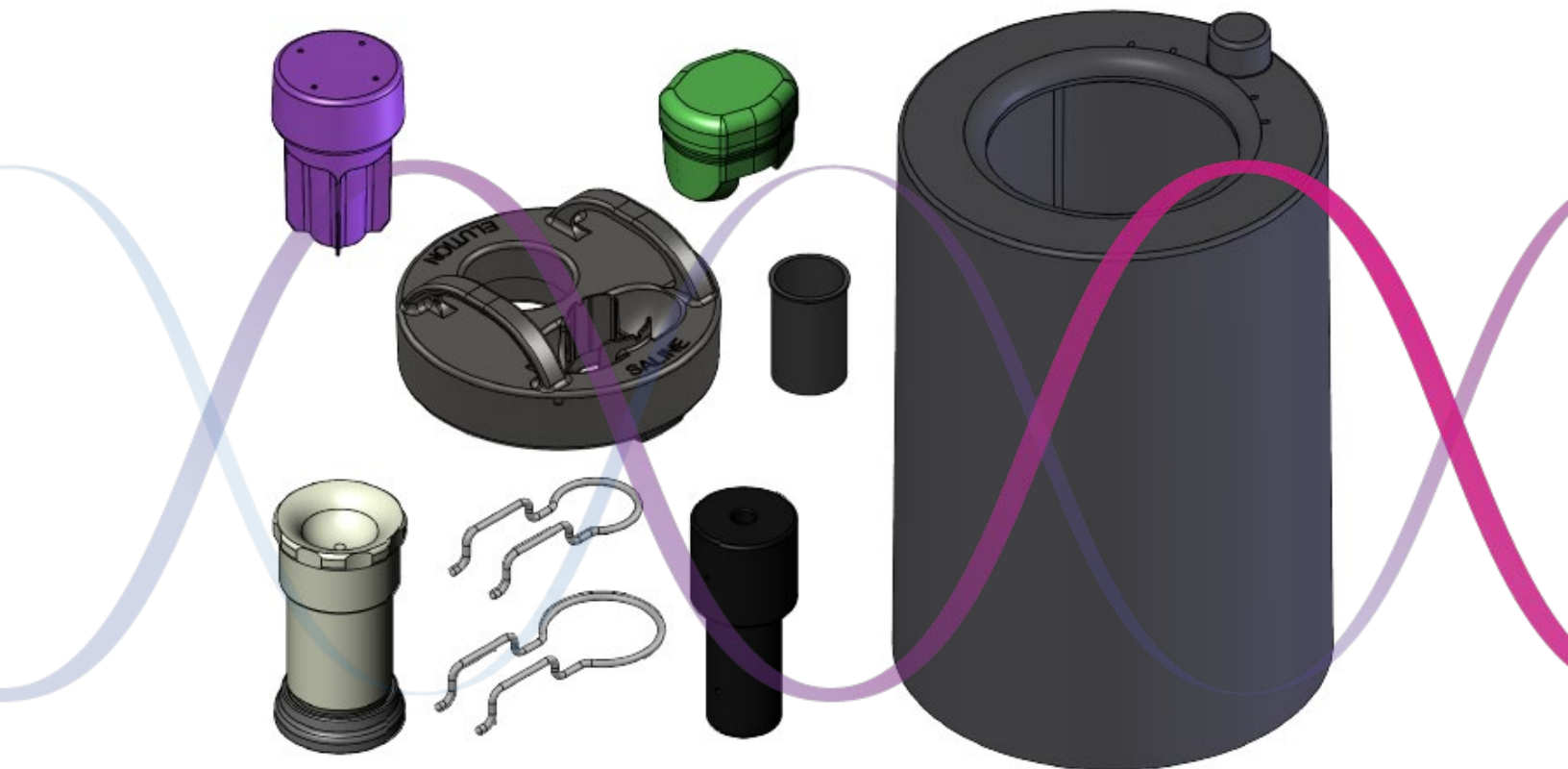


# Generator Accessories Ultra-Technekow™ V4 (technetium Tc 99m generator)

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.

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### **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.

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### **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.

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**For additional Important Risk Information, see accompanying Full Prescribing Information.  
For Curium Ultra-Technekow™ V4 Customers only. Do not share.**

**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.

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**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.

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**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.

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### 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



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### 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.

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**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, Technostat 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 ( $\text{Na}^{99\text{m}}\text{TcO}_4$ ).

**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 ( $\text{Na}^{99\text{m}}\text{TcO}_4$ ) 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 ( $\text{Na}^{99\text{m}}\text{TcO}_4$ ) 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.

**For additional Important Risk Information, see accompanying Full Prescribing Information.**

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**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  $[\text{TcO}_4]^-$  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.

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#### **CAUTION!**

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

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# ELUTION PROCEDURES

## 2.1 ELUTION

### **WARNING!**

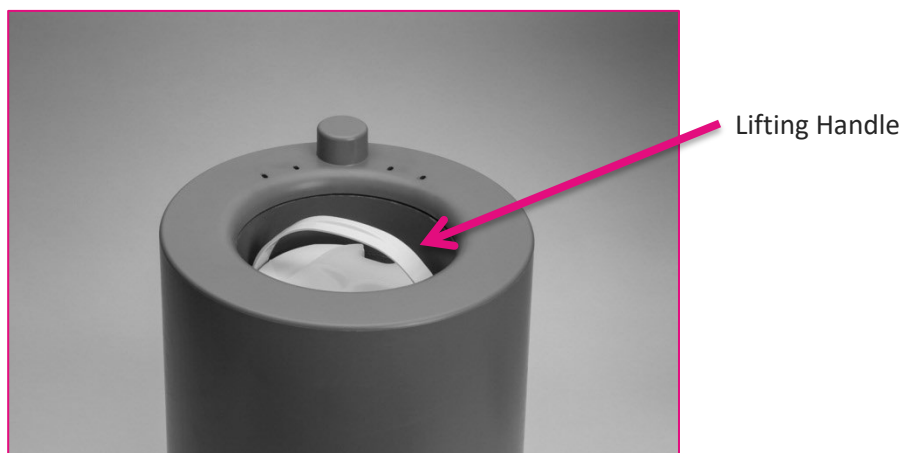
Be sure to wear appropriate PPE for setting up the generator.

### **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® Ilse (1:128 Dilution). Other chemicals should not be used to disinfect the non-porous polycarbonate surface of the generator.

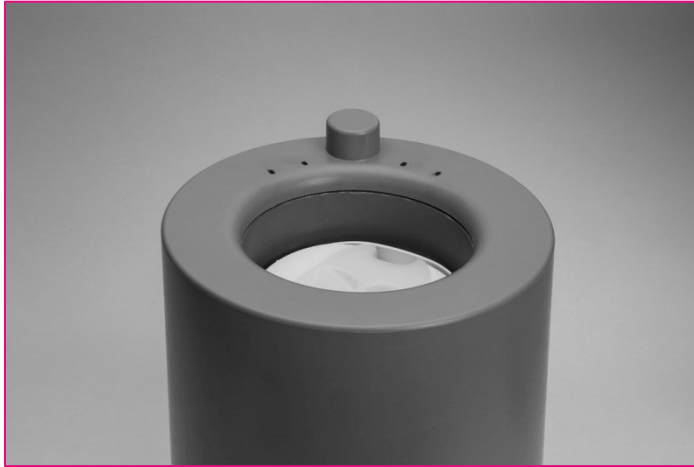
### 2.1.1. PREPARATION STEPS

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



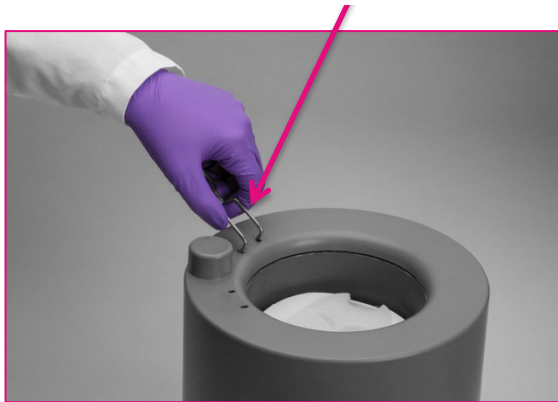
Move the handle to the side in between the generator and the Auxiliary Shield so it does not cover the generator top.

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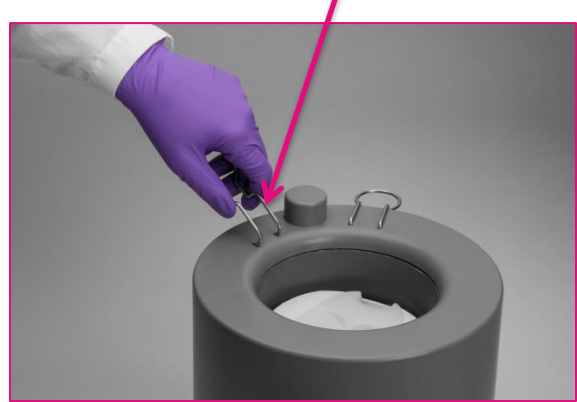


2. Secure the Tip Cap Replacement Tool Ring and Technestat Vial Holder Ring into the holes located on top of the Auxiliary Shield Cover.

Tip Cap Replacement  
Tool Ring

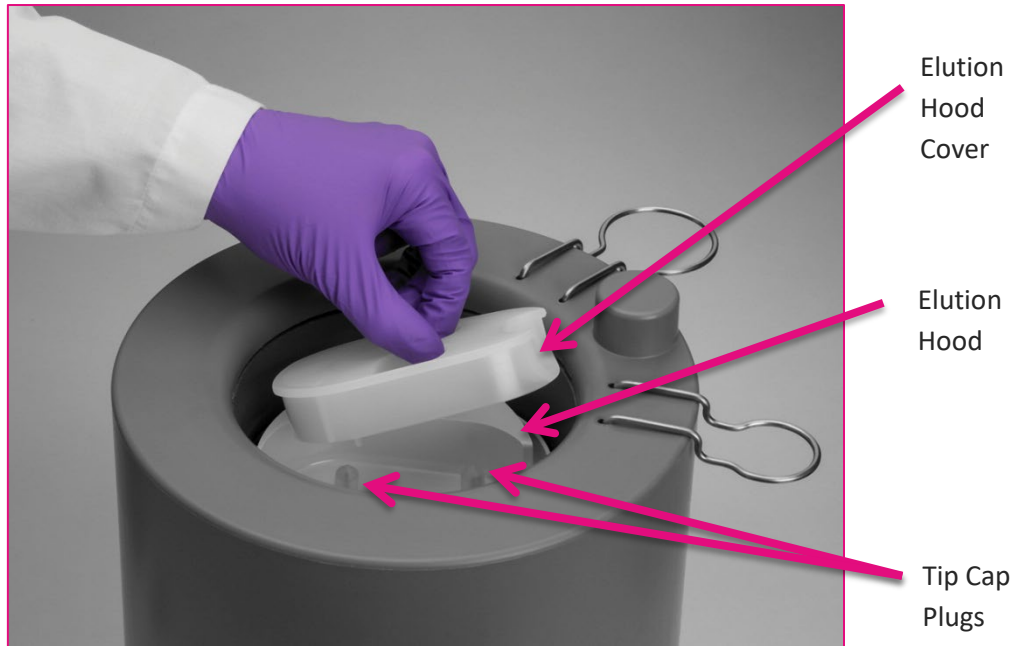


Technestat  
Vial Holder Ring



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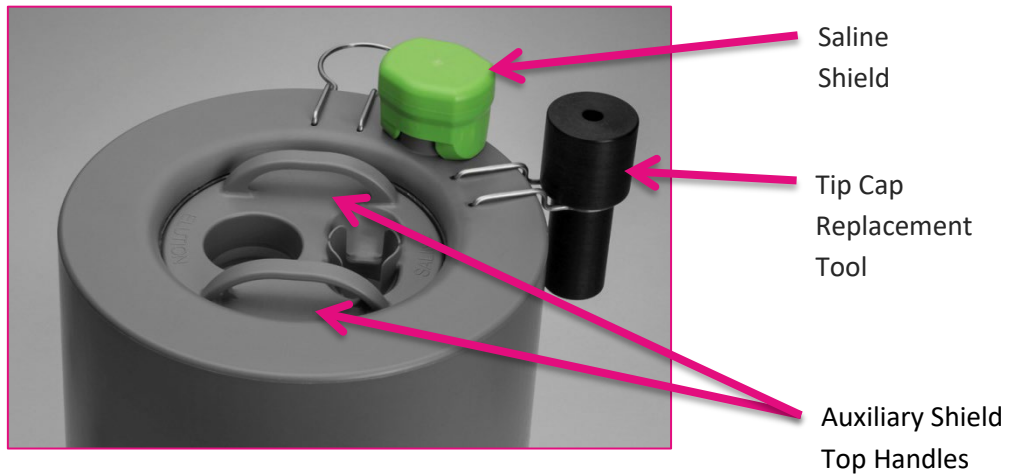
3. Remove and store the Elution Hood Cover.



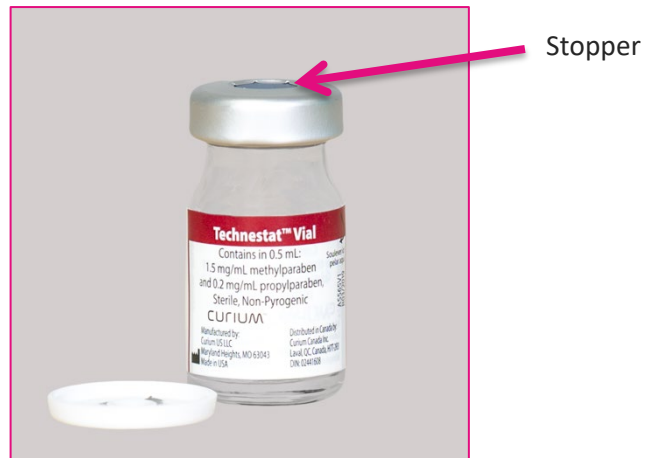
Place the Auxiliary Shield Top on top of the generator using the handles; align the Auxiliary Shield Top with the Elution Hood. Rotate slowly until the raised ribs on the bottom of the Auxiliary Shield Top drop into the recessed area in the Elution Hood. Place the Saline Shield and the Tip Cap Replacement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

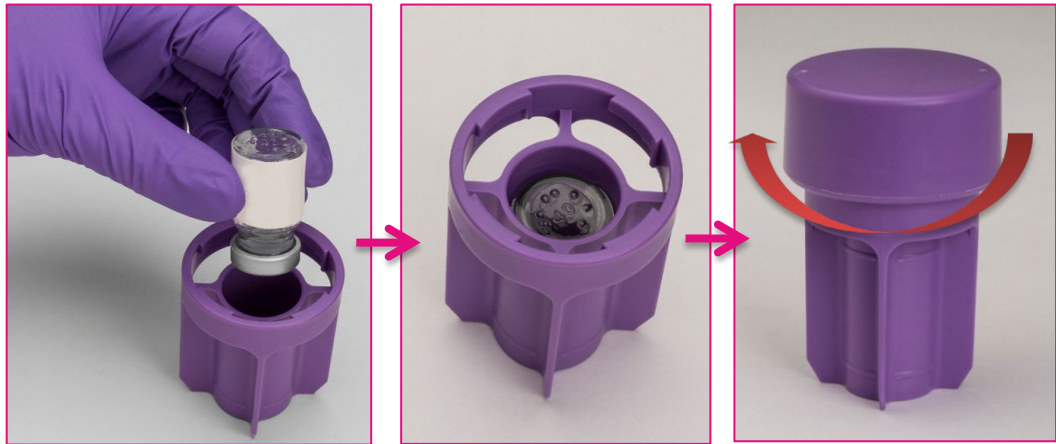


**For additional Important Risk Information, see accompanying Full Prescribing Information.  
For Curium Ultra-Technekow™ V4 Customers only. Do not share.**

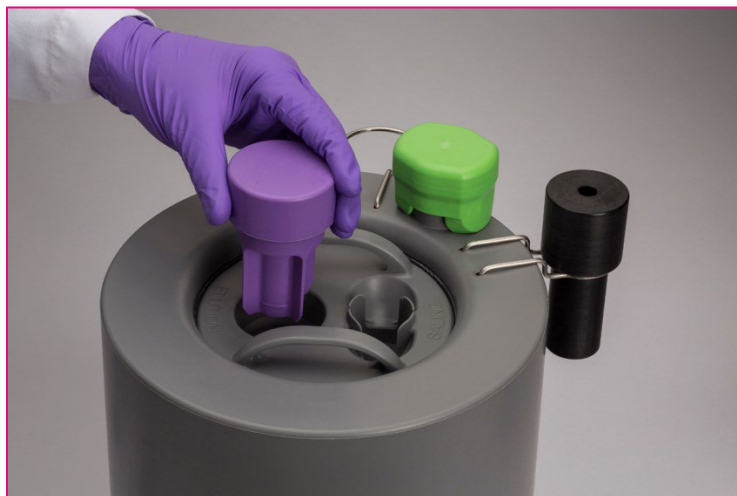
5. Place the Technestat vial in the Technestat tool body. Attach and turn the Technestat cap 30 degrees clockwise to secure. There may be positive pressure in the Technestat vial.

**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.



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For Curium Ultra-Technekow™ V4 Customers only. Do not share.**

## 2.1.2. ELUTION STEPS

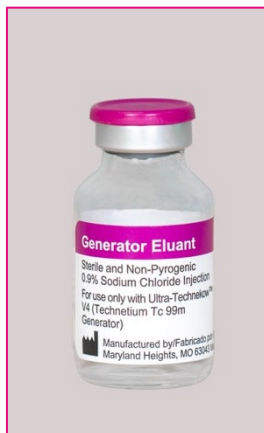
### WARNING!

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!

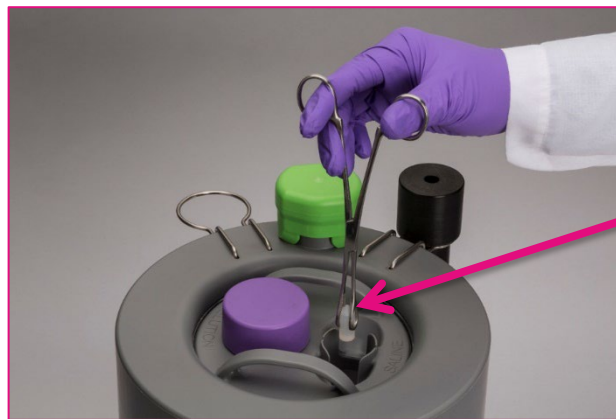
If radioactive drips occur, clean up all excess fluid and dispose of in accordance with local nuclear regulations. Failure to follow this warning could result in personal injury and/or elevated levels of radiation exposure.

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

For additional Important Risk Information, see accompanying Full Prescribing Information.  
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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.

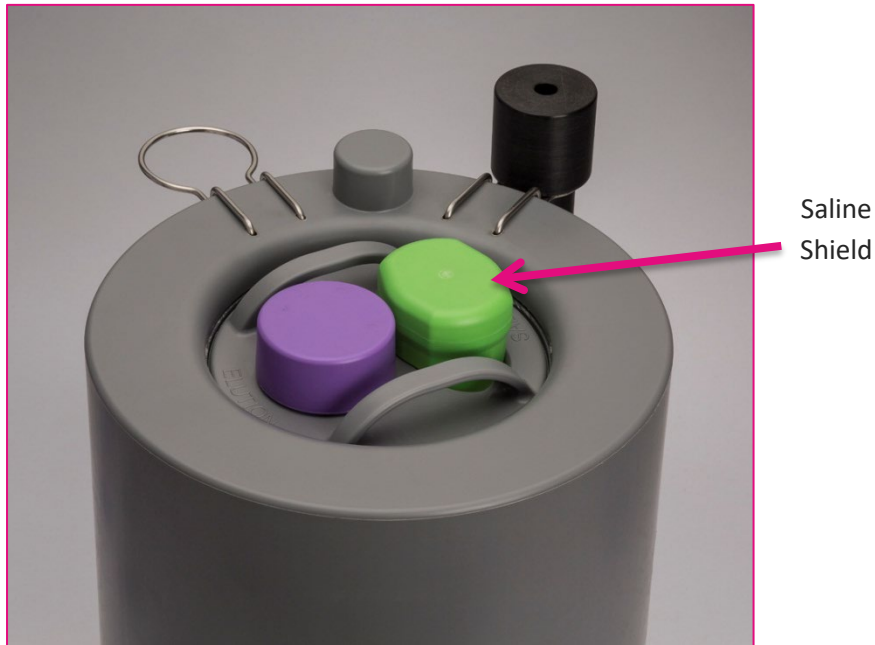


**CAUTION!**

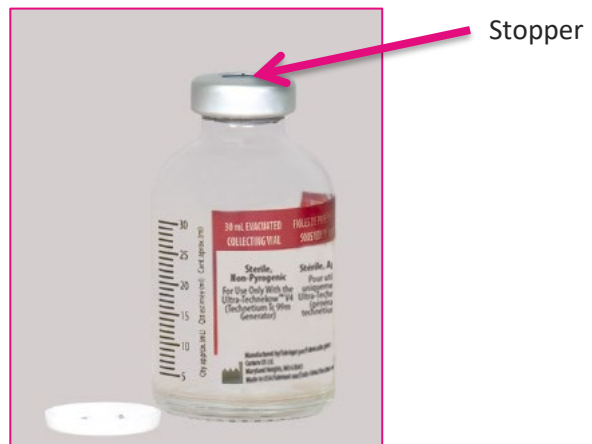
Visually inspect for damages before beginning elution or dispensing. If damage is detected such as exposed lead and scratches, do not attempt to use the tool. Call the number on page 25 to order replacement parts. Failure to follow this warning could result in personal injury and/or elevated levels of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

For additional Important Risk Information, see accompanying Full Prescribing Information.  
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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.

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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).



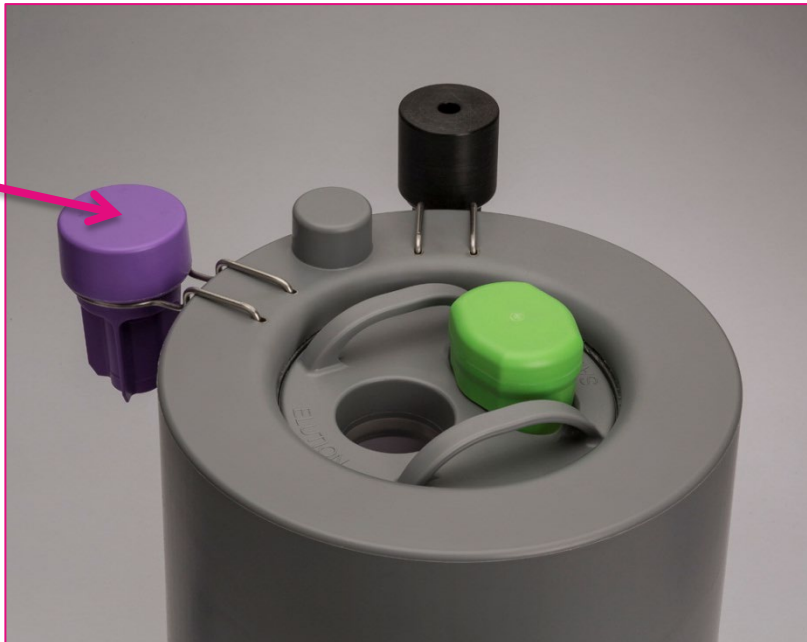
**For additional Important Risk Information, see accompanying Full Prescribing Information.  
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Close the lid; making sure that the tabs on the lid line up with the grooves on the elution tool body. Turn the lid 45 degrees clockwise to lock it.



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

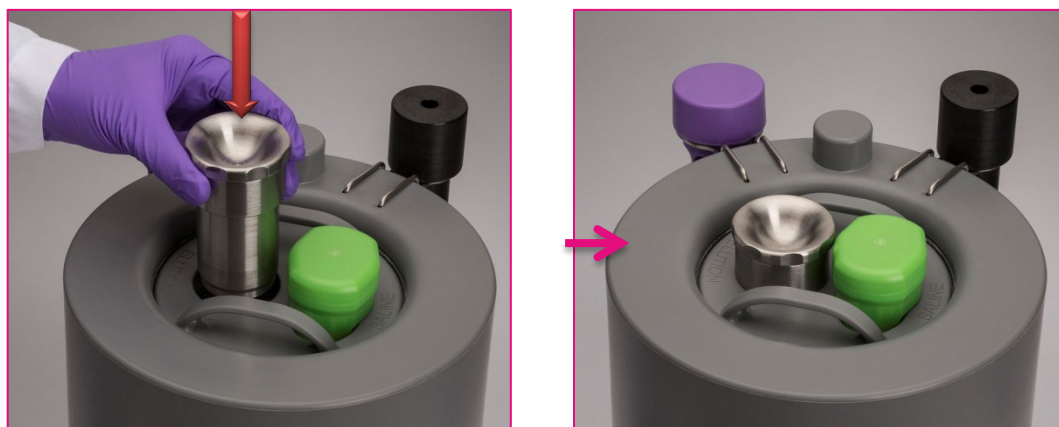
Technestat  
Vial Holder



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

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

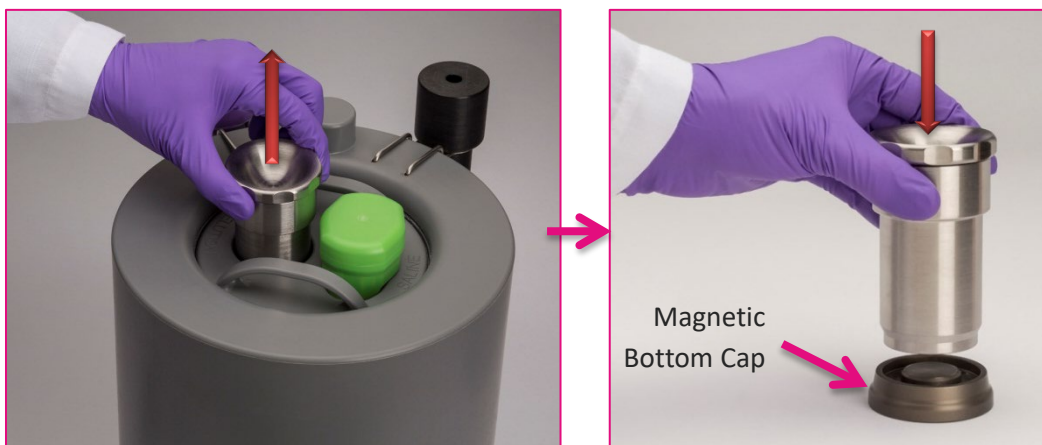


**NOTE:** Depending on the volume being eluted, allow time (the generator should not take longer than 5 minutes to elute) for the completion of the elution and equilibration of the evacuated vial to atmospheric pressure before removing the Elution Tool. Never interrupt elution by lifting the Elution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

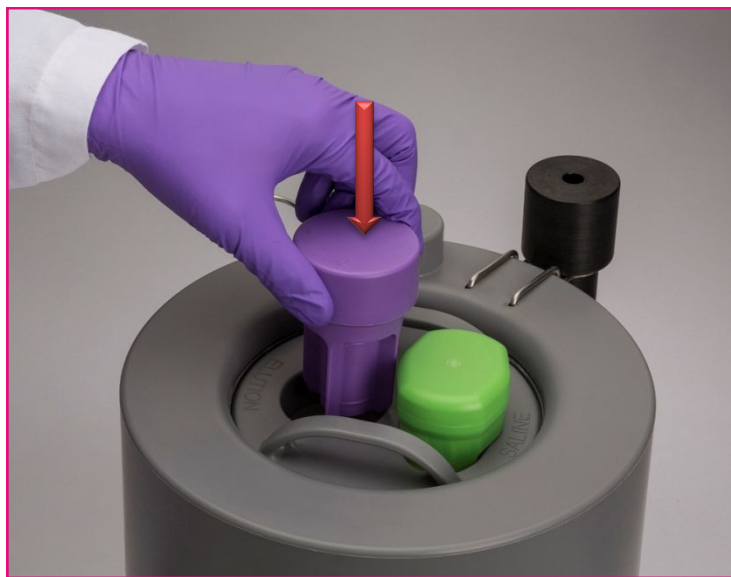
**WARNING!**

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.

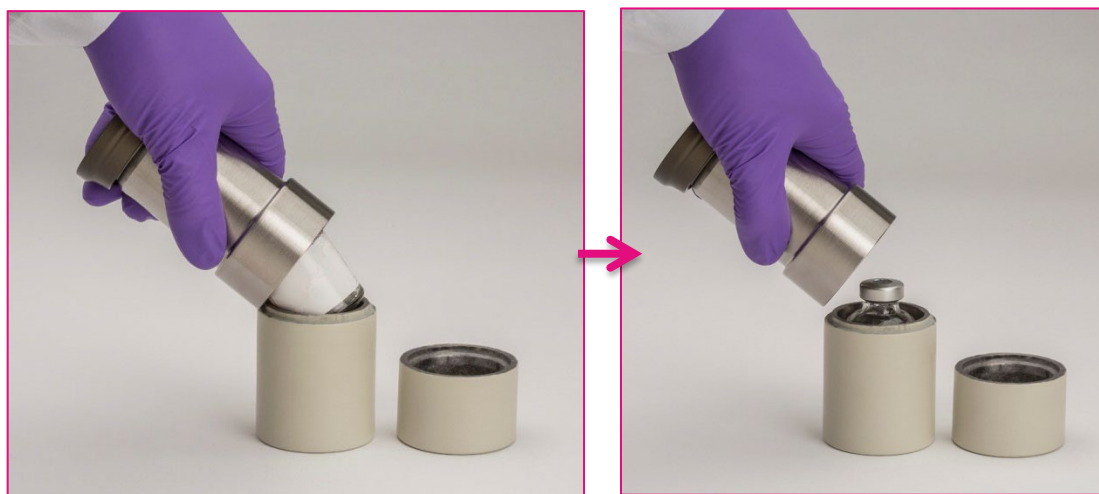


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- Remove the evacuated vial from the elution tool body and follow written site procedures to determine the correct sodium pertechnetate activity eluted and vial concentration as well as the radionuclidic purity.

**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.



- 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.



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



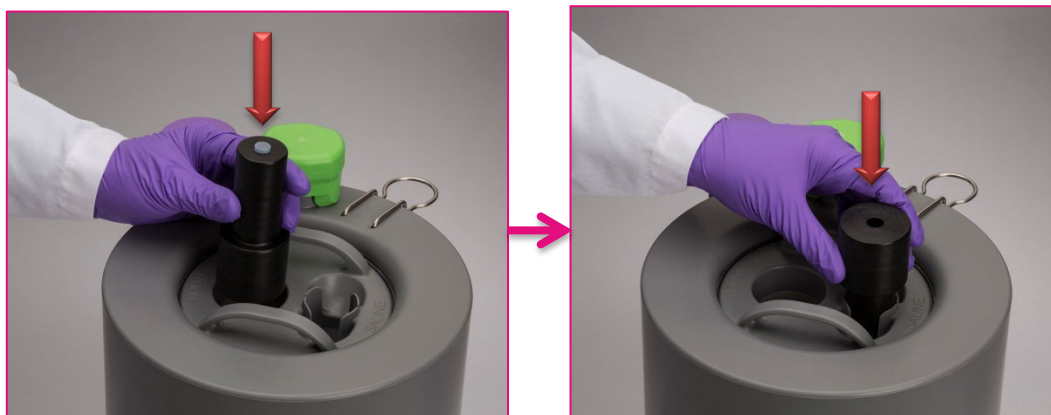
12. After withdrawal of sodium pertechnetate Tc 99m, place the Elution Tool on top of the Magnetic Bottom Cap.



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## 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.

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For Curium Ultra-Technekow™ V4 Customers only. Do not share.**

# 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.

- |   |                       |
|---|-----------------------|
| • Decon-Spore 200® Plus                             | 1:20 or 1:40 Dilution |
| • Hydrogen peroxide                                 | 3%                    |
| • Sporidicin® Disinfectant Spray, Solution, Aerosol | Ready to Use          |
| • Vesphene® Ilse                                    | 1:128 Dilution        |

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For Curium Ultra-Technekow™ V4 Customers only. Do not share.



**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*

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Decon-Spore 200® Plus is a registered trademark of Veltex Associates, Inc. Sporicidin® is a registered trademark of Contec, Inc.

Vesphene® is a registered trademark of Steris Corporation.

APP-CU-23-004 / GN0025 1023

**For additional Important Risk Information, see accompanying Full Prescribing Information.**

**For Curium Ultra-Technekow™ V4 Customers only. Do not share.**

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

9010/9190

Ultra-Technekow™ V4  
(Technetium Tc 99m Generator)**Ultra-Technekow™ V4  
(Technetium Tc 99m Generator)****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 microneter 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 <sup>1</sup>
0.18	10 <sup>2</sup>
0.27	10 <sup>3</sup>

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
<b>Effective Dose (mSv)</b>	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
<b>Administered activity in MBq (mCi)</b>	<b>1110 (30)</b>	<b>740 (20)</b>	<b>555 (15)</b>	<b>370 (10)</b>
<b>Organ</b>				
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
<b>Effective Dose (mSv)</b>	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**

- 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.
- 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.
- Remove and store the tip cap plugs from the needles.
- Remove the flip-top cap of the eluant vial; disinfect the stopper with a bactericide 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.
- Place the saline shield on top of the auxiliary shield top to cover the eluant vial.
- Remove the flip-top cap of an evacuated vial; disinfect the

