

Directions for use

The Gentech® generator is delivered with 0.9% Sodium Chloride injection BP (saline) vials, evacuated elution vials, sterile swabs and needles. The generators are sterile and pyrogen free when they leave ANSTO. Observe aseptic technique during the use of the Gentech® generator.



1

Remove the Gentech® generator and its accessories from the transport packaging. Install in the Gentech® garage or the user shielding.

2

Lift the Gentech® handle. Rotate the cover until the yellow saline spike cover and elution outlet filter are exposed. Push the handle down to lock the lid in the operating position.

3

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

4

Place a Gentech® saline vial into the **new** Gentech® saline vial holder, provided in the foam insert of the transport packaging with every generator. Swab the exposed part of the saline vial's silicon septum with a sterile swab provided. **Ensure to allow to dry.**

5

Remove the yellow protective cap from the Gentech® saline spike.

6

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

7

Remove the white plastic lid from the elution vial shield. Unscrew the metal top. Remove the red flip-off seal from a 30 mL evacuated elution vial. Place the decapped vial in the elution vial shield and screw on the metal cap to hold the vial in place. Swab the top of the evacuated elution vial shield and the exposed part of the septum of the evacuated elution vial, with a sterile swab provided. **Ensure to allow to dry.**

8

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

9

Invert the prepared elution vial shield onto the sterile needle. Lower the evacuated elution vial shield until the evacuated elution vial is fully penetrated by the sterile needle. **Allow at least 3 minutes to complete the elution.**

10

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

11

Visually check the saline vial is empty. Through the elution vial shield window, check that the elution has occurred. If the elution did not occur, repeat steps **3** and **4**, and **6** to **10** with fresh saline and evacuated elution vials.

12

Remove the elution vial shield from the sterile needle. Cover the elution vial shield with the white plastic lid.

13

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

14

Do not remove the saline vial assembly until the next elution.

15

Record the appropriate information on the elution vial in accordance with your facility procedures, such as date, time and the contents being radioactive.

16

Assay the contents of the vial for its Tc-99m content using a previously calibrated Tc-99m dose calibrator (or other suitable measuring instrument). Record the results.

17

Perform a gamma spectroscopy test to determine the extent of Mo-99 breakthrough. The method described by *Richards and O'Brien may be used.

SUBSEQUENT ELUTIONS

1. Remove the used saline vial (by twisting anti-clockwise) then repeat steps **3**, **4**, and **6**, **7**.
2. Remove the used elution needle (by twisting anti-clockwise) and replace with a fresh sterile needle.
3. Repeat steps **9** through to **17**.

TROUBLESHOOTING TIPS

When generator is not eluting:

1. Check that the elution needle is not loose (see step **8**).
2. Try another evacuated elution vial.
3. If you inadvertently removed the elution vial before it finished eluting, the column will have become wet and will need to be dried. Attach a fresh evacuated elution vial, but do **not** replace the saline vial unless it still contains some saline. In this case, replace it with an empty saline vial. This will allow air and not saline, to pass through and this will dry off the column. This process using an empty saline vial and a new evacuated elution vial can be repeated to ensure the column is dry.
4. Call ANSTO Customer Service on **1800 251 572** or email health@ansto.gov.au

To prevent damaging the spike, ensure:

1. To use the new Gentech® saline vial holder, provided with every new generator in the foam insert of the packaging of every new Gentech® generator.
2. The protective flip off seal is removed from the saline vial.
3. The lid of the Gentech® generator garage is fully open, to allow clear access to the Gentech® generator.
4. The yellow protective cap is removed from the saline spike.
5. The saline vial is placed on the spike vertically and not at an angle.
6. Following swabbing of the silicon septum of the saline vial, **ensure to allow to dry**



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