Rapid-i™ Kit

Vitrolife

US

EN: Incorrect handling or sealing of the RapidStrew can cause a pressure build up inside that may result in damage or even explosion of the straw during the warming procedure.

Indication for use

Cryopreservation device intended to be used to contain, vitrify and maintain human embryos and/or oocytes (life).

Contraindications

None known.

Product Description

Rapid-i™ Kit consists of the following three items:

Item	Material	Dimensions (Length x Diameter)
Rapid-i	PBMA	80 x 2mm
RapidStrew	Mediprene	130 x 3mm
Tool	Stainless steel	115 x 2 mm

Rapid-i Kit is available with different colour codes (blue, green, red, yellow and transparent) to simplify identification and cryostorage management.

Storage Instructions

Store at +16 to 25°C.

Discard device after completion of procedure.

Directions for use

The product shall be used by an IVF professional.

The patient target group is an adult or reproductive age population of female patients undergoing fertility preservation.

Preparation of the oocytes or embryos for vitrification has to be accurate and according to the instructions provided with the vitrification media.

The following equipment and material are needed in addition to the Rapid-i Kit device:

- SmartStrw™
- A stereo microscope with a heated stage
- Ultrasonic sealer
- Needle nose tweezers
- Cutter
- Labels with patient identification intended for storage in liquid nitrogen or cryowasher pen
- Liquid nitrogen
- Cryoware with goblet and appropriate storage vessel or equivalent equipment

Read all of the instructions before beginning the vitrification procedure.

Verification

Check the Rapid-i™ Kit for damage and for the long term storage without leaving liquid nitrogen in advance, prior to the procedure.

Use the SmartStrw and the Ultrasonic sealer close to the working area allowing easy handling during vitrification.

Fill the SmartStrw with liquid nitrogen up to 1 cm from the top and place the lid on top of the box. Place the sealed the top of the RapidStrew at a sufficient distance from the liquid nitrogen.

NOTE: Always operate with the lid on top of the opened the SmartStrw.

Prepare the straws with vitrification media according to the instructions provided with the media. Place the straws close to the cryotop.

Check that the Rapid-i™ kit packaging is intact and that the use by date has not expired. Open the package using aseptic technique. Place the Rapid-i™ kit in the SmartStrw in the sterile field.

Label the each number of RapidStrews needed with the patient's identification or according to local regulations. Place the label below the big black mark of the RapidStrew.

Prepare 1-5 cryotops or embryos per Rapid-i™ for vitrification by following the instructions provided with the vitrification media.

No later than 2 minutes before vitrification, place the cryotop or embryos into the Rapid-i™ kit. Place the RapidStrew into the Rapid-i kit into the RapidStrew.

Fill the Rapid-i™ kit with liquid nitrogen up to 1 cm from the top and place the lid on top of the box. Always hold the top of the RapidStrew at a sufficient distance from the liquid nitrogen.

WARNING: *The warmed RapidStrew shall not be removed from liquid nitrogen. Removal of the warmed RapidStrew could lead to damage of the RapidStrew.*

Place the warmed RapidStrew (straw with attached goblet) into the SmartStrw.

Move the sealed RapidStrew from the lid and into the goblet, so that the RapidStrew with the cryotop or embryos stay submerged in liquid nitrogen. **The lowest black mark of the RapidStrew must always be immersed in liquid nitrogen.**

Warning

Place the SmartStrw close to the working area allowing easy handling during warming.

Fill the SmartStrw with liquid nitrogen up to 1 cm from the top and place the lid on top of the box. Place the sealed the top of the RapidStrew at a sufficient distance from the liquid nitrogen.

WARNING: *Place the RapidStrew into the SmartStrw. Place the RapidStrew with the cryotop or embryos into the SmartStrw.*

Move the sealed RapidStrew from the lid and into the goblet, so that the RapidStrew with the cryotop or embryos stay submerged in liquid nitrogen. **The lowest black mark of the RapidStrew must always be immersed in liquid nitrogen.**

Warming

Place the SmartStrw close to the working area allowing easy handling during warming.

Fill the SmartStrw with liquid nitrogen up to 1 cm from the top and place the lid on top of the box.

Prepare the dishes and media according to the instructions provided with the media. Place the dishes close to the SmartStrw.

Move the cryotopw and goblet containing the RapidStrews from the SmartStrw into the SmartStrw lid.

Place the RapidStrew into the SmartStrw lid and ensure that the RapidStrew is secure in the lid and that the lower end touches the bottom of the goblet.

Warm the RapidStrew with your fingers around the black mark for a few seconds and place it back into the SmartStrw. The RapidStrew well above the black mark and cut 2.5 mm above the black mark. Place the RapidStrew in the dish and cut the lid and release the cryotop or embryo.

WARNING: Under any condition, always cut the RapidStrew below the black mark (2.5 mm).

Lift the Rapid-i (using needle nose tweezers) out of the goblet and place it in the SmartStrw. Fill the SmartStrw with liquid nitrogen up to 1 cm from the top and place the lid on top of the box.

Place the cryotop or embryo into the dish

blapot 20 – 30 sekundy pro umístění prvního procesu Rapid v uzavřené komoře.

Vyndat z komory pracovní plochu mikroplatnem marke Vitrofix za pomoci pinzety nebo vakuové pinzety.

Připravte obsah procesního Rapid-u v Zarážce pod mikroskopem. Vlhkým papírem nebo vlhkým tampónem zlehka otřete pracovní plochu a nechte ji 30 sekund vyschnout. Nanesete jednu kapku Rapid-u na pracovní plochu a umístěte vzorek do kapky.

UPOZORNĚNÍ: Uvnitř pracovní plochy otevřete kádci dvakrát a zatryskněte ji. Tímto zajistíte, že vzorek bude zcela ponořen do Rapid-u.

UPOZORNĚNÍ: Uvnitř pracovní plochy nesmí zůstat žádné bubliny. Pokud ano, bublinu odstraníte tak, že ji vyfoukáte z pipety.

Zakryjte vzorek krycím sklíčkem a nechte jej 5 minut. Pro optimální výsledky zajistěte, aby byl vzorek ponořen do Rapid-u po celou dobu jeho zpracování.

Po uplynutí 5 minut vyjmeme vzorek z Rapid-u a zapneme ventilátor. Vzorek ponecháme 10 sekund v Rapid-u, aby se ventilátor mohl rozběhnout a vzorek se mohl vysušit.

Po 10 sekundách vyndejte vzorek z Rapid-u a vložte jej do Rapid-u 1. Vzorek ponechejte v Rapid-u 1 10 sekund a poté jej vyndejte a vložte do Rapid-u 2. Vzorek ponechejte v Rapid-u 2 10 sekund a poté jej vyndejte a vložte do Rapid-u 3. Vzorek ponechejte v Rapid-u 3 10 sekund a poté jej vyndejte a vložte do Rapid-u