

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 CODE	ID (µm)	OD (µm)	BEVEL (degrees)	TIP ANGLE (degrees)	TIP LENGTH (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 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 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).



MICROPIPETTES

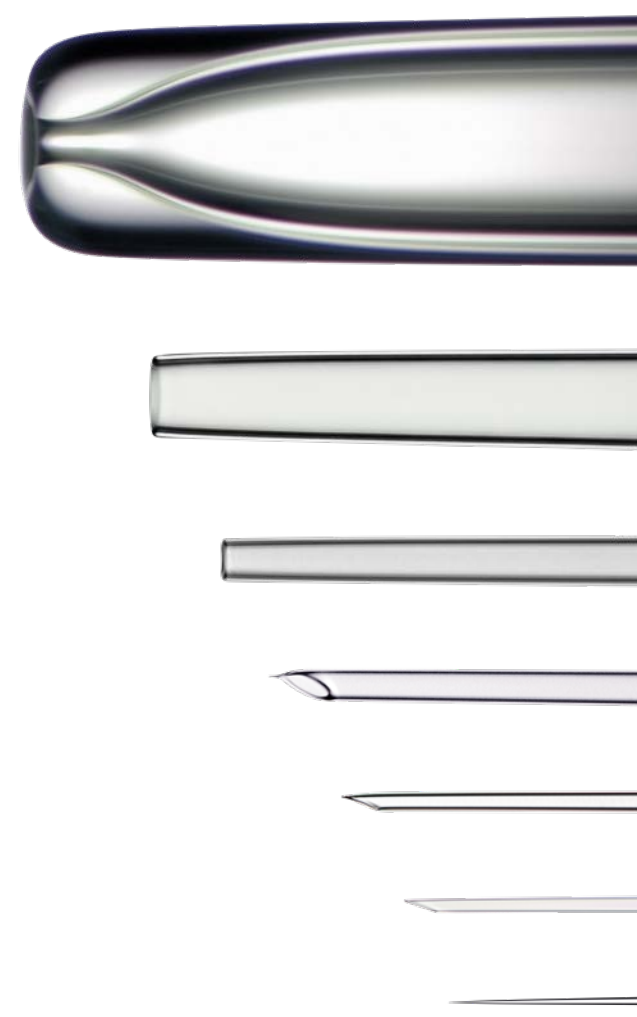
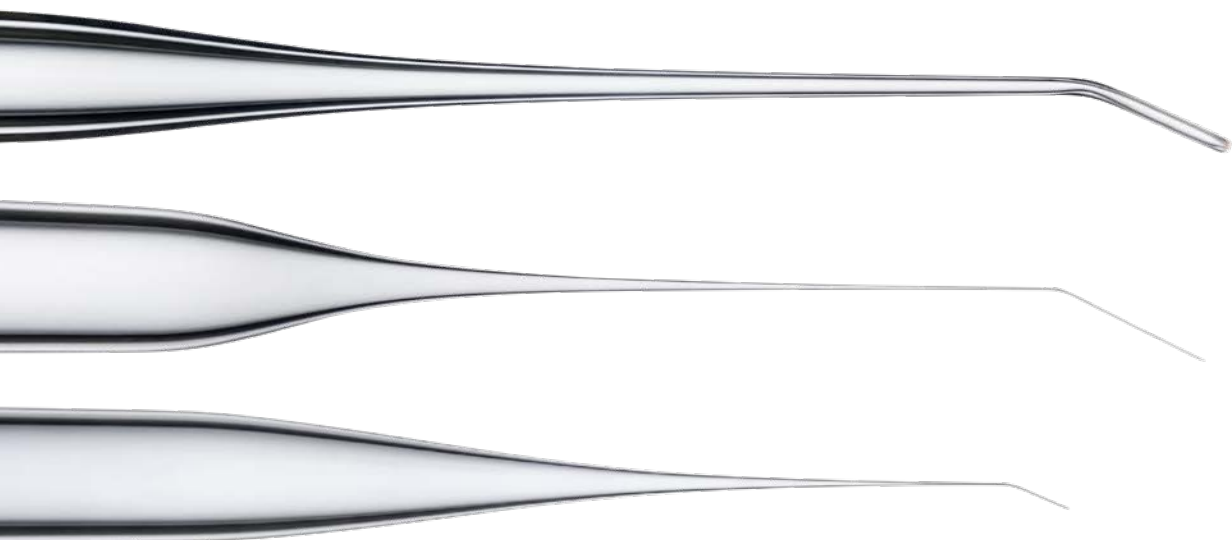
MADE FOR MIRACLES



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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 MΩ-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.

QUALITY ASSURANCE AND QUALITY CONTROL

ICSION has a comprehensive array of rigorous 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^{-6} 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 Therapeutic Goods (ARTG).



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™ 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 colour-coded packaging.
- Pipettes are packaged in a holder that allows easy and safe removal.

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.

