



## EN INSTRUCTIONS FOR USE (IFU)

### INTENDED USE

Micromanipulation Pipettes are used to manipulate human gametes and embryos in assisted reproduction and associated procedures.

### INDICATIONS FOR USE

- **Injection pipette:** To aspirate and inject a sperm or spermatid into an oocyte.
- **Holding pipette:** To hold an oocyte or embryo in position using light suction.
- **Biopsy pipette:** To remove polar bodies from oocytes and remove blastomeres and trophectoderm cells from embryos, for genetic testing.
- **Partial Zona Dissection (PZD) pipette:** To mechanically cut an opening in the zona pellucida to assist in embryo hatching or embryo biopsy.
- **Assisted Hatching (AH) pipette:** To apply acidic solution onto the zona pellucida to thin or create a hole in the zona to assist in embryo hatching or embryo biopsy.

### INSTRUCTIONS FOR USE

1. Inspect packaging. Discard if the sterile barrier is compromised.
2. Carefully peel open the pouch at the label end. Avoid pressing the holder while doing so.
3. Carefully remove the holder from the pouch.
4. Gently hold the pipette's mid-section with thumb and forefinger.
5. Using your free hand, squeeze the holder's base at its centre to release the grip on the pipette.
6. Extract the pipette without it touching the holder's walls.
7. Fit the pipette into a microtool holder.

### STORAGE

- Store dry at room temperature away from sunlight.

### PRECAUTIONS, WARNINGS & CONTRAINDICATIONS

- For qualified personnel use only.
- Handle with care to avoid injury. Glass pipettes are fragile.
- Single use only. Reuse may cause cross contamination.
- Discard pipette if packaging is compromised or if contaminated during unpacking.
- Do not use broken or expired pipettes.
- Use aseptic techniques.
- Dispose following medical waste procedures.
- No known contraindications for this device.
- Report serious incidents involving this device to the manufacturer and relevant European competent authority, if applicable.

### GENERAL INFORMATION

- Manufactured in a cleanroom to various geometries from extensively cleaned borosilicate glass.
- Sterilised by gamma irradiation to SAL  $10^{-6}$ .
- MEA (1-cell, 96h):  $\geq 80\%$  expanded blastocyst.
- Endotoxin:  $<20$  EU/device.
- A paper copy of this IFU is available free of charge upon request. Contact: [icsion@icsionmedical.com](mailto:icsion@icsionmedical.com).
- A current version of this IFU is available at: [icsionmedical.com/ifu](http://icsionmedical.com/ifu).

### PRODUCT SPECIFICATION KEY

Specifications are arranged as per '*PT-ID/OD-TA-TL*' where:

- PT = Pipette type ('I' = injection, 'PI' = piezo injection, 'H' = holding, 'B' = biopsy, 'PZD' = PZD, 'AH' = AH).
- ID = Tip inner diameter ( $\mu\text{m}$ ).
- OD = Tip outer diameter (holding pipettes only) ( $\mu\text{m}$ ).
- TA = Tip angle ( $^{\circ}$ ).
- TL = Tip length (non-standard lengths only) (mm).

Other code indicators: R = rigid taper, BV = bevelled biopsy pipette, L = left hand bend, N = non-spiked injection pipette, C = conical tipped holding pipette, X = superfine glass. Standard parameters: 1.0mm tip length and long parallel taper.



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