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DEVICE DESCRIPTION

RI EZ-Strip is a plastic pipette fitted with an actuator handle. The tip of the RI EZ-Strip is available in a range of internal diameter sizes. Sizes 200µm, 290µm and 600µm are suitable for specimen handling and Size 145µm Long is suitable for handling in tubes. Sizes 131µm, 135µm, 145µm, 155µm and 170µm are suitable for oocyte denudation.

Denudation may be performed on oocytes in preparation for Intracytoplasmic Sperm Injection (ICSI) and In Vitro Fertilization (IVF) techniques. Assisted reproduction fertilization is proven more successful if the oocyte is first denuded. It allows easier access of the sperm to the zona pellucida and better visibility, and therefore more effective manipulation of the injection pipette whilst conducting ICSI procedures. The technique of denuding is where the oocyte is repeatedly aspirated and expelled through pipette tips of incrementally smaller internal diameters to remove the outer layers of cumulus and corona cells. Generally two sizes of pipette are used to achieve this. The oocyte is presented in media with an enzyme constituent, hyaluronidase, which promotes the denuding process. The sizes selected depend on the size of the oocyte, user preference and practice.

CAUTION

- **Caution:** US Federal Law restricts this device to sale by or on the order of a physician.
- Do not re-use - reuse poses a high risk of cross contamination.

Caution: These tools are intended for one-time use only and must remain covered until ready to use in order to maintain both sterility and prevent contamination. The user is warned to follow safe, established laboratory practices in order to prevent accidental DNA contamination after the RI EZ-Strip has been removed from its protective covering.

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BEFORE USE

- Check that the packaging has not been damaged. If the sterile barrier has been compromised, discard.
- Check use-by date on pouch. If out of date, discard.
- Select the appropriate pipette tip size to ensure minimal distortion and damage to the sample ie the internal diameter of the pipette tip should be appropriate for the size of the sample to be denuded or transferred. This can be done by placing the pipette tip next to the sample to determine suitability.
- Check the pipette tip under your microscope to ensure it is clear. Rotate the tip 90° and check again. If it is not clear, discard.
- To avoid creating bubbles in the media first apply pressure to the membrane before immersing the tip.
- Rinse the tip by depressing the membrane and immersing the tip in some media. Then slowly release the pressure to aspirate media into the pipette tip. Depress the membrane again to expel the media. Repeat this action a few times to complete the rinsing process.
- If using for the first time (before attempting clinical use), familiarise yourself with the device using plain water or media, and discarded eggs or embryos. Dispose of the practice tip after use.

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PREPARATION

1. Remove the RI EZ-Strip from its pouch.
2. Carefully pull the test tube lid to remove, taking care not to damage the pipette tip.
3. Fit test tube lid to the opposite end of the actuator to form a handle. (See Fig.1)

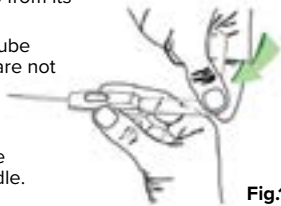


Fig.1

HOW TO USE

For general handling:

1. Apply pressure to the membrane of the actuator and immerse the tip into the media. If working under oil, it is important to apply positive pressure when passing through the oil layer.
2. Once the sample is located, slowly release the pressure on the membrane to aspirate the sample (with media) into the pipette.
3. The sample can now be moved at this stage.
4. To expell the sample from the tip depress the membrane on the actuator again as step 1.

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Caution: This tool may be used to handle polar body, blastomere or trophoctoderm biopsy samples for pre-implantation genetic diagnosis (PGD) on the genetic material in the biopsied cell(s). Test for PGD are currently developed and their performance characteristics are determined by individual laboratories for their own use. The performance of these tests may vary depending on the particular assay and disease evaluated. Currently, these tests have not been cleared or approved by the US Food and Drug Administration (FDA).

- RI EZ-Strip should only be used by qualified personnel who have been approved by the relevant authorised bodies.
- The introduction of RI EZ-Strip for routine clinical use should be risk assessed prior to use.
- This product has a three year shelf life.

INTENDED USE

For denudation i.e. to remove the cumulus from an oocyte prior to Intracytoplasmic Sperm Injection (ICSI) and In Vitro Fertilization (IVF) and for handling gametes, embryos and biopsied cells (polar bodies, blastomeres and trophoctoderm) during Assisted Reproductive Technology (ART) procedures.

CONTRAINDICATIONS

RI EZ-Range pipettes are not intended for biopsy of cells from oocytes or embryos.

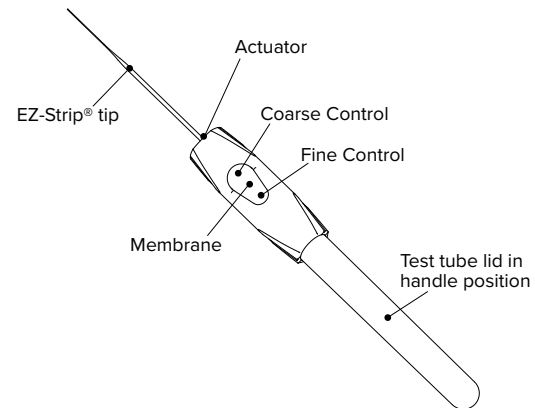
INTENDED PATIENT POPULATION

For those who require assisted reproductive treatments to improve their chances of a healthy pregnancy and outcome.

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For denudation:

1. Transfer the sample into media with an enzyme constituent, hyaluronidase, which promotes the denuding process.
2. Repeat steps 2 and 4, as above, a sufficient number of times to denude the sample.
3. Always keep the media level visible in the pipette.



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MEDICAL CONDITION

The medical condition is infertility and genetic disease.

CLINICAL BENEFIT

The clinical benefit of using this medical device during ART procedures is to improve the patient's chances of a viable pregnancy and long-term health of the offspring.

INTENDED ENVIRONMENT OF USE

For use in a controlled clinical environment where Assisted Reproductive Techniques (ART) are used.

INTENDED USER

Trained clinical professional working in Assisted Reproductive Techniques (ART) with locally relevant qualifications.

DISPOSAL

- Remove the plastic cover from the handle position, and place it over the pipette.
- Dispose of the RI EZ-Strip and packaging in a suitable container.

OBIGATION TO INFORM

Any serious incident that has occurred in relation to this device should be reported to CooperSurgical via phone number +1 203-601-5200 Ext 3100 or by email at ProductSurveillance@coopersurgical.com and to the local Health Authority in your country. A serious incident may have caused or contributed to a death, a delay in a procedure which resulted in death or serious injury, or a malfunction that could have caused an adverse event.

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QUALITY ASSURANCE

- Sterilised by gamma irradiation to a Sterility Assurance Level (SAL) of 10⁻⁶.
- Non-embryotoxic, Pass Level: 1-Cell MEA: ≥80% hatched blastocysts at 120h.
- Non-Pyrogenic (Limulus Amebocyte Lysate [LAL] Test), Pass Level: <20 Eu/device.
- Certificate of analysis available on request.
- Depending on the size of the tip the volumetric capacity of the RI EZ-Strip is 55.6µl - 60.2µl.

SYMBOL GLOSSARY Source: ISO 15223-1

	Consult instructions for use		Do not use if packaging is damaged
	Do not re-use		Sterilised using gamma irradiation
	Keep away from direct sunlight (UV)		80% Store between 20% and 80% relative humidity limits
	Batch code		30°C Store between 10°C and 30°C temperature limits
	Use-by date		Date of manufacture
	Manufacturer		Unique Device Identifier
	Medical Device		Authorised representative in the European Community
	Catalogue or Part number		

剥离吸管使用说明

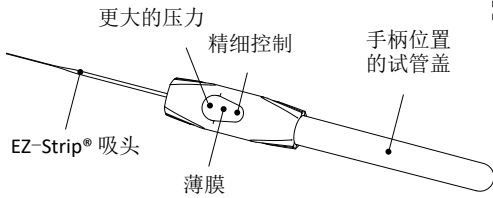


图 1

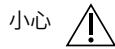
型号: EZ-Strip

结构及组成

- 产品由聚碳酸酯构成。
- 产品由131、135、145、145L、155、170、200、290、600 规格组成。

使用前

- 检查包装是否有损坏。如果无菌屏障受损, 请丢弃。
- 检查包装袋上的失效日期。如果过期, 请丢弃。
- 选择合适的移液器吸头尺寸, 以确保最低限度的变形和样本损坏, 即移液器吸头的内径应适合待剥脱或转移的样本的尺寸。这可以通过将移液器吸头放在样本旁边以确定适合性来完成。
- 在显微镜下检查吸头是否清晰。如果不清晰, 请丢弃。
- 为了避免在培养基中产生气泡, 在浸入吸头之前先向薄膜施加压力。
- 通过按下薄膜使吸头浸入培养基中来清洗吸头。然后慢慢地释放压力, 将培养基吸入移液器吸头。再次按下薄膜以排出培养基。重复此操作几次以完成清洗过程。
- 如果是第一次使用(在尝试临床使用之前), 请使用普通的水或培养基以及废弃的蛋或胚胎来熟悉装置。用于练习的吸头在使用之后应丢弃。



小心

- 请勿重复使用 - 重复使用会造成交叉污染的高风险。
- EZ-Strip® 只能由经过相关授权机构批准的合格人员使用。
- 小心: 美国联邦法律将此装置限制为由医师销售或遵医嘱销售。

预期用途

产品用于IVF体外人工受精、受精卵的孵化和活检。

EZ-Strip® 用于剥脱应用, 即在实施卵胞浆内单精子注射 (ICSI) 和体外受精 (IVF) 辅助生殖技术之前从卵母细胞中去除卵丘, 并影响细胞、胚胎和卵母细胞的培养皿到培养皿转移。

禁忌症

尚无与使用此装置相关的已知禁忌症。

制备

1. 从包装袋中取出 EZ-Strip®。
2. 小心地拉动试管盖将其取下, 注意不要损坏 EZ-Strip®。
3. 将试管盖安装到 EZ-Strip® 的另一端, 形成一个手柄。(见图 1)



图 2

使用方法

1. 进行剥脱时, 将样本转移到含有酶组分透明质酸酶的培养基中, 这促进了剥脱过程。
2. 用手指或拇指压力对 EZ-Strip® 的柔性薄膜施加压力, 并将吸头浸入培养基中。如果在油下工作, 在通过油层时施加正压力非常重要。

装置说明

EZ-Strip® 是一款驱动和塑料移液器吸头单一装置组合。EZ-Strip® 的吸头有多种内径尺寸可供选择, 适用于卵母细胞剥脱和标本转移。

剥脱可在实施卵胞浆内单精子注射 (ICSI) 和体外受精 (IVF) 技术的制备过程中在卵母细胞上进行。如果卵母细胞最先被剥脱, 则辅助生殖受精被证明更加成功。它使精子更容易进入透明带并确保更好的可见性, 从而在执行 ICSI 程序时更有效地操作注射移液器。剥脱技术是指通过内径逐渐变小的移液器吸头反复吸出和排出卵母细胞以去除卵丘和电晕细胞的外层。通常使用两种尺寸的移液器来实现此目的。尺寸选择取决于卵母细胞的大小、用户偏好和操作习惯。

质量保证

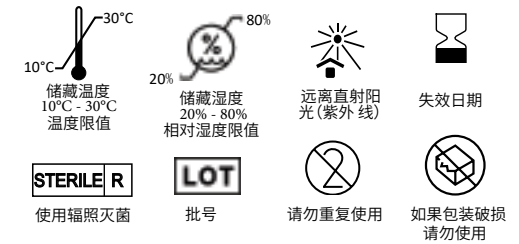
- 通过 γ 辐照灭菌至 10^{-6} 的无菌保证水平 (SAL)。
- 经小鼠胚胎实验 (MEA) 证实无胚胎毒性, 通过水平: 第 2 天 $\geq 80\%$ 的双细胞, 第 6 天 $\geq 80\%$ 的胚泡。
- 经鲎变形细胞裂解液 (LAL) 试验证明无活体致热源。通过水平: <20 Eu/装置。
- 可根据要求提供分析证书。
- 3. 一旦找到样本, 慢慢地松开薄膜, 将它与一些培养基一起吸入 EZ-Strip®。必要时, 在此阶段转移样本。
- 4. 再次按下薄膜以排出样本/培养基。
- 5. 重复操作足够多的次数以剥脱样本。
- 6. 在薄膜的窄端施加少量压力以进行更多控制。在较宽的一端施加更大的压力。(见图 2)
- 7 始终保持 EZ-Strip® 中的培养基液位可见。
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生产地址: Bickland Industrial Park, Falmouth, Cornwall, TR11 4TA, U.K.
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- 代理人名称: 库博医疗科技(上海)有限公司
代理人住所: 上海市静安区万航渡路889号15F01、08室(名义楼层) 联系方式: 021-65637021
- 售后服务单位: 库博医疗科技(上海)有限公司
联系电话: 021-65637021

弃置

- 从手柄位置取下塑料盖, 将其放在移液器上。
- 将 EZ-Strip® 及其包装丢弃在合适的容器中。

储藏条件

建议将本产品储藏在具有以下条件的室内。



小心: 美国联邦法律将此装置限制为由医师销售或遵医嘱销售。

· 使用期限: 3 年
生产日期见标签

· 医疗器械注册证编号: 国械注进 20172180405
产品技术要求编号: 国械注进 20172180405 4

产品型号/规格及其划分说明

规格尺寸如下

型号	产品编号	规格	规格尺寸 (mm)			包装规格	初装材料
			管端部内径 Φ	管尾部内径	管长		
EZ-Strip	7-72-1131/20	131	0.131	ID - 1.0 OD - 1.5	90	单包装, 20个/盒	聚脂-聚 乙烯
	7-72-1135/20	135	0.135				
	7-72-1145/20	145	0.145				
	7-72-1145L/20	145L	0.146				
	7-72-1155/20	155	0.155				
	7-72-1170/20	170	0.17				
	7-72-1200/20	200	0.2				
	7-72-1290/20	290	0.29				
	7-72-1600/20	600	0.6				