

TABLE OF CONTENTS

SAFETY	3
INTRODUCTION	4
1.1. INTENDED USE	4
1.2. QUALIFICATIONS	4
1.3. SPECIFICATIONS	5
1.3.1. SYSTEM COMPONENTS	5
1.3.2. VIAL SIZE	6
1.3.3. ENVIRONMENTAL	6
1.4. CONSUMABLES	6
1.4.1. VIALS	6
1.5. TERMS	6
1.6. MEANING OF SYMBOLS	8
ELUTION PROCEDURES	9
2.1. ELUTION	9
2.1.1. PREPARATION STEPS	9
2.1.2. ELUTION STEPS	14
2.2. EXPIRED GENERATOR DISPOSAL	23
MAINTENANCE PROCEDURES	24
3.1. MAINTENANCE SCHEDULE	24
3.1.1. DAILY INSPECTION	24
3.2. CLEANING PROCEDURES	24
3.2.1. CLEANING	24
3.3. HOW TO ORDER PARTS	25
3.3.1. LIST OF PARTS	25

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.

**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.

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.

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

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



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

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

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.

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

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.

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

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

ELUTION PROCEDURES

2.1 ELUTION

WARNING!

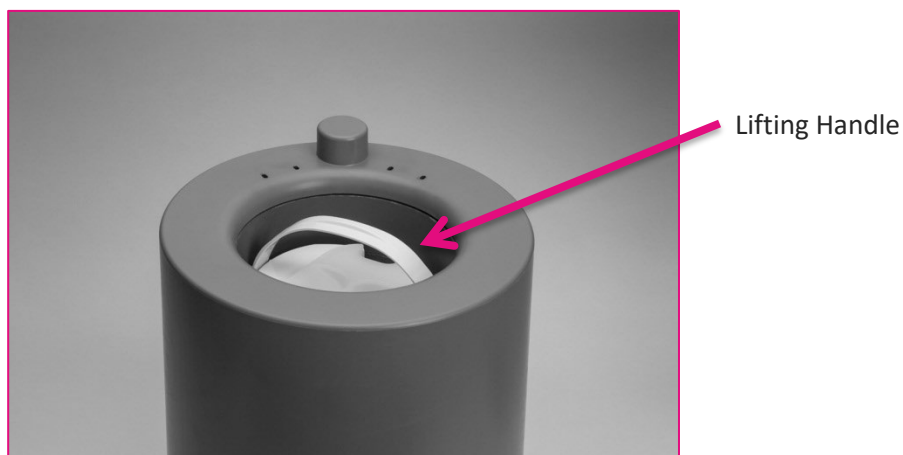
Be sure to wear appropriate PPE for setting up the generator.

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.

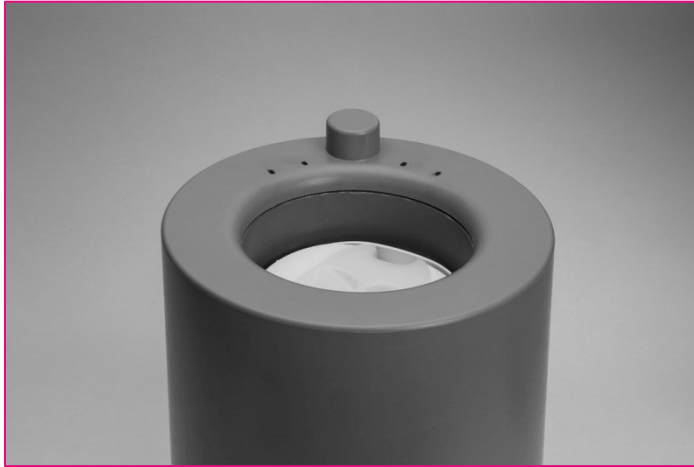
2.1.1. PREPARATION STEPS

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



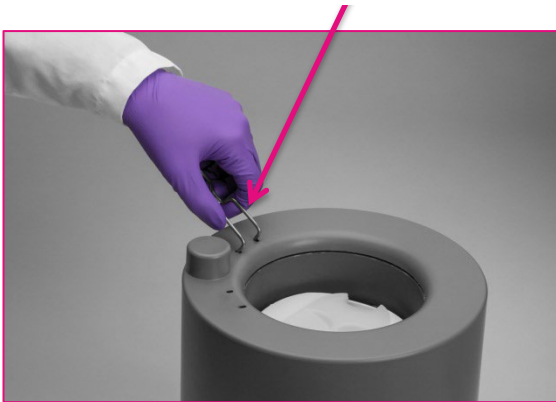
Move the handle to the side in between the generator and the Auxiliary Shield so it does not cover the generator top.

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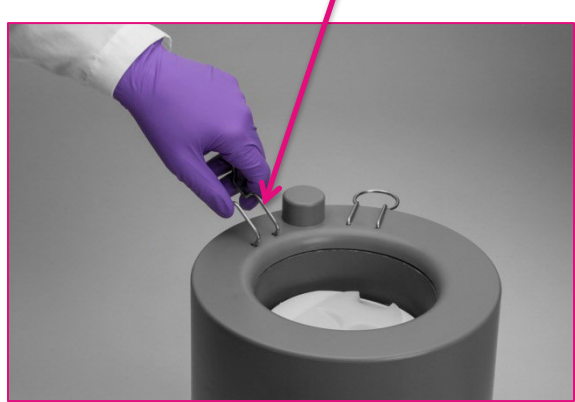


2. Secure the Tip Cap Replacement Tool Ring and Technestat Vial Holder Ring into the holes located on top of the Auxiliary Shield Cover.

Tip Cap Replacement
Tool Ring

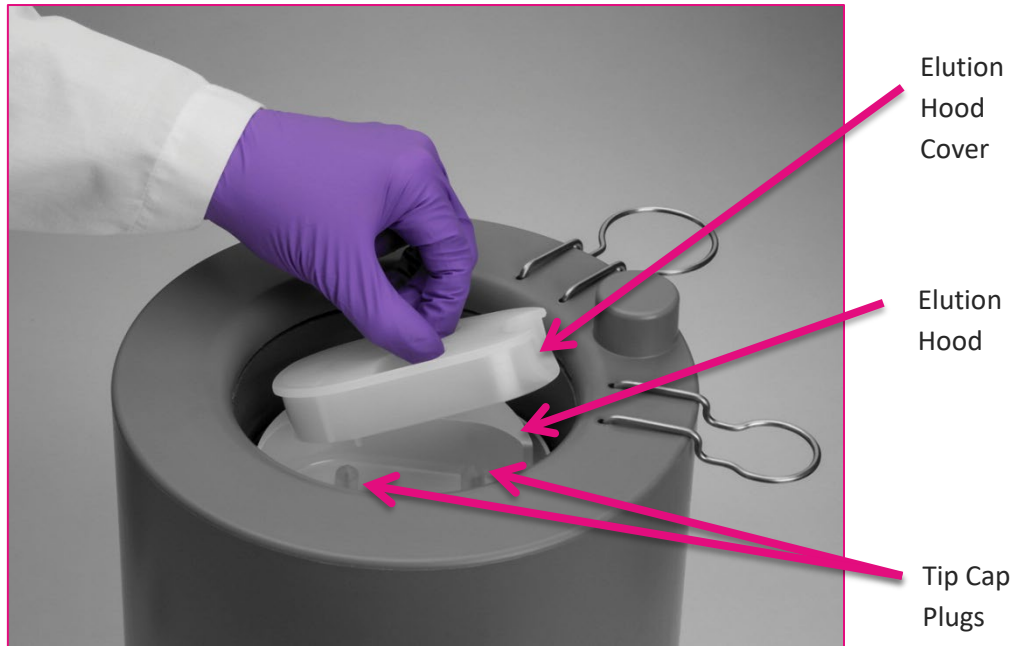


Technestat
Vial Holder Ring



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

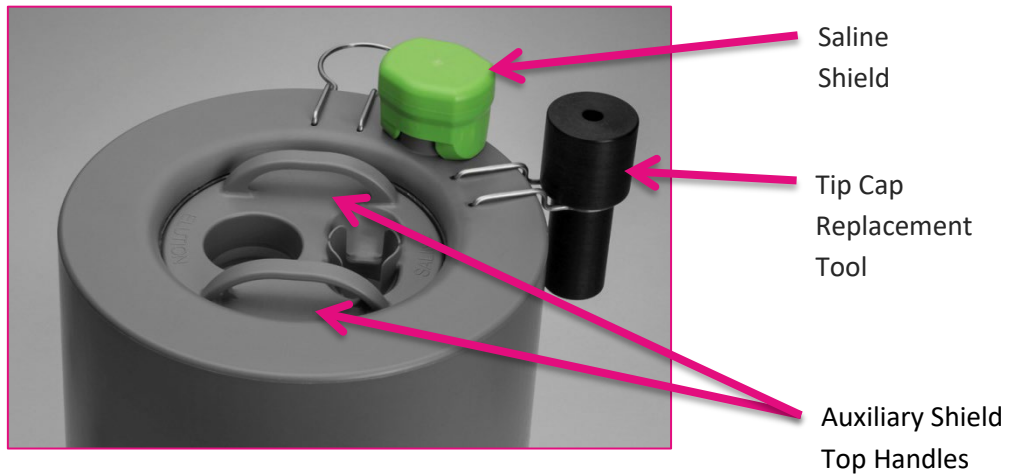
3. Remove and store the Elution Hood Cover.



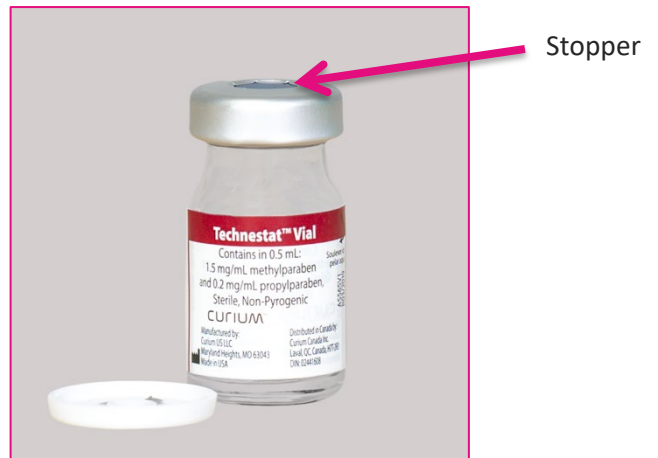
Place the Auxiliary Shield Top on top of the generator using the handles; align the Auxiliary Shield Top with the Elution Hood. Rotate slowly until the raised ribs on the bottom of the Auxiliary Shield Top drop into the recessed area in the Elution Hood. Place the Saline Shield and the Tip Cap Replacement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

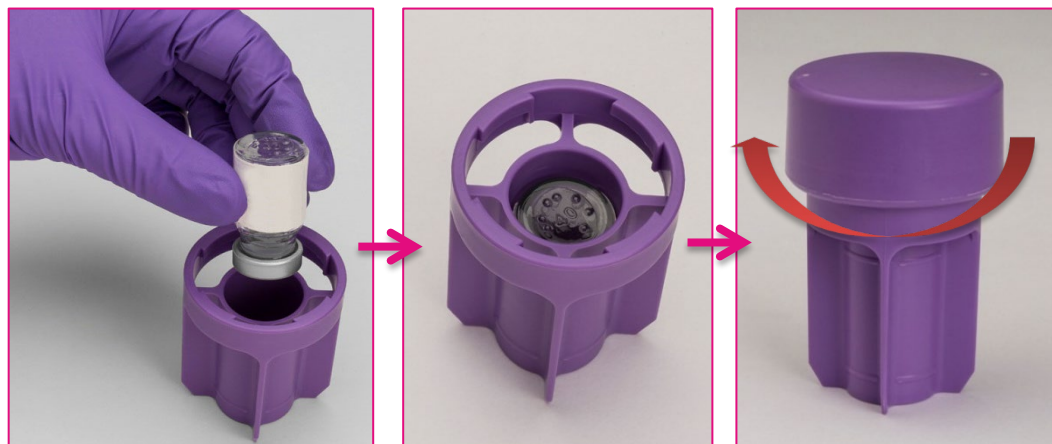


**For additional Important Risk Information, see accompanying Full Prescribing Information.
For Curium Ultra-Teknekow™ V4 Customers only. Do not share.**

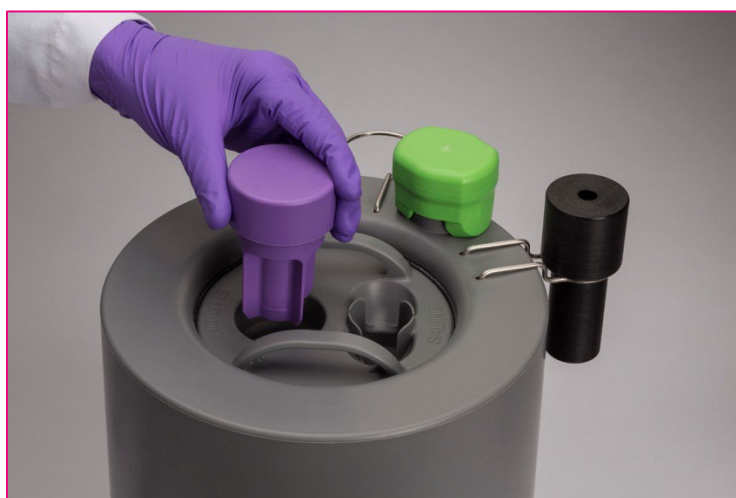
5. Place the Technestat vial in the Technestat tool body. Attach and turn the Technestat cap 30 degrees clockwise to secure. There may be positive pressure in the Technestat vial.

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.



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

2.1.2. ELUTION STEPS

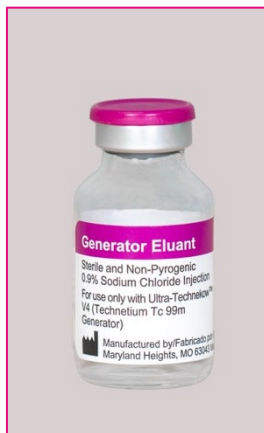
WARNING!

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!

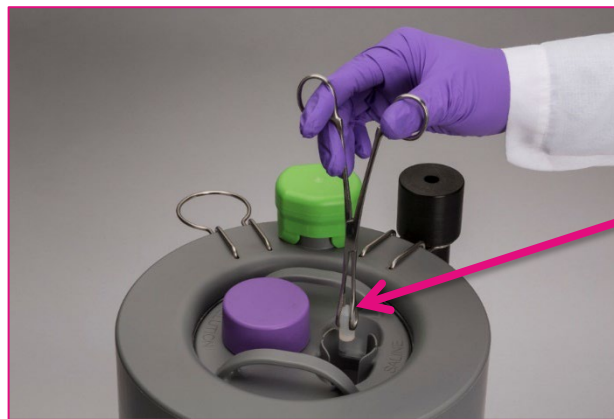
If radioactive drips occur, clean up all excess fluid and dispose of in accordance with local nuclear regulations. Failure to follow this warning could result in personal injury and/or elevated levels of radiation exposure.

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.



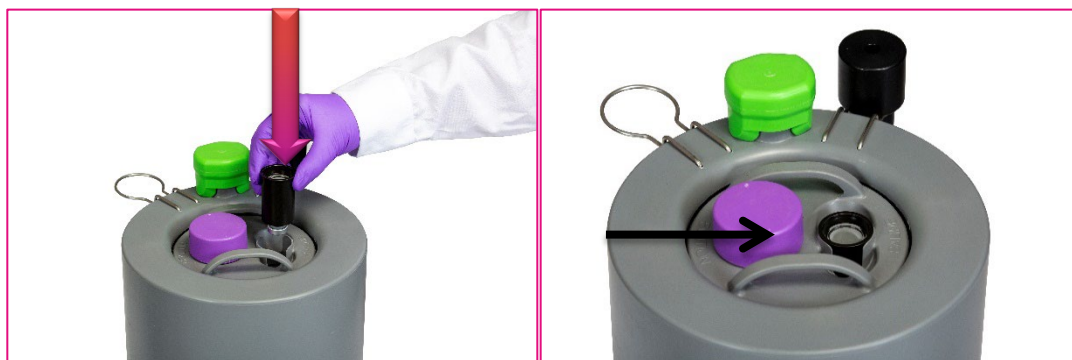
Tip Cap Plug removed

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

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.

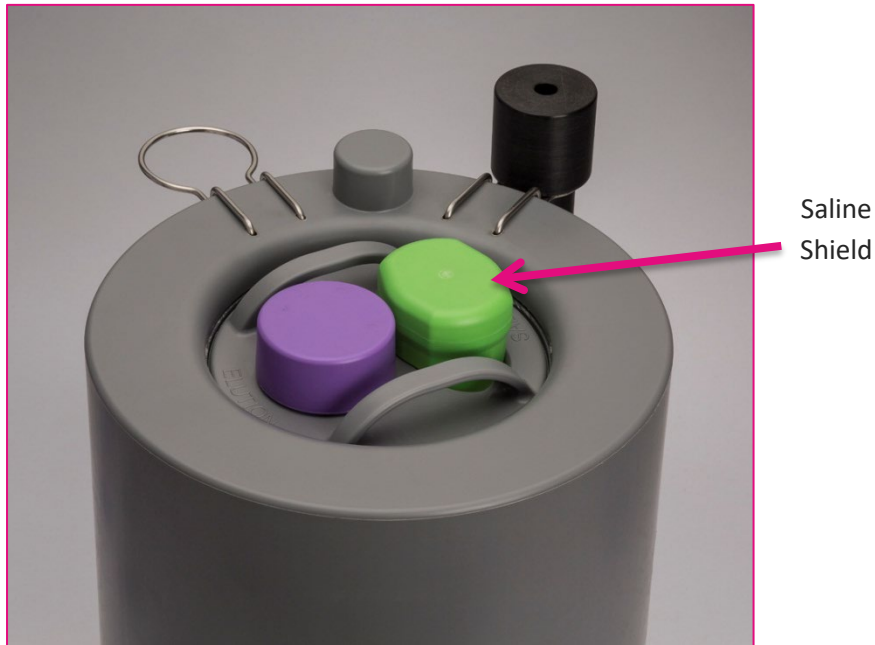


CAUTION!

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

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.

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



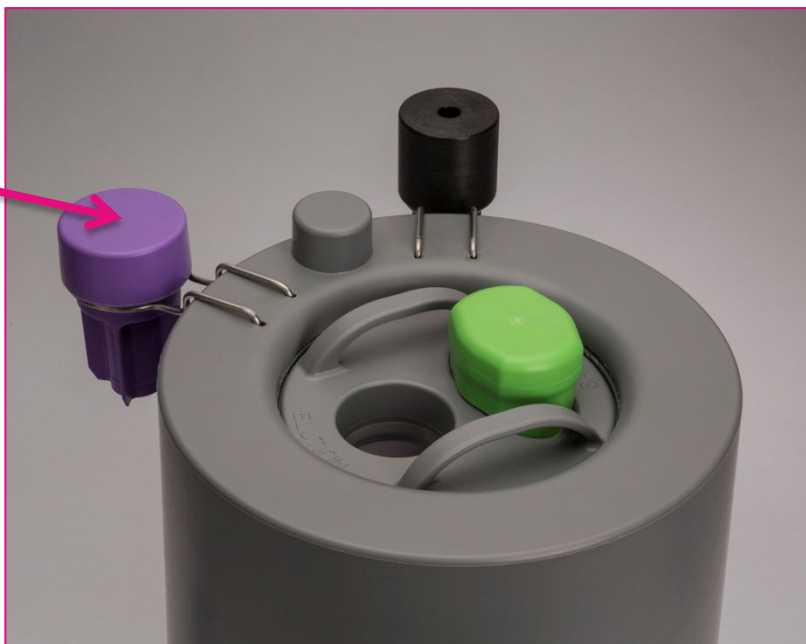
**For additional Important Risk Information, see accompanying Full Prescribing Information.
For Curium Ultra-Technekow™ V4 Customers only. Do not share.**

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.

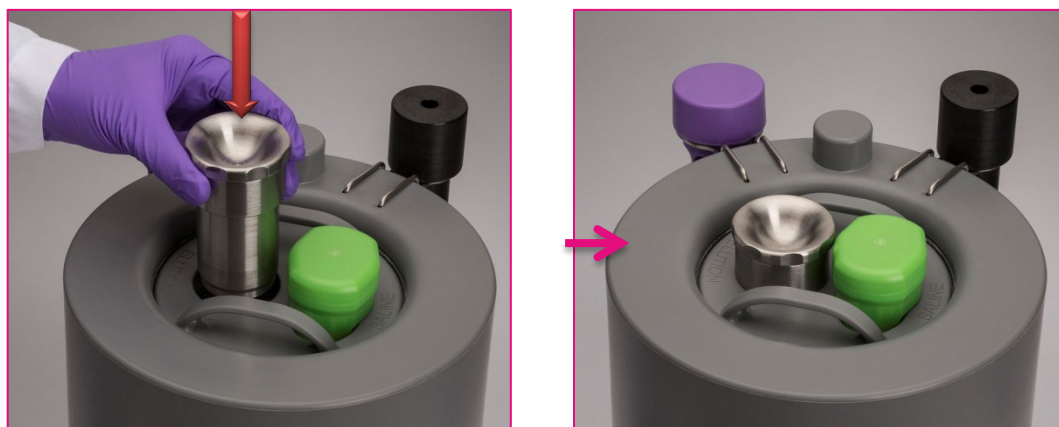
Technestat
Vial Holder



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

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

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

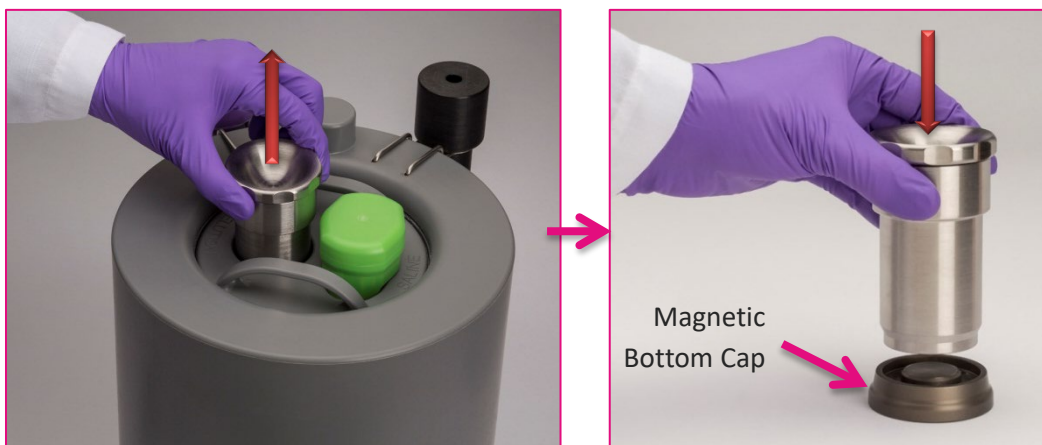


NOTE: Depending on the volume being eluted, allow time (the generator should not take longer than 5 minutes to elute) for the completion of the elution and equilibration of the evacuated vial to atmospheric pressure before removing the Elution Tool. Never interrupt elution by lifting the Elution Tool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

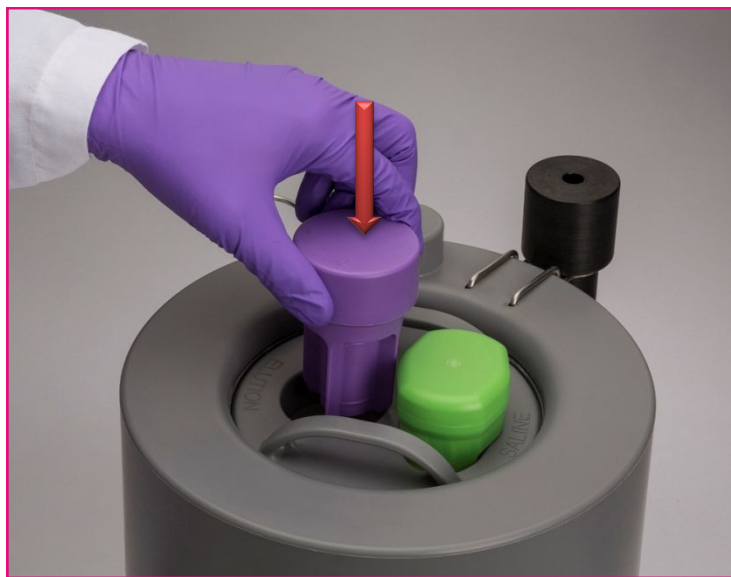
WARNING!

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.

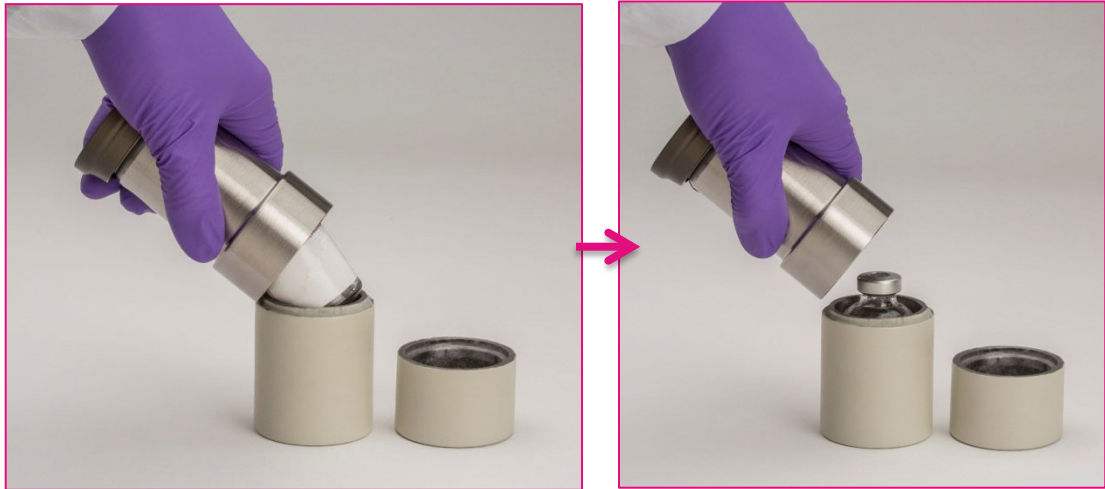


**For additional Important Risk Information, see accompanying Full Prescribing Information.
For Curium Ultra-Technekow™ V4 Customers only. Do not share.**

- 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.



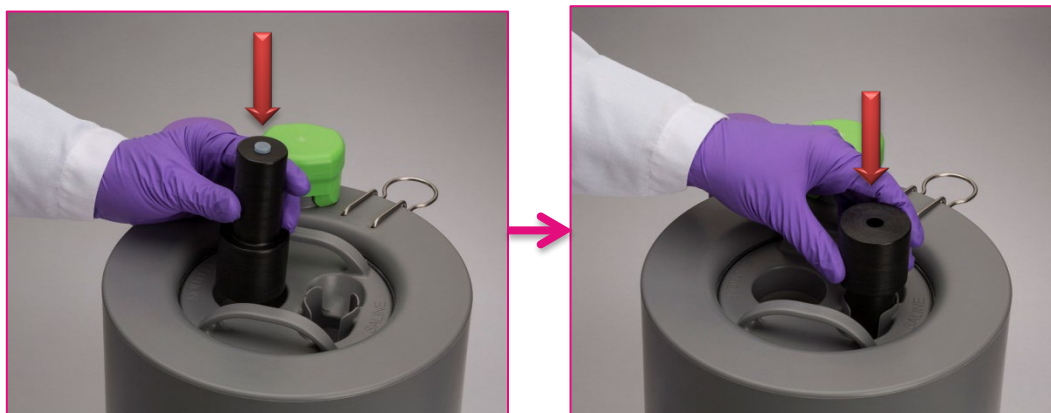
12. After withdrawal of sodium pertechnetate Tc 99m, place the Elution Tool on top of the Magnetic Bottom Cap.



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

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.

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

- | | |
|---|----------------|
| • Hydrogen peroxide | 3% |
| • Sporidicin® Disinfectant Spray, Solution, Aerosol | Ready to Use |
| • Vesphene® Ilse | 1:128 Dilution |

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

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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