#### **SPECIFICATIONS**

ICSION manufactures a comprehensive range of specifications to cater to customer requirements. While many commonly ordered specifications are set out below, we can also manufacture custom specifications.

| PIPETTE              | PRODUCT<br>CODE | ID<br>(μm) | OD<br>(µm) | BEVEL<br>(degrees) | TIP ANGLE<br>(degrees) | TIP LENGTH<br>(mm) | TAPER    |
|----------------------|-----------------|------------|------------|--------------------|------------------------|--------------------|----------|
| HOLDING              | H-15/120-XX     | 15         | 120        | -                  | 20, 25, 30, 35         | 1.0                | Parallel |
|                      | H-20/100-XX     | 20         | 100        | -                  | 20, 25, 30, 35         | 1.0                | Parallel |
|                      | H-25/120-XX     | 25         | 120        | -                  | 20, 25, 30, 35         | 1.0                | Parallel |
|                      | H-30/120-XX     | 30         | 120        | -                  | 20, 25, 30, 35         | 1.0                | Parallel |
| INJECTION            | I-4.0-XX        | 4.0-4.5    | -          | 30                 | 20, 25, 30, 35         | 1.0                | Parallel |
|                      | I-4.0-XXN*      | 4.0-4.5    | -          | 20                 | 20, 25, 30, 35         | 1.0                | Parallel |
|                      | I-4.0-XXL**     | 4.5-5.0    | -          | 30                 | 20, 25, 30, 35         | 1.0                | Parallel |
|                      | I-4.0-XX-0.6    | 4.0-4.5    | -          | 30                 | 20, 25, 30, 35         | 0.6                | Parallel |
|                      | I-4.5-XX        | 4.5-5.0    | -          | 30                 | 20, 25, 30, 35         | 1.0                | Parallel |
|                      | I-4.5-XXL**     | 4.5-5.0    | -          | 30                 | 20, 25, 30, 35         | 1.0                | Parallel |
|                      | I-5.0-XX        | 5.0-5.5    | -          | 30                 | 20, 25, 30, 35         | 1.0                | Parallel |
| PIEZO<br>INJECTION   | PIX-4.0-XX      | 4.0-4.5    | -          | -                  | 20, 25, 30             | 1.0                | Piezo    |
|                      | PIX-4.5-XX      | 4.5-5.0    | -          | -                  | 20, 25, 30             | 1.0                | Piezo    |
|                      | PIX-5.0-XX      | 5.0-5.5    | -          | -                  | 20, 25, 30             | 1.0                | Piezo    |
| BIOPSY               | B-15-XX         | 15         | -          | -                  | 30, 35                 | 1.0                | Parallel |
|                      | B-20-XX         | 20         | -          | -                  | 30, 35                 | 1.0                | Parallel |
|                      | B-23-XX         | 23         | -          | -                  | 30, 35                 | 1.0                | Parallel |
|                      | B-23-XX-BV      | 23         | -          | 40                 | 30, 35                 | 1.0                | Parallel |
|                      | B-25-XX         | 25         | -          | -                  | 30, 35                 | 1.0                | Parallel |
|                      | B-27-XX         | 27         | -          | -                  | 30, 35                 | 1.0                | Parallel |
|                      | B-30-XX         | 30         | -          | -                  | 30, 35                 | 1.0                | Parallel |
|                      | B-35-XX         | 35         | -          | -                  | 30, 35                 | 1.0                | Parallel |
|                      | B-40-XX         | 40         | -          | -                  | 30, 35                 | 1.0                | Parallel |
| ASSISTED<br>HATCHING | AH-09-XX        | 9          | -          | -                  | 30, 35                 | 1.0                | Parallel |
|                      | AH-11-XX        | 11         | -          | -                  | 30, 35                 | 1.0                | Parallel |
| PZD                  | PZD-XX-0.6      | 0-1        | -          | -                  | 30, 35                 | 0.6                | Rigid    |

\* Non-spiked injection pipette.

\*\* Left hand bend.

\*\*\* "XX" represents tip angle (i.e. I-4.0-30 has a 30 degree tip angle).



**ICSION Medical Pty Ltd** U13-15, 22 Ware Street Thebarton SA 5031

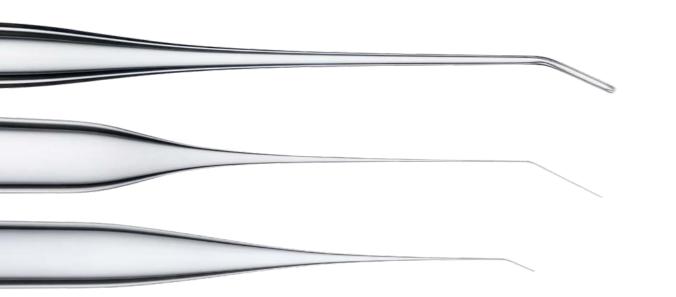
+61-417456657 icsion@icsionmedical.com

# **MICROPIPETTES** MADE FOR MIRACLES









#### QUALITY CONTROL ICSION has a comprehensive array of rigorous

QUALITY ASSURANCE AND

QA and QC measures including:

- ✓ 100% in-process inspection by experienced technicians with strict rejection standards covering cleanliness and dimensional tolerances.
- ✓ Additional production lot inspections undertaken prior to packaging.
- Post-sterilisation testing by an experienced embryologist using ICSI equipment to ensure proper functionality with fertility media, oil and PVP.
- ✓ 96h 1-cell to expanded blastocyst mouse embryo assay (MEA) product testing by an ISO 17025 accredited independent laboratory.
- Endotoxin (LAL) product testing by an ISO 17025 accredited independent laboratory.
- Regular independent bioburden testing of the cleanroom, airlock and gloves worn by staff.
- Regular independent bioburden and endotoxin testing of ultrapure water used in production.
- ✓ Packaging validated as per ISO 11607-1 and ASTM D4169.
- Packaging and sterilisation validated to a Sterilisation Assurance Level (SAL) of 10<sup>-6</sup> as per ISO 11137.

#### **REGULATORY CERTIFICATIONS**

ICSION products are CE marked under the EU Medical Device Regulation 2017/745 (MDR) and are included in the Australian Register of **( €** 0123

Therapeutic Goods (ARTG).

### PRODUCTS

ICSION manufactures a wide range of micromanipulation pipettes including:

- Holding pipettes.
- Injection pipettes, including Piezo injection pipettes.
- Polar body, blastomere and trophectoderm biopsy pipettes.
- Assisted hatching pipettes.
- Partial zona dissection pipettes.
- Other pipettes used in research applications.



## **COMMITMENT TO QUALITY**

ICSION's commitment to quality is paramount. We are ISO 13485 certified to ensure a robust and thorough quality management system and our manufacturing facility is state-of-the-art.

#### **ULTRACLEAN MANUFACTURING**

An ultraclean manufacturing environment ensures ultraclean micropipettes. This is achieved as follows:

- ✓ Manufacturing and packaging in an ISO 14644 certified cleanroom.
- ✓ Multiple tiers of air filters to remove VOCs, bacteria and particles from the air.
- ✓ Use of cleanroom coveralls, hoods, overshoes, masks and gloves.
- ✓ Use of ultrapure water (18.2 M $\Omega$ -cm, TOC < 20 ppb) for all relevant cleanroom processes.
- Extensive cleaning of borosilicate glass capillaries in ultrapure water.
- ✓ Heat treating borosilicate glass capillaries to destroy potential endotoxins, RNA and DNA.
- ✓ Comprehensive ultraclean environmental and manufacturing controls and procedures.



#### **EXCELLENCE IN DESIGN**

ICSION offers a range of designs. Notable features include:

- Holding pipette tips are flat and square to provide greater support for oocytes and embryos.
- Injection pipette spikes are carefully crafted and assessed to optimise clinical outcomes.
- Non-spiked injection pipettes are offered with a sharp bevel.
- Injection pipettes have long parallel tapers for excellent fluid control and visibility. Steeper tapers are also available.
- Piezo injection pipettes are made from both standard and Superfine<sup>™</sup> glass.
- Biopsy pipettes and assisted hatching pipettes are carefully checked for cutting flaws and are lightly heat polished to minimise cell damage.
- Partial zona dissection pipettes have sharp tips and steep tapers for easier penetration of the zona pellucida.
- · Pipettes have polished bases to prevent damage to microtool holder seals.
- Pipettes are individually packed in colourcoded packaging.
- Pipettes are packaged in a holder that allows easy and safe removal.