KITAZATO®

ULTRA-FAST VITRI

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EC | REP

EN- ULTRA-FAST VITRI

GENERAL INFORMATION Basic UDI-DI: 458223146VTUN. This Instructions for Use covers VT601UF. Target population: Patients undergoing IVF procedures. For professional use only. **INTENDED USE** This product is to be used for vitrification of oocytes (MII) (Hereafter referred as "specimen"). **CONTENT** 1 No. 1 ES vials (Color: blue) 1x1.5 ml or 1x4 ml. • No. 2 VS vials (Color: clear) 3x1.5 ml or 3x4 ml. **Caution:** Before use, check the specifications of the container and labelling (number on top of the cap, cap color, vial labelling, color, solution name, and volume). If you notice anything unusual regarding the items mentioned above, don't use the product and contact the distributor. **STORAGE AND HANDLING** Keep refrigerated (2-8°C). Use aseptic conditions in a clean bench. **RECOMMENDED EQUIPMENT** • Cryotop® • Repro Pipette or a standard dish • Cooling Rack **Caution:** Use devices intended for its particular use. We recommend the use of Kitazato products in combination with this device. **COMPOSITION** • HEPES with Basic Culture Medium • Ethylene Glycol • Dimethyl Sulfoxide • Trehalose • Hydroxypropyl Cellulose • Gentamicin (VT601X). **PRODUCT SPECIFICATIONS** The following tests were performed for each lot of this product: • Sterility: 5A • Endotoxin: less than 0.25 IU/ml (Method: LAL) • Mouse Embryo Assay: > 80% • pH (9) • Osmolality (EP), MSDS and Certificate of Analysis are available upon request and/or can be downloaded from our website (https://kitazato-vf.com). **INSTRUCTIONS FOR USE Preparation:** • Fill 90 % of the Cooling Rack with fresh liquid nitrogen. • Bring ES and VS to room temperature. **Caution:** Use a sterilized pipette, with a suitable internal diameter for oocytes. The recommended internal diameter is 140 µm for oocytes (MII). **Ultra-Fast Vitri procedure: A. Vitrification procedure using Repro Plate: Equilibrium (1 min):** 1. Place oocyte(s) (up to four together) in a 50 µL drop of ES on a sterilized dish. It will bend to shrink until the minimum volume is reached. This occurs in 1 minute. **Vitrification: (1 min): Caution:** Complete steps from 3 to 7 in 60 seconds. 2. Aspirate the specimen with a pipette and transfer it to a 50 µL drop of VS2 for 30 seconds. 3. Place the specimen near the black mark on the Repro Plate using a pipette. 4. Aspirate the specimen from ES with the tip of a pipette. 5. Transfer the specimen to the TOP centre of the VS1 on the second well. 6. Aspirate the specimen with a pipette and blow it out. Repeat this process 3 times to ensure the specimen is in the TOP of the ES (well #1). 7. Transfer the specimen to the BOTTOM of VS2 on the third well with a pipette. 8. Change the position of the specimen in the VS2 of the third well with a pipette. 9. Place the specimen near the black mark on the Cryotop® strip. 10. Make sure the specimen is in the TOP of the Cryotop® strip. 11. Place it (less than 0.1 µL) of third well under a microscope. 9. Plunge the Cryotop® immediately in liquid nitrogen and shake it vigorously. 10. Insert the Cryotop® in the outer straw and store it in a storage tank avoiding transferring through liquid nitrogen. **Warming: (1 min): Caution:** Complete steps from 1 to 5 in 60 seconds. **Ultra-Fast Vitri: Equilibration (1 min):** 1. Place oocyte(s) (up to four together) in a 50 µL drop of ES on a sterilized dish. It will bend to shrink until the minimum volume is reached. This occurs in 1 minute. **Vitrification: Caution:** Complete steps from 2 to 7 in 60 seconds. 2. Aspirate the specimen with a pipette and transfer it to a 50 µL drop of VS2 for 30 seconds. 3. Place the specimen near the black mark on the Repro Plate using a pipette. 4. Aspirate the specimen from ES with the tip of a pipette. 5. Transfer the specimen into a single 50 µL drop of VS1 for 30 seconds. 3. Aspirate the specimen with a pipette and transfer it to a 50 µL drop of VS2 for 30 seconds. 4. Place the specimen near the black mark on the Repro Plate using a pipette. Make sure the specimen is in the TOP in the Repro Plate. 5. Aspirate the specimen from ES with the tip of a pipette. 6. Transfer the specimen to the TOP centre of the VS1 on the second well. 7. Aspirate the specimen with a pipette and blow it out. Repeat this process 3 times to ensure the specimen is in the TOP of the ES (well #1). 8. Transfer the specimen to the BOTTOM of VS2 on the third well with a pipette. 6 Change the position of the specimen in the VS2 of the third well with a pipette. 7. Place the specimen near the black mark on the Cryotop® strip. 8. Make sure the specimen is in the TOP of the Cryotop® strip. 9. Place it (less than 0.1 µL) of third well under a microscope. 9. Plunge the Cryotop® immediately in liquid nitrogen and shake it vigorously. 10. Insert the Cryotop® in the outer straw and store it in a storage tank avoiding transferring through liquid nitrogen. **Warming: (1 min): Caution:** Complete steps from 1 to 5 in 60 seconds. **Ultra-Fast Vitri: Equilibration (1 min):** 1. Place oocyte(s) (up to four together) in a 50 µL drop of ES on a sterilized dish. It will bend to shrink until the minimum volume is reached. This occurs in 1 minute. **Vitrification: Caution:** Complete steps from 1 to 7 in 60 seconds. 2. Aspirate the specimen with a pipette and transfer it to a 50 µL drop of VS2 for 30 seconds. 3. Place the specimen near the black mark on the Repro Plate using a pipette. 4. Aspirate the specimen from ES with the tip of a pipette. 5. Transfer the specimen into a single 50 µL drop of VS1 for 30 seconds. 3. Aspirate the specimen with a pipette and transfer it to a 50 µL drop of VS2 for 30 seconds. 4. Place the specimen near the black mark on the Repro Plate using a pipette. Make sure the specimen is in the TOP in the Repro Plate. 5. Aspirate the specimen from ES with the tip of a pipette. 6. Transfer the specimen to the TOP centre of the VS1 on the second well. 7. Aspirate the specimen with a pipette and blow it out. Repeat this process 3 times to ensure the specimen is in the TOP of the ES (well #1). 8. Transfer the specimen to the BOTTOM of VS2 on the third well with a pipette. 6 Change the position of the specimen in the VS2 of the third well with a pipette. 7. Place the specimen near the black mark on the Cryotop® strip. 8. Make sure the specimen is in the TOP of the Cryotop® strip. 9. Place it (less than 0.1 µL) of third well under a microscope. 9. Plunge the Cryotop® immediately in liquid nitrogen and shake it vigorously. 10. Insert the Cryotop® in the outer straw and store it in a storage tank avoiding transferring through liquid nitrogen. **Warming: (1 min): Caution:** Complete steps from 1 to 5 in 60 seconds. **STORAGE INSTRUCTIONS AND STABILITY** Store the vials at 2 to 8 °C. Keep away from sunlight. This product is stable until the expiry date labelled on the vial. Ultra-Fast Vitri media bottles can be used up to one week after first opening. **WARNINGS AND PRECAUTIONS** • Do not use the product if you notice anything unusual regarding its specifications on the label (number, color, name, volume). • Device is sterilized by ethylene oxide. Do not use if the sterile barrier is damaged. • Don't use if the package or containers are opened or damaged. • Upon delivery media must be stored in original unopened containers and refrigerated at 2-8 °C. • Don't re-sterilize and discard if the media is not stored refrigerated (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 in relation to the device must be reported to Kitazato Corporation and, if applicable, to the competent authority of the EU Member State in which the user and/or patient is established. **Note:** Instructions for use are electronically available at Kitazato-vf.com or upon request. **WARNINGS** • Read the instructions for use prior to use. • Use Kitazato Thawing Media (Kitazato Thawing Media (MS) (#1615) or Kitazato Ultra-Fast Thawing Media) intended for used by medical specialists trained in fertility treatments. • Aseptic technique should be used. • Use sterilized equipment and materials only. • In case of eye or skin contact with Ultra-Fast Vitri media, immediately wash eyes/skin with water. • Morphologically abnormal oocytes or oocytes of poor grade oocytes 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 is responsible for correct specimen handling. • Incorrect use or failure to follow the provided IFU. **CONTRAINDICATIONS** • Ultra-Fast Vitri contains antibiotic gentamicin sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic. **SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP)** Performance characteristics of Ultra-Fast Vitri are described in SSCP available in EUDAMED: https://ec.europa.eu/tools/eudamed or our website https://kitazato-vf.com.

BG- ULTRA-FAST VITRI

ОБЩА ИНФОРМАЦИЯ Основен UDI-DI: 458223146VTUN. Тази инструкция за употреба обхваща VT601UF. Целева популация: Пациенти, преминаващи през ЕМ. Само за професионална употреба. **ПРЕДНАЗНАЧЕНИЕ** Целта на продукта е да се използва за витрификация на яйцеклетки (МII) (наричани по-долу проба). **СЪДЪРЖАНИЕ** • No 1 ES флакони (цвят: синя): 1x1,5 ml, или 1x4 ml. • No 2 VS флакони (цвят: бистра): 3x1,5 ml, или 3x4 ml. **Внимание:** Преди използване проверете спецификациите на контейнера и етикетите (номер в гърлото на капачка, цвят на капачката, цвят на етикета на флакона, име на разтвора и обем). Ако забележите нещо необичайно по отношение на артикулите, споменати погоре, не използвайте продукта и се свържете с дистрибутора. **СЪХРАНЕНИЕ** Съхранявайте при 2-8°C. Не замразявайте. Работете с чиста при асептични условия на чиста лейка. **ПРЕПОРЪЧИТЕЛНО ОБОРУДВАНЕ** • Cryotop® • ReproPlate или стандартна чинийка • Охлаждащ стойка **Внимание:** Използвайте устройства, предназначени за конкретната цел. Препоръчваме използването на продуктите на Китазато в комбинация с това устройство. **СЪСТАВ** • HEPES в основна хранителна среда • Етилен гликол • Диметилсулфоксид • Трехалоза • Хидроксипропилцелулоза • Гентамицин (VT601X). **СПЕЦИФИКАЦИИ НА ПРОДУКТА** За всяка партида от този продукт бяха изпълнени следните тестове: • Стерилност: SAL 10-3 • Ендотоксини по LAL методология • Тест-система MEA (бластоцистите след 96 часа): > 80% • pH (EP) • Осмоларитет (EP). Сертификатите за анализ са достъпни при поискване и/или могат да бъдат изтеглени от нашия уебсайт (https://kitazato-vf.com). **ИНСТРУКЦИИ ЗА УПОТРЕБА Подготовка:** • Напълнете 90% от охлаждащата решетка с прясен течен азот. • Довеждете ES и VS до стайна температура. **Внимание:** Използвайте стерилизирана пипета с подходящ вътрешен диаметър за яйцеклетки. Препоръчителният вътрешен диаметър е 140 µm за яйцеклетки (MII). **Ultra-Fast Vitri процедура: А. Процедура за витрификация с помощта на Repro Plate: Равновесяване (1 min):** 1. Поставете яйцеклетка(и) (до четири на пластинката Repro) с помощта на пипета, 2. Преместете яйцеклетката (MII) от съда за купчина в ТОР центъра на ES. Тонът ще се свие докато не бъде достигнат минималният обем. Това отнема 1 минута. **Витрификация: (1 min): Внимание:** Изпълнете стъпки от 2 до 7 за 60 секунди. 1. Аспирайте 300 µL VS в епруета и го третирайте лично на Repro Plate с помощта на пипета. 2. Аспирирайте образеца от ES с помощта на пипета. 3. Преместете образеца в ТОР-ИМ центъра на VS1 на втория кладенец. 4. Аспирирайте образеца с помощта на пипета и го продухайте. Повторете този процес 3 пъти, като променете позицията във VS1 на втория кладенец. 5. Преместете образеца на ДЪНОТО на VS2 на третия кладенец с пипета. 6 Променете позицията на образеца в VS2 на третия кладенец с пипета. 7. Поставете образеца близо до черната маркировка на лентата Cryotop®. 8. Уверете се, че образецът е на Cryotop® с минимален обем VS (по-малък от 0,1 µL) на третия ямка под микроскоп. 9. Потопете Cryotop® веднага в течен азот и го разклатете енергично. 7. Поставете Cryotop® в външната слама и го съхранявайте в резервоар за съхранение, като избягвате прехвърлянето му през въздуха при стайна температура.

Е. Процедура за витрификация с помощта на стандартен съд: Равновесяване (1 min): 1. Поставете яйцеклетка(и) (до четири) в капка от 50 µL ES върху стерилизиран съд. Тъй ще заоколо да се свива, докато се достигне минималният обем. Това отнема за 1 минута. **Витрификация: Внимание:** Изпълнете стъпки от 1 до 5 за 60 секунди. 1. Аспирирайте образеца от капката ES с помощта на пипета. 2. Преместете образеца в една капка VS1 от 50 µL за 30 секунди. 3. Аспирирайте образеца с пипета и го преместете в капка VS2 от 50 µL за 30 секунди. 4. Поставете образеца близо до черната маркировка на лентата Cryotop®. 5. Уверете се, че образецът е на Cryotop® с минимален обем VS (по-малък от 0,1 µL) на третия ямка под микроскоп. 6. Потопете Cryotop® веднага в течен азот и го разклатете енергично. 7. Поставете Cryotop® в

Do not re-use this product
Do not re-sterilize
Keep away from sunlight
Keep away from heat
Keep away from moisture
Keep away from radioactive material
Keep away from flame
Keep away from electrical equipment
Keep away from magnetic material
Keep away from electromagnetic radiation
Keep away from cold
Keep away from contaminated material
Keep away from biological hazard
Keep away from infectious material
Keep away from biological material
Keep away from animal origin material
Keep away from human origin material
Keep away from pyrogens
Keep away from sterile material
Keep away from non-sterile material
Keep away from oil and grease
Keep away from chemicals
Keep away from explosives
Keep away from oxidizing material
Keep away from pressure
Keep away from vibration
Keep away from shock
Keep away from light
Keep away from sharp objects
Keep away from liquids
Keep away from dust
Keep away from humidity
Keep away from heat source
Keep away from cold source
Keep away from ignition source
Keep away from open flame
Keep away from static electricity
Keep away from electrostatic discharge
Keep away from electromagnetic interference
Keep away from electromagnetic field
Keep away from electromagnetic radiation
Keep away from electromagnetic wave
Keep away from electromagnetic pulse
Keep away from electromagnetic noise

STERILE / A	LOT	REF	HD	EN	DE	FR	ES	PT	IT	EL	DA	SV	FI	NO	PL	CS	SK	HU	RO	BG	HR	SR	SL	ET	LV	LT	UA
Unique Device Identifier	Medicaltype	Date of manufacture	Gebruiksaanwijzing	Gebruiksaanwijzing	Mode d'emploi	Instrucciones de uso	Instruções de utilização	Istruzioni per l'uso	Οδηγίες χρήσεως	Brugsanvisning	Bruksanvisning	Käyttöohje	Bruksanvisning	Instrukcja obsługi	Návod k použití	Návod na použitie	Használati utasítás	Instrucțiuni de utilizare	Инструкция за употреба	Upute za uporabu	Упутство за употребу	Navodilo za uporabo	Kasutusjuhend	Lietošanas pamācība	Naudojimo instrukcija	Інструкція з використання
Catalogue number	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile
Batch number	Sterilization method	Sterilization method	Sterilisatiemethode	Sterilisatiemethode	Méthode de stérilisation	Método de esterilización	Método de esterilização	Metodo di sterilizzazione	Μέθοδος αποστείρωσης	Sterilisationsmetode	Sterilisationsmetod	Sterilointimenetelmä	Sterilisasjonsmetode	Metoda sterylizacji	Metoda sterilizace	Metóda sterilizácie	Sterilizálási módszer	Metoda de sterilizare	Метод на стерилизация	Metoda sterilizacije	Метод стерилизације	Metoda sterilizacije	Steriliseerimismeetod	Sterilizācijas metode	Sterilizacijos metodas	Метод стерилізації
Use by date	Do not use if package is damaged	Do not use if package is damaged	Niet gebruiken indien verpakking beschadigd is	Niet gebruiken indien verpakking beschadigd is	Ne pas utiliser si l'emballage est endommagé	No utilizar si el envase está dañado	Não utilizar se a embalagem estiver danificada	Non utilizzare se la confezione è danneggiata	Μη χρησιμοποιείτε εάν η συσκευασία είναι κατεστραμμένη	Anvendes ikke hvis emballagen er beskadiget	Använd inte om förpackningen är skadad	Ei käytä, jos pakkaus on vaurioitunut	Skal ikke brukes hvis emballasjen er skadet	Nie używać, jeśli opakowanie jest uszkodzone	Nepoužívat, je-li obal poškozen	Nepoužívať, ak je obal poškodený	Ne használja, ha a csomagolás sérült	A nu se folosi dacă ambalajul este deteriorat	Не използвайте, ако опаковката е повредена	Ne koristiti ako je ambalaža oštećena	Не користити ако је амбалажа оштећена	Ne uporabljati, če je embalaža poškodovana	Ärge kasutage, kui pakend on kahjustatud	Nelietot, ja iepakojums ir bojāts	Nenaudoti, jeigu pakuotė pažeista	Не використовувати, якщо упаковка пошкоджена
Manufacturer	Non-medicinal product	Non-medicinal product	Niet-medisch product	Niet-medisch product	Produit non médicinal	Producto no medicinal	Produto não medicinal	Prodotto non medicinale	Μη φαρμακευτικό προϊόν	Ikke-medicinsk produkt	Icke-medicinsk produkt	Ei-lääkevalmiste	Ikke-medisinsk produkt	Produkt niemedyczny	Nezdravotnický výrobek	Nezdravotnícky výrobok	Nem orvosi termék	Produs nemedicinal	Немедицинско изделие	Nemedicinski proizvod	Немедицинско средство	Mittemeditsiinitoote	Nemedicīnisks izstrādājums	Nemedicininė prekė	Немедичний виріб
Consult instructions for use	Do not resterilize	Do not resterilize	Niet opnieuw steriliseren	Niet opnieuw steriliseren	Ne pas stériliser à nouveau	No volver a esterilizar	Não reesterilizar	Non risterilizzare	Μη επαναποστείρωση	Ikke gensterilisér	Får ej resterilisera	Ei saa steriloida uudelleen	Ikke resterilisér	Nie ponownie sterylizować	Neresterilizovat	Neresterilizovať	Ne sterilizálja újra	A nu se reutiliza	Не е подходящо за повторна стерилизация	Ne ponovno sterilizirati	Не стерилисати поново	Ei steriliseerimiskõlbulik	Nesterilizēt atkārtoti	Nesterilizuoti pakartotinai	Не стерилізувати повторно
Do not use if package is damaged	Consult instructions for use	Consult instructions for use	Gebruiksaanwijzing raadplegen	Gebruiksaanwijzing raadplegen	Consulter le mode d'emploi	Consulte el manual de instrucciones	Consulte o manual de instruções	Consultare le istruzioni per l'uso	Συμβουλευθείτε τις οδηγίες χρήσεως	Se brugsanvisningen	Läs bruksanvisningen	Katso käyttöohje	Se bruksanvisning	Zapoznać się z instrukcją obsługi	Viz návod k použití	Pozrite si návod na použitie	Olvassa el a használati utasítást	Consultați instrucțiunile de utilizare	Вижте инструкцията за употреба	Pogledajte upute za uporabu	Погледајте упутство за употребу	Glejte navodilo za uporabo	Vaata kasutusjuhendit	Skatīt lietošanas pamācību	Žiūrėti naudojimo instrukciją	Ознайомитися з інструкцією з використання
Sterile	Do not resterilize	Do not resterilize	Niet opnieuw steriliseren	Niet opnieuw steriliseren	Ne pas stériliser à nouveau	No volver a esterilizar	Não reesterilizar	Non risterilizzare	Μη επαναποστείρωση	Ikke gensterilisér	Får ej resterilisera	Ei saa steriloida uudelleen	Ikke resterilisér	Nie ponownie sterylizować	Neresterilizovat	Neresterilizovať	Ne sterilizálja újra	A nu se reutiliza	Не е подходящо за повторна стерилизация	Ne ponovno sterilizirati	Не стерилисати поново	Ei steriliseerimiskõlbulik	Nesterilizēt atkārtoti	Nesterilizuoti pakartotinai	Не стерилізувати повторно
Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile