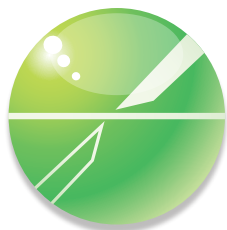




CONSUMABLES



RI Pipettes

Instructions For Use

7-71-500UM, Issue 21, 22/12/14, MRF 1613

CAUTION



- Do not re-use - reuse poses a high risk of cross contamination.



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 pipette has been removed from its protective covering.

- Pipettes should only be used by qualified personnel who have been approved by the relevant authorised bodies.
- Caution: US Federal law restricts this device to sale by or on the order of a physician.



Caution: This tool may be indicated for polar body or blastomere biopsy, which may be done in order to perform pre-implantation genetic diagnosis (PGD) on the genetic material in the biopsied cell(s). Tests 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).

- Handle glass pipettes with care.

These instructions are for use with :-

- ICSI Injection pipettes
- ICSI Holding pipettes
- Assisted Hatching pipettes
- Biopsy pipettes
- Mechanical Dissection pipettes

INTENDED USE

To manipulate human gametes and embryos during assisted reproduction techniques (ART).

CONTRAINDICATIONS

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

INDICATIONS FOR USE by pipette type

- **ICSI Injection pipettes** - to aspirate and inject sperm into the cytoplasm of an oocyte during intracytoplasmic sperm injection (ICSI).

ICSI injection pipettes are available with a spike or no spike, depending on user preference. A larger internal diameter ICSI injection pipette is also available to aspirate sperm from a testicular tissue sample prior to ICSI.

- **ICSI Holding pipettes** - to anchor the oocyte under vacuum during intracytoplasmic sperm injection (ICSI).
- **Large Holding** - to anchor embryos under vacuum during biopsy procedures. The large holding pipette is available in a range of large internal diameters.
- **Assisted Hatching pipettes** - to direct Acid Tyrode's solution onto the zona pellucida of an embryo to create a hole and allow the embryo to hatch.
- **Biopsy pipettes** - to remove blastomere(s) from embryos or polar bodies from oocytes, which may be done in order to perform preimplantation genetic diagnosis (PGD) on the genetic materials in the biopsied cell(s).

Biopsy pipettes are available in a range of internal diameters and with a spiked, non-spiked or flat profile to suit user preferences.

- **Mechanical Dissection pipettes*** - to create a slit or slits in the zona pellucida of an oocyte for partial zona dissection (PZD).

*Currently does not have US FDA market clearance for clinical use .

DEVICE DESCRIPTION

The RI Pipette is a borosilicate glass micropipette, individually handmade and offered in a range of different tip geometries to enable the assisted reproduction technique (ART) for which it is intended. Pipettes are available in a range of bend angles to suit micromanipulator set up and different internal diameters and tip profiles to suit most user preferences.

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.
- Check the pipette tip under your microscope to ensure it is clear and undamaged. If not, discard.

PREPARATION

Remove the Twista-Pak™ from its pouch.

1. Pull the Twista-Pak™ lid to remove.
2. Twist the Twista-Pak™ base to access the pipette. (see Fig. 1)
3. Carefully remove the pipette. Always hold the pipette away from the sharp tip. (see fig. 2)

Fig. 1

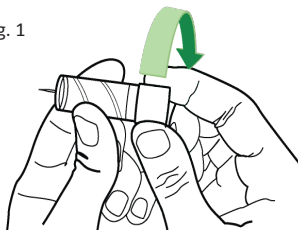
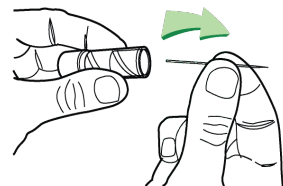


Fig. 2



4. Take care when handling.
5. The pipette tip is extremely fragile and any contact with the tip will cause damage.

HOW TO USE

1. Insert the non working-end of the pipette tip into the toolholder of a micromanipulator – follow the micromanipulator user manual instructions where applicable.
2. Connect the micro-injector in accordance with manufacturer's instructions.
3. Apply pressure and lower the pipette tip into the media.

QUALITY ASSURANCE

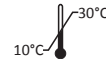
- Manufactured and packed in a cleanroom environment.
- Sterilised by gamma irradiation to Sterility Assurance Level 10^{-6} .
- Non-embryotoxic proven by Mouse Embryo Assay (MEA), Pass Level: $\geq 80\%$ blastocyst after 120h.
- Non-toxic to sperm, proven by Human Sperm Survival Assay (HSSA). Pass Level: $\geq 70\%$ motility at 24h. (For ICSI-Plus™ pipettes only)
- Non-pyrogenic, proven by Limulus Amoebocyte Lysate (LAL) Test. Pass Level: < 20 Eu/device.
- Certificate of analysis available on request.

STORAGE CONDITIONS

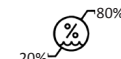
It is recommended that this product is stored indoors in the following conditions.



Keep away from direct sunlight (UV)



Store between 10°C and 30°C temperature limits



Store between 20% and 80% relative humidity limits

DISPOSAL

- Release the pressure in the syringe before releasing the pipette from its holder.
- Dispose of the pipette and its packaging in a suitable container.



Sterilised using gamma irradiation



Do not re-use



Do not use if packaging is damaged



Batch code



Expiry date



Refer to instructions



Caution: US Federal law restricts this device to sale by or on the order of a physician.



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