



December 17, 2014

URGENT FIELD SAFETY NOTICE

StatSpin MP Centrifuge (SSMP)
RT12 Tube Rotor – Kit (RT12)

Dear StatSpin SSMP Distributor,

As a valued partner, we wanted to make you aware of a Field Safety Corrective Action we are initiating. This information is regarding the use of the **RT12 Rotor** used in the StatSpin MP Centrifuges.

Attached is the Field Safety Notice regarding the RT12 Rotor Assembly used on the StatSpin MP Centrifuge. As an Iris International Distributor, please forward the attached letter to all StatSpin MP Centrifuge end users.

Please complete the attached response form within 10 days of receiving this letter and return the form to the designated contact stated at the bottom of the response form.

If you have any questions regarding this letter, please feel free to contact Scott Milsom, Director, StatSpin Business at smilsom@beckman.com.

We apologize for any inconvenience this announcement has caused you or your customers. As always, we appreciate your continued support and cooperation.

Sincerely,

A handwritten signature in blue ink that reads "Sudha Gupta".

Sudha Gupta
Director of Quality Assurance

Enclosures: Urgent Field Safety Notice
Response Form



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StatSpin MP Centrifuge (SSMP)
RT12 Tube Rotor – Kit (RT12)

Dear Customer,

Iris International is sending this letter regarding the RT12 Rotor and the SSMP Centrifuge. The letter contains important information that needs your immediate attention.

ISSUE:	<p>Iris International has received reports of uncontained debris (part fragments) as a result of rotor breakage and lid failures on similar centrifuge models which use the RT12 rotor and shield.</p> <p>The information included in this letter is intended to supplement the current SSMP Operator Manual. A shield was implemented on similar models and this notification is to inform SSMP users that the shield must be used when operating the centrifuge.</p> <p>There have been no reports of the StatSpin MP Centrifuge failing to contain debris when users operate StatSpin MP centrifuges according to the StatSpin MP Operator’s Manual (Doc # 55-001806-001) and RT12 Tube Rotor Instructions (Doc # 54-006155-001).</p>
IMPACT:	<ul style="list-style-type: none">• If the RT12 rotor breaks and the centrifuge fails to contain debris, escaping debris may result in possible operator injury, direct exposure to biohazardous materials, and/or loss of sample.• Rotor breakage may result in damage to the centrifuge
ACTIONS:	<ul style="list-style-type: none">• Rotors should be inspected for cracks and should be replaced immediately when a crack or visible wear occurs.• If rotor breakage results in damage to your centrifuge, do not use your centrifuge until it is repaired.• To ensure operator safety while utilizing the StatSpin MP centrifuges, please remember the following key points:<ul style="list-style-type: none">• Operating Requirements<ul style="list-style-type: none">○ Whenever you are using or maintaining the centrifuge, wear Personal

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Protective Equipment (PPE).

- Maintain a 300 mm clearance around the centrifuge for ventilation and safety (*Operator's Manual; Section 1, Unpacking and Installation, Install Note 2*).
- Make sure the tube rotor is balanced before operation (*Operator's Manual; Section 3, Operating Instructions, Caution #5*).

- Hardware Requirements

- The RT12 rotor has a finite lifespan that is dependent on usage. The RT12 rotor and the shield should be replaced after approximately 3600 cycles, which is equivalent to 18 months of service running an average of 10 cycles per day. (*RT12 Tube Rotor Instructions: Rotor Lifetime*).
- Verify the laboratory is using the latest version (Rev H) of the Operator's Manual. Revision letter is located in lower right corner of page 14 of the Operator's Manual. If you need the StatSpin MP Centrifuge Operator's Manual revision H visit the Beckman Coulter website at <http://www.beckmancoulter.com> .
- The shield must be used in conjunction with the RT12 rotor at all times. See diagram below:



- Replace the RT12 rotor and shield if you have exceeded the rotor's usable life of 3600 cycles.
- If you are unsure of the age of your RT12 rotor, discontinue use and order a replacement rotor and shield (REF X00-006153-001).
- Please order replacement RT12 rotors directly from your local distributor.



	<ul style="list-style-type: none">○ When replacing the RT12 rotor and shield please follow the instructions included with the RT12 rotor. We have attached these instructions for your convenience.○ Periodically inspect the lid assembly for cracks and wear. If you observe signs of damage or wear, contact your distributor or an authorized service provider for repair.○ Clean the lid following the Cleaning instructions (Operator's Manual; Section 5, Maintenance).
RESOLUTION:	IRIS International is currently investigating this issue.

Share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected products to other laboratories, please provide them a copy of this letter.

Beckman Coulter will be managing the logistics of this notice. If you have any questions regarding this letter, additional information can be requested:

- Via website at <http://www.beckmancoulter.com>.
- Or by contacting your local distributor.

We apologize for the inconvenience to your laboratory.

Sincerely,

Sudha Gupta
Director Quality Assurance

Enclosure: Tube Rotor Instructions for RT12 kit

REF RT12 – Kit (Includes: RT12 Rotor, O-Ring & (2) SV12 Adaptors & Shield, Exp Labels)

Rotor Lifetime

The RT12 rotor has a finite life span that is dependent on usage. The rotor should be replaced after approximately 3600 cycles which is equivalent to 18 months of service running an average of 10 cycles per day. Rotors should be inspected for cracks and should be replaced immediately when any crack or visible wear occurs. SV12 adaptors should be replaced at the same time as RT12 rotor.

Always replace the shield when replacing the RT12 rotor.



Caution

Universal Precautions should be followed on all specimens, regardless of whether a specimen is known to contain an infectious agent.¹

Intended Use

For *in vitro* diagnostic use.

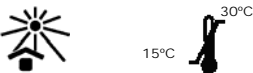


For use with product numbers: SSMP and SSVT.

Use **SV12 Adaptors** for BD Microtainer® Tubes with flow-top collector **ONLY**.

Do not spin glass tubes.

Storage

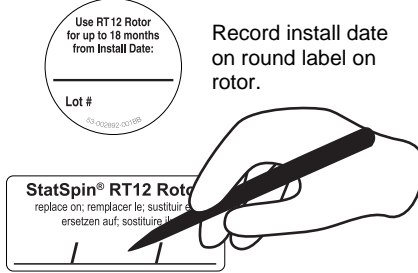


Instructions for Use

1. Install RT12 rotor in centrifuge by pushing the rotor down onto the rotor-holder, using moderate force.
2. Shield Installation instructions: Press the shield into the bowl until it makes full contact with the bottom of the bowl.



Note: To remove the shield, pull up on the center edge of the shield.



Note: Write date on the reminder label with a date 18 months from the install date of rotor

3. Insert collection tubes in rotor. Balance rotor using either another sample or a tube containing water. Balancing does not have to be exact.

OR

For use w/ BD Microtainer

4. Install (2) SV12 microtainer adaptors into RT12 rotor. Adaptor should drop into rotor sleeve freely. Do not apply excessive force. Adaptors must be used in sets. Be sure (2) are installed prior to spin.
5. Insert BD Microtainer tubes in rotor. Balance rotor using either another sample or a tube containing water. Balancing does not have to be exact.
6. Close and latch cover.
7. Select cycle.
8. When cycle is complete, open cover and remove tubes.
9. As a general rule, the rotor should not be left on the rotor-holder as this may compress the O-ring, decreasing its ability to hold the rotor.
10. **Do not spin glass tubes.** Do not spin any tube not supported in the rotor by a collar at the top of the tube or which fits so loosely that it rests on the bottom of the rotor sleeve.
11. If rotor is left in centrifuge and only tubes are exchanged between runs, push down rotor on the rotor-holder before spinning another sample, to ensure rotor is seated properly.

Maintenance

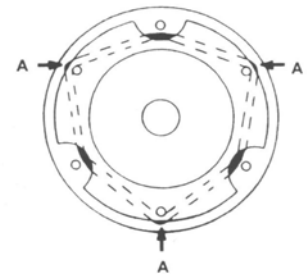
- **Cleaning** – The rotor, shield and SV12 inserts may be cleaned with a water-dampened cloth.
- **Lubrication of O-Ring** – If the rotor becomes difficult to install, apply a very small amount of silicone-type lubricant to the 3 points on the O-ring gasket.

Microtainer is a registered trademark of Becton, Dickinson and Company

- The O-ring should be inspected regularly and replaced immediately if it appears “flattened” or worn.
- The O-ring should be replaced as preventive maintenance at least once a year.
- The O-ring should be replaced when a new rotor is installed.

Caution: Do not operate the centrifuge without a shield in place when using an RT12 rotor. Do not use a shield with the RH12 Microhematocrit rotor

- To replace O-ring: remove Rotor from rotor-holder use a pointed object (such as a large paperclip) to remove O-ring from the rotor-holder. Install new O-ring by weaving it behind and in front of the 6 pins on the rotor holder.



Reference

1. “Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline – Third Edition.” CLSI document M29-A3 [ISBN 1-56238-567-4, CLSI, 940 West Valley Rd. Suite 1400, Wayne, PA 19087-1898 USA, 2005



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