User Manual

SAS™ & SAS-SE™

Air Syringes

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CE

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1 SECTION 1 - PREFACE

Thank you for choosing the SAS™ or SAS-SE™.

This manual provides all the necessary information to use the Research Instruments SAS™ and SAS-SE™ syringes. 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 in Section 2 for more information.

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

In no event does Research Instruments Ltd (RI) assume the liability for any technical or editorial errors of commission, or omission; nor is Research Instruments 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 SAS™ & SAS-SE™ manual belongs with the syringes and should be passed on with the syringes if relocated to another clinic.

The use of ™ in this manual indicates a trademark of Research Instruments Ltd. Any other brand names referred to in this manual are trademarks of their respective owners.

⚠ This indicates cautionary text which should be followed to avoid injury to users or damage to samples.

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

SECTION 2 - INTRODUCTION

Intended Use

To control the aspiration or expulsion of spermatozoa and biopsy samples to and from a micropipette and to hold oocytes and embryos during Intracytoplasmic Sperm Injection (ICSI), biopsy and assisted hatching procedures.

Applicable Part Numbers

Part Number	Description
6-34-520	SAS™ Air Syringe
6-34-530	SAS-SE™ Air Syringe

Micromanipulator Compatibility

The SAS™ and SAS-SE™ can be used in conjunction with any micromanipulation system that is fitted with industry standard 1mm OD micropipettes. However, Research Instruments micropipettes are recommended.

Installation

Please follow the installation instructions to ensure the correct operation of your syringe. Installation of the SAS™ and SAS-SE™ syringes 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

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.

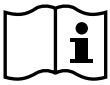
Before releasing the pipette from its holder, release the pressure in the syringe by pressing the release button on the top.

Handle glass pipettes with care.

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 MPH 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

Safety/Information Symbols

Symbol	Meaning
CE	In accordance with Annex II of the European Medical Device Directive 93/42/EEC, as amended by 2007/47/EC.
	Indicates the medical device manufacturer.
	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 medical device itself.
	Consult instructions for use.
SN	Serial number.
Rx Only	Caution: US Federal law restricts this device for sale to or on the order of a licensed healthcare practitioner.

SECTION 4 - PRODUCT OVERVIEW

Welcome to the user manual for the Research Instruments SAS™ and SAS-SE™ screw-actuated air syringes. This manual covers set-up, operation and maintenance of the syringes.

For air-assisted micro-injection and micro-aspiration, the SAS™ and SAS-SE™ syringes apply suction or pressure to a micropipette. They can generate high pressure when required, but they are sensitive enough to balance the capillary action of media in a micropipette and to precisely position a sample.

The syringes are a complete unit incorporating a heavy base, which enables them to be ergonomically positioned for operation in conjunction with the control lever of a micromanipulator. Aspiration/injection is obtained by turning the rotator.

Inventory

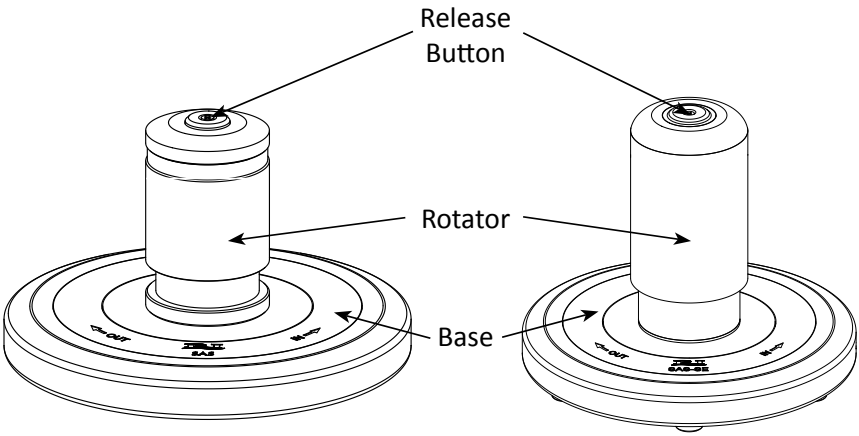
SAS-SE™

- 1 x SAS-SE™
- 3 metres of tubing
- SAS™ and SAS-SE™ user manual
- Pressure warning label

SAS™

- 1 x SAS™
- 3 metres of tubing
- 2 Spare o-rings
- SAS™ and SAS-SE™ user manual
- Pressure warning label

Hardware Overview



SAS™ SAS-SE™

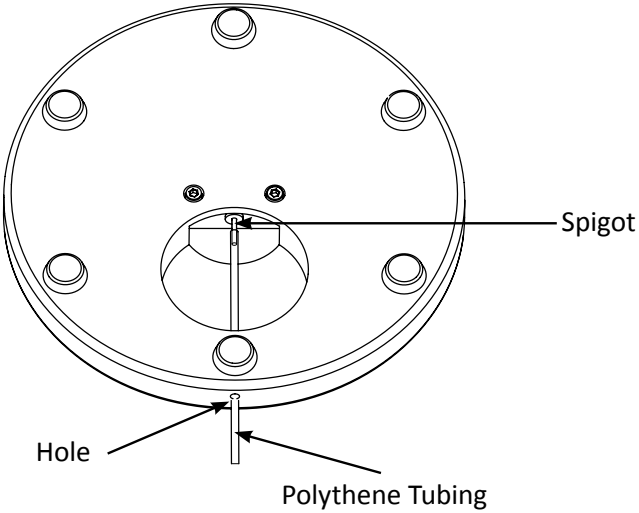
SAS™ Specification Table

Description	SAS™	SAS-SE™
Piston stroke	23mm	30mm
Max displaced volume*	18.5ml	24ml
Volume displaced per turn*	1.6ml	1.6ml
Weight	1.4kg	1.7kg
Overall dimensions	125mm diameter x 95mm high	125mm diameter x 120mm high

*At atmospheric pressure only. Due to pressure differences, the actual volume displaced in the pipette is considerably smaller, and will vary according to the geometry of the micropipette and the viscosity of the media used.

SECTION 5 - SET-UP

> ⚠ Do not fill the syringe or tubing with oil.

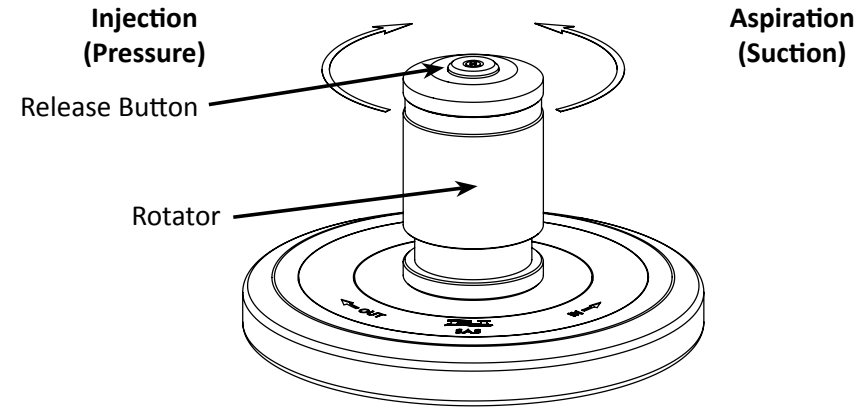


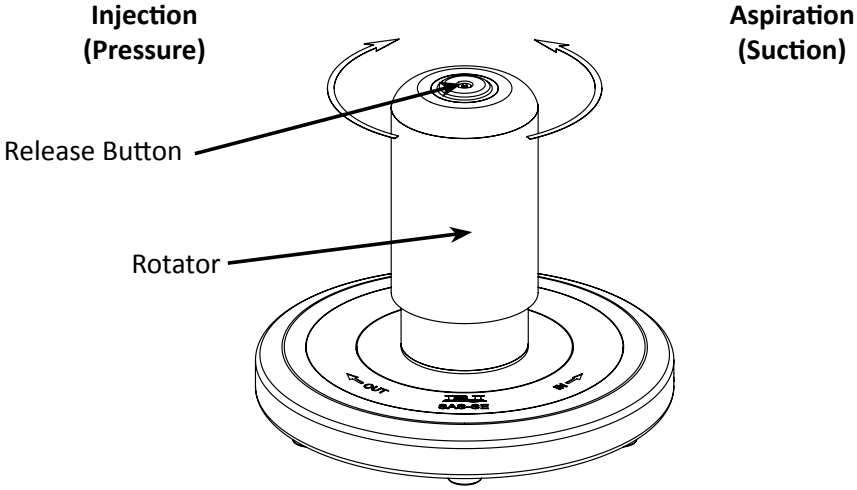
1. To set up the syringe, turn the unit upside down.
2. Insert the end of the hard polythene tubing through the hole in the side of the base.
3. Push the tubing over the spigot, ensuring that the tubing is securely fitted.
4. The other end of the tubing is fitted to the micropipette holder. Please refer to the manipulator or micropipette holder instructions for how to connect the tubing to the micropipettes.
5. Equilibrate the system (see page 9).

It is recommended that SAS™ and SAS-SE™ syringes are positioned on the bench adjacent to the micromanipulation system controls. It is common to position the syringes on opposite sides of the micromanipulation system to their respective pipettes to enable the syringe and micromanipulation system controls to be used at the same time.

SECTION 6 - BASIC OPERATION

Aspiration/Injection is obtained by turning the rotator on top of the syringe.





⚠ 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. Press the release button to release the pressure before loosening the micropipette holder tip to remove a micropipette.

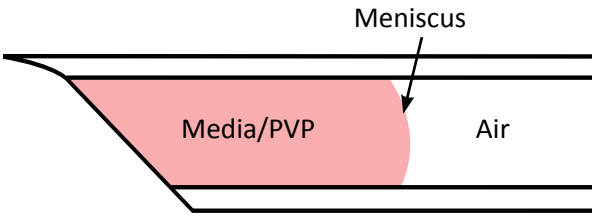
Equilibrating a Micropipette

This procedure balances the pressure in the syringe with the capillary action of the pipette to allow optimum control of sperm injection.

The following is a typical procedure. However, other methods are possible such as using medium without PVP. Individual clinics may develop their own procedures.

1. Place a drop of PVP/media in a Petri dish.
2. Ensure the rotator is near the lower end of the movement. Turn the rotator down (clockwise) if necessary.
3. Press the release button.
4. Using the micromanipulator set-up lever, lower the micropipette into the PVP/media drop. Do not allow the PVP/media to enter the tubing. The level of the PVP/media should always be clearly visible inside the pipette.
5. Turn the rotator anti-clockwise (ie upwards) five to six turns for an injection pipette and one turn for a holding pipette.
6. Press the release button.
7. Leave to equilibrate for 1-2 minutes.
8. Equilibration is successful when the meniscus of the media inside the micropipette is static, and responds to small movements of the control knob in either direction.

   Additionally, under high 20x or 40x magnification, expel the media almost to the end of the pipette to see the meniscus responding to the control of the syringe.



SECTION 7 - TROUBLESHOOTING

Problem	Possible cause	Solution
Unable to aspirate/inject. No pressure. Too much lag. Sperm moves slowly up the pipette.	Micropipette may be blocked	Change the micropipette for a new one.
	The specimen may have dried up	Warm stage heat can dry an unprotected or insufficiently protected specimen. A generous layer of mineral oil over the specimen in its medium drop will protect it from drying out.
	There may be an air leak in the injector system	Check in order: 1. Check that the nose piece of the micropipette holder has been tightened properly. 2. Check the connection of the hard plastic tubing onto the syringe spigot. If the connection is loose cut off approximately 10mm from the tubing and reconnect. See Section 5 - Set-up. 3. Check the connection of the hard plastic tubing onto the micropipette holder. If the connection is loose, cut off approximately 10mm from the tubing and reconnect. See Section 5 - Set-up. 4. Check the o-ring in the micropipette holder nose piece. If the o-ring is worn out due to a long period of use it will need replacement. Refer to manipulator or micropipette holder instructions for further information about replacing the o-ring seal.

Problem	Possible cause	Solution
Sperm is moving in/out of the pipette too quickly.	Check the micropipette holder tip is completely clear. Any tiny shards of broken glass will break the seal.	Remove the micropipette holder tip from the tubing. Separate the parts as required to remove all shards of glass.
	The o-ring inside the rotator may need replacing (SAS™ only).	See Section 7 Care and Maintenance for instructions.
	Your injection micropipette needs equilibrating.	Please see instructions for equilibrating a micropipette on page 9.
	Equilibration is not complete or the rotator has been turned too far.	Press the release button. Capillary action will cause the PVP/medium to move up the pipette. This can be countered with a small clockwise movement of the rotator to balance the pressure.

If the problem persists, contact RI or your distributor for assistance.

⚠ Do not fill the syringe or tubing with oil.

SECTION 8 - CARE AND MAINTENANCE

Cleaning

If oil or media is introduced into the system it will need to be dismantled and cleaned. This should be entrusted to an RI-authorised technician only.

Use a dust cover to protect the syringes 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.

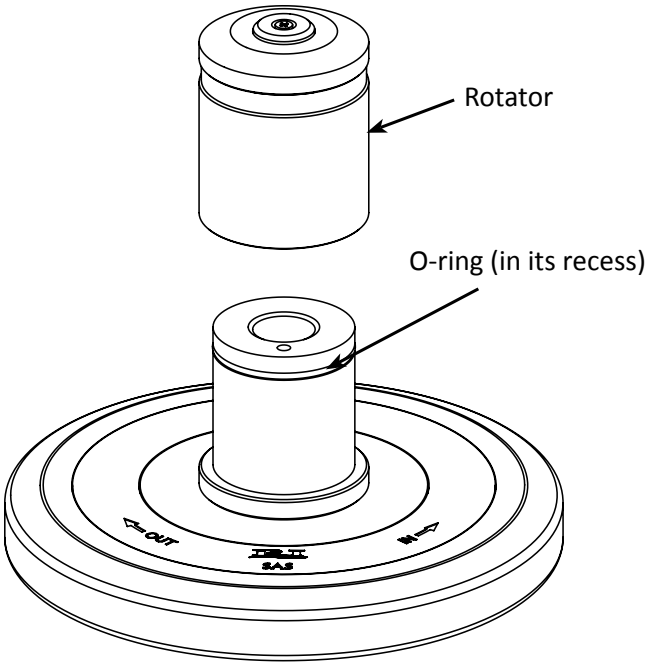
Liquid Spills

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

Fitting a New O-ring (SAS™ model only)

After a lot of use the o-ring may need replacing to ensure smooth and accurate operation.

1. Remove the rotator by unscrewing it completely, revealing the o-ring. The o-ring is situated in a recess in the lower part of the syringe.
2. Ease the old o-ring off the mechanism.
3. A spare o-ring will have been supplied with the original purchase.
4. Apply Krytox™ GPL205 grease, available from RI, to the o-ring recess.
5. Place the new o-ring in the recess, apply a little more Krytox™ GPL205 grease on top of the o-ring and re-assemble.



SECTION 9 - REPAIRS AND RETURNS PROCEDURES

Reuse Statement

Assuming your SAS™ and/or SAS-SE™ are regularly maintained and routinely serviced, they should perform as required for a minimum of 7 years continual use, after which time we recommend you consider replacement. Should you notice impaired performance and/or any issues where safety is compromised, or have any other concerns during the use of this SAS™ and/or SAS-SE™, seek the advice of Research Instruments or an authorised representative promptly. The year of manufacture is stated on the label on the base of the syringe.

RI Repairs System

In the event that you have a problem with an RI instrument, please follow the procedure below to ensure prompt attention.

1. Read the 'Troubleshooting' section.
2. If you require any further help contact your distributor or RI directly. RI will try to resolve the problem as quickly as possible.

RI Returns System

1. Contact RI to obtain a Returned Materials Authorisation (RMA) number. **Note:** Goods will not be replaced or refunded without prior agreement and clearly stating the RMA number.
2. Pack the item carefully in its original packaging. RI will not accept responsibility for damage due to incorrect packaging. Replacement items or additional repairs will be invoiced.
3. Clearly label the package with the RMA number, mark the package "Urgent - Returned Items For Repair", and ship to the address on the next page. Goods should be insured for their full value during shipping.

Disposal of Goods

Dispose of the syringe in accordance with local regulations.

Contact Details

Research Instruments Ltd, Bickland Industrial Park,
Falmouth, Cornwall, TR11 4TA, UK
Tel: +44 (0) 1326 372 753 Fax: +44 (0) 1326 378 783
E-mail: service@research-instruments.com
Website: www.research-instruments.com

For all queries or service issues please contact your authorised distributor or RI's service team on service@research-instruments.com

Obligation to Inform

In compliance with the European Medical Device Directive 93/42/EEC as amended, it is your duty to inform RI and your competent authority if you believe this device has, or may have, caused or contributed to the death of a patient or user or to a serious deterioration in their state of health.

Feedback

Thank you for purchasing an RI product. To help RI 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 feedback@research-instruments.com. Your feedback will help us develop the product and supporting materials to meet your future needs.

Thank you