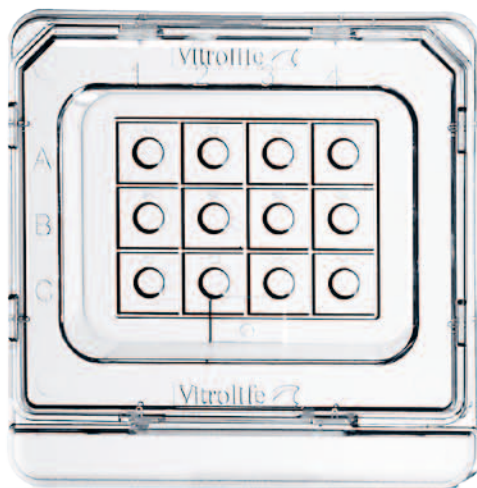
Designed for you

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.

SPECIALIZED 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.



Labelling area

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



α -numeric identification

The α -numeric identification secures and facilitates embryo identification, both when viewed in and outside of the microscope. *Micro-droplet 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

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

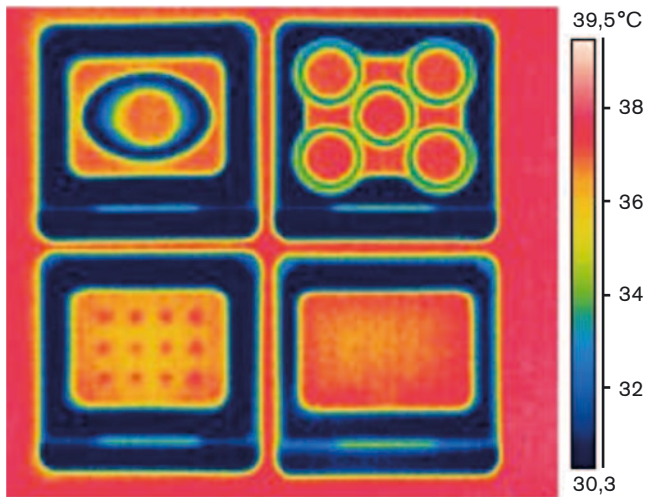
The protective grid between the micro-wells prevents mixing of droplets. *Micro-droplet dish.*



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

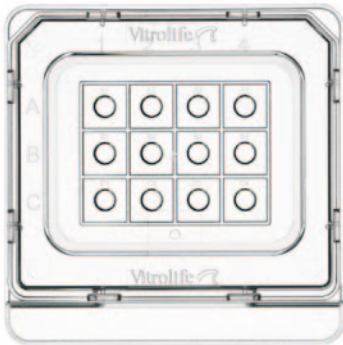
To secure patient identification, dishes have a dedicated area for labels or barcodes for convenient and safe ID-management. The label area is away from the handling area.



Convenient handling

The square dishes are designed with an easy grip-feature, which enables stacking and makes for easy handling and optimized 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 optimized for 25-35 μ 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 multi-purpose dish for fertilization, 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^{-6}
- USP Class VI tested polystyrene
- Non-pyrogenic at less than 0.25 endotoxin units/mL
- Quality standard – Medical Device EU Class IIa
- MEA using multiple endpoints, including 1-cell, expanded blastocysts on day 5 $\geq 80\%$ and cell count

EMBRYO SAFE TUBES & PIPETTES



MEA-tested

Multiple endpoints, including 1-cell, expanded blastocysts on day 5 $\geq 80\%$ and cell count. *All products.*



HSSA-tested

Motility $\geq 70\%$. *Products for sperm handling.*



Two-position cap

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



Vitrolife Labware includes a wide variety of high-quality tubes and pipettes in different sizes to suit your needs. The assortment includes collection, centrifuge and sample tubes. 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^{-6}
- USP Class VI tested polystyrene/polypropylene/polyethylene
- Non-pyrogenic at less than 0.25 endotoxin units/mL
- Quality standard – Medical Device EU Class IIa, Canada CMD/CAS, Australia TGV
- MEA using multiple endpoints, including 1-cell, expanded blastocysts on day 5 $\geq 80\%$ and cell count.
- HSSA $\geq 70\%^*$

** On products intended for use with semen.*

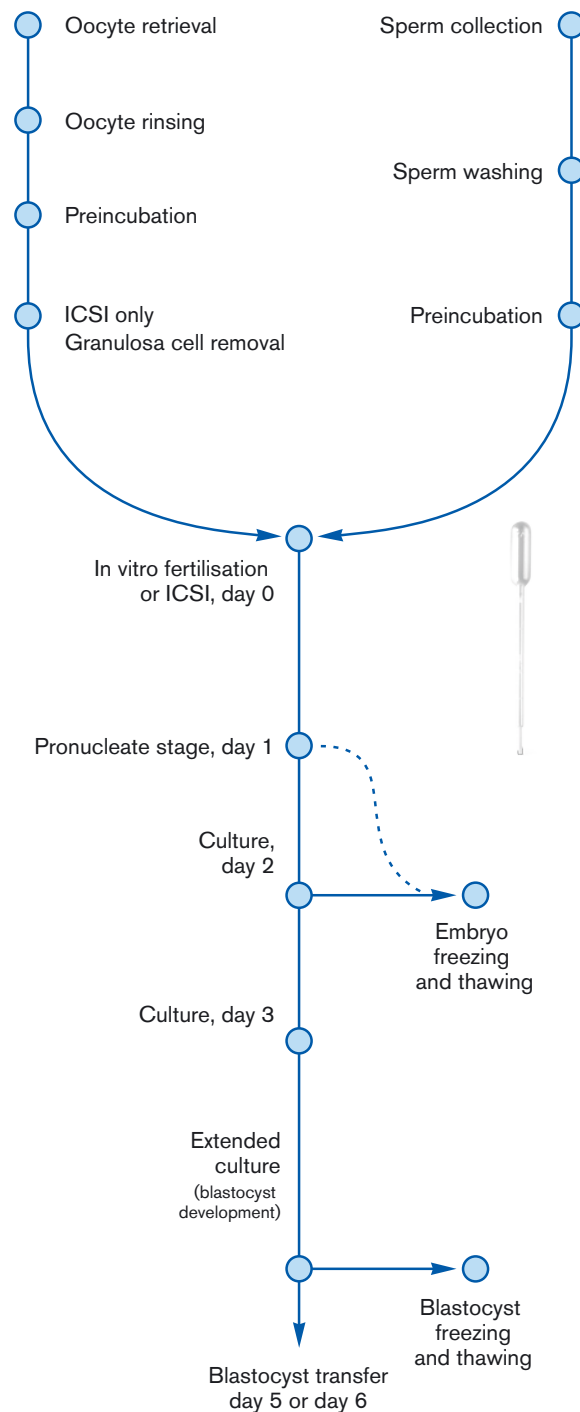
Plastic Pasteur pipettes

Our plastic Pasteur pipettes have the safety and precision required for IVF tasks, so you no longer need to wash and sterilize glass Pasteur pipettes.

WORKING TOGETHER

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

The G-Series™



Vitrolife Labware



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.

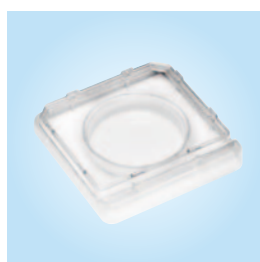
Features

- MEA-tested
- Sterile, non-cytotoxic, non-pyrogenic
- CE-marked for IVF
- Optimal heat transfer: totally flat bottom with 100% full contact on every individual dish and on every type of dish. (See thermal image on page 8)
- Secure patient and embryo identification
- Easy-grip for convenient handling
- Easy stacking
- Ramped edges in wells (culture dishes)
- Adapted to X/Y stage microscopes (squared dishes)

Sterility and testing

- Sterility assurance level (irradiation) 10^{-6}
- USP Class VI tested polystyrene
- Non-pyrogenic at less than 0.25 endotoxin units/mL
- Quality standard – Medical Device EU Class IIa, Canada CMD/CAS, Australia TGV
- MEA using multiple endpoints, including 1-cell, expanded blastocysts on day 5 $\geq 80\%$ and cell count.

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



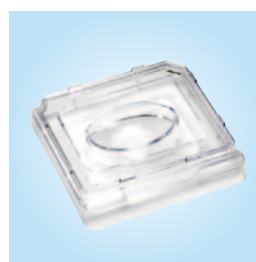
Culture dish 40 mm



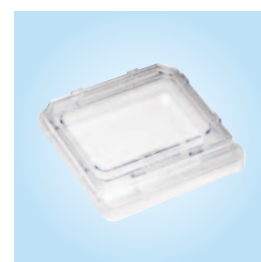
Micro-droplet Culture dish



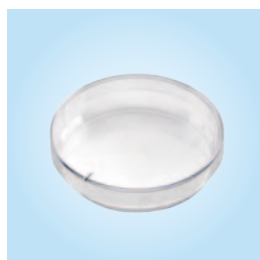
5-well Culture dish



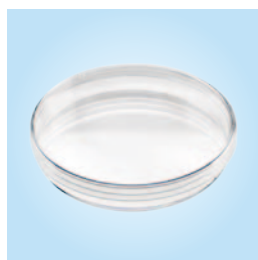
Centre Well dish



ICSI dish



Culture dish 60 mm



Collection dish 90 mm

TUBES

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

Features

- MEA-tested
- HSSA-tested tubes for sperm including all lids
- Sterile, non-cytotoxic, non-pyrogenic
- CE-marked for IVF
- Tubes with two-position caps:
 - Leave loose for gas exchange
 - Push down for tight seal
- Wide range

Sterility and testing

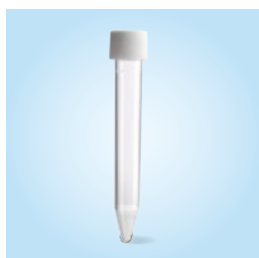
- Sterility assurance level (irradiation) 10^{-6}
- USP Class VI tested polystyrene/polypropylene/polyethylene
- Non-pyrogenic at less than 0.25 endotoxin units/mL
- Quality standard – Medical Device EU Class IIa, Canada CMD/CAS, Australia TGV
- MEA using multiple endpoints, including 1-cell, expanded blastocysts on day 5 $\geq 80\%$ and cell count.
- HSSA $\geq 70\%$ *

Product	Cap type	Base shape	Material	Recommended max RCF x g	REF
Oocyte collection tube 14 mL	Two position cap (PE)	Round	PS	n/a	16101
Centrifuge tube 13.5 mL	Screw cap (PE)	Conical	PS	3200	16104
Centrifuge tube 15 mL	Screw cap (PE)	Conical	PP	3800	16105
Centrifuge tube 50 mL	Screw cap (PE)	Conical	PP	9200	16106

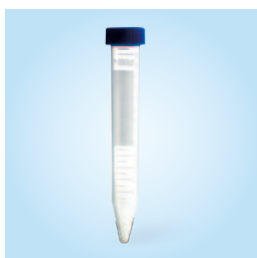
PP = Polypropylene (USP Class VI), PS = Polystyrene (USP Class VI), PE = Polyethylene (USP Class VI)



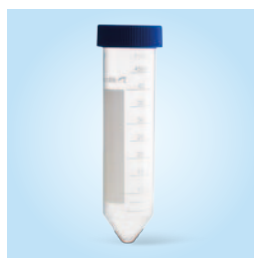
Oocyte collection tube 14 mL



Centrifuge tube 13.5 mL



Centrifuge tube 15 mL



Centrifuge tube 50 mL

*Not applicable for the oocyte collection tube, REF 16101

PIPETTES

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

Features

- MEA-tested
- Sterile, non-cytotoxic, non-pyrogenic
- CE-marked for IVF
- Colour coded
- Easy-to-read
- Negative graduations
- Reverse graduations

Sterility and testing

- Sterility assurance level (irradiation) 10^{-6}
- USP Class VI tested polystyrene/polyethylene
- Non-pyrogenic at less than 0.01 endotoxin units/mL
- Quality standard – Medical Device EU Class IIa, Canada CMD/CAS, Australia TGV
- MEA using multiple endpoints, including 1-cell, expanded blastocysts on day 5 $\geq 80\%$ and cell count.

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

PS = Polystyrene (USP Class VI), PE = Polyethylene (USP Class VI)



Pasteur pipette 1 mL



Pasteur pipette 3 mL



Serological pipette 1 mL



Serological pipette 2 mL



Serological pipette 5 mL



Serological pipette 10 mL

TOGETHER. ALL THE WAY™

For inquiries or to know more about Vitrolife Labware,
please contact your local sales representative.
Contact information is also available on our web site.

ORDERS & CUSTOMER SUPPORT

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REFERENCES 1. Gardner DK and Lane M (2007). Embryo culture systems. In *Vitro Fertilization A Practical Approach*. Ed. DK Gardner. Informa Healthcare, New York. pp 221-282. 2. Gardner DK (2008). Dissection of culture media for embryos: the most important and less important components and characteristics. *Reprod. Fertil. Dev.* 20, 9-18. 3. Nijs et al. (2009) *Fertil Steril.* Aug; 92(2): 527-535. 4. Gardner DK (2007). Human embryonic development in vitro. In *Human IVF*. Ed. SL Tan. Taylor & Francis, New York. pp 295-312. 5. Vitrolife (data on file). 6. Gardner et al. (2005). Quality Control in Human In Vitro Fertilization. *Semin. Reprod. Med.* 23, 319-324. 7. Gardner DK and Lane M (1997). Culture and selection of viable blastocysts: a feasible proposition for human IVF? *Hum. Reprod. Update* 3 367-382.

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PATENT NUMBERS 40 mm Culture Dish REF 16001, Micro-droplet Dish REF 16003, 5-well Culture Dish REF 16004, Centre-well Dish REF 16005, ICSI Dish REF 16006 – US patent number US 61/405,956. Danish/EU PA 2010 70447.