

## **Summary of Safety and Clinical Performance**

## **Vitrification and Thawing Media**

The purpose of this Summary of Safety and Clinical Performance (SSCP) is to offer public access to an updated summary of the main issues concerning the safety and clinical performance of the device. This document does not replace the Instructions of Use (IFU), which is the main document to ensure the safety of the device, and neither is it intended to provide advice on the diagnostic or treatment of particular medical conditions to the intended users.

### 0 Abbreviations

IFU instructions for use

MDR Medical Device Regulation

NB notified body

PMCF post-market clinical follow-up

PMS post-market surveillance

PSUR periodic safety update report

SRN single registration number for an economic operator

SSCP summary of safety and clinical performance

TD technical documentation

UDI-DI Unique Device Identification - device identifier

ART Assisted Reproductive Technology

ESHRE European Society of Human Reproduction and Embryology

**GMP Good Manufacturing Practice** 

MEA Mouse Embryo Assay

ICSI Intra Cytoplasmatic Sperm Injection

IVF In vitro fertilization procedures

ART Assisted Reproductive Technologies

### 1 Device identification and general information

## 1.1 Device trade name(s)

- Kitazato Vitrification and Thawing Media without gentamicin: VT801/VT802.
- Kitazato Vitrification and Thawing Media with gentamicin: VT601/VT602 and VT601N/VT602N.
- Kitazato Vitrification and Thawing Media with gentamicin Individual Solutions: VT601-BS, VT601-ES, VT601-VS, VT601UF, VT601UF-4, VT601UF-ES x 4, VT601UF-VS x 4, VT601UF-ES4x4, VT601UF-VS4x4, VT602-TS, VT602-DS, VT602-WS, VT602UF-TSx4.

## 1.2 Manufacturer's name and address

Kitazato Corporation

Address: 100-10 Yanagishima, Fuji, Shizuoka 416-0932 Japan

Phone: (+81) 545 65 7122 Fax: (+81) 545 65 7128

E-mail: ce\_registration@kitazato.co.jp



## 1.3 Manufacturer's single registration number (SRN)

Kitazato Corporation SRN JP-MF-000018374

### 1.4 Basic UDI-DI

### Kitazato Vitrification and Thawing Media: 458223146VTUN

### 1.5 Medical device nomenclature description/text

Applicable EMDN code: U08020501: Materials/Solutions for Freezing/Thawing For Assisted Reproduction

### 1.6 Class of device

Vitrification and Thawing Media is considered medical devices Class III according to MDR (Regulation (EU) 2017/745) Annex VIII

## 1.7 Year when the first certificate (CE) was issued covering the device

Vitrification and Thawing Media is CE certified since 2013. KITAZATO Vitrification media are CE marked and marketed in EU for 7 years with no safety issue. VT80 obtained CE mark in 2013 and VT60 obtained CE mark in 2019, both media have the same formulation except gentamicin, whose clinical/benefit risk was accepted by MHRA, contained in VT60 media.

### 1.8 Authorized representative; name and the SRN

Biomedical Supply, S.L. (DIBIMED) C/ Jorge Comín, 3 Valencia. 46015. Spain Tel +34 96 305 63 95 Fax +34 96 305 63 96 info@dibimed.com

SRN: SRN ES-AR-000014358

## 1.9 NB's name and single identification number

BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9 1066 EP Amsterdam The Netherlands

NB identification number: 2797

## 2 Intended use of the device

## 2.1 Intended purpose

Vitrification and Thawing Media is used for:

- Vitrification Media: vitrification of oocytes (MII) and embryos
- Thawing Media: thawing vitrified oocytes (MII) and embryos. Including Ultra-Fast Warm.

Ultra-Fast Vitri is intended for the vitrification of MII oocytes.

## 2.2 Indication(s) and intended patient groups

The media are designed to enable vitrification and thawing of oocytes (MII) and embryos.



Direct physical contact occurs between the vitrification and thawing media products and embryos. No direct contact with the uterus mucosal membranes of the patient.

Vitrification and Thawing media are intended to be used by medical specialist trained in fertility treatment (laboratory technicians, embryologists, or medical doctors). Vitrification and Thawing media are used in specialized laboratories performing fertilization techniques, including IVF, ICSI and sperm preparation/ analysis

#### 2.3 Contraindications and/or limitations

• Vitrification/Thawing media VT60X contain the antibiotic gentamicin sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic.

### 3 Device description

## 3.1 Description of the device

Products described in this Summary of Safety and Clinical Performance Report are Vitrification and Thawing media, which are designed to enable:

Vitrification Media: vitrification of oocytes (MII) and embryos

Thawing Media: thawing vitrified oocytes (MII) and embryos

This product is a set of medium to cryopreserve oocytes and embryos for Assisted Reproductive Technologies procedures (hereinafter, ART). This product contains two types, Vitrification Media and Thawing Media – with gentamicin and without gentamicin. Media with gentamicin are also provided with phenol red or without phenol red.

Vitrification media composition includes cryoprotectant agents (CPA) which its gradual addiction allows adequate permeation into oocytes (MII) or embryos to substitute water molecules and create a glassy state with more stable intracellular environment vitrified

Thawing media composition allows rehydration of vitrified oocytes (MII) or embryos with a decrease in CPA concentration preventing osmotic shock and enabling good and safe cell rehydration.

Vitrification and Thawing Media family of products comprises following variants:

### With phenol red:

- VT801/VT802 (without gentamicin)
- VT601/VT602/VT602UF/VT601UF (with gentamicin)

## Without phenol red:

VT601N/VT602N (with gentamicin)

VT601/VT602/VT602UF/VT601UF & VT601N/VT602N with gentamicin does not change anything to the content of the vials and their intended use.

The added gentamicin complies with Ph. Eur. Monograph Standard 0331, is EDQM-certified.

Vitrification and Thawing media are sterilized using aseptic processing techniques (filtration).

The media can be used up to 15 days after bottle opening (when sterile conditions are maintained, and the products are stored at 2-8°C).

## 3.2 A reference to previous generation(s) or variants if such exist, and a description of the

No previous generation of the devices have been brought on the market by Kitazato Corporation.



## 3.3 Description of any accessories which are intended to be used in combination with the device

No accessories for Kitazato Vitrification and Thawing media are identified.

## 3.4 Description of any other devices and products which are intended to be used in combination with the device

No devices and products for Vitrification and Thawing media are identified.

## 4 Risks and warnings

## 4.1 Residual risks and undesirable effects

No known undesirable side-effects are identified.

## 4.2 Warnings and precautions

Besides the above, attention should be paid to the following warnings and precautions (as described in the instructions for use):

Warnings Precautions

- · Read the instructions for use prior to use.
- Use KITAZATO thawing media to thaw the oocytes (MII) or embryos vitrified with KITAZATO vitrification media
- This product is intended to be used by medical specialists trained in fertility treatment.
- · Aseptic technique should be used.
- Use sterilized equipment and materials only.
- In case of eye or skin contact with Vitrification/Thawing media, immediately flush eye/skin with water.
- Morphologically abnormal oocytes, embryos, or significantly poor grade oocytes or embryos are unsuitable for cryopreservation.
- Observe all federal, state, and local environmental regulations when discarding the product.
- In case of contamination, dispose the product appropriately in a prescribed manner.
- The user shall be responsible for any problems caused by incorrect use or not following the present IFU.

- Don't re-sterilize.
- Don't use solution that shows cloudiness or becomes discolored.
- Don't use the product if you notice anything unusual regarding the specifications on the label (number, color, name, volume).
- Device is sterilized if the vial is unopened or undamaged.
- Don't use if the package or container are opened or damaged.
- Upon delivery media must be stored in original unopened container and refrigerated at 2-8 °C.
- Don't use and discard if the media is not stored under refrigeration (2 to 8 °C).
- Don't use the product after expiration date.

Any serious incident (as defined in European Medical Device Regulation, 2017/745) that has occurred should be reported to Kitazato Corporation and, if applicable, the competent authority of the EU Member State in which the user and/or patient is established.

## 4.3 Summary of any field safety corrective action (FSCA including FSN)

No field safety corrective actions with regard to Vitrification and Thawing media were needed.



## 5 Summary of clinical evaluation and post-market clinical follow-up (PMCF)

### 5.1 Summary of clinical data related to similar/equivalent devices

Vitrification and Thawing Media is not equivalent to any device in the market.

## 5.2 Summary of clinical data from literature

According to multiple manuscripts available in the literature, the use of products on the market similar to Vitrification and Thawing Media demonstrates their performance and safety (Section 11 References) Additionally, papers where these devices have been implemented have reported ART outcomes comparable with the ART outcomes published by the European Society of Human Reproduction and Embryology (ESHRE).

Thus, from the literature data it could be concluded that devices with the same intended use than Vitrification and Thawing Media, are not detrimental for fertilization and embryo development, without interfering with the general ART procedure.

## 5.3 Real-world evidence analysis

The Vienna consensus report published in 2017 is the result of a 2-day consensus meeting of expert professionals from Sweden, Turkey, UK, Australia, Italy, Spain, Belgium, Austria, Ireland, Canada, USA, and Norway. As a starting point for the discussion, two surveys were organized to collect information on indicators used in IVF laboratories worldwide. During the meeting, the results of the surveys, scientific evidence (where available), and personal clinical experience were integrated into presentations by experts on specific topics. After presentation, each proposed indicator was discussed until consensus was reached within the panel (ESHRE Special Interest Group of Embryology 2017).

The following minimal competency limits concerning embryological outcomes are reported by the expert group:

Minimal competency limits reported by the ESHRE Special Interest Group of Embryology and Alpha Scientists in Reproductive Medicine in 2017.	ICSI normal fertilization rate:	≥65% (lower range: 55%)
ne Vienna consensus: report of an expert meeting on the evelopment of art laboratory performance indicators (ESHRE pecial Interest Group of Embryology 2017)	IVF normal fertilization rate:	≥60% (lower range: 50%)

Each year, the ESHRE publishes a peer-reviewed report, which collects, analyses and reports ART data generated in Europe. The most recent report includes data from 1197 institutions in 29 countries, with a total of 918.159 treatment cycles (covering the time period from 1 January to 31 December 2016) C. Wyns et al., ART in Europe, 2016: results generated from European registries by ESHRE. Hum Reprod Open. 2020; 2020(3) (Wyns et al. 2020) and is summarized in the table below:

ART in Europe, 2016: results generated from European registries by ESHRE		Intra cytoplasmic sperm injection (ICSI):	Frozen embryo replacement (FER):	Intrauterine insemination(IUI):
A total of 918 159 treatment cycles, involving 156 002 with IVF, 407 222	, ,	Clinical pregnancy rate per aspiration:	Pregnancy rate per thawing:	using husband semen (IUI-H):
with ICSI, 248 407 with frozen embryo replacement (FER), 27 069 with preimplantation genetic testing	28.0% (range: 13.2 -	25% (range: 18.7 - 41.9%)	<b>30.9%</b> (range: 21.4 - 51.9%)	Delivery rate per cycle: 8.9% (range: 0.9 -
(PGT), 73 927 with egg donation (ED), 654 with IVM of oocytes and	Clinical pregnancy	Clinical pregnancy	Pregnancy rate per	24.7%)
4878 with FOR (frozen oocyte replacement) were recorded. European data on IUI using husband	34.8%	rate per transfer: 33.2%	transfer: <b>31.9%</b> (range: 22.5 – 57.6%)	using donor semen (IUI-D):



/ partner's semen (IUI-H) and donor semen (IUI-D) were reported from 1197 institutions offering IUI in 29 countries and 24 countries, respectively. A total of 162 948 treatments with IUI-H and 50 467 treatments with IUI-D were included.	(range: 22.4 - 69.5%)  Delivery rate per aspiration: 20.8% (range: 9.8 - 33.9%)	(range: 25.6 - 70.3%)  Delivery rate per aspiration: 18.5% (range: 12.3 - 46.5%)	Delivery rate per thawing: 22.0% (range: 13.0 - 45.3%)  Delivery rate per transfer: 22.7% (range: 13.0 - 47.6%)	Delivery rate per cycle: <b>12.4%</b> (range: 5.1 - 44.4%)
	Since multiple factors can have an influence on the ART outcomes (ART policy, approach of the clinic, patients characteristics), a value within the range of the ESHRE value is acceptable.			

As there are no alternative treatment options that can be used for oocyte/embryo vitrification/thawing during IVF/ART procedures, all data included in the ESHRE report are generated using Kitazato media or similar device available on the market. Reported outcomes in the benchmark paper can therefore be considered as benchmark data for ART procedures. Nevertheless, when comparing clinical data, one should be aware that:

- ✓ During ART processes, oocytes/embryos come into contact with several (other) ART media and undergo a lot of manipulations that all can have an influence on the reported outcomes.
- ✓ Depending on the patient characteristics, different outcomes can be obtained.

A literature search is performed to investigate whether embryological and/or clinical ART outcomes obtained during literature search are consistent with the embryological competency limits and/or with the clinical ART outcomes described in the benchmark papers from the ESHRE.

There were several papers retrieved in literature studying the performance of Vitrification and Thawing Media or similar devices. It can be concluded from these papers that embryological and clinical ART outcomes, when equivalent Kitazato Vitrification and Thawing Media are used, fall within the range of the outcomes described in the benchmark papers from the ESHRE (Wyns et al. 2020) (ESHRE Special Interest Group of Embryology 2017), suggesting a safe and adequate performance of media.

Papers describing the use of Vitrification and Thawing Media or similar media are listed in Section 11 'References' below.

Clinical data from Kitazato Vitrification and Thawing Media or similar media obtained from real-world evidence are consistent with the outcomes described in this benchmark paper to assess clinical safety and performance as well as benefit-risks of the media.

#### 5.4 Device registries

In addition, clinical data is obtained from IVF centers that use Kitazato Vitrification and Thawing Media. ART outcomes of these clinics are consistent with clinical outcomes described in national public registers of the countries in which the IVF centers are located or with the ART outcomes as described in the benchmark paper from the ESHRE (Wyns et al. 2020). The outcomes can be considered as benchmark data, as these national outcomes are generated with equivalent or a similar device available on the market.

Clinical outcomes from the years 2019 till 2024 of 22 IVF clinics (details are confidential) are included in the clinical evaluation report of Vitrification and Thawing media. It could be concluded that the ART results of these IVF clinics are consistent with clinical outcomes described in the national public registers of the country and/or are consistent with the outcomes reported in the benchmark ESHRE article. This all indicates a good and safe performance of Vitrification and Thawing Media.



### 5.5 An overall summary of the clinical performance and safety

Vitrification and Thawing media should be able to cryopreserve oocytes (MII) and embryos in a non-toxic and pathogen-free environment. As oocytes and embryos are highly sensitive to minimum changes in their medium, the outcome of ART procedures will be inevitably affected by presence of water inside the cells which leads to cell destruction during cryopreservation. Thus, Vitrification and Thawing media provide an optimal condition allowing convenient exchange between water and CPAs and preserving an intact cell membrane which will end up in not being detrimental for fertilization and embryo development.

According to the information from the clinical evaluation report, it can be concluded that Vitrification and Thawing media functions as stated by the manufacturer. Vitrification and Thawing media can be safely and effectively used for cryopreservation of oocytes and embryos without leading to a detrimental effect on ART outcomes. Furthermore, also the literature search of similar devices on the market with the same intended use, and data collected from IVF Clinics demonstrate the performance and safety of Vitrification and Thawing media are consistent with competency limits reported by ESHRE (Wyns et al. 2020).

Moreover, no infrequent complications or problems were detected.

### 5.6 Ongoing or planned post-market clinical follow-up

On a yearly basis, Kitazato Corporation will perform literature search for Vitrification and Thawing Media as well as for gentamicin antibiotic added. Additionally, clinical data retrieved from IVF centers using Vitrification and Thawing Media will be evaluated.

This Summary of Safety and Clinical Performance will be refreshed with data from the post-market clinical follow-up, if this is required to guarantee that any clinical and/ or safety information described in this summary stays right and complete.

## 6 Possible diagnostic or therapeutic alternatives

Multiple articles available in the literature demonstrate comparable results among the different media on the market with the same intended use of Vitrification and Thawing Media, reporting ART outcomes comparable with the ART outcomes published by the European Society of Human Reproduction and Embryology (ESHRE).

### 7 Suggested profile and training for users

Vitrification and Thawing Media are used in specialized laboratories performing fertilization techniques, including IVF, ICSI and sperm preparation/analysis. The intended users are medical specialists trained in fertility treatment (lab technicians, embryologists, or medical doctors).

# 8 Reference to any applicable common specification(s), harmonized standard(s) or applicable guidance document(s)

The following guidance document was used:

MDCG 2019-09: Summary of safety and clinical performance. A guide for manufacturers and notified bodies (August 2019, full applicable).

EN ISO 13408-1:2015. Aseptic processing of health care products – Part 1: general requirements (full applicable)



EN ISO 13408-2:2018 Aseptic processing of health care products – Part 2: Filtration (full applicable)

### 9 Revision history

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
1	2022/06/21	Initial version	Date: not yet Validation language: English
2	2023/11/16	Update as per BSI review	Date: not yet Validation language: English
3	2023/12/12	Update to include new vial pack variants	Date: 02/02/2024 Validation language: English
4	2024/04/17	Updated device registries and product references	Date: 18/06/2024 Validation language: English
5	2024/09/20	Updated device registries and product references	Date: not yet Validation language: English
6	2025/01/24	Updated intended use	This version has been validated by the Notified Body. Date: 17/02/2025 Validation language: English

## 10 Summary of the safety and clinical performance for patients

As the device is for professional use only, a summary of the safety and clinical performance of the device intended for patients is not applicable.

### 11 References

- Sheikhi O, Golsorkhtabaramiri M, Esmaeilzadeh S, Mahouti T, Heidari FN. (2018). Reproductive outcomes of vitrified blastocyst transfer in modified natural cycle versus mild hormonally stimulated and artificial protocols: A randomized control trial. JBRA Assist Reprod. Sep 1;22(3):221-227. https://doi.org/10.5935/1518-0557.20180040
- 2. Parmegiani L, Beilby KH, Arnone A, Bernardi S, Maccarini AM, Nardi E, Cognigni GE, Filicori M. (2018). Testing the efficacy and efficiency of a single "universal warming protocol" for vitrified human embryos: prospective randomized controlled trial and retrospective longitudinal cohort study. J Assist Reprod Genet.35(10):1887-1895. https://doi.org/10.1007/s10815-018-1276-4
- 3. Montjean D, Pauly V, Gervoise-Boyer M, Amar-Hoffet A, Geoffroy-Siraudin C, Boyer P. (2019). Is it worth it to cryopreserve embryos with blastulation delay at day 5? Zygote. 27(4):219-224. https://doi.org/10.1017/s0967199419000157
- 4. Diaz-Garcia C, Domingo J, Garcia-Velasco JA, Herraiz S, Mirabet V, Iniesta I, Cobo A, Remohí J, Pellicer A. (2018). Oocyte vitrification versus ovarian cortex transplantation in fertility preservation for adult women undergoing gonadotoxic treatments: a prospective cohort study. Fertil Steril, 109(3):478-485. https://doi.org/10.1016/j.fertnstert.2017.11.018
- Cobo A, García-Velasco J, Domingo J, Pellicer A, Remohí J. (2018). Elective and Onco-fertility preservation: factors related to IVF outcomes. Hum Reprod.33(12):2222-2231. https://doi.org/10.1093/humrep/dey321



- Kontopoulos G, Simopoulou M, Zervomanolakis I, Prokopakis T, Dimitropoulos K, Dedoulis E, Grigorakis S, Agapitou K, Nikitos E, Rapani A, Vlahos N. (2019). Cleavage Stage versus Blastocyst Stage Embryo Transfer in Oocyte Donation Cycles. Medicina (Kaunas). 55(6):293. https://doi.org/10.3390/medicina55060293
- 7. Cimadomo D, Capalbo A, Levi-Setti PE, Soscia D, Orlando G, Albani E, Parini V, Stoppa M, Dovere L, Tacconi L, Ievoli E, Maggiulli R, Ubaldi FM, Rienzi L. (2018). Associations of blastocyst features, trophectoderm biopsy and other laboratory practice with post-warming behavior and implantation. Hum Reprod. 33(11):1992-2001. https://doi.org/10.1093/humrep/dey291
- 8. An G, Zou Z, Flannigan R, Liu J, Du H, Fu X, Guo F, Zhang W. (2018). Outcome of Oocyte Vitrification Combined with Microdissection Testicular Sperm Extraction and Aspiration for Assisted Reproduction in Men. Med Sci Monit. 24:1379-1386. https://doi.org/10.12659/msm.909026
- Kuroda K, Ezoe K, Kato K, Yabuuchi A, Segawa T, Kobayashi T, Ochiai A, Katoh N, Takeda S. (2018). Infertility treatment strategy involving combined freeze-all embryos and single vitrified-warmed embryo transfer during hormonal replacement cycle for in vitro fertilization of women with hypogonadotropic hypogonadism. J Obstet Gynaecol Res. 44(5):922-928. https://doi.org/10.1111/jog.13597
- 10.Ozgur K, Bulut H, Berkkanoglu M, Humaidan P, Coetzee K. (2018). Frozen embryo transfer can be performed in the cycle immediately following the freeze-all cycle. J Assist Reprod Genet. 35(1):135-142. https://doi.org/10.1007/s10815-017-1048-6
- 11.Bodri D, Nair S, Gill A, Lamanna G, Rahmati M, Arian-Schad M, Smith V, Linara E, Wang J, Macklon N, Ahuja KK. (2018). Shared motherhood IVF: high delivery rates in a large study of treatments for lesbian couples using partner-donated eggs. Reprod Biomed Online. 36(2):130-136. https://doi.org/10.1016/j.rbmo.2017.11.006
- 12. Seshadri S, Saab W, Exeter H, Drew E, Petrie A, Davies M, Serhal P. (2018). Clinical outcomes of a vitrified donor oocyte programme: A single UK centre experience. Eur J Obstet Gynecol Reprod Biol. 225:136-140.https://doi.org/10.1016/j.ejogrb.2018.04.017
- 13. Sekhon, L., Lee, J. A., Flisser, E., Copperman, A. B., & Stein, D. (2018). Blastocyst vitrification, cryostorage and warming does not affect live birth rate, infant birth weight or timing of delivery. Reproductive BioMedicine Online, 37(1), 33–42. https://doi.org/10.1016/j.rbmo.2018.03.008
- 14. Cimadomo D, Rienzi L, Romanelli V, Alviggi E, Levi-Setti PE, Albani E, Dusi L, Papini L, Livi C, Benini F, Smeraldi A, Patassini C, Ubaldi FM, Capalbo A. (2018). Inconclusive chromosomal assessment after blastocyst biopsy: prevalence, causative factors and outcomes after re-biopsy and re-vitrification. A multicenter experience. Hum Reprod. 33(10):1839-1846. https://doi.org/10.1093/humrep/dey282 (Ref. Cobo A. et al., 2008 for the vitrification)
- 15.Magli MC, Albanese C, Crippa A, Tabanelli C, Ferraretti AP, Gianaroli L. (2019). Deoxyribonucleic acid detection in blastocoelic fluid: a new predictor of embryo ploidy and viable pregnancy. Fertil Steril. 111(1):77-85. https://doi.org/10.1016/j.fertnstert.2018.09.016
- 16.Sekhon L, Feuerstein J, Pan S, Overbey J, Lee JA, Briton-Jones C, Flisser E, Stein DE, Mukherjee T, Grunfeld L, Sandler B, Copperman AB. (2019). Endometrial preparation before the transfer of single, vitrified-warmed, euploid blastocysts: does the duration of estradiol treatment influence clinical outcome? Fertil Steril. 111(6):1177-1185.e3. https://doi.org/10.1016/j.fertnstert.2019.02.024
- 17.Rienzi L, Cimadomo D, Delgado A, Minasi MG, Fabozzi G, Gallego RD, Stoppa M, Bellver J, Giancani A, Esbert M, Capalbo A, Remohì J, Greco E, Ubaldi FM, Meseguer M. (2019). Time of morulation and trophectoderm quality are predictors of a live birth after euploid blastocyst transfer: a multicenter study. Fertil Steril. 112(6):1080-1093.e1 https://doi.org/10.1016/j.fertnstert.2019.07.1322 (Ref 65 for the vitrification)
- 18.Cimadomo D, Soscia D, Vaiarelli A, Maggiulli R, Capalbo A, Ubaldi FM, Rienzi L. (2019). Looking past the appearance: a comprehensive description of the clinical contribution of poor-quality blastocysts to increase live birth rates during cycles with aneuploidy testing. Hum Reprod.



- 34(7):1206-1214. https://doi.org/10.1093/humrep/dez078 (Ref. Cimadomo D. et al., 2018a for the vitrification)
- 19.Lin PY, Huang CC, Chen HH, Huang BX, Lee MS. (2019). Failed sperm retrieval from severely oligospermic or non-obstructive azoospermic patients on oocyte retrieval day: Emergent oocyte cryopreservation is a feasible strategy. PLoS One. 14(11). https://doi.org/10.1371/journal.pone.0224919
- 20.Cimadomo D, Vaiarelli A, Colamaria S, et al. Luteal phase anovulatory follicles result in the production of competent oocytes: intra-patient paired case-control study comparing follicular versus luteal phase stimulations in the same ovarian cycle. Hum Reprod. 2018;33(8):1442-1448. https://doi.org/10.1093/humrep/dey217
- 21.Coll, L., Parriego, M., Boada, M., Devesa, M., Arroyo, G., Rodríguez, I., Coroleu B., Vidal F., Veiga, A. (2018). Transition from blastomere to trophectoderm biopsy: comparing two preimplantation genetic testing for aneuploidies strategies. Zygote, 26(3), 191–198. https://doi.org/10.1017/s0967199418000084
- 22.La Marca, A., Dal Canto, M., Buccheri, M., Valerio, M., Mignini Renzini, M., Rodriguez, A., & Vassena, R. (2018). A novel transnational fresh oocyte donation (TOD) program based on transport of frozen sperm and embryos. Human Reproduction. https://doi.org/10.1093/humrep/dey331
- 23. Cardenas Armas, D. F., Peñarrubia, J., Goday, A., Guimerá, M., Vidal, E., Manau, D., & Fabregues, F. (2019). Frozen-thawed blastocyst transfer in natural cycle increase implantation rates compared artificial cycle. Gynecological Endocrinology, 1–5. https://doi.org/10.1080/09513590.2019.1600668
- 24.Hernandez-Nieto C, Lee JA, Slifkin R, Sandler B, Copperman AB, Flisser E. (2019). What is the reproductive potential of day 7 euploid embryos? Human Reproduction. 34(9):1697-1706. https://doi.org/10.1093/humrep/dez129
- 25.Cobo, A., Giles, J., Paolelli, S., Pellicer, A., Remohí, J., & García-Velasco, J. A. (2020). Oocyte vitrification for fertility preservation in women with endometriosis: an observational study. Fertility and Sterility. https://doi.org/10.1016/j.fertnstert.2019.11.017
- 26.Cornet-Bartolomé D., Rodriguez A., García D., Barragán M., Vassena R. (2020). Efficiency and efficacy of vitrification in 35 654 sibling oocytes from donation cycles. Hum Reprod. https://doi.org/10.1093/humrep/deaa178
- 27.Rienzi L, Cimadomo D, Maggiulli R, et al. Definition of a clinical strategy to enhance the efficacy, efficiency and safety of egg donation cycles with imported vitrified oocytes. Hum Reprod. 2020;35(4):785-795. https://doi.org/10.1093/humrep/deaa009.