



EZ-Tip®

Instructions For Use

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CAUTION



- Do not re-use - reuse poses a high risk of cross contamination.
- For vial of 20 only; unused pipette tips are not sterile once vial is opened.
- Only use with an actuator accepting 0.9mm EZ-Tips®, eg EZ-Grip®.
- EZ-Tip® should only be used by qualified personnel who have been approved by the relevant authorised bodies.
- The introduction of EZ-Tip® for routine clinical use should be risk assessed prior to use.
- Caution: US Federal law restricts this device to sale by or on the order of a physician.

INTENDED USE

The EZ-Tip® is for denudation, ie removing the cumulus from an oocyte prior to the assisted reproduction techniques of Intracytoplasmic Sperm Injection (ICSI) and In Vitro Fertilisation (IVF), and effecting dish to dish transfer of cells, embryos and oocytes.

CONTRAINDICATIONS

There are no known contraindications associated with the use of this device.

DEVICE DESCRIPTION

EZ-Tip® is a plastic pipette tip. The tip of the EZ-Tip® is available in a range of internal diameter sizes, suitable for oocyte denudation and specimen transfer.

Denudation may be performed on oocytes in preparation for Intracytoplasmic Sperm Injection (ICSI) and In Vitro Fertilisation (IVF) techniques. Assisted reproduction fertilisation 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 sizes selected depend on the size of the oocyte, user preference and practice.

QUALITY ASSURANCE

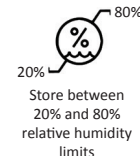
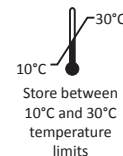
- Sterilised by gamma irradiation to a Sterility Assurance Level (SAL) of 10^{-6} .
- Non-embryotoxic proven by Mouse Embryo Assay (MEA), Pass Level: Day 2 $\geq 80\%$ 2-cells, Day 6 $\geq 80\%$ blastocysts.
- Non-pyrogenic, proven by Limulus Amoebocyte Lysate (LAL) Test. Pass Level: <20 Eu/device.
- Certificate of analysis available on request.

DISPOSAL

- Remove the pipette from actuator.
- Dispose of the EZ-Tip® and packaging in a suitable container.

STORAGE CONDITIONS

It is recommended that this product is stored indoors in the following conditions.



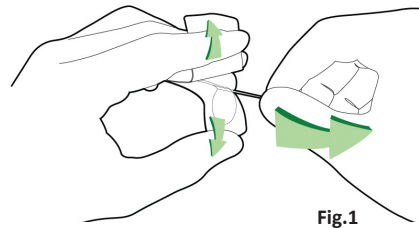
BEFORE USE

- Check that the packaging has not been damaged. If the sterile barrier has been compromised, discard.
- Check expiry 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 tip under your microscope to ensure it is clear. If it is not clear, discard.
- To avoid creating bubbles in the media, first apply pressure to the plunger of the actuator before immersing the tip.
- Rinse the tip by depressing the plunger of the actuator and immersing the tip in some media. Then slowly release the plunger to aspirate media into the pipette tip. Depress the plunger of the actuator 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.

PREPARATION

EZ-Tip® Singles

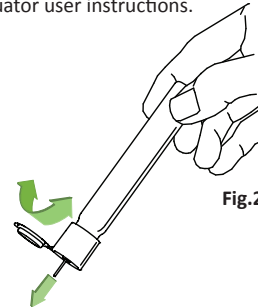
1. Remove one blister pack tray from the box and snap off a single EZ-Tip® unit.
2. Peel back the lid halfway, starting at the wide end (See Fig.1).
3. Bend back the tray to expose the EZ-Tip® pipette, then remove.
4. Load the EZ-Tip® into the actuating device in accordance with actuator user instructions.



EZ-Tip® Vial of 20

NOTE: To minimise the exposure of the EZ-Tips remaining in the vial to potential contaminants, it is recommended the vial is opened within a laminar flow cabinet and the lid is closed between each use.

1. Remove the EZ-Tip® vial from its pouch.
2. Flip the vial lid open.
3. Holding the vial at its base, angle downwards and lightly shake from side to side, or tap the vial to dispense EZ-Tips® (See Fig.2).
4. Load the EZ-Tip® into the actuating device in accordance with actuator user instructions.



HOW TO USE

1. For denudation, transfer the sample into media with an enzyme constituent, hyaluronidase, which promotes the denuding process.
2. Apply pressure to the plunger 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.
3. Once the sample is located, slowly release the plunger to aspirate it with some media into the EZ-Tip®. Transfer the sample at this stage if required.
4. Depress the actuator plunger again to expel the sample/media.
5. Repeat this action a sufficient number of times to denude the sample.
6. Always keep the media level visible in the EZ-Tip®.

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