

## Instructions for Use \_ Microtools

### Device Name

Microtools

### Indication for Use

Microtools are intended for micromanipulation of human gametes and embryos in vitro during assisted reproduction technology (ART).

The target group is gametes and embryos derived from an adult or reproductive-age population who undergoes fertility treatment.

### Description

Microtools are made of borosilicate glass and sterilized by irradiation procedure. Microtools include Injection Pipette, Holding Pipette, Biopsy Pipette, Partial Zona Dissection Pipette, Assisted Hatching Pipette, Denuding Pipette and Transfer Pipette.

### Intended User

The product should be used by embryology laboratory professionals who are performing assisted reproductive technology procedures.

### Contraindications

No known contraindications.

### Matching Devices/Tools

Model	Matching Devices/Tools	Specifications for Matching Devices/Tools
Injection Pipette, Holding Pipette, Biopsy Pipette, Partial Zona Dissection Pipette, Assisted Hatching Pipette	Micromanipulator	The inner diameter of the front of the holder is about 1mm.
Denuding Pipette	Holder, Silicone Bulb	The inner diameter of the opening of the silicone bulb is about 1.2 mm.
Transfer Pipette	Syringe	1mL syringe

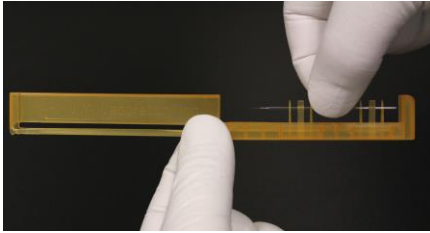
### Recommended Procedures

#### Preparation for Use:

- a. Hold case from its ends, pull and slide from each side.



- b. Gently hold and lift pipette out the case.



Note: This preparation procedure does not apply to the Transfer Pipette.

#### Injection Pipette

The Injection Pipette (or ICSI pipette) is used to inject a single sperm directly into an oocyte.

#### Holding Pipette

The Holding Pipette is used to ensure immobility of oocytes or embryos during ICSI or biopsy procedures.

#### Denuding Pipette

The Denuding Pipette is used for the removal of cumulus cells from the cumulus-oocyte complexes (COCs). The Denuding Pipette is also used for transferring oocytes, blastomeres, and embryos.

#### Biopsy Pipette

The Biopsy Pipette is used for removal of a blastomere from an embryo or polar bodies from oocytes for pre-implantation genetic diagnosis (PGD) on the genetic material in the biopsied cells.

#### Partial Zona Dissection (PZD) Pipette

The Partial Zona Dissection Pipette is used to create an incision in the zona pellucida to enable assisted hatching.

#### Assisted Hatching (AH) Pipette

The Assisted Hatching Pipette is used to create a hole in the zona pellucida to enable embryo assisted hatching using Tyrode's acid solution.

#### Transfer Pipette


The Transfer Pipette is used to transfer COCs into washing or culture dishes after oocyte collection.

### **Storage and Transport Instructions**

The device should be stored at temperature 0-30°C and relative humidity 35-75%. It should be handled with great care during transportation, prevented from pressuring, dropping down and wet weathers.

### **Precautions**

1. To prevent bio-contamination, Microtools are intended for single use only and should not be reused or re-sterilized.
2. Discard product if the product or packaging is damaged or wet or if the pipette has been contaminated during unpacking or mounting. Do not use broken pipettes.
3. Remove Microtools from their protective covering just before use, in an appropriate environment. Sterility is no longer guaranteed if the pouch is opened.
4. Be careful not to get punctured by the glass sharps.
5. Don't touch the tip to avoid damage of the pipette when using.

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6. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

7. Dispose of medical waste in accordance with the relevant local regulations of EU Member States.

### Clinical Benefits

1. The product can be used for micromanipulation of human gametes and embryos in vitro during assisted reproduction technology (ART), including denuding cumulus cells from the oocytes, ICSI, embryo biopsy, assisted hatching and oocyte and embryo transfer from culture dish or medium droplet.

2. The product can be used as a device for control or support of conception.



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### Glossary of Symbols

Symbols as defined in ISO 15223-1:

	Manufacturer
	Date of manufacture
	Catalogue number
	Batch code
	Use-by date

	Sterilized using irradiation
	Authorized representative in the European Community
	Medical device
	Unique device identifier
	Do not re-use
	Do not use if package is damaged and consult instructions for use
	Single sterile barrier system
	Temperature limit
	Humidity limitation
	Caution
	Fragile, handle with care
	CE marking and notified body ID
	Caution: Federal law restricts this device to sale by, or on the order of physician.