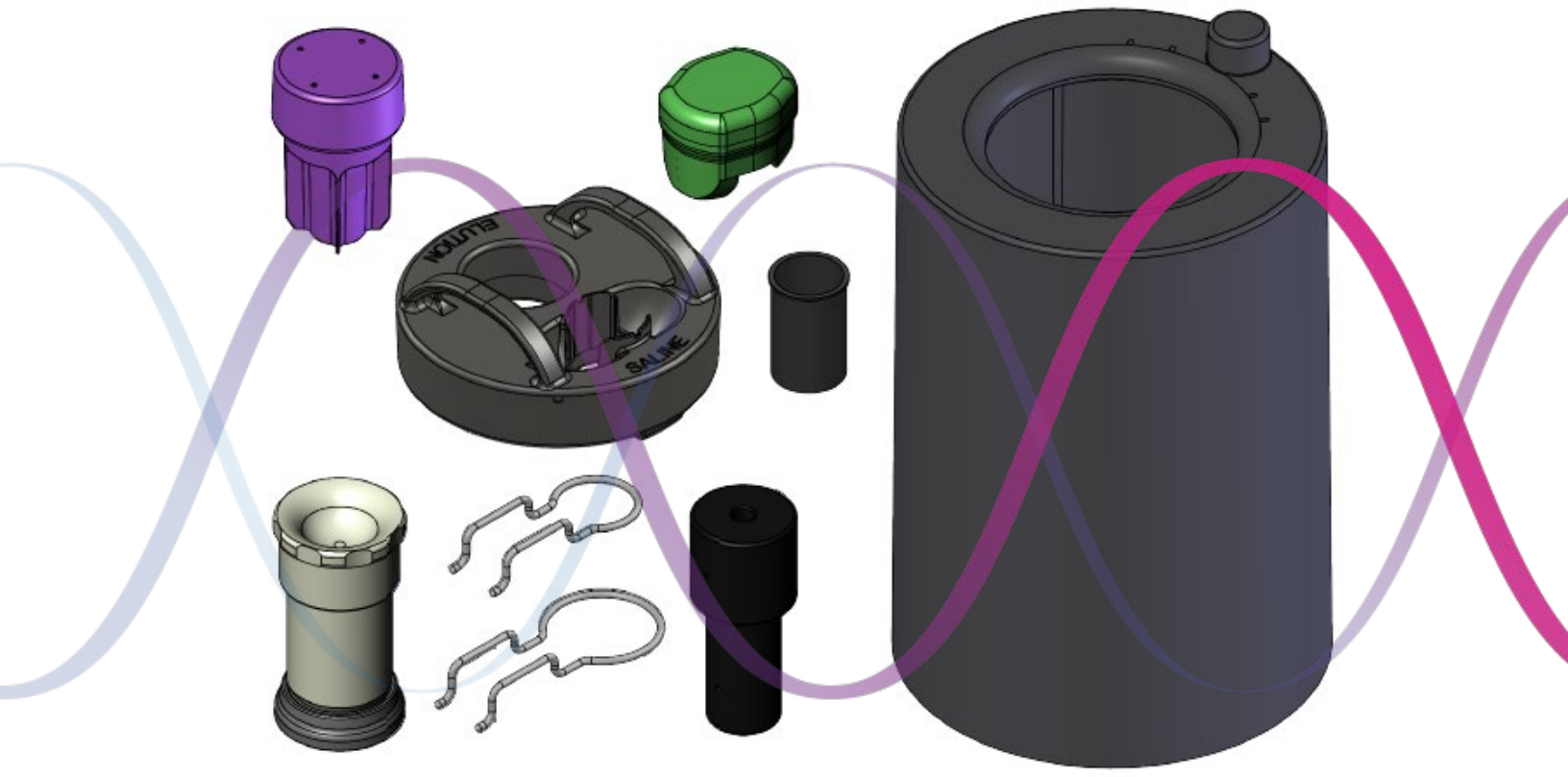
LIFE FORWARD

Generator Accessories
Ultra-Technekow™ V4
(technetium Tc 99m generator)

User Manual for Installation, Service & Parts



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SAFETY

The Ultra-Technekow™ V4 (technetium Tc 99m generator), referred to hereafter in this manual as the Ultra-Technekow V4 generator or UTK-V4 generator, may be received, used and administered only by authorized persons in designated clinical settings. Its receipt, storage, use, transfer and disposal are subject to the regulations and/or appropriate licenses of local competent official organizations. Users are to be nuclear medicine professionals who have had training in the safe use and handling of radioactive material and who also have received training specific to the nuclear pharmacy and these tools. Reading this manual will allow the operator to become familiar with components and procedures.

RADIATION SAFETY PRECAUTIONS

Refer to your site's written instruction for the minimum appropriate Personal Protection Equipment (PPE) for the safe and proper handling of radioactive material. ***NOTE:*** One microcurie of Tc-99 on the skin will deliver a dose rate of 21 R/hr. Use caution throughout the handling and elution of the UTK-V4 generator, as well as during cleanup of the Pharmacy Tools to prevent skin contamination. If skin contamination is suspected, discontinue the process and perform appropriate surveys. Notify your Health Physics department and/or your supervisor so that decontamination procedures can be initiated.

WARNING!

The generator houses needles in two locations. Sticks, minor scratches, cuts or puncture of the skin could cause internal radioactive contamination if the needle is covered with radioactive residue. Seek immediate medical attention as required by the nuclear pharmacy or nuclear medicine facility. Failure to follow this warning could result in personal injury and/or elevated levels of radiation exposure.

WARNING!

The generator should either be returned to Curium US LLC or disposed of in accordance with applicable nuclear regulations. Under no circumstance should the generator be disassembled. Failure to follow this warning could result in personal injury and/or elevated levels of radiation exposure. As required by the Nuclear Regulatory Commission (NRC) license, the Curium manufacturing facility, located in Maryland Heights, MO is expected to maintain control of the DU shields. Therefore, prompt return of the DU-shield generators and proper chain of custody procedures must be observed by all parties involved in the return shipment of a DU generator.

WARNING!

Always dispose of radioactive materials in accordance with local radioactive material license requirements and corresponding regulations. Failure to follow this warning could result in personal injury and/or elevated levels of radiation exposure.

WARNING!

Used syringes should always be disposed of in accordance with local radioactive material license requirements and corresponding regulations. Failure to follow this warning could result in personal injury and/or elevated levels of radiation exposure.

WARNING!

Radioactive drips can occur at the elution needle of the generator during elution. Clean up all excess fluid and dispose of in accordance with local radioactive material license and corresponding regulations. Failure to follow this warning could result in personal injury and/or elevated levels of radiation exposure.

IMPORTANT RISK INFORMATION

Ultra-Technekow V4 (technetium Tc 99m generator)

WARNINGS AND PRECAUTIONS

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

As in the use of any radioactive material, care should be taken to minimize radiation exposure to the patient consistent with proper patient management and to ensure minimum radiation exposure to occupational workers.

INTRODUCTION

The Pharmacy Tools are to be used for elution and kit preparation.

1.1. INTENDED USE

The Pharmacy Tools are used in the process of eluting sodium pertechnetate Tc 99m solution from the UTK-V4 generator. These tools are only to be used with Curium's UTK-V4 generators.

1.2. QUALIFICATIONS

Users are to be nuclear medicine professionals who have had training in the safe use and handling of radioactive material and also who have received training specific to the nuclear pharmacy and the tools. The tools are used typically in a controlled environment such as a nuclear pharmacy or nuclear medicine facility. The daily setup of the device is typically performed by trained nuclear medicine professionals.

1.3. SPECIFICATIONS

The Pharmacy Tool Pack consists of components that are intended to be used for both elution and dispensing of the radionuclide solution. The Auxiliary Shield Top, Elution Tool, Saline Shield, and Technestat™ Vial Holder are comprised of high density material that provides shielding protection to users during elutions. The Auxiliary Shield Cover is used to protect the Auxiliary Shield. The Tip Cap Replacement Tool is used to cover the elution and eluant needles with stored tip cap plugs. The Tip Cap Replacement Tool Ring and Technestat Vial Holder Ring are tool holders for the Tip Cap Replacement Tool and Technestat Vial Holder, respectively. The Saline Vial Alignment Insert adapts the eluant vial to the Saline Port of the Auxiliary Shield Top. Please note that the Elution Tool is shipped separately and is a component of the Pharmacy Tool Pack.

1.3.1. SYSTEM COMPONENTS

1.3.2. VIAL SIZE

- 5 mL Technestat Vial – provided with the UTK-V4 generator
- 30 mL Evacuated Vial – sold separately
- 20 mL Generator Eluant Vial – sold separately in fill volumes of 5 mL, 10 mL, and 20 mL of 0.9% saline

1.3.3. ENVIRONMENTAL

Pharmacy Tools Transport and
Storage Temperature: .....-40 °C to +70 °C (-40 °F to +158 °F)
10% to 100% relative humidity
(non-condensing)

Pharmacy Tools Operating Temperature: ..... 0 °C to +40 °C (32 °F to +104 °F)
30% to 75% relative humidity
(non-condensing)

Biohazard Disposal: Dispose of biohazardous material in accordance with the requirements of your hospital, facility or local regulations.

1.4. CONSUMABLES

***NOTE*:** The use of consumables not complying with the equivalent safety requirements of this equipment may lead to a reduced level of radiation safety and sterility of the resulting system.

1.4.1. VIALS

Evacuated Vial

- N18930 — 30 mL - 30 vials/case

0.9% Saline Vials (Generator Eluant)

- 28805 — 5 mL fill - 30 vials/case
- 28810 — 10 mL fill - 30 vials/case
- 28820 — 20 mL fill - 30 vials/case

1.5. TERMS

Auxiliary Shield – Shielding assembly consisting of seven lead rings stacked up on top of a lead base that provides protection from radiation exposure.

Auxiliary Shield Cover – High impact polypropylene cover used to protect the lead rings from damage.

Auxiliary Shield Top – Device placed on top of the generator to aid in the guidance of the Elution Tool, Technestat Vial Holder, Saline Vial and Saline Shield. It also provides protection from radiation exposure.

Dispensing – The process of preparing "kits" or unit doses and distributing based on a medical order or prescription by a nuclear pharmacy.

Eluant Vial – Vial containing 5 mL, 10 mL, or 20 mL of a saline solution specifically intended to be used with the UTK-V4 generator.

Eluant Needles – The Eluant Needles consist of an inlet needle and a vent needle. The inlet needle, along with the vent needle, pierces the stopper of the saline vial during an elution. The inlet needle delivers the saline to the column and from there to the evacuated vial. The purpose of the vent needle is to allow filtered air into the saline vial and fluid path during an elution. This allows the evacuated vial to draw through all of the saline during an elution and then equilibrate to atmospheric pressure.

Eluate – The radioactive material obtained by passing the eluant through the UTK-V4 generator.

Elution – The process of extracting the eluant through the generator fluid path with the intention of obtaining the eluate sodium pertechnetate ($Na^{99m}TcO_4$).

Elution Needle –The Elution Needle pierces the evacuated vial stopper initiating an elution and delivers the eluate into the vial.

Elution Tool Body – The shielding device used to house the 30 mL evacuated vial and receives the radioactive solution during the elution of the generator. It also serves as a holder for the vial during the dispensing process.

Elution Tool Magnetic Bottom Cap – The component with magnets used to cover the stopper end of the elution tool body.

Evacuated Vial – The sterile vial with the air removed from its inside that is used as a receptacle for the eluate sodium pertechnetate ($Na^{99m}TcO_4$) during elution.

Generator – Reference to the UTK-V4 generator, a drug product that contains a Molybdenum-99 source which is designed to provide a supply of sodium pertechnetate ($Na^{99m}TcO_4$) when an eluant is passed through the generator.

Mo-99 or "Moly-99" – Molybdenum-99 (radioisotope)

Nuclear Pharmacy – A pharmacy specializing in the preparation, dispensing, distribution and disposal of radiopharmaceuticals.

PPE – Personal Protective Equipment appropriate for the safe handling of radioactive isotopes.

Saline Shield – The device placed over the saline vial to provide radiation shielding during and after an elution.

Saline Vial Alignment Insert – An adapter to properly align the saline vial stopper with the generator needles during placement on the generator.

Technestat Vial – The vial that contains a bacteriostatic solution that helps to maintain sterility of the Elution needle. A Technestat vial is placed in the Technestat Vial Holder which is then placed on the Elution needle in between elutions. The Technestat solution is used to protect the needle from bacterial growth in lieu of alcohol which can have an adverse effect on the generator.

Technestat Vial Holder – The device used to house the Technestat vial. The Technestat Vial Holder has two pieces: the body and the cap. The body contains the Technestat vial and the Technestat cap attaches to the body to provide radiation shielding. In between elutions, a Technestat vial holder containing a Technestat vial is placed on the Eluant needle.

Tc 99m – Radioisotope, in the chemical form of pertechnetate ion $[TcO_4]^-$ produced as a result of the decay of Mo-99.

Tip Cap Replacement Tool – The device used to put tip cap plugs back onto the needles.

UTK-V4 Generator– The abbreviation for the Curium's Ultra-Technekow™ V4 (technetium Tc 99m generator).

Unit Dose – The syringe containing a single dose for patient use.

1.6. MEANING OF SYMBOLS

SYMBOLS LOCATED IN THIS MANUAL

Please regard any message that follows a Warning or Caution symbol.

WARNING!

WARNING! – A warning is the result of hazards which could result in personal injury and/or elevated levels of radiation exposure.

CAUTION!

CAUTION! – A caution is the result of hazards which could result in equipment or property damage.

ELUTION PROCEDURES

2.1 ELUTION

WARNING!

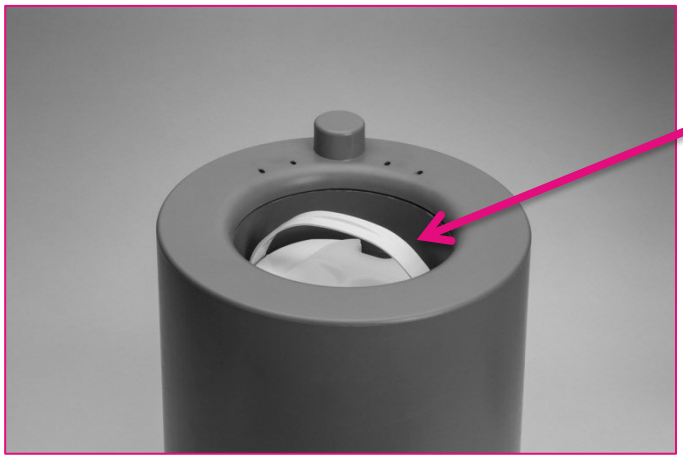
Be sure to wear appropriate PPE for setting up the generator.

CAUTION!

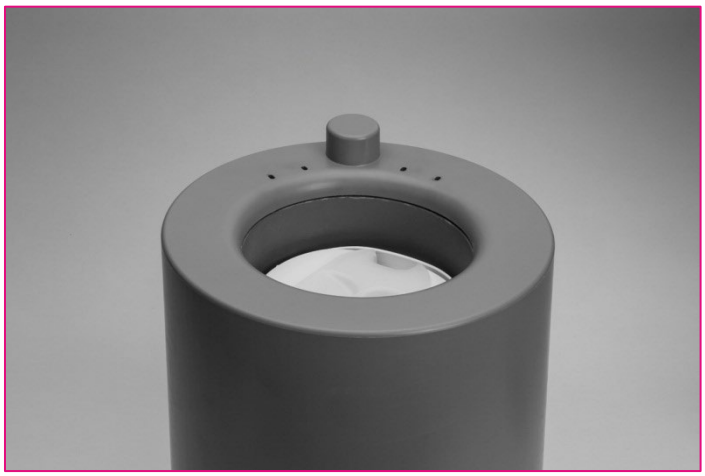
The following disinfectants may be used to wipe down the non-porous polycarbonate surface of the generator: hydrogen peroxide (3%), Sporicidin® Disinfectant Spray, Solution, Aerosol (Ready to Use) or Vesphene ® IIse (1:128 Dilution). Other chemicals should not be used to disinfect the non-porous polycarbonate surface of the generator.

2.1.1. PREPARATION STEPS

1. Carefully lower the generator into the Auxiliary Shield utilizing the lifting handle.

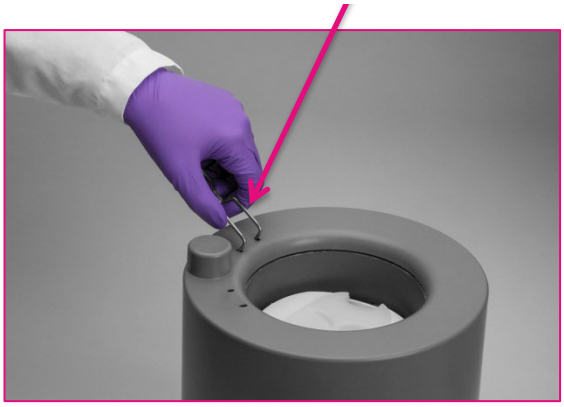


Move the handle to the side in between the generator and the Auxiliary Shield so it does not cover the generator top.

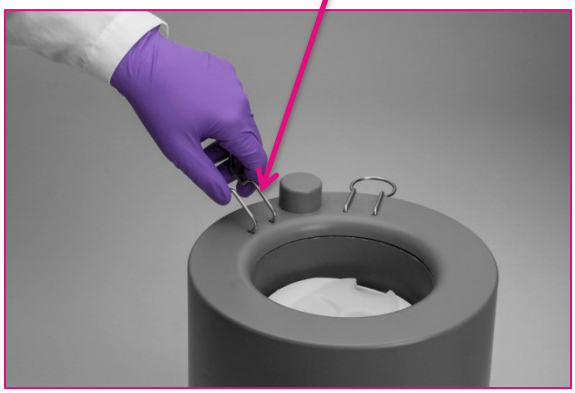


2. Secure the Tip Cap Replacement Tool Ring and Technestat Vial Holder Ring into the holes located on top of the Auxiliary Shield Cover.

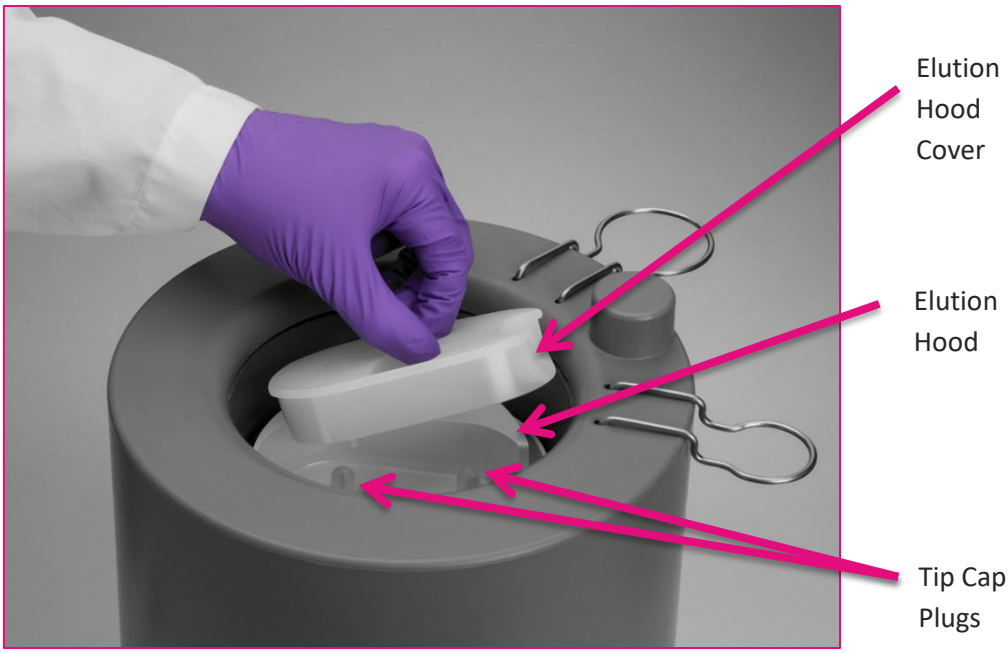
Tip Cap Replacement
Tool Ring



Technestat
Vial Holder Ring



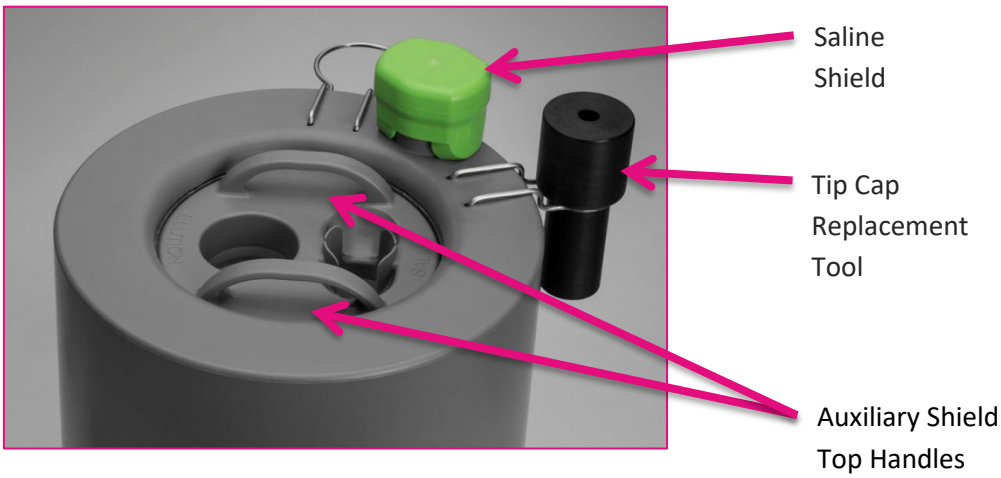
3. Remove and store the Elution Hood Cover.



Place the Auxiliary Shield Top on top of the generator using the handles; align the Auxiliary Shield Top with the Elution Hood. Rotate slowly until the raised ribs on the bottom of the Auxiliary Shield Top drop into the recessed area in the Elution Hood. Place the Saline Shield and the Tip Cap Replacement Tool in their respective tool holders on the Auxiliary Shield Cover.

CAUTION!

Visually inspect for damages before beginning elution or dispensing. If damage is detected such as exposed lead and scratches, do not attempt to use the tool. Call the number on page 25 to order replacement parts. Failure to follow this warning could result in personal injury and/or elevated radiation exposure.

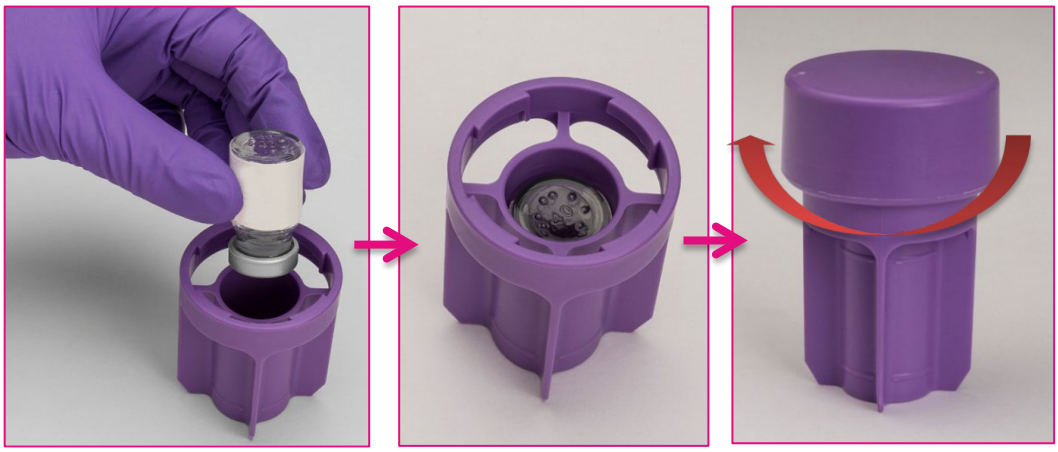


4. Remove the Technestat vial from the Generator Accessory Pack, remove the flip-top cap, disinfect the stopper, and allow the disinfected area to dry prior to use.

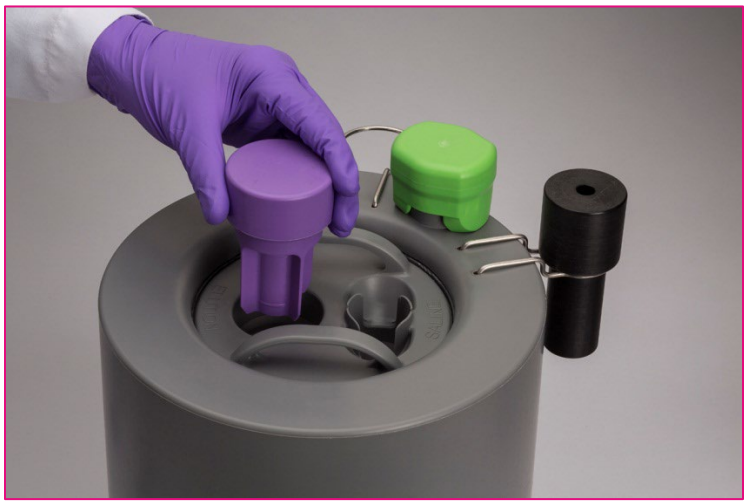
5. Place the Technestat vial in the Technestat tool body. Attach and turn the Technestat cap 30 degrees clockwise to secure. There may be positive pressure in the Technestat vial.

CAUTION!

Visually inspect for damages before beginning elution or dispensing. Do not attempt to use the tool if damage, such as exposed lead or scratches, is detected. Call the number on page 25 to order replacement parts. Failure to follow this warning could result in personal injury and/or elevated levels of radiation exposure.



Remove the tip cap plug from the elution needle and place the Technestat Vial Holder onto the elution needle. Store the tip cap plug for later reuse during generator disposal.



2.1.2. ELUTION STEPS

WARNING!

Be sure to wear proper PPE. Steps 9 through 11 should be performed in a properly shielded area. The face and body should be kept away from the shine path of the vial contents. Use the elution tool lid as protection from radiation exposure. Failure to follow this warning could result in personal injury and/or elevated levels of radiation exposure.

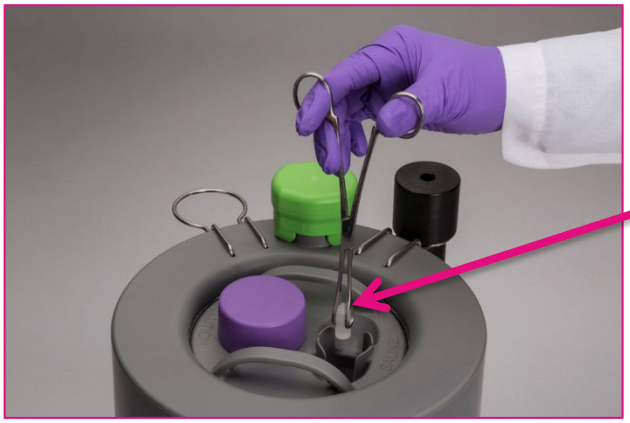
WARNING!

If radioactive drips occur, clean up all excess fluid and dispose of in accordance with local nuclear regulations. Failure to follow this warning could result in personal injury and/or elevated levels of radiation exposure.

1. Remove an eluant vial from the Eluant pack, remove the flip-top cap, disinfect the stopper and allow the disinfected area to dry prior to use.

Stopper

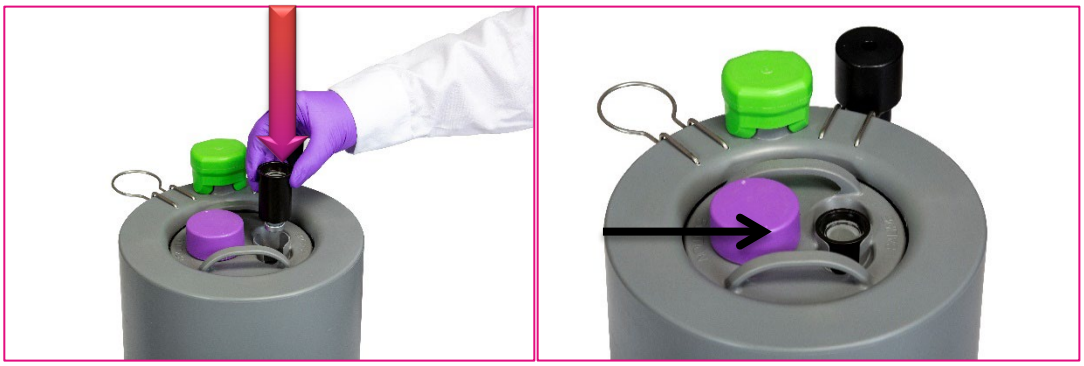
2. Carefully remove the tip cap plug from the eluant needle using forceps by pulling straight up without rotation. Store the tip cap plug for later reuse during generator disposal.



Tip Cap Plug removed

Place the vial (stopper down) into the Saline Vial Alignment Insert.

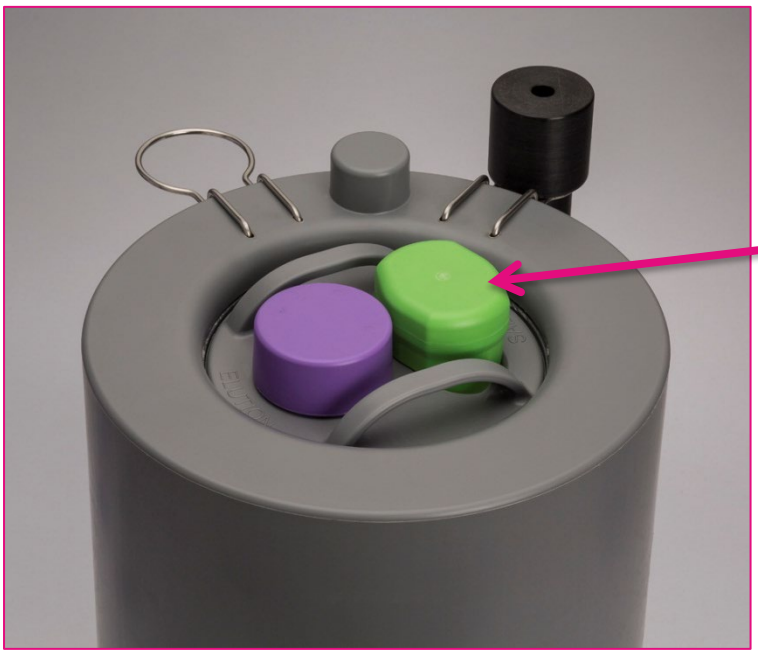
Place the Saline Vial Alignment Insert and vial into the Saline Port of the Auxiliary Shield Top. Firmly push down the eluant vial until the stopper is punctured and seated at the base of the eluant needles.



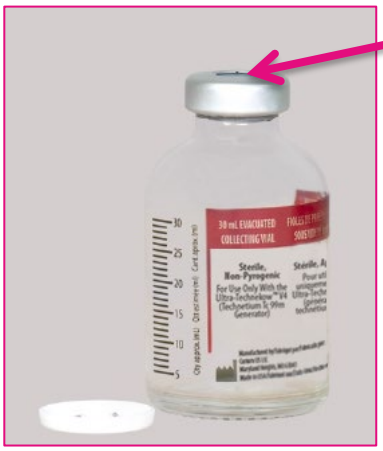
CAUTION!

Visually inspect for damages before beginning elution or dispensing. If damage is detected such as exposed lead and scratches, do not attempt to use the tool. Call the number on page 25 to order replacement parts. Failure to follow this warning could result in personal injury and/or elevated levels of radiation exposure.

Place the Saline Shield on top of the eluant vial (make sure the Saline Shield sits flush with top surface of the auxiliary shield).



3. Remove the 30 mL evacuated vial from the Evacuated Vial Pack, remove the flip-top cap, disinfect the stopper, and allow the disinfected area to dry prior to use.



CAUTION!

Visually inspect for damages before beginning elution or dispensing. If damage is detected such as surface cracks and unmagnetized bottom cap, do not attempt to use the tool. Call the number on page 25 to order replacement parts. Failure to follow this warning could result in personal injury and/or elevated levels of radiation exposure.

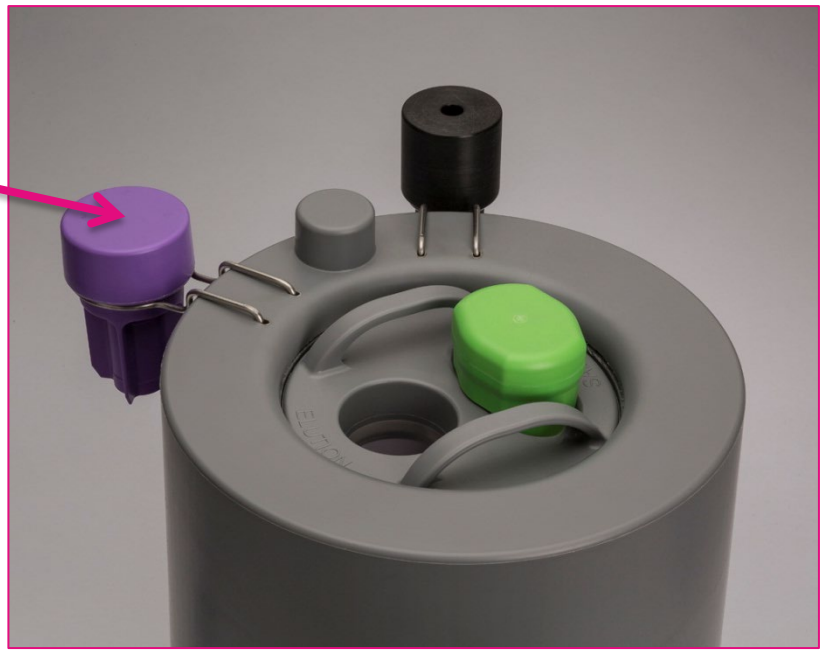
4. Turn the lid on the Elution Tool 45 degrees counterclockwise to unlock it.

5. Place the 30 mL evacuated vial in the elution tool body (stopper side down).

Close the lid; making sure that the tabs on the lid line up with the grooves on the elution tool body. Turn the lid 45 degrees clockwise to lock it.

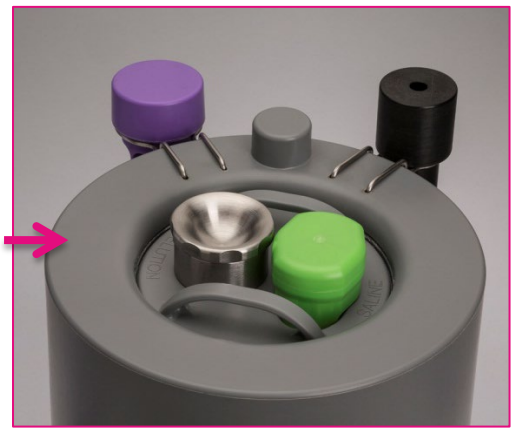
6. Remove the Technestat Vial Holder from the elution needle. Place the Technestat Vial Holder in its tool ring.

Technestat Vial Holder



NOTE: Piercing the stopper of the evacuated vial with the elution needle will begin the elution.

7. Remove the magnetic bottom cap and carefully insert the Elution Tool onto the elution needle.

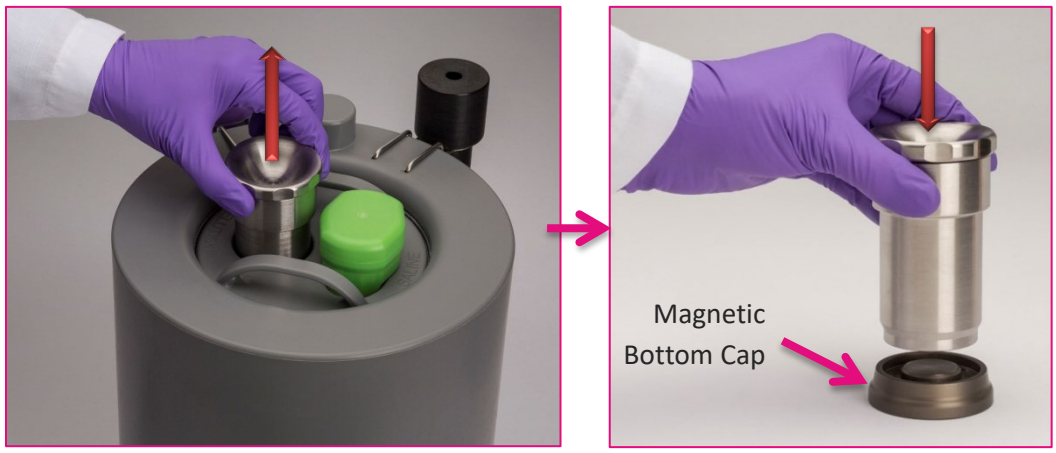


NOTE: Depending on the volume being eluted, allow time (the generator should not take longer than 5 minutes to elute) for the completion of the elution and equilibration of the evacuated vial to atmospheric pressure before removing the Elution Tool. Never interrupt elution by lifting the Elution Tool or removing the saline vial.

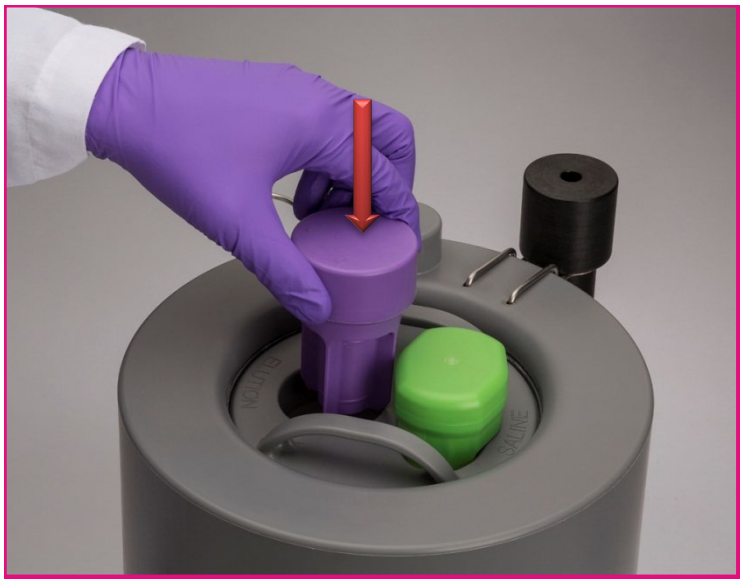
WARNING!

For steps 8 through 11, if radioactive drips occur, clean up all excess fluid and dispose of it in accordance with local nuclear regulations. Failure to follow this warning could result in personal injury and/or elevated levels of radiation exposure.

8. After the elution is complete, remove the Elution Tool by lifting straight up to avoid elution needle damage, then proceed to place it on the Magnetic Bottom Cap.



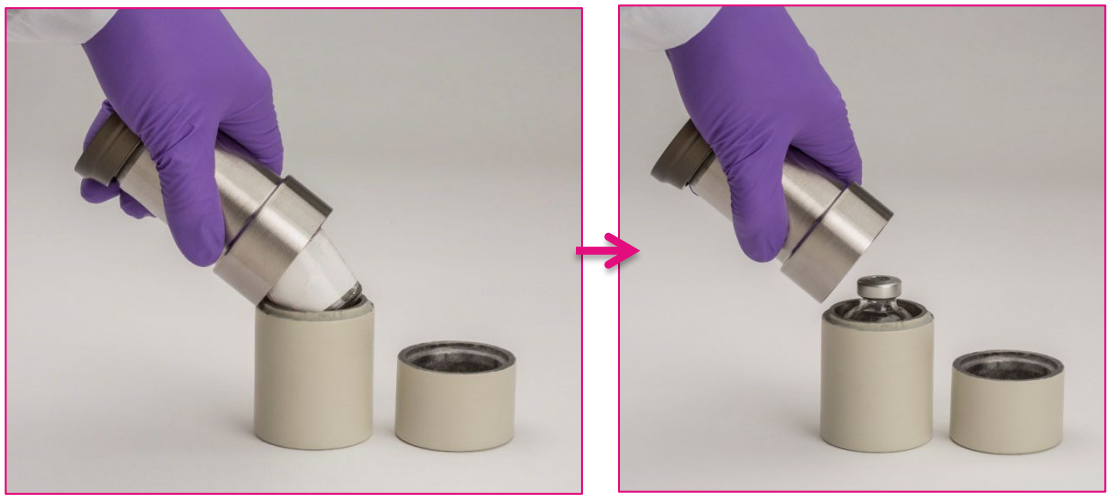
Put the Technestat Vial Holder back onto the elution needle to maintain proper shielding and needle sterility. Leave the Saline Vial Alignment Insert and empty saline vial on the generator until the next elution to keep the needles covered between elutions.



9. Remove the evacuated vial from the elution tool body and follow written site procedures to determine the correct sodium pertechnetate activity eluted and vial concentration as well as the radionuclidic purity.

WARNING!

The evacuated vial now contains a radioactive solution. The face and body should be kept away from the shine path of the vial contents. Use the elution tool lid as protection from radiation exposure. Failure to follow this warning could result in personal injury and/or elevated levels of radiation exposure.



10. Place the evacuated vial back into the elution tool body. Close the lid, making sure that the tabs on the lid line up with the grooves on the elution tool body. Turn the lid 45 degrees clockwise to lock it.

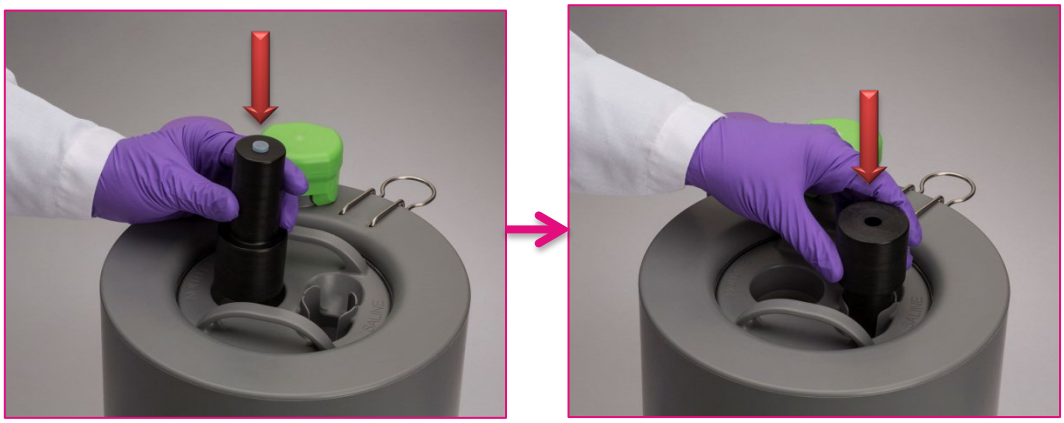
NOTE: The face and body should be kept away from the opening. Use the elution tool lid as protection from radiation exposure.

11. Remove the Magnetic Bottom Cap. Per site procedures, remove the required volume/dose of sodium pertechnetate Tc 99m needed.

12. After withdrawal of sodium pertechnetate Tc 99m, place the Elution Tool on top of the Magnetic Bottom Cap.

2.2. EXPIRED GENERATOR DISPOSAL

1. Following the life of the generator, remove and properly dispose of the used Technestat vial and eluant vial. Remove and save the Saline Vial Alignment Insert for future use.
2. Use the Tip Cap Replacement Tool to cover the elution and eluant needles with stored tip cap plugs.
   2.1. Remove and place the Saline Shield on the storage location on the Auxiliary Shield.
   2.2. Place tip cap plugs, pointed end first, into both pockets of the Tip Cap Replacement Tool.
   2.3. Gently insert the Tool into the appropriate well (Elution or Saline).
   2.4. Push the Tool firmly down until it stops, to fully seat the tip cap plug onto the needle.
   2.5. Return the Tip Cap Replacement Tool to its Tool Holder
3. Remove the Auxiliary Shield Top and store for future use.



4. Put the Elution Hood Cover back onto the generator.
5. The intact generator assembly should be either returned to Curium or disposed of in accordance with applicable regulations.
6. If being returned to Curium US LLC, strictly follow the procedures in Curium's Ultra-Technekow V4 Generator Return Training Module. Prompt return of the DU-shielded generators and proper chain of customer procedures must be observed by all parties involved in the return shipment of a DU generator.

MAINTENANCE PROCEDURES

This section contains maintenance procedures for the Pharmacy Tools. Guidelines for periodic inspections and cleaning are included in this section.

WARNING!

Preventive Maintenance must be performed by a trained nuclear medicine professional that is completely familiar with the use and operation of the Pharmacy Tools.

3.1. MAINTENANCE SCHEDULE

3.1.1. DAILY INSPECTION

Although the Pharmacy Tools are maintenance free, units need to be inspected prior to each use.

Inspect to ensure that:

- All parts of the tool are functioning properly.
- Lead is not exposed.

3.2. CLEANING PROCEDURES

3.2.1. CLEANING

Pharmacy Tools should be cleaned periodically.

WARNING!

The Pharmacy Tools themselves do not emit ionizing radiation. The UTK-V4 generator, as well as the evacuated vial in the Elution Tool after elution of the generator, does.

Sterile antiseptic wipes may be used to clean the Pharmacy Tools, as may any of the following disinfectants listed below:

NOTE: After the use of disinfectant cleaners, remove any residue and wipe clean. Be sure to remove any surface particulate that can cause contamination. A non-abrasive brush or scouring pad may be used if required. Failure to follow these instructions may lead to contamination and could damage the components.

• Hydrogen peroxide	3%
• Sporicidin® Disinfectant Spray, Solution, Aerosol	Ready to Use
• Vesphene® IIse	1:128 Dilution

WARNING!

Disinfectants NOT listed above should not be used for cleaning the Pharmacy Tools or the UTK-V4 generator. Use of the Technestat vial between elutions provides sterility of the elution needle, and if the eluant vial is kept in place, the eluant and vent needles do not need to be disinfected.

3.3. HOW TO ORDER PARTS

All parts may be ordered directly from Curium US LLC. When ordering parts, always include the part number required and the description of the part as indicated in the parts list. For further information contact:

Curium US LLC
2703 Wagner Place
Maryland Heights, MO 63043 USA

For US Parts: .....888-744-1414 ext. 1 then 2
For Canada Parts: 866-885-5988
For Technical Support: .....888-744-1414 ext. 2 then 1

3.3.1. LIST OF PARTS

PART DESCRIPTION	US PART NUMBER	CANADA PART NUMBER
Pharmacy Tool Kit	**N829PTK**	**N829PTK**
Elution Tool	**N829ET**	**829ETCA**
Auxiliary Shield Top*	**N829AT**	**829ATC**
Saline Shield*	**N829SS**	**829SSC**
Technestat Vial Holder*	**N829TH**	**829THC**
Auxiliary Shield Cover*	**N829AC**	**829ACC**
Tip Cap Replacement Tool*	**N829TT**	**829TTC**
Technestat Vial Holder Ring*	**N829THR**	**829THRC**
Tip Cap Replacement Tool Ring*	**N829TTR**	**829TTRC**
Saline Vial Alignment Insert*	**N829SVA**	**N829SVA**

**Included in Pharmacy Tool Kit*

APP-CU-22-025 / GN0025 1122

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Ultra-Technekow™ V4 (Technetium Tc 99m Generator)

9010/9190

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(Technetium Tc 99m Generator)

Ultra-Technekow™ V4 (Technetium Tc 99m Generator)

9010/9190

A901IS R5/2022

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(Generador de Tecnecio Tc 99m)

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Rx only

For the Production of Sodium Pertechnetate Tc 99m Injection

DESCRIPTION

The Ultra-Technekow™ V4 Generator is prepared with fission-produced molybdenum Mo-99 adsorbed onto alumina in a column shielded by lead, tungsten, or depleted uranium. The column assembly and shielding are encased in a plastic container that is covered with a plastic elution hood. The elution hood has an opening for the column assembly double inlet needles and an opening for the single outlet needle. The needles accommodate the sterile eluant vials that contain 0.9% Sodium Chloride Injection and sterile evacuated collection vials. A sterile vial containing a bacteriostat is supplied with the generator for the customer to aseptically seal the outlet needle after each elution.

This terminally sterilized generator provides a closed system for the production of sterile metastable technetium Tc-99m, which is produced by the decay of molybdenum Mo-99. Incorporated between the column outlet and the collection vial is a sterile 0.22 micrometer filter. Sterile, non-pyrogenic isotonic solutions of Sodium Pertechnetate Tc 99m Injection in 0.9% Sodium Chloride Injection can be obtained conveniently by periodic aseptic elution of the generator. These solutions should be clear, colorless, and free from any particulate matter. The Sodium Pertechnetate Tc 99m Injection is suitable for intravenous injection and direct instillation.

The carrier-free solution may be used as is, or diluted to the proper concentration. Over the life of the generator, an elution will contain an amount of technetium Tc-99m in direct proportion to the quantity of Mo-99 decay since the previous elution of the generator. The quantity of Tc-99m in the eluate is determined by quantity of Mo-99 on the column, and the elapsed time between elutions.

Each eluate of the generator should not contain more than the USP limit of 0.15 kilobecquerel molybdenum Mo-99 per megabecquerel technetium Tc-99m (0.15 microcurie Mo-99 per millicurie Tc-99m) per administered dose at the time of administration and an aluminum ion concentration of not more than 10 micrograms per milliliter of the generator eluate, both of which must be determined by the user before administration.

Since the eluate does not contain an antimicrobial agent, it should not be used after 12 hours from the time of generator elution.

Physical Characteristics

Technetium Tc-99m decays by isomeric transition with a physical half-life of 6 hours. The principal photon that is useful for detection and imaging studies is listed in Table 1.

Table 1. Principal Radiation Emission Data

Radiation	Mean Percent Per Disintegration	Energy (keV)
Gamma-2	89.07	140.5

External Radiation

The specific gamma ray constant for technetium Tc-99m is 0.795 R/hr-mCi at 1 cm. The first half-value layer is 0.023 cm of lead (Pb). A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from interposition of various thicknesses of Pb is shown in Table 2. For example, the use of 0.27 cm thickness of Pb will attenuate the radiation emitted by a factor of about 1000.

Table 2. Radiation Attenuation by Lead Shielding

Shield Thickness (Pb) cm	Coefficient of Attenuation
0.023	0.5
0.09	10^{-1}
0.18	10^{-2}
0.27	10^{-3}

Molybdenum Mo-99 decays to technetium Tc-99m with a molybdenum Mo-99 half-life of 2.75 days, or 66 hours (see Table 3). The physical decay characteristics of molybdenum Mo-99 are such that only 88.6% of the decaying molybdenum Mo-99 atoms form technetium Tc-99m. Generator elutions may be made at any time, but the amount of technetium Tc-99m available will depend on the interval measured from the last elution. Approximately 47% of the maximum available technetium Tc-99m is reached after 6 hours and 95% after 23 hours. To correct for physical decay of molybdenum Mo-99 and technetium Tc-99m, the fractions that remain at selected intervals of time are shown in Tables 3 and 4.

Table 3. Physical Decay Chart; Molybdenum Mo-99, Half-Life 66 Hours

Days	Percent Remaining	Days	Percent Remaining
0	100	10	8
1	78	11	6
2	60	12	5
3	47	13	4
4	37	14	3
5	28	15	2
6	22	20	0.6
7	17	25	0.2
8	13	30	0.05
9	10		

Table 4. Physical Decay Chart; Technetium Tc-99m, Half-Life 6 Hours

Hours	Percent Remaining	Hours	Percent Remaining
0*	100	9	35
1	89	10	32
2	79	11	28
3	71	12	25
4	63	14	20
5	56	16	16
6	50	18	13
7	45	24	6
8	40		

*Calibration Time

CLINICAL PHARMACOLOGY

The pertechnetate ion distributes in the body similarly to the iodide ion but is not organified when trapped in the thyroid gland. Pertechnetate concentrates in the thyroid gland, salivary glands, stomach and choroid plexus. After intravenous administration it gradually equilibrates with the extracellular space. A fraction is promptly excreted via the kidneys.

Following the administration of Sodium Pertechnetate Tc 99m as an eye drop, the drug mixes with tears within the conjunctival space. Within seconds to minutes it leaves the conjunctival space and escapes into the inferior meatus of the nose through the nasolacrimal drainage system. During this process the pertechnetate ion passes through the canaliculi, the lacrimal sac and the nasolacrimal duct. In the event of any anatomical or functional blockage of the drainage system there will be a backflow resulting in tearing (epiphora). Thus the pertechnetate escapes the conjunctival space in the tears.

While the major part of the pertechnetate escapes within a few minutes of normal drainage and tearing, it has been documented that there is some degree of transconjunctival absorption with turnover of 1.5% per minute in normal individuals, 2.1% per minute in patients without any sac and 2.7% per minute in patients with inflamed conjunctiva due to chronic dacryocystitis. Individual values may vary but these rates are probably representative and indicate that the maximum possible pertechnetate absorbed will remain below one thousandth of that used in other routine diagnostic procedures.

INDICATIONS AND USAGE

The Ultra-Technekow™ V4 generator is a source of sodium pertechnetate Tc 99m for use in the preparation of FDA-approved diagnostic radiopharmaceuticals, as described in the labeling of these diagnostic radiopharmaceutical kits.

Sodium Pertechnetate Tc 99m is used **IN ADULTS** as an agent for:

- Thyroid Imaging
- Salivary Gland Imaging
- Urinary Bladder Imaging (direct isotopic cystography) for detection of vesico-ureteral reflux
- Nasolacrimal Drainage System Imaging (dacryoscintigraphy)

Sodium Pertechnetate Tc 99m is used **IN PEDIATRIC PATIENTS** as an agent for:

- Thyroid Imaging
- Urinary Bladder Imaging (direct isotopic cystography) for the detection of vesico-ureteral reflux

CONTRAINDICATIONS

None.

WARNINGS

Radiation risks associated with the use of Sodium Pertechnetate Tc 99m are greater in pediatric patients than in adults and, in general, the younger the patient the greater the risk owing to greater absorbed radiation doses and longer life expectancy. These greater risks should be taken firmly into account in all benefit risk assessments involving pediatric patients.

Long-term cumulative radiation exposure may be associated with an increased risk of cancer.

Only use generator eluant specified for use with the Ultra-Technekow™ V4 Generator. Do not use any other generator eluant or saline from any other source.

PRECAUTIONS

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

As in the use of any radioactive material, care should be taken to minimize radiation exposure to the patient consistent with proper patient management and to ensure minimum radiation exposure to occupational workers.

After the termination of the nasolacrimal imaging procedure, blowing the nose and washing the eyes with sterile distilled water or an isotonic sodium chloride solution will further minimize the radiation dose.

Since the eluate does not contain an antimicrobial agent, it should not be used after 12 hours from time of generator elution.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate carcinogenic or mutagenic potential or whether Sodium Pertechnetate Tc 99m may affect fertility in males or females.

Pregnancy

In animal reproductive studies, Sodium Pertechnetate Tc 99m (as free pertechnetate) has been shown to cross the placental barrier. It is not known whether Sodium Pertechnetate Tc 99m can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity.

Sodium Pertechnetate Tc 99m should be given to pregnant women only if the expected benefits to be gained clearly outweigh the potential hazards.

Ideally, examinations using radiopharmaceutical drug products - especially those elective in nature - of women of childbearing capability should be performed during the first ten days following the onset of menses.

Nursing Mothers

Technetium Tc-99m is excreted in human milk during lactation, therefore, formula-feedings should be substituted for breast-feedings.

Pediatric Use

See **INDICATIONS AND USAGE** and **DOSAGE AND ADMINISTRATION** sections. Also see the description of additional risk under **WARNINGS**.

ADVERSE REACTIONS

Allergic reactions including anaphylaxis have been reported infrequently following the administration of Sodium Pertechnetate Tc 99m.

DOSAGE AND ADMINISTRATION

Sodium Pertechnetate Tc 99m is administered by intravenous injection. When imaging the nasolacrimal drainage system, instill the Sodium Pertechnetate Tc 99m by the use of a device such as a micropipette or similar method which will ensure the accuracy of the dose.

For imaging the urinary bladder and ureters (direct isotopic cystography), the Sodium Pertechnetate Tc 99m is administered by direct instillation aseptically into the bladder via a urethral catheter, following which the catheter is flushed with approximately 200 mL of sterile saline directly into the bladder.

The suggested dose ranges employed for various diagnostic indications in the average ADULT PATIENT (70 kg) are as follows:

Vesico-ureteral imaging:	18.5 to 37 MBq (0.5 to 1 mCi)
Thyroid gland imaging:	37 to 370 MBq (1 to 10 mCi)
Salivary gland imaging:	37 to 185 MBq (1 to 5 mCi)
Nasolacrimal drainage system:	Maximum dose of 3.7 MBq (100 μCi)

The recommended dosages in PEDIATRIC PATIENTS are:

Vesico-ureteral imaging:	18.5 to 37 MBq (0.5 to 1 mCi)
Thyroid gland imaging:	2.22 to 2.96 MBq (60 to 80 μCi) per kg body weight

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. If the solution is discolored, discontinue use of the generator immediately. The solution to be administered as the patient dose should be clear, colorless, and contain no particulate matter.

Radiation Dosimetry

The estimated absorbed radiation doses to an average **ADULT** and **PEDIATRIC** patient from an intravenous injection of various doses of Sodium Pertechnetate Tc 99m distributed uniformly in the total body are shown in Tables 5 and 6.

Table 5. Absorbed Radiation Doses from Intravenous Injection

Organ	Absorbed Radiation Dose (mGy) for a 1110 MBq (30mCi) dose
Adrenals	4.1
Urinary Bladder Wall	20
Bone Surfaces	6.2
Brain	2.2
Breasts	2
Gallbladder Wall	8.3
Stomach Wall	29
Small Intestine	18
ULI Wall	63
LLI Wall	23
Heart Wall	3.5
Kidneys	6
Liver	4.7
Lungs	2.9
Muscle	3.6
Ovaries	11
Pancreas	6.3
Red Marrow	4.1
Skin	2
Spleen	4.8
Testes	3.1
Thymus	2.7
Thyroid	24
Uterus	9
Remaining Tissues	3.9
Effective Dose (mSv)	14

To obtain radiation absorbed dose in rads (30 mCi dose) from the above table, divide individual organ values by a factor of 10 (does not apply for effective dose).

Table 6. Pediatric Absorbed Radiation Doses (mGy) from Intravenous Injection

Age	**15 years**	**10 years**	**5 years**	**1 year**
Administered activity in MBq (mCi)	**1110 (30)**	**740 (20)**	**555 (15)**	**370 (10)**
Organ				
Adrenals	5.3	5.4	6.2	7.1
Urinary Bladder Wall	26	22	18	22
Bone Surfaces	7.6	7.5	8.1	10
Brain	2.8	3.1	3.7	4.5
Breasts	2.6	2.6	3.2	4.1
Gallbladder Wall	11	12	13	13
Stomach Wall	38	36	43	59
Small Intestine	22	23	26	30
ULI Wall	81	89	110	140
LLI Wall	31	33	40	48
Heart Wall	4.5	4.6	5.2	6.4
Kidneys	7.2	6.9	7.8	8.5
Liver	6	6.7	8	9.1
Lungs	3.8	3.8	4.4	5.3
Muscle	4.5	4.5	5	6
Ovaries	14	13	14	17
Pancreas	8.1	8.2	8.9	10
Red Marrow	5.1	5	5.2	6
Skin	2.5	2.6	3.2	3.8
Spleen	6	6	6.7	7.8
Testes	4.1	4.3	4.9	6
Thymus	3.6	3.5	4.2	5.3
Thyroid	40	41	67	81
Uterus	11	11	12	14
Remaining Tissues	4.8	4.8	5.4	6.4
Effective Dose (mSv)	19	19	23	29

To obtain radiation absorbed dose in rads (30 mCi dose) from the above table, divide individual organ values by a factor of 10 (does not apply for effective dose).

The estimated absorbed radiation doses to an ADULT patient from the nasolacrimal imaging procedure using a maximum dose of 3.7 megabecquerels (100 microcuries) of Sodium Pertechnetate Tc 99m are shown in Table 7.

Table 7. Absorbed Radiation Doses from Dacryoscintigraphy

Tissue	3.7 MBq (100 μCi) Dose of Sodium Pertechnetate Tc 99m	
	mGy	rad
Eye Lens:		
If lacrimal fluid turnover is 16%/min	0.140	0.014
If lacrimal fluid turnover is 100%/min	0.022	0.002
If drainage system is blocked	4.020	0.402
Total Body*	0.011	0.001
Ovaries*	0.030	0.003
Testes*	0.009	0.001
Thyroid*	0.130	0.013

*Assuming no blockage of draining system.

In pediatric patients, an average 30 minute exposure to 37 MBq (1 mCi) of Tc-99m pertechnetate following instillation for direct cystography, will result in the following estimated radiation doses:

Table 8. Absorbed Radiation Doses from Cystography (PEDIATRIC)

Age	Bladder wall dose, mGy (rad)	Gonadal dose, mGy (rad)
1 year	3.6 (0.36)	0.15 (0.015)
5 years	2.0 (0.2)	0.095 (0.0095)
10 years	1.3 (0.13)	0.066 (0.0066)
15 years	0.92 (0.092)	0.046 (0.0046)

HOW SUPPLIED

The Ultra-Technekow™ V4 (Technetium Tc 99m) Generators contain the following amount of molybdenum Mo-99 at the date and time of calibration stated on the label.

Catalog No.		
9010 NDC 69945-010-03	37 gigabecquerels	(1.0 curie)
9015 NDC 69945-015-04	55.5 gigabecquerels	(1.5 curies)
9020 NDC 69945-020-05	74 gigabecquerels	(2.0 curies)
9025 NDC 69945-025-06	92.5 gigabecquerels	(2.5 curies)
9030 NDC 69945-030-07	111 gigabecquerels	(3.0 curies)
9035 NDC 69945-035-08	129.5 gigabecquerels	(3.5 curies)
9051 NDC 69945-051-09	185 gigabecquerels	(5.0 curies)
9060 NDC 69945-060-10	222 gigabecquerels	(6.0 curies)
9075 NDC 69945-075-11	277.5 gigabecquerels	(7.5 curies)
9110 NDC 69945-110-12	407 gigabecquerels	(11.0 curies)
9140 NDC 69945-140-13	518 gigabecquerels	(14.0 curies)
9160 NDC 69945-160-14	592 gigabecquerels	(16.0 curies)
9190 NDC 69945-190-15	703 gigabecquerels	(19.0 curies)

Each generator is supplied with the following components for the elution of the generator:

- 1 - Technestat™ Vial, 5 mL, containing 0.5 mL of 1.5 mg/mL methylparaben and 0.2 mg/mL propylparaben, sterile, non-pyrogenic
- 1 - Package Insert

SUPPLIED SEPARATELY

- 30 - Evacuated Collecting Vials, 30 mL, sterile, non-pyrogenic, supplied with:
  - 90 - Radioactive Materials Labels – Collection Vial (30 en, 30 fr, 30 es)
  - 90 - Radioactive Materials Labels – Elution Shield (30 en, 30 fr, 30 es)
- 1 - Package Insert
- 30 - Generator Eluant, 0.9% Sodium Chloride Injection, sterile, non-pyrogenic, available in 5 mL, 10 mL, or 20 mL volumes, with 1 package insert. The eluant does not contain an antimicrobial agent. Each milliliter of Generator Eluant contains 9 milligrams of Sodium Chloride.

Storage

Store generator and Sodium Pertechnetate Tc 99m solution at controlled room temperature 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Expiration Date

The generator should not be used after the expiration date stated on the label.

The expiration time of the Sodium Pertechnetate Tc 99m solution is not later than 12 hours after time of elution. If the eluate is used to reconstitute a kit, the radiolabeled kit should not be used after 12 hours from the time of generator elution or after the expiration time stated on the labeling for the prepared drug, whichever is earlier.

Directions for Use of the Technetium Tc 99m Generator

NOTE 1: Immediately upon delivery, the generator should be placed within a minimum of one-inch of lead shielding in such a manner so as to minimize radiation exposure to attending personnel.

NOTE 2: Wear waterproof gloves during the elution procedure and during subsequent reconstitution of kits with the eluate.

NOTE 3: Use a shielded syringe to withdraw patient dose or to transfer Sodium Pertechnetate Tc 99m into mixing vials during kit reconstitution.

NOTE 4: The needles in the generator are sterile beneath their covers, and the generator has been cleaned underneath the top cover. Additional disinfection of these areas with agents containing alcohol may unfavorably influence the Tc-99m yield.

Eluting the generator every 24 hours will provide optimal amounts of Sodium Pertechnetate Tc 99m. However, the generator may be eluted whenever sufficient amounts of technetium Tc-99m have accumulated within the column.

For Example

Time After First Elution (hrs.)	Approximate Yield (% of First Elution)
1	10
2	19
3	27
4	35
5	41
6	47

Elution

1. Lift the generator by its handle and place it inside the auxiliary shield. Move the handle so that it is not covering the generator top by pushing it off to the side in between the generator and the auxiliary shield.
2. Remove and store the elution hood cover. Place the auxiliary shield top onto the top of the generator and align it with the elution hood.
3. Remove and store the tip cap plugs from the needles.
4. Remove the flip-top cap of the eluant vial; disinfect the stopper with a bacteriocide such as 70% isopropyl alcohol, allowing the stopper to dry before use. Invert the eluant vial and place stopper first into the saline vial alignment insert. Place the saline vial alignment insert and vial into the saline port of the auxiliary shield top and firmly push down the eluant vial until the stopper is punctured and seated at the base of the eluant needles.
5. Place the saline shield on top of the auxiliary shield top to cover the eluant vial.
6. Remove the flip-top cap of an evacuated vial; disinfect the stopper, allowing the stopper to dry before use. Place the evacuated vial into the elution tool.
7. Position the shielded evacuated vial by carefully lowering the elution tool into place on the elution needle. Piercing the septum of the evacuated vial with the elution needle will begin the elution process.
8. Wait until the evacuated vial has completely filled itself. This may take a few minutes. **Never interrupt the elution by lifting the elution tool!**
9. **NOTE: Do not use generator eluate if its appearance is discolored, and discontinue use of the generator.**
10. Remove the flip-top cap of the Technestat vial; disinfect the stopper, allowing the stopper to dry before use. Secure the Technestat vial into the Technestat vial holder.
11. Carefully remove the elution tool and replace with the shielded Technestat vial.
12. Determine the technetium Tc-99m concentration and molybdenum Mo-99 content for dispensing purposes. The generator eluate may be assayed using an appropriate detection system. The manufacturer's instructions for operation of the instrument/equipment should be followed for measurement of Technetium Tc-99m and Molybdenum Mo-99 activity. **NOTE: Molybdenum Mo-99 Breakthrough Limit** - The acceptable limit is 0.15 kilobecquerel molybdenum Mo-99 per megabecquerel technetium Tc-99m (0.15 microcurie Mo-99 per millicurie Tc-99m) per administered dose in the Injection, at the time of administration (see USP, Sodium Pertechnetate Tc 99m Injection).
13. Determine the aluminum ion concentration of the eluate. **NOTE: Aluminum Ion Breakthrough Limit** - The acceptable limit is not more than 10 micrograms per milliliter of eluate (see USP, Sodium Pertechnetate Tc 99m Injection).

Subsequent Elutions

1. Remove the saline shield and then remove saline vial alignment insert from the saline port to remove the eluant vial from the eluant needles. Remove the vial from the saline vial alignment insert and reuse the saline vial alignment insert for subsequent elutions.
2. Remove the shielded Technestat vial by carefully lifting the Technestat vial shield from the elution needle.
3. Repeat steps 4 through 12 of the Elution procedure above.

Vacuum Loss

If the vacuum in the collecting vial is lost, do not attempt to re-evacuate the vial, but discard and use a new collecting vial.

Expired Generator Disposal

1. Following the life of the generator, remove and dispose of the used Technestat vial and the eluant vial.
2. Cover the elution and eluant needles with the stored tip cap plugs.
3. Place the stored elution hood cover onto the top of the generator.
4. The intact generator assembly should be either returned to Curium US LLC or disposed of in accordance with applicable regulations.

This generator may be received, used and administered only by authorized persons in designated clinical settings. Its receipt, storage, use, transfer and disposal are subject to the regulations and/or appropriate licenses of local competent official organizations.

Manufactured by:
Curium US LLC
Maryland Heights, MO 63043 USA
Made in USA

A901IS
Revised 5/2022

STERILE

curium™

Ultra-Technekow™ V4
(Generador de Tecnecio Tc 99m)

Solamente Rx
Solo por prescripción médica

Para la Producción de Inyección de Pertecnetato de Sodio Tc 99m

DESCRIPCIÓN

El Generador Ultra-Technekow™ V4 se prepara con molibdeno Mo-99 producido por fisión, adsorbido en alúmina en una columna blindada con plomo, tungsteno o uranio empobrecido. El ensamblaje de la columna y el blindaje están contenidos en un recipiente de plástico cubierto con un campana de elución de plástico. La campana de elución posee una abertura para las agujas de doble entrada del ensamblaje de la columna y una abertura para la aguja de salida simple. Las agujas se adaptan a los viales estériles de eluyente que contienen 0.9% de cloruro de sodio inyectable y viales estériles de recolección evacuados. Un vial estéril con un bacteriostático se suministra junto con el generador para que el cliente selle de manera aséptica la salida de la aguja luego de cada elución.

Este generador sometido a esterilización terminal, proporciona un sistema cerrado para la producción de tecnecio Tc 99m metaestable, estéril, el cual se produce por la desintegración del molibdeno Mo-99. Entre la columna de salida y el vial de recolección se encuentra un filtro estéril de 0,22 micrómetros. Las inyecciones de soluciones isotónicas, no pirógenas y esterilizadas de pertecnetato de sodio Tc 99m, en inyección de cloruro de sodio al 0.9% pueden ser obtenidas fácilmente mediante elución aséptica periódica del generador. Estas soluciones deben ser transparentes, incoloras, y libres de cualquier partícula. La Inyección de Pertecnetato de Sodio Tc 99m es adecuada para inyección intravenosa e instilación directa.

La solución libre de vehículo puede ser usada como viene, o diluida a la concentración adecuada. Durante la vida del generador, una elución contendrá una cantidad de tecnecio Tc 99m en proporción directa a la cantidad de desintegración de Mo-99 desde la elución previa del generador. La cantidad de Tc 99m en el eluato es determinada por la cantidad de Mo-99 en la columna, y el tiempo transcurrido entre las eluciones.

Cada eluato del generador no debe contener más del límite USP de 0,15 kilobecquereles de molibdeno Mo-99 por megabecquerel de tecnecio Tc 99m (0,15 microcurios Mo-99 por milicurio Tc 99m) por dosis administrada en el momento de la administración y una concentración de ion aluminio no mayor a 10 microgramos por mililitro del eluato del generador, debiendo ser determinados ambos por el usuario antes de la administración.

Puesto que el eluato no contiene un agente antimicrobiano, no debe ser usado después de 12 horas desde el momento de elución del generador.

Características físicas

El Tecnecio Tc 99m se desintegra por transición isomérica con una vida media física de 6 horas. El fotón principal, útil para estudios de detección e imágenes, se muestra en la Tabla 1.

Tabla 1. Datos de Emisión de Radiación Principal

Radiación	Porcentaje promedio por desintegración	Energía (keV)
Gamma-2	89,07	140,5

Radiación externa

La constante de rayos gamma específica para el tecnecio Tc 99m es 0,795 R/hr-mCi a 1 cm. La primera capa de valor medio es 0,023 cm de plomo (Pb). En la Tabla 2 se muestra un rango de valores para la atenuación relativa de la radiación emitida por este radionúclido que resulta de interposición de varios grosores de Pb. Por ejemplo, el uso de un grosor de 0,27 cm de Pb atenuará la radiación emitida en aproximadamente 1000 veces.

Tabla 2. Atenuación de Radiación por Protección con Plomo

Grosor del Blindaje (Pb) cm	Coeficiente de Atenuación
0,023	0,5
0,09	10^{-1}
0,18	10^{-2}
0,27	10^{-3}

El molibdeno Mo-99 se desintegra hasta tecnecio Tc 99m con una vida media de molibdeno Mo-99 de 2,75 días, o 66 horas (véase la Tabla 3). Las características de desintegración física de molibdeno Mo-99 son tales que sólo 88,6% de los átomos de molibdeno Mo-99 que se desintegran forman tecnecio Tc 99m. Pueden hacerse eluciones del generador en cualquier momento, pero la cantidad de tecnecio Tc 99m disponible dependerá del intervalo medido desde la última elución. Aproximadamente 47% del tecnecio Tc 99m máximo disponible se alcanza después de 6 horas y 95% después de 23 horas. Para corregir la desintegración física del molibdeno Mo-99 y del tecnecio Tc 99m, las fracciones restantes a intervalos seleccionados de tiempo se muestran en la Tablas 3 y 4.

Tabla 3. Tabla de Desintegración Física; Molibdeno Mo-99, Vida Media 66 Horas

Días	Porcentaje Restante	Días	Porcentaje Restante
0	100	10	8
1	78	11	6
2	60	12	5
3	47	13	4
4	37	14	3
5	28	15	2
6	22	20	0,6
7	17	25	0,2
8	13	30	0,05
9	10		

Tabla 4. Tabla de Desintegración Física; Tecnecio Tc 99m, Vida Media 6 Horas

Horas	Porcentaje Restante	Horas	Porcentaje Restante
0*	100	9	35
1	89	10	32
2	79	11	28
3	71	12	25
4	63	14	20
5	56	16	16
6	50	18	13
7	45	24	6
8	40		

*Tiempo de calibración

FARMACOLOGÍA CLÍNICA

El ion pertecnetato se distribuye en el cuerpo de manera similar al ion yoduro pero no es organificado cuando es atrapado en la glándula tiroides. El pertecnetato se concentra en la glándula tiroides, glándulas salivales, estómago y plexo coroide. Después de la administración intravenosa gradualmente se equilibra con el espacio extracelular. Una fracción es excretada prontamente a través de los riñones.

Luego de la administración de Pertecnetato de Sodio Tc 99m en forma de colirio, el fármaco se mezcla con las lágrimas dentro del espacio conjuntival. En cuestión de segundos a minutos sale del espacio conjuntival y escapa hacia el meato inferior de la nariz a través del sistema de drenaje nasolagrimal. Durante este proceso el ion pertecnetato pasa a través de los canalículos, el saco lagrimal y el conducto nasolagrimal. En caso de cualquier bloqueo anatómico o funcional del sistema de drenaje, habrá un flujo retrógrado que resultará en lagrimeo (epífora). En consecuencia, el pertecnetato escapa del espacio conjuntival en las lágrimas.

A pesar de que la mayor parte del pertecnetato escapa en unos pocos minutos de drenaje normal y lagrimeo, se ha documentado que hay cierto grado de absorción transconjuntival con recambio de 1,5% por minuto en individuos normales, 2,1% por minuto en pacientes sin ningún saco y 2,7% por minuto en pacientes con conjuntiva inflamada debido a dacriocistitis crónica. Los valores individuales pueden variar pero estas tasas son probablemente representativas e indican que el máximo posible de pertecnetato absorbido permanecerá debajo de una milésima del usado en otros procedimientos diagnósticos de rutina.

INDICACIONES Y USO

El generador Ultra-Technekow™ V4 es una fuente de pertecnetato de sodio Tc 99m para ser usado en la preparación de radiofármacos para diagnóstico aprobados por la FDA, como se describe en la etiqueta de estos kits de radiofármacos para diagnóstico.

El Pertecnetato de Sodio Tc 99m se usa **EN ADULTOS** como agente para:

- Imágenes Tiroideas
- Imágenes de la Glándula Salival
- Imágenes de la Vejiga Urinaria (cistografía isotópica directa) para detección de reflujo vesicoureteral
- Imágenes del Sistema de Drenaje Nasolagrimal (dacriocentellografía)

El Pertecnetato de Sodio Tc 99m se usa **EN PACIENTES PEDIÁTRICOS** como agente para:

- Imágenes Tiroideas
- Imágenes de la Vejiga Urinaria (cistografía isotópica directa) para detección de reflujo vesicoureteral

CONTRAINDICACIONES

Ninguna.

ADVERTENCIAS

Los riesgos de radiación asociados con el uso de Pertecnetato de Sodio Tc 99m son mayores en pacientes pediátricos que en adultos y, en general, a medida que el paciente es más joven, mayor es el riesgo debido a mayores dosis de radiación absorbidas y mayor expectativa de vida. Estos riesgos mayores deben ser tomados firmemente en cuenta en todas las evaluaciones riesgo-beneficio que involucran pacientes pediátricos.

La exposición acumulada a la radiación a largo plazo puede asociarse con un mayor riesgo de cáncer.

Utilice solamente el eluyente de generador especificado para uso con el Generador Ultra-Technekow™ V4. No use ningún otro eluyente de generador o solución salina de cualquier otra fuente.

PRECAUCIONES

Como con cualquier otro material radioactivo, se debe tener cuidado para minimizar la exposición del paciente a la radiación, de manera consistente con un manejo adecuado del paciente y para asegurar una mínima exposicion del personal a la radiación.

Los radiofármacos solo deben ser usados por médicos calificados mediante el entrenamiento específico y la experiencia en el uso y manejo seguros de radionúclidos y cuya experiencia y entrenamiento han sido aprobados por el organismo gubernamental autorizado para otorgar licencia para el uso de radionúclidos.

Después de terminar el procedimiento de imágenes nasolagrimales, sonar la nariz y lavar los ojos con agua destilada estéril o una solución de cloruro de sodio isotónica minimizará adicionalmente la dosis de radiación.

Puesto que el eluato no contiene un agente antimicrobiano, no debe ser usado después de 12 horas a partir de la elución del generador.

Carcinogénesis, mutagénesis, deterioro de la fertilidad

No se han realizado estudios a largo plazo en animales para evaluar el potencial carcinogénico o mutagénico, o si el Pertecnetato de Sodio Tc 99m puede afectar la fertilidad en machos o hembras.

Embarazo

Se ha demostrado en estudios de reproducción en animales que el Pertecnetato de Sodio Tc 99m (en forma de pertecnetato libre) cruza la barrera placentaria. No se sabe si el Pertecnetato de Sodio Tc 99m puede causar daño fetal cuando se administra a una mujer embarazada o si puede afectar la capacidad de reproducción.

El Pertecnetato de Sodio Tc 99m sólo debe ser administrado a mujeres embarazadas si los beneficios esperados claramente superan los peligros potenciales.

Idealmente, los exámenes que utilizan radiofármacos - especialmente aquellos de naturaleza electiva - en mujeres con capacidad reproductiva, deben realizarse durante los primeros diez días luego del inicio de la menstruación.

Lactancia

El tecnecio Tc 99m es excretado en la leche humana durante la lactancia, por lo tanto la lactancia artificial debe sustituir a la materna.

Uso pediátrico

Ver las secciones **INDICACIONES Y USO** y **DOSIFICACIÓN Y ADMINISTRACIÓN**. Ver también la descripción de riesgo adicional en **ADVERTENCIAS**.

REACCIONES ADVERSAS

Se han reportado reacciones alérgicas, incluyendo anafilaxia, de manera infrecuente luego de la administración de Pertecnetato de Sodio Tc 99m.

DOSIFICACIÓN Y ADMINISTRACIÓN

El Pertecnetato de Sodio Tc 99m se administra por inyección intravenosa. Cuando se obtienen imágenes del sistema de drenaje nasolagrimal, instile el Pertecnetato de Sodio Tc 99m usando un instrumento como una micropipeta o un método similar que asegure la precisión de la dosis.

Para imágenes de la vejiga urinaria y uréteres (cistografía isotópica directa), el Pertecnetato de Sodio Tc 99m se administra por instilación directa asépticamente en la vejiga a través de un catéter uretral, luego de lo cual el catéter se lava con aproximadamente 200 ml de solución salina estéril directamente en la vejiga.

Los rangos de dosis sugeridos empleados para varias indicaciones diagnósticas en el PACIENTE ADULTO promedio (70 kg) son los siguientes:

Imágenes Vesicoureteral:	18,5 a 37 MBq (0,5 a 1 mCi)
Imágenes de la glándula Tiroides:	37 a 370 MBq (1 a 10 mCi)
Imágenes de la glándula Salival:	37 a 185 MBq (1 a 5 mCi)
Sistema de drenaje Nasolagrimal:	Dosis máxima de 3,7 MBq (100 µCi)

Las posologías recomendadas en PACIENTES PEDIÁTRICOS son:

Imágenes Vesicoureteral:	18,5 a 37 MBq (0,5 a 1 mCi)
Imágenes de la glándula Tiroides:	2,22 a 2,96 MBq (60 a 80 µCi) por kg peso corporal

La dosis del paciente debe ser medida por un sistema de calibración de radioactividad adecuado inmediatamente antes de la administración.

Los fármacos parenterales deben ser inspeccionados visualmente para detectar partículas en suspensión y decoloración antes de la administración, siempre que la solución y el recipiente lo permitan. Si la solución está decolorada, suspenda de inmediato el uso del generador. La solución a ser administrada como dosis para el paciente debe ser transparente, incolora, y no debe contener partículas en suspensión.

Dosimetría de radiación

En las Tablas 5 y 6 se muestran las dosis de radiación absorbida estimadas para un paciente **ADULTO** y **PEDIATRICO** promedio provenientes de una inyección intravenosa de varias dosis de Pertecnetato de Sodio Tc 99m, distribuida uniformemente en todo el cuerpo.

Tabla 5. Dosis de radiación absorbidas en Adultos proveniente de inyección intravenosa

Órgano	Dosis de radiación absorbidas (mGy) for a 1110 MBq (30mCi) Dosis
Suprarrenales	4,1
Pared de la vejiga urinaria	20
Superficies óseas	6,2
Cerebro	2,2
Senos	2
Pared de la vesícula biliar	8,3
Pared estomacal	29
Intestino delgado	18
Pared del intestino grueso superior	63
Pared del intestino grueso inferior	23
Pared del corazón	3,5
Riñones	6
Hígado	4,7
Pulmones	2,9
Músculo	3,6
Ovarios	11
Páncreas	6,3
Médula roja	4,1
Piel	2
Bazo	4,8
Testículos	3,1
Timo	2,7
Tiroides	24
Útero	9
Tejidos restantes	3,9
Dosis efectiva (mSv)	14

Para obtener la dosis absorbida de radiación en rads (dosis de 30 mCi) a partir de la tabla arriba indicada, divida los valores de los órganos individuales por un factor de 10 (no aplica para la dosis efectiva).

Tabla 6. Dosis de radiación absorbidas (mGy) en pacientes Pediátricos proveniente de inyección intravenosa

Edad	15 años	10 años	5 años	1 año
Actividad administrada en MBq (mCi)	**1110 (30)**	**740 (20)**	**555 (15)**	**370 (10)**
Órgano				
Suprarrenales	5,3	5,4	6,2	7,1
Pared de la vejiga urinaria	26	22	18	22
Superficies óseas	7,6	7,5	8,1	10
Cerebro	2,8	3,1	3,7	4,5
Senos	2,6	2,6	3,2	4,1
Pared de la vesícula biliar	11	12	13	13
Pared estomacal	38	36	43	59
Intestino delgado	22	23	26	30
Pared del intestino grueso superior	81	89	110	140
Pared del intestino grueso inferior	31	33	40	48
Pared del corazón	4,5	4,6	5,2	6,4
Riñones	7,2	6,9	7,8	8,5
Hígado	6	6,7	8	9,1
Pulmones	3,8	3,8	4,4	5,3
Músculo	4,5	4,5	5	6
Ovarios	14	13	14	17
Páncreas	8,1	8,2	8,9	10
Médula roja	5,1	5	5,2	6
Piel	2,5	2,6	3,2	3,8
Bazo	6	6	6,7	7,8
Testículos	4,1	4,3	4,9	6
Timo	3,6	3,5	4,2	5,3
Tiroides	40	41	67	81
Útero	11	11	12	14
Tejidos restantes	4,8	4,8	5,4	6,4
Dosis efectiva (mSv)	19	19	23	29

Para obtener la dosis absorbida de radiación en rads (dosis de 30 mCi) a partir de la tabla arriba indicada, divida los valores de los órganos individuales por un factor de 10 (no aplica para la dosis efectiva).

Las dosis estimadas de radiación absorbida para un paciente ADULTO en el procedimiento de imágenes del conducto nasolagrimal usando una dosis máxima de 3,7 megabecquereles (100 microcurios) de Pertecnetato de Sodio Tc 99m se muestran en la Tabla 7.

Tabla 7. Dosis de radiación absorbida proveniente de Dacriocentellografía

Tejido	Dosis de 3,7 MBq (100 µCi) de Pertecnetato de Sodio Tc 99m	
	mGy	rad
Cristalino:		
Si el recambio del líquido lagrimal es 16%/min	0,140	0,014
Si el recambio del líquido lagrimal es 100%/min	0,022	0,002
Si el sistema de drenaje está bloqueado	4,020	0,402
Cuerpo total*	0,011	0,001
Ovarios*	0,030	0,003
Testículos*	0,009	0,001
Tiroides*	0,130	0,013

*Asumiendo que no hay bloqueo del sistema de drenaje.

En pacientes pediátricos, una exposición promedio de 30 minutos a 37 MBq (1 mCi) de pertecnetato Tc-99m luego de instilación para cistografía directa, resultará en las siguientes dosis de radiación estimadas:

Tabla 8. Dosis de Radiación Absorbidas a partir de Cistografía (PEDIÁTRICA)

Edad	Dosis de la pared vesical, mGy (rad)	Dosis gonadal, mGy (rad)
1 año	3,6 (0,36)	0,15 (0,015)
5 años	2,0 (0,2)	0,095 (0,0095)
10 años	1,3 (0,13)	0,066 (0,0066)
15 años	0,92 (0,092)	0,046 (0,0046)

PRESENTACIÓN

Los generadores Ultra-Technekow™ V4 (Tecnecio Tc 99m) contienen la siguiente cantidad de molibdeno Mo-99 en la fecha y hora de calibración mencionada en la etiqueta.

No. de Catálogo

9010 NDC 69945-010-03	37 gigabecquereles	(1,0 curio)
9015 NDC 69945-015-04	55,5 gigabecquereles	(1,5 curios)
9020 NDC 69945-020-05	74 gigabecquereles	(2,0 curios)
9025 NDC 69945-025-06	92,5 gigabecquereles	(2,5 curios)
9030 NDC 69945-030-07	111 gigabecquereles	(3,0 curios)
9035 NDC 69945-035-08	129,5 gigabecquereles	(3,5 curios)
9051 NDC 69945-051-09	185 gigabecquereles	(5,0 curios)
9060 NDC 69945-060-10	222 gigabecquereles	(6,0 curios)
9075 NDC 69945-075-11	277,5 gigabecquereles	(7,5 curios)
9110 NDC 69945-110-12	407 gigabecquereles	(11,0 curios)
9140 NDC 69945-140-13	518 gigabecquereles	(14,0 curios)
9160 NDC 69945-160-14	592 gigabecquereles	(16,0 curios)
9190 NDC 69945-190-15	703 gigabecquereles	(19,0 curios)

Cada generador viene con los siguientes componentes para su elución:

- 1 - Vial de Technestat™, 5 ml, que contiene 0,5 ml de metilparabeno 1,5 mg/ml y propilparabeno 0,2 mg/ml, estériles, no pirogénicos
- 1 - Prospecto adjunto

POR SEPARADO SE SUMINISTRAN

- 30 - Viales de recolección evacuados, 30 ml, estériles, no pirogénicos, suministrados con:
  - 90 - Etiquetas de Material Radiactivo –Vial de recolección (30 en, 30 fr, 30 es)
  - 90 - Etiquetas de Material Radiactivo – Blindaje de elución (30 en, 30 fr, 30 es)
  - 1 - Prospecto adjunto
- 30 - Eluyente de generador, Inyección de Cloruro de Sodio 0,9%, estéril, no pirogénicos, disponible en volúmenes de 5 ml, 10 ml, o 20 ml, con 1 prospecto adjunto. El eluyente no contiene un agente antimicrobiano. Cada mililitro de eluyente del generador contiene 9 miligramos de cloruro de sodio.

Almacenamiento

Almacene el generador y la solución de Pertecnetato de Sodio Tc 99m a temperatura controlada de 20° a 25°C (68° a 77°F) [vea Temperatura Ambiente Controlada USP].

Fecha de caducidad

El generador no debe ser usado después de la fecha de caducidad que aparece en la etiqueta.

El tiempo de caducidad de la solución de Pertecnetato de Sodio Tc 99m no es mayor a 12 horas después del momento de la elución. Si se usa el eluato para reconstituir un kit, el kit radiomarcado no debe ser usado después de 12 horas a partir del momento de elución del generador o después del tiempo de caducidad especificado en la etiqueta para el fármaco preparado, lo que ocurra primero.

Indicaciones para el uso del generador de tecnecio Tc 99m

NOTA 1: Inmediatamente después de ser entregado, el generador debe ser colocado dentro de un mínimo de una pulgada de blindaje de plomo de una manera tal que se minimice la exposición a la radiación por parte del personal asistente.

NOTA 2: Use guantes a prueba de agua durante el procedimiento de elución y durante la subsiguiente reconstitución de kits con el eluato.

NOTA 3: Use una jeringa blindada para extraer la dosis del paciente o para transferir Pertecnetato de Sodio Tc 99m a los viales de mezcla durante la reconstitución del kit.

NOTA 4: Las agujas en el generador están estériles debajo de sus cubiertas, y el generador ha sido limpiado debajo de la cubierta superior. La desinfección adicional de estas áreas con agentes que contengan alcohol pueden influenciar de manera desfavorable el rendimiento de Tc 99m.

Eluir el generador cada 24 horas proporcionará cantidades óptimas de Pertecnetato de Sodio Tc 99m. Sin embargo, el generador puede ser eluido siempre que se hayan acumulado cantidades suficientes de tecnecio Tc 99m dentro de la columna.

Por ejemplo

Tiempo Después de la Primera Elución (hrs.)	Rendimiento Aproximado (% de Primera Elución)
1	10
2	19
3	27
4	35
5	41
6	47

Elución

1. Levante el generador por su asa y colóquelo dentro del blindaje auxiliar. Mueva el asa para que no cubra la parte superior del generador, empujándola a un lado entre el generador y el blindaje auxiliar.
2. Retire y guarde la tapa de la campana de elución. Coloque la cubierta del blindaje auxiliar sobre la parte superior del generador y alinéelo con la campana de elución.
3. Retire y guarde los tapones de las cubiertas de las agujas.
4. Remueva la tapa abatible de la ámpula de eluyente; desinfecte el émbolo con un bactericida, como el alcohol de isopropilo al 70%, permitiendo el secado del émbolo antes de su uso. Invierta el ámpula de eluyente y coloque el émbolo primero en el inserto de alineación del ámpula de solución salina. Coloque el inserto de alineación del ámpula de solución salina y el ámpula en el puerto de solución salina del capuchón de blindaje auxiliar y empujar el ámpula de eluyente firmemente hacia abajo hasta perforar el émbolo y que esté asentada en la base de las agujas de eluyente.
5. Coloque la protección de solución salina sobre el blindaje auxiliar superior para tapar el vial de eluyente.
6. Retire la tapa abatible de un vial de evacuación; desinfecte el tapón, permitiendo que el tapón se seque antes de su uso. Coloque el vial de evacuación en el instrumento de elución.
7. Coloque en posición el vial de evacuación blindado bajando cuidadosamente el instrumento de elución hasta que quede en lugar en la aguja de elución. Perforar el septum del vial de evacuación con la aguja de elución, hará que comience el proceso de elución.
8. Espere hasta que el vial de evacuación se haya llenado completamente. Esto tomará unos pocos minutos. **Nunca interrumpa la elución levantando el instrumento de elución!**
9. **NOTA: No utilice el eluato del generador si su apariencia está decolorada, y descontinúe el uso del generador.**
10. Retire la tapa abatible del vial Technestat; desinfecte el tapón permitiendo que el mismo se seque antes de su uso. Asegure el vial Technestat en su soporte.
11. Retire cuidadosamente el instrumento de elución y reemplácelo con el vial Technestat blindado.
12. Determine la concentración de tecnecio Tc 99m y el contenido de molibdeno Mo-99 para propósitos de preparación. El eluato del generador puede ser sometido a análisis usando un calibrador de dosis con cámara de ionización, detector de centelleo u otro sistema de detección apropiado. Se deben seguir las instrucciones del fabricante para el funcionamiento del instrumento/equipo para medir la actividad del Tecnecio Tc-99m y Molibdeno Mo-99. **NOTA: Límite de Irrupción de Molibdeno Mo-99** - El límite aceptable es 0,15 kilobecquereles de molibdeno Mo-99 por megabecquerel de tecnecio Tc 99m (0,15 microcurio Mo-99 por milicurio Tc 99m) por dosis administrada en la inyección, en el momento de la administración. (Vea USP, Inyección de Pertecnetato de Sodio Tc 99m).
13. Determine la concentración del ion aluminio del eluato. **NOTA: Límite de Irrupción del Ion Aluminio** - El límite aceptable no es mayor a 10 microgramos por mililitro de eluato (Vea USP, Inyección de Pertecnetato de Sodio Tc 99m).

No se garantiza la esterilidad del producto en caso de que el empaque primario tenga señales de haber sufrido ruptura previa.

Eluciones subsiguientes

1. Remueva el blindaje salino y luego remueva el inserto de alineación del ámpula de solución salina para remover el ámpula de eluyente de las agujas de eluyente. Remueva el ámpula del inserto de alineación del ámpula de solución salina y reutilice el inserto de alineación del ámpula de solución salina para posteriores eluciones.
2. Retire el vial blindado de Technestat levantando cuidadosamente su blindaje de la aguja de elución.
3. Repita los pasos del 4 al 12 del procedimiento de Elución arriba mencionado.

Pérdida de vacío

Si se pierde el vacío en el vial de recolección, no intente volver a evacuar el vial, sino que descarte y use un nuevo vial de recolección.

Eliminación del generador expirado

1. Luego de la vida del generador, retire y elimine el vial Technestat usado y el vial del eluyente.
2. Cubra las agujas de elución y de eluyente con los tapones de las cubiertas de aguja almacenadas.
3. Coloque la cubierta de la campana de elución guardada en la parte superior del generador.
4. El ensamblaje intacto del generador debe ser devuelto a Curium US LLC, o desechado de acuerdo con regulaciones aplicables.

Este generador puede ser recibido, usado y administrado solamente por personas autorizadas en ambientes clínicos designados. Su recepción, almacenamiento, uso, transferencia y descarte están sujetos a las regulaciones y/o licencias apropiadas de organizaciones oficiales locales competentes.

Fabricado por:
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Maryland Heights, MO 63043 E.U.A
Hecho en E.U.A

A9011S
Revisado 5/2022

STERILE

CURIUM™

A9011S R5/2022

Ultra-Technekow™ V4
(Generador de Tecnecio Tc 99m)

9010/9190

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