

RI SOS™ Oil Syringe

User Manual

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SECTION 1 - PREFACE

Thank you for choosing the SOS.

This manual provides all the necessary information to use the Research Instruments SOS syringe. The syringes should be operated by trained personnel only. All sections of this manual should be read and understood fully before use. Please see the Intended Use for more information.

If you are unsure of any of the information contained in this manual, contact Research Instruments (RI) or an authorised representative before attempting to use the syringes.

In no event does RI assume the liability for any technical or editorial errors of commission, or omission; nor is RI liable for direct, indirect, incidental, or consequential damages arising out of the use or inability to use this manual.

RI is constantly updating its products, and therefore reserves the right to introduce changes in design, equipment and technical features at any time.

The SOS manual belongs with the syringe and should be passed on with the syringe if relocated to another facility.

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CooperSurgical Distribution
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SECTION 2 - INTRODUCTION TO THE SOS

Intended Use

To provide aspiration capabilities to micropipettes during Assisted Reproductive Technology (ART) procedures.

Intended User

Trained clinical professional with locally relevant qualifications.

Clinical Benefits

To facilitate treatment of a patient by manipulation or modification of the patients' reproductive cells and / or tissue in vitro.

Intended Patient Population

For those who require assisted reproduction treatments to improve their chances of a healthy pregnancy.

Applicable Part Numbers

Part Number	Description
6-34-700	SOS Oil Syringe

Micromanipulator Compatibility

The SOS can be used in conjunction with any micromanipulation system that is designed to be fitted with industry standard 1mm OD micropipettes. However CooperSurgical, Origio or TPC micropipettes are recommended.

Installation

Please follow the installation instructions to ensure the correct operation of your syringe. Installation of the SOS syringe should be carried out by qualified and trained personnel only. Incorrect installation could result in poor overall performance.

Relocation of this syringe should be treated as a re-installation and should, therefore, be carried out by trained personnel.

The only user-serviceable parts are those detailed in the Troubleshooting and Care and Maintenance Sections.

SECTION 3 - SAFETY WARNINGS & CAUTIONS

Warnings



High pressure can be generated in the system when using small diameter micropipettes, viscous fluids, or if a micropipette becomes blocked. This may cause micropipettes to shoot out of the holder. Before releasing the pipette from its holder, release the pressure in the syringe by pressing the release button on the top.

To minimise the risk of injury:

- Never point the pipette towards yourself or anyone else
- Always make sure the pipette is securely mounted in the holder before use
- Release the pressure before loosening the micropipette tip
- When removing a pipette from the holder, be sure to hold the pipette between your fingers as the holder tip is loosened

A self-adhesive warning label is supplied, which should be placed in a prominent position as close as possible to the device when in use.

Cautions



The syringes should be operated by qualified and trained personnel only.

Glossary of Safety and Information Symbols

Source: ISO 15223-1

Symbol	Meaning
	In accordance with the European Medical Device Regulation 2017/745
	Authorized representative in the European Community
	Consult instructions for use
	WARNING: Indicates a potentially hazardous situation which, if not avoided, could result in serious injury or death.
	CAUTION: Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the device itself.
	Manufacturer
	Date of manufacture
	Medical device
	Catalogue or Part number
	Serial number
	Unique Device Identifier

SECTION 4 - PRODUCT OVERVIEW

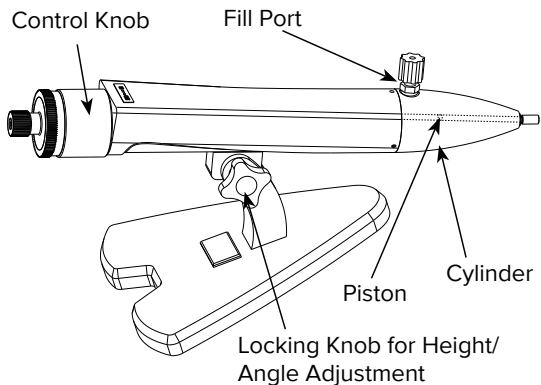
Welcome to the user manual for the Research Instruments SOS syringe. This manual covers set-up, operation and maintenance of the syringe.

The SOS (Screw-actuated Oil Syringe) is designed for the precise transfer and injection of spermatozoa in Intracytoplasmic Sperm Injection (ICSI) by using oil. Oil is essentially incompressible, so precisely and instantly transfers the movement of the control knob to the sample in the pipette.

We recommend sterile filtered paraffin oil, available from your media supplier. In order to work correctly, the syringe and tubing must be filled with oil with no visible air bubbles, apart from a small bubble that is necessary between the media and the oil in the micropipette.

Inventory

- 1 x SOS
- 5 metres of tubing
- Spares kit and service instructions
- SOS user manual
- Pressure warning label



Specification Table

Description	Measurement
Piston stroke	50mm
Maximum displaced volume	830µl
Volume displaced per turn	8.3µl
Total fill volume (including tubing)	Approx. 2ml
Weight	1.5kg
Overall dimensions	260 x 135 x 80mm

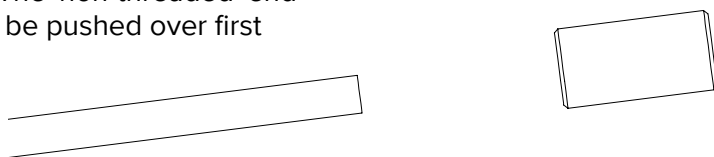
SECTION 5 - SET-UP

Fitting Tubing to a SOS

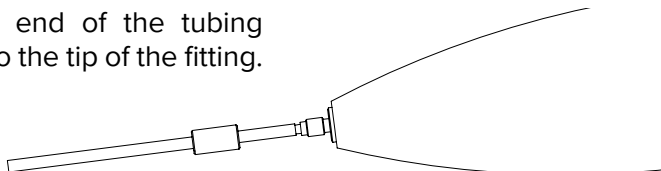
Use hard polythene tubing as supplied by RI. Use of any other tubing may result in poor specimen control.

1. Slide the nut over the tubing.

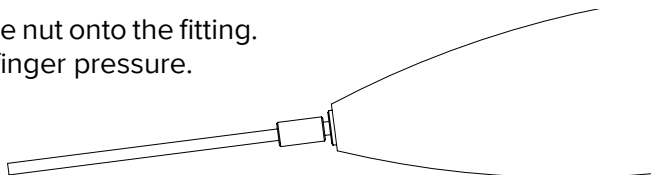
Note: The non-threaded end should be pushed over first



2. Push the end of the tubing firmly onto the tip of the fitting.



3. Tighten the nut onto the fitting. Use only finger pressure.

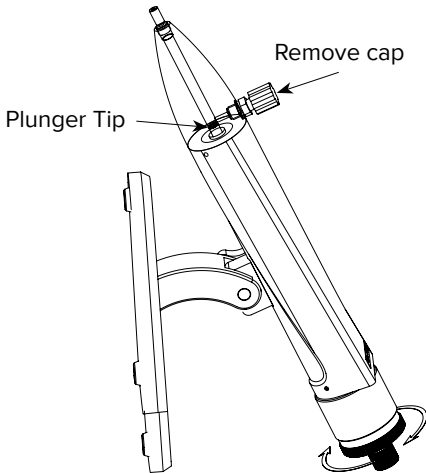


4. Fit the other end of the tubing to the micropipette holder.

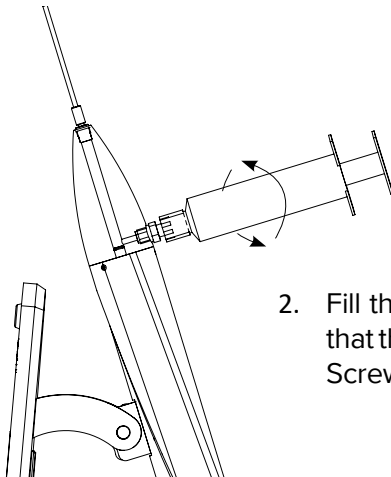


Filling a SOS with Oil

RI recommends sterile filtered paraffin oil. Syringes and caps must be screwed onto the fill port with gentle finger pressure only. Overtightening may damage the fittings.



1. Turn the control knob to move the plunger below the fill port (if not already below). Stand the SOS on end as shown. Remove the cap from the fill port.



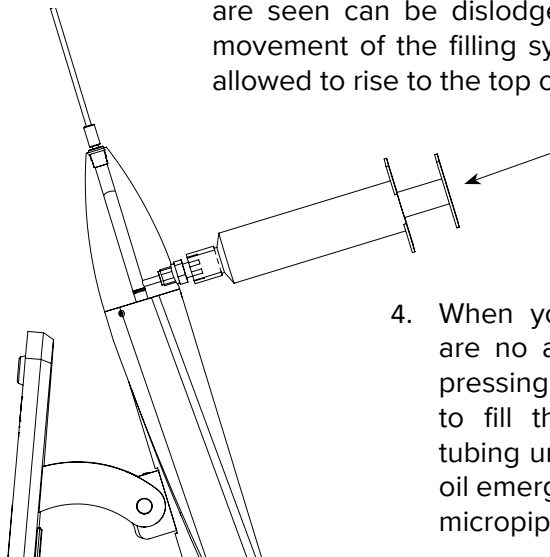
2. Fill the syringe supplied with oil ensuring that there are no air bubbles in the syringe. Screw the syringe onto the fill port.

Section 5

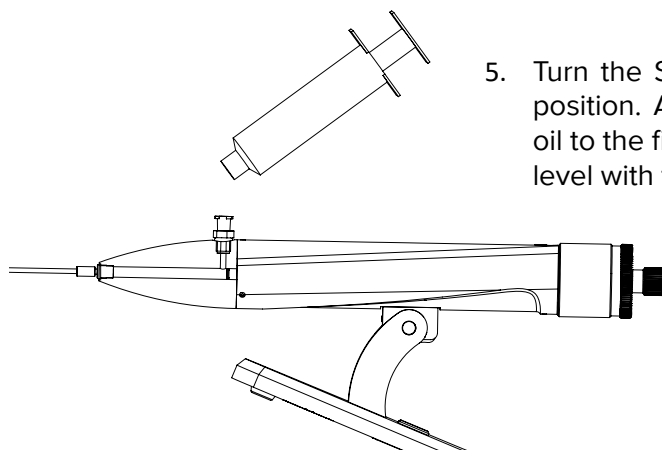
Set-up

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3. Press the syringe plunger slowly until the level of oil in the cylinder is just below the tip. Look closely for any air bubbles in the oil. Any that are seen can be dislodged by a short, sharp movement of the filling syringe and should be allowed to rise to the top of the oil.

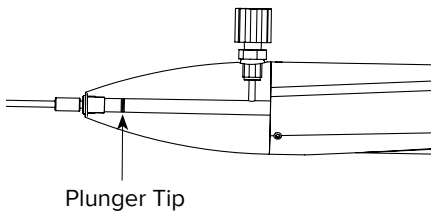
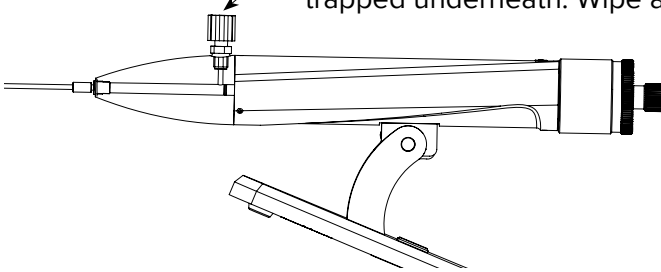


4. When you are certain there are no air bubbles, continue pressing the syringe plunger to fill the cylinder and the tubing until a small amount of oil emerges from the tip of the micropipette holder.

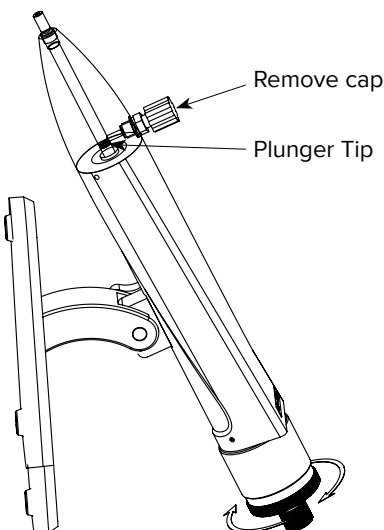


5. Turn the SOS to a horizontal position. Add a few drops of oil to the fill port until the oil is level with the top of the port.

6. Refit the cap ensuring that no air bubbles are trapped underneath. Wipe away any spilled oil.



7. With each procedure the operating position of the plunger will move further towards the tip of the SOS. When the plunger is close to the tip as shown, the system should be topped up with oil.



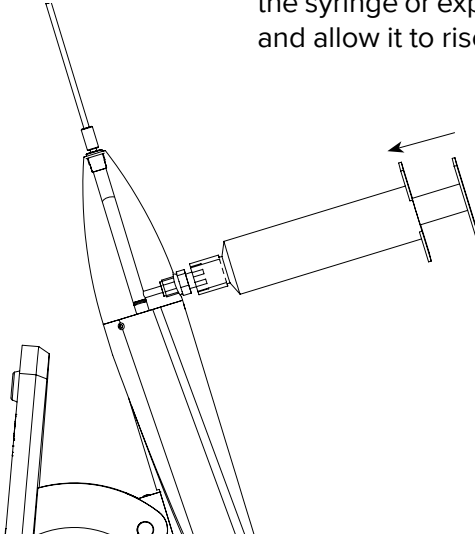
8. Turn the control knob to move the plunger below the fill port. Stand the SOS on end as shown below. Remove the cap from the fill port. Fill the syringe with oil ensuring that there are no air bubbles in the syringe.

Section 5

Set-up

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9. Add a few drops of oil to the fill port and insert the syringe ensuring that no air bubbles are trapped. If an air bubble is seen then reattach the syringe or expel the bubble into the cylinder and allow it to rise to the top before continuing.



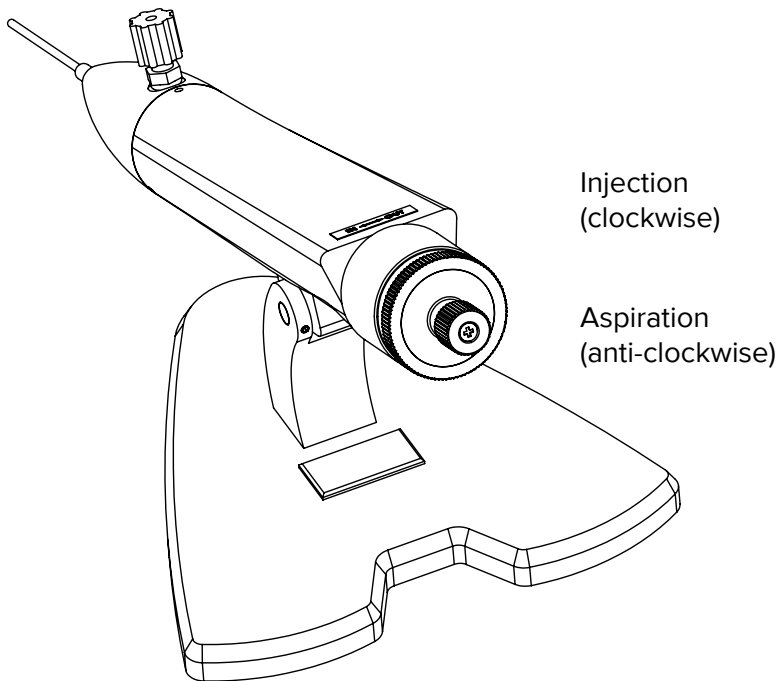
10. Now press the syringe plunger slowly to fill the cylinder and the tubing. Next fill the port and replace the cap.

SECTION 6 - BASIC OPERATION

Fitting a Micropipette

1. Hold the micropipette holder vertically and turn the control knob clockwise until a drop of oil emerges from the tip. Slide the micropipette into the holder and tighten the tip.
2. Part fill the micropipette with oil by turning the SOS control knob, but make sure there is an air bubble between the oil and the media. This avoids contact between the oil and the media, reducing the risk of contamination.

Using a SOS



SECTION 7 - TROUBLESHOOTING

Problem	Possible cause	Solution
Poor control	Air bubbles	Check for and remove air bubbles - see Section 5 - Set-up, Filling a SOS with Oil, Step 3.
	Blocked micropipette	Replace the micropipette.
	Oil leak	Check for leaks. Cut 10mm from the end of the tubing and refit see Section 5 - Set-up, Fitting Tubing.
		Replace the O-ring in the cylinder if necessary - see service instructions included with the spares kit.
	Incorrect oil	Use sterile filtered paraffin oil.

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If the problem persists, contact your distributor for assistance.

SECTION 8 - CARE & MAINTENANCE

Cleaning

If oil or media is introduced into the system it will need to be dismantled and cleaned. This should be entrusted to a CooperSurgical technician only.

Use a dust cover to protect the SOS when not in use. This will minimise the need for cleaning. We recommend and supply a non-PVC dust cover as plasticisers commonly used in flexible PVC are known to be embryotoxic.

Always remove any spilt liquid or dirt immediately and keep instruments clean and dry.

Liquid Spills

If liquid is spilt inadvertently, dry the instrument immediately. If it is suspected that liquids have gone inside the instrument then contact Customer Service for advice before use.

SECTION 9 - WARRANTY INFORMATION AND LIMITS ON LIABILITY

CooperSurgical warrants that this item will be free from defects in materials and workmanship for one year from the date of installation. If CooperSurgical determines that the product fails to conform to that warranty during the one-year period, CooperSurgical will repair or replace the product, at CooperSurgical's discretion, free of charge.

To return the product to CooperSurgical, a customer must comply with CooperSurgical's Returned Goods Policy described in this manual and the warranty requires the customer to return the product to CooperSurgical in accordance with the CooperSurgical Returns Instruction. CooperSurgical will return products (that it repaired or replaced under warranty) to the same customer who returned those products, at CooperSurgical's expense F.O.B. the customer's facility. Under all other circumstances, CooperSurgical will return products to the same customer who returned those products at the customer's expense.

CooperSurgical's warranties do not cover damage caused by misuse, improper care, improper use of chemicals or cleaning methods, loss, theft, use of non-authorized parts, servicing by non-authorized personnel or negligent or intentional conduct on the part of the owner or user of the product, nor do they cover normal wear and tear or general maintenance. Any modifications or changes to a product will void that product's warranty. CooperSurgical's warranties do not apply to any single- or limited-use, disposable or consumable components or items.

CooperSurgical is not responsible for, and the owner and operator of the product shall defend, indemnify and hold harmless CooperSurgical from and against, all claims, damages, and other losses resulting from the improper servicing, maintenance, repair, use or operation of the product or the owner or operator's negligence or willful misconduct, and use of inadequate packing and packaging when returning product for repair.

The above warranties are in lieu of, and CooperSurgical hereby disclaims, all other warranties, express or implied, written or oral, with respect to CooperSurgical products, including the warranties of merchantability and fitness for a particular purpose. No terms, conditions, understandings or agreements that purport to modify the above warranties or that make any additional warranties for any CooperSurgical product shall have any legal effect unless made in writing and signed by an authorized CooperSurgical corporate officer.

CooperSurgical shall not under any circumstances be liable for lost profits, damages from loss of use or lost data, or indirect, special, incidental or consequential damages under its warranties or otherwise for any claim related to CooperSurgical products, even if CooperSurgical has been advised, knew or should have known of the possibility of such damages. CooperSurgical's liability with respect to a product covered by a warranty or otherwise shall be limited in all circumstances to the purchase price of that product.

SECTION 10 - RETURNING PRODUCT FOR REPAIR

Please refer to the 'Troubleshooting' section in this manual before returning the product. If problems continue with the device, please follow these instructions:

Returned Goods Policy

Goods will be accepted for return for the following reasons:

- If shipment was made without the customer's authorization or order
- If incorrect items were shipped
- If defective items were shipped
- If defective goods are covered by the standard warranty

To return product, please contact Customer Service for a Returned Merchandise Authorization (RMA) number. Items will not be accepted without an RMA number. Please have the following information:

- Reason for returning the goods
- Quantity, description, part number, serial number of the goods
- Date of receipt of order
- Customer's purchase order and the CooperSurgical or Origio invoice number

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All used products must be cleaned and sterilized prior to shipment. A signed decontamination declaration may be required.

All products should be carefully and adequately packed, preferably in original packaging. Replacement items or additional repairs will be invoiced.

All packaging should be clearly labeled with the RMA number and statement "Urgent – Returned Items for Repair". If authorization to return a product is granted you will be provided with a return address label.

Shipments must be sent prepaid by the customer and insured for their full value during shipping. Freight collect shipments will not be accepted, and goods will be returned to the sender.

If the customer intends to return equipment ordered in error, the following restocking charges and terms will apply:

- 25 percent within 60 days from date of shipment
- Goods must be returned unused, in the original carton, and in marketable condition
- Refurbishing and replacement charges will be added to the restocking charges for damaged or missing items
- No return after 60 days
- No refund on sterile, single-use disposable products

Customer Service Contact details

Tel: +45 46 79 02 02

Fax: +45 46 79 03 02

E-mail: sales@coopersurgical.com

fertility.coopersurgical.com

Contact details for customers in the USA

Tel: 800-243-2974

Fax: 800-262-0105

fertility.coopersurgical.com

Obligation to Inform

If a serious incident is suspected from using the SOS Oil Syringes, report the details of the incident to CooperSurgical via phone number +1 203-601-5200 Ext 3100 or by email at ProductSurveillance@coopersurgical.com and to the local Health Authority in your country. A serious incident may have caused or contributed to a death, a delay in a procedure which resulted in death or serious injury, or a malfunction that could have caused an adverse event.

Feedback

Thank you for purchasing an RI product. To help CooperSurgical develop the best tools for ART, we rely on customer feedback. If you have any suggestions for how we can improve our products or the information we provide with them, please send them to Customer Service. Your feedback will help us develop the product and supporting materials to meet your future needs.

Thank you.

