

Directions for Use



The generator is delivered in the kit that comes with your choice of Sodium Chloride BP injection vials, sterile swabs, needles and evacuated vials. The generators are sterile and pyrogen free when they leave ARI, Menai, NSW. Observe aseptic technique during the use of the generator.

1

Remove generator and its accessories from the transport packaging. Install in user shield.



2

Lift Gentech handle. Rotate cover until you expose the blue saline spike and outer filter. Push down handle to lock the lid in the operating position.



3

Remove flip off seal from saline vial (5, 10 or 20 mL). For elution volume between 5 and 20mL, aseptically remove unwanted saline from 10 or 20 mL vials with hypodermic needle and discard. Recommended minimum elution volume is 5 mL.



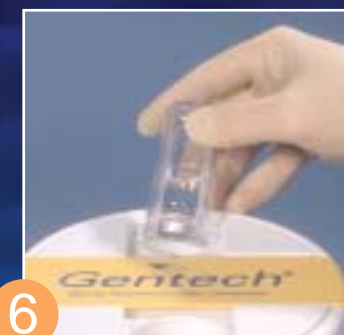
4

Place Gentech 0.9% Sodium Chloride BP (Saline) vial into Gentech saline cover. Swab the exposed part of the silicone septum with the pre-injection swab provided. **Allow to dry.**



5

Remove the blue protective cap from the Gentech saline spike.



6

Align the lugs of the Gentech saline cover with grooves in the port of the Gentech top and push down firmly. When vial is fully depressed, turn clockwise in direction of arrows to engage vial on the saline spike and lock the saline cover in place.



7

Remove white plastic lid from the elution vial shield. Unscrew metal top and remove the red flip-off seal from the 30 mL evacuated elution vial. Place it into the elution vial shield and screw in the top to hold vial in place. Swab top of elution vial shield and the exposed part of the septum with the pre-injection swab provided. **Allow to dry.**



8

Grip the red protective cap (male luer closure), turn it anti-clockwise through 90° and remove from the outlet filter. Attach a sterile elution needle (screw clockwise) with elution needle cover in place. (Caution: do not over-tighten). Remove elution needle cover.



9

Invert elution vial shield with evacuated vial over elution needle. Lower the elution vial shield until it is fully penetrated by the elution needle. Allow at least 3 minutes to complete elution.

10

Observe emptying of the saline vial and filling of the elution pot indicated by the sight and sound of air bubbles in the elution vial.

11

Check through the elution vial shield window that elution occurred. If elution did not occur, repeat steps 3 and 4 and 6 to 10 with a fresh evacuated vial.



12

Remove the elution vial shield with the collection vial from the elution needle. Cover elution vial with the elution vial shield lid.

13

Put elution needle cover back on to the elution needle and leave it in place until next elution. (Replace with fresh sterile elution needle and cover before each elution).



14

Do not remove saline vial assembly until the next elution.

15

Affix label to the elution vial shield indicating elution time and date and that the contents are radioactive.

16

Assay the contents of the vial for its ^{99m}Tc contents using a previously calibrated ^{99m}Tc dose calibrator (or other suitable measuring instrument). Record the results and calculate the total ^{99m}Tc content of the vial.

17

Perform a gamma spectroscopy test to determine extent of molybdenum [⁹⁹Mo] breakthrough. Alternate method described by Richards and O'Brien* could also be used.

Troubleshooting Tips

When Generator Is Not Eluting:

1. Check that the elution needle is not loose (see step 8).
2. Try another elution vial.
3. If you inadvertently remove the elution vial before it finishes eluting, the column will become wet and will need to be dried. Attach a fresh elution vial but don't replace the saline vial - this will allow air (not saline) to pass through and this will make the column dry.
4. Call ARI.

To Prevent Damaging the Spike:

1. Ensure that the protective flip off seal is removed from the saline vial.
2. Ensure that the blue protective cap is removed from the saline spike.
3. Ensure that the saline vial is placed on the spike vertically and not at an angle.



Ansto radiopharmaceuticals
and industrials

PMB 1, Menai NSW 2234
Australia wide: 1800 251 572
International: + 612 9543 4544
Facsimile: + 612 9543 6511
Website: www.ansto.gov.au/ari

Subsequent Elutions

1. Remove used saline vial (by twisting anti-clockwise), then repeat steps 3, 4, and 6, 7.
2. Remove used elution needle (by twisting anti-clockwise) and replace with a fresh sterile elution needle.
3. Repeat steps 9 through to 17. (Include a Molybdenum [⁹⁹Mo] breakthrough test on each elution).

Reference

* Richards, P. and O'Brien, M.J., Rapid determination of ⁹⁹Mo in separated ^{99m}Tc. J. Nucl. Med., 10: 517, 1969.

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