Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ultra-TechneKow FM, Radionuclide Generator

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Technetium (^{99m}Tc) is produced by means of a (^{99} Mo/^{99m}Tc) generator and decays with the emission of gamma radiation with a mean energy of 140 keV and a half-life of 6 hours to technetium (^{99}Tc) which, in view of its long half-life of 2.13 x 10^5 years can be regarded as quasi stable. A sterile generator contains the parent isotope ^{99}Mo, adsorbed to an aluminum oxide column. The ^{99}Mo on the column is in equilibrium with the formed daughter isotope ^{99m}Tc. The generators are supplied with the following ^{99}Mo activity amounts:

At activity reference time

GBq	**(mCi)**	**GBq**	**(mCi)**
2.15	(58)	17.20	(465)
4.30	(116)	21.50	(581)
6.45	(174)	25.80	(697)
8.60	(232)	30.10	(814)
10.75	(291)	34.40	(930)
12.90	(349)	43.00	(1162)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Radionuclide generator
A lead-shielded radionuclide generator consisting of adsorbed ^{99} Mo in a glass column. A Type I glass vial contains a clear, colourless sterile aqueous solution as eluent. Type I, evacuated sterile glass vials for eluate collection and column drying are provided with the Generator, as well as a vial for protection of the eluate needle.
7 disinfection swabs.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

This medicinal product is for diagnostic use only.
The eluate from the generator (Sodium Pertechnetate (^{99m} Tc) Injection Ph. Eur.) may be used as a reagent for labelling of various carrier compounds supplied as kits or administered directly in-vivo. When administered intravenously, the sterile sodium pertechnetate (^{99m} Tc) solution is used as a diagnostic aid in the following:

- Thyroid scintigraphy: direct imaging and measurement of thyroid uptake to give information on the size, position, nodularity and function of the gland in thyroid disease.
- Salivary gland scintigraphy: to assess salivary gland function and duct patency.
- Location of ectopic gastric mucosa: Meckel's diverticulum.
- Cerebral scintigraphy: to identify breaches in the blood-brain barrier caused by tumour, infarction, haemorrhage and oedema, when no other methods are available. When used in conjunction with pre-treatment with a reducing agent to affect technetium-99m-labelling of red blood cells.

When used in conjunction with pre-treatment with a reducing agent to
effect technetium (^{99m}Tc)- labelling of red blood cells:

- Cardiac and vascular scintigraphy

- angiocardioscintigraphy for:
*Evaluation of ventricular ejection fraction.
*Evaluation of global and regional cardiac wall motion.
*Myocardial phase imaging.

- organ perfusion or vascular abnormalities imaging.

- Diagnosis and localisation of occult gastrointestinal bleeding.

Following instillation of sterile sodium pertechnetate (^{99m}Tc) solution into the eye:

- Lacrimal duct scintigraphy: to assess patency of tear ducts.

4.2 Posology and method of administration

Sodium pertechnetate (^{99m}Tc) is normally administered intravenously at activities which vary widely to the clinical information required and the equipment employed. Pre-treatment of patients with thyroid blocking agents or reducing agents may be necessary for certain indications.

Recommended activities are as follows:

Adults and the Elderly
- Thyroid scintigraphy: 18.5-80 MBq. Scintigraphy performed 20 minutes after intravenous injection.
- Salivary gland scintigraphy: 40 MBq. Scintigraphy performed immediately after intravenous injection and at regular intervals up to 15 minutes.
- Meckel's divertivulum scintigraphy: 400 MBq. Scintigraphy performed immediately after intravenous injection and at regular intervals up to 30 minutes.
- Brain scintigraphy: 370-800 MBq. Rapid sequential images are taken immediately within the first minute after intravenous administration; static images 1 to 4 hours later. Thyroid and choroid plexus should be blocked to avoid non-specific ^{99m}Tc uptake.
- Cardiac and vascular scintigraphy: 740-925 MBq. Red cells are labelled *in-vivo* or *in-vitro* by pre-treating with a reducing agent. Dynamic images are taken in the first minute after intravenous administration, followed by regular images over 30 minutes.
- Gastrointestinal bleeding: 740-925 MBq. Red cells are labelled *in-vivo* or *in-vitro* by pre-treating with a reducing agent. Dynamic images are taken in the first minute after intravenous administration, followed by regular images at appropriate intervals for up to 24 hours.
- Lacrimal dust scintigraphy: 2-4 MBq each eye. Drops are instilled into the eye and dynamic images are taken over 2 minutes, followed by static images at appropriate intervals over 20 minutes.

Children
The activity for administration to children may be calculated from the recommended range of adult activity and adjusted according to body weight or surface area. However, the Paediatric Task Group of EANM recommends that the activity to be administered to a child should be calculated from the body weight according to the following table:

Fraction of adult dose:

3 kg = 0.1	32 kg = 0.65
4 kg = 0.14	34 kg = 0.68
6 kg = 0.19	36 kg = 0.71
8 kg = 0.23	38 kg = 0.73
10 kg = 0.27	40 kg = 0.76
12 kg = 0.32	42 kg = 0.78

14 kg = 0.36	44 kg = 0.80
16 kg = 0.40	46 kg = 0.82
18 kg = 0.44	48 kg = 0.85
20 kg = 0.46	50 kg = 0.88
22 kg = 0.50	52-54 kg = 0.90
24 kg = 0.53	56-58 kg = 0.92
26 kg = 0.56	60-62 kg = 0.96
28 kg = 0.58	64-66 kg = 0.98
30 kg = 0.62	68 kg = 0.99

In the very young (up to 1 year) a minimum dose of 20 MBq (10MBq in thyroid scintigraphy) for direct administration or 80 MBq for red blood cell labelling is necessary in order to obtain images of sufficient quality.

4.3 Contraindications

None known.

4.4 Special warnings and precautions for use

Radiopharmaceutical agents should be used only by qualified personnel with the appropriate government authorisations for the use and manipulations of radionuclides. This radiopharmaceutical may be received, used and administered only by authorised personnel in designated clinical settings. Its receipt, storage, use, transfer and disposal are subject to the regulations and/or appropriate licences of local competent official organisations. Radiopharmaceuticals should be prepared by the user in a manner which satisfies both radiation safety and pharmaceutical quality requirements. Appropriate aseptic precautions should be taken complying with the requirements of Good Pharmaceutical Manufacturing Practice for radiopharmaceuticals.

4.5 Interaction with other medicinal products and other forms of interaction

Drug interactions have been reported in brain scintigraphy where there can be increased uptake of (^{99m}Tc) pertechnetate in the walls of cerebral ventricles as a result of methotrexate-induced ventriculitis. In abdominal images drugs, such as atropine, isoprenaline and analgesics, can result in a delay in gastric emptying and redistribution of pertechnetate.

4.6 Fertility, pregnancy and lactation

^{99m} Tc (as free pertechnetate) has been shown to cross the placental barrier. When it is necessary to administer radioactive medicinal products to a woman of childbearing potential, information should always be sought about pregnancy. Any woman who has missed a period should be assumed to be pregnant until proven otherwise.

Where uncertainty exists, it is particularly important that the radiation exposure should be the minimum consistent with achieving the desired clinical information. Alternative techniques which do not involve ionising radiation should be considered. Radionuclide procedures carried out on pregnant women also involve radiation doses to the foetus.

Only imperative investigations should be carried out during pregnancy, when the likely benefit exceeds the risk incurred by the mother and the foetus. Direct administration of 800 MBq sodium pertechnetate (^{99m}Tc) to a patient results in an absorbed dose to the uterus of 6.5 mGy.

Following pre-treatment of patients with a blocking agent, administration of 800 MBq sodium pertechnetate (^{99m}Tc) results in an absorbed dose to the uterus of 5.3 mGy. Administration of 925 MBq ^{99m}Tc labelled red blood cells results in an absorbed dose to the uterus of 4.3 mGy. Doses above 0.5 mGy should be regarded as a potential risk to the foetus.

Before administering the radioactive medicinal product to a woman who is breast-feeding, consideration should be given as to whether the investigation could be reasonably delayed until the mother has ceased breast-feeding and as to whether the most appropriate choice of radiopharmaceutical has been made. If the administration is considered necessary, breast-feeding should be interrupted and the expressed feeds discarded. Breast-feeding can be restarted when the activity level in the milk will not result in a radiation dose to the child greater than 1 mSv.

4.7 Effects on ability to drive and use machines

Effects on ability to drive and use machines have not been described.

4.8 Undesirable effects

Allergic reactions have been reported following intravenous injection of sodium pertechnetate (^{99m}Tc) and include urticaria, facial oedema, vasodilation, pruritus, cardiac arrythmias and coma. For each patient, exposure to ionising radiation must be justifiable on the basis of likely clinical benefit. The activity administered must be such that the resulting radiation is as low as reasonably achievable bearing in mind the need to obtain the intended diagnostic or therapeutic result. Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects.

For diagnostic nuclear medicine investigations, the current evidence suggests that that these adverse effects will occur with low frequency because of the low radiation doses incurred. For most diagnostic investigations using a nuclear medicine procedure, the radiation dose delivered is less than 20 mSv EDE. Higher doses may be justified in some clinical circumstances.

This product contains no ingredients that have a recognized action or effect, or knowledge of which is important for safe and effective use of the product.

4.9 Overdose

In the event of the administration of a radiation overdose with sodium pertechnetate (^{99m}Tc), the absorbed dose should be reduced where possible by increasing the elimination of the radionuclide from the body. Measures to reduce possible harmful effects include frequent voiding of urine and promotion of diuresis and faecal excretion. Very little supportive treatment can be undertaken in the event of an overdose of ^{99m}Tc-labelled red blood cell since elimination is dependent on the normal haemolytic process.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Various Thyroid diagnostic Radiopharmaceuticals.
ATC code: V09F X01.
No pharmacological activity has been observed in the range of doses administered for diagnostic purposes.

5.2 Pharmacokinetic properties

The pertechnetate ion has similar biological distribution to iodide and perchlorate ions, concentrating temporarily in salivary glands, choroid plexus, stomach (gastric mucosa) and in the thyroid gland, from which it is released, unchanged. The pertechnetate ion also tends to concentrate in areas with increased vascularisation or with abnormal vascular permeability, particularly when pre-treatment with blocking agents inhibits uptake in glandular structures. ^{99m}Tc is selectively excluded from the cerebrospinal fluid. Following intravenous administration, pertechnetate (^{99m}Tc) is distributed throughout the vascular system from which it is cleared by three main mechanisms:

- Rapid removal, depending on the diffusion equilibrium with interstitial fluid.

- Intermediate rate of removal, depending on the concentration of the pertechnetate in glandular tissues, mainly thyroid, salivary and gastric fundus glands which have an ionic mechanism.
- Slow removal, by glomerular filtration by the kidneys, dependent on rate of urinary excretion.

Plasma clearance has a half-life of approximately 3 hours. Excretion during the first 24 hours following administration is mainly urinary (approximately 25%) with faecal excretion occurring over the next 48 hours. Approximately 50% of the administered activity is excreted within the first 50 hours.

When selective uptake of pertechnetate (^{99m}Tc) in glandular structures is inhibited by the pre-administration of blocking agents, excretion follows the same pathways but there is a higher rate of renal clearance. When pertechnetate (^{99m}Tc) is administered in association with pre-treatment with reducing agents such as stannous / medronate which cause a “stannous loading” of red blood cells, up to approximately 95% of the administered activity is taken up by the red blood cells where it becomes bound within the cells. Any unbound pertechnetate (^{99m}Tc) is cleared by the kidneys; radioactivity in the plasma normally constitutes less than 5% of the intravascular activity. The fate of the technetium-99m follows that of the labelled erythrocytes themselves and the activity is cleared very slowly. A small level of elution of activity from the circulating red cells is thought to occur.

5.3 Preclinical safety data

1) There is no information on acute, sub-acute and chronic toxicity from single or repeated dose administration. The quantity of Sodium pertechnetate (^{99m}Tc) administered during clinical diagnostic procedures is very small and apart from allergic reactions, no other adverse reactions have been reported.

2) Reproductive Toxicity: Placental transfer of (^{99m}Tc) from intravenously administered sodium pertechnetate (^{99m}Tc) has been studied in mice. The pregnant uterus was found to contain as much as 60% of the injected ^{99m}Tc when administered without perchlorate pre-administration. Studies performed on pregnant mice during gestation, gestation and lactation, and lactation alone showed changes in progeny which included weight reduction, hairlessness and sterility.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Chloride
Water for Injections

6.2 Incompatibilities

In the absence of compatibility studies this medicinal product must not be mixed with other medicinal products except those mentioned in section 12.

6.3 Shelf life

The expiry date for this product is 9 days after activity reference time. The eluate can be used for 8 hours. Expiry date for the eluent is 3 years after manufacture; expiry date for both TechneVials and sterile vial is 1 year after manufacture.

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate. Generators must be kept in an Ultra TechneKow safe (with at least 57 mm of lead protection) or behind an adequate laboratory shield. The eluate must be stored at 2-8°C. Eluent vial, TechneVials and sterile vial must be stored below 25°C. Storage should be in accordance with national regulations for radioactive materials.

6.5 Nature and contents of container

6.5.1 Generator

The generator consists of a cartridge containing an aluminium oxide column charged with ^{99}Mo and locked between two filters. One side of the cartridge is connected to the shielded, sterile supply needle in the eluent holder. The other side is connected to the similarly shielded, sterile outlet needle in the elution station. A second sterile needle in the eluent holder serves to eliminate the under pressure in the eluent vial under sterile conditions. The generator column is shielded by 28 to 56 mm of lead, depending on the ^{99}Mo activity. The shielded generator with the built-in station and the eluent holder are packed in a hermetically sealed tin, which is also the package. Elution occurs by placing the eluent vial on the needles in the eluent holder, followed by complete or partial filling of evacuated vials.

Elution yield	≥80% (vials of 11 and 25 ml) ≥75% (vial of 5 ml)

6.5.2. Accessories

The first time an Ultra-TechneKow FM is supplied, it comes with:

- 1 TechneVial shield or UltraVial Shield
- 1 Sterile Vial shielding, unless supplied with the Ultra-TechneKow safe.

Each Ultra-TechneKow FM is supplied with:

- 7 TechneVials, sterile, evacuated vials of 5, 11 or 25 ml.
- 1 Sterile Vial is provided with the elution set.
- 1 Eluent vial, 100 ml of sterile, physiological salt solution.
- 7 Disinfection swabs.
- 7 Labels with the radioactivity symbol.

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Mallinckrodt Medical B.V
Westerduinweg 3
1755 LE Petten
The Netherlands

8 MARKETING AUTHORISATION NUMBER

PA 690/17/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28 April 2000

Date of last renewal: 28 April 2010

10 DATE OF REVISION OF THE TEXT

September 2011

11 DOSIMETRY

According to ICRP 53, the radiation doses absorbed by a patient following direct administration of sodium pertechnetate (^{99m}Tc) are as follows:

1) Without pre-treatment with blocking agent**:**

Absorbed dose per unit activity administered (mGy/MBq)

Organ	**Adult**	**15 Year**	**10 Year**	**5 Year**	**1 Year**
Adrenals	3.6E-03	4.7E-03	7.1E-03	1.1E-02	1.9E-02
Bladder wall	1.9E-02	2.3E-02	3.4E-02	5.1E-02	9.1E-02
Bone surfaces	3.9E-03	4.7E-03	6.9E-03	1.0E-02	1.9E-02
Breast	2.3E-03	2.3E-03	3.5E-03	5.7E-03	1.1E-02
GI tract					
Stomach wall	2.9E-02	3.6E-02	5.0E-02	8.1E-02	1.5E-01
Small intestine	1.8E-02	2.2E-02	3.4E-02	5.2E-02	9.0E-02
ULI wall	6.2E-02	7.7E-02	1.3E-01	2.1E-01	3.9E-01
LLI wall	2.2E-02	2.8E-02	4.6E-02	7.4E-02	1.4E-01
Kidneys	5.0E-03	6.0E-03	8.7E-03	1.3E-02	2.1E-02
Liver	3.9E-03	4.8E-03	8.0E-03	1.3E-02	2.2E-02
Lungs	2.7E-03	3.4E-03	5.1E-03	7.9E-03	1.4E-02
Ovaries	1.0E-02	1.3E-02	1.9E-02	2.7E-02	4.5E-02
Pancreas	5.9E-03	7.2E-03	1.1E-02	1.6E-02	2.7E-02
Salivary glands	9.3E-03	1.2E-02	1.7E-02	2.4E-02	3.9E-02
Red marrow	6.1E-03	7.1E-03	9.8E-03	1.3E-02	2.0E-02
Spleen	4.4E-03	5.3E-03	7.9E-03	1.2E-02	2.1E-02
Testes	2.7E-03	3.7E-03	5.9E-03	9.3E-03	1.7E-02
Thyroid	2.3E-02	3.7E-02	5.6E-02	1.2E-01	2.3E-01
Uterus	8.1E-03	1.0E-02	1.6E-02	2.4E-02	4.0E-02
Other tissue	3.4E-03	4.0E-03	6.0E-03	9.3E-03	1.7E-02
Effective Dose Equivalent (mSv/MBq)					
1	**1.3E-02**	**1.6E-02**	**2.5E-02**	**4.0E-02**	**7.3E-02**

2) With pre-treatment with blocking agent:

Absorbed dose per unit activity (mGy/MBq) when blocking agents are given.

Organ	**Adult**	**15 Year**	**10 Year**	**5 Year**	**1 Year**
Adrenals	3.3E-03	4.1E-03	6.3E-03	9.5E-03	1.7E-02
Bladder wall	3.2E-02	3.9E-02	5.7E-02	8.4E-02	1.5E-01
Bone surfaces	3.8E-03	4.5E-03	6.7E-03	1.0E-02	1.8E-02
Breast	2.5E-03	2.5E-03	3.6E-03	5.7E-03	1.1E-02
GI tract					
Stomach wall	3.2E-03	4.1E-03	6.6E-03	9.3E-03	1.7E-02
Small intestine	4.1E-03	4.9E-03	7.6E-03	1.1E-02	2.0E-02
ULI wall	3.8E-03	4.9E-03	7.1E-03	1.1E-02	1.9E-02
LLI wall	4.5E-03	5.9E-03	9.2E-03	1.3E-02	2.3E-02
Kidneys	4.7E-03	5.7E-03	8.2E-03	1.2E-02	2.1E-02

Liver	3.1E-03	3.8E-03	5.9E-03	9.0E-03	1.6E-02
Lungs	2.8E-03	3.5E-03	5.2E-03	7.9E-03	1.4E-02
Ovaries	4.7E-03	6.0E-03	8.9E-03	1.3E-02	2.3E-02
Pancreas	3.5E-03	4.4E-03	6.7E-03	1.0E-02	1.8E-02
Red marrow	4.5E-03	5.4E-03	7.8E-03	1.1E-02	1.8E-02
Spleen	3.2E-03	3.9E-03	5.9E-03	9.0E-03	1.6E-02
Testes	3.2E-03	4.4E-03	6.8E-03	1.1E-02	1.9E-02
Thyroid	2.1E-03	3.5E-02	5.7E-03	9.0E-03	1.6E-02
Uterus	6.6E-03	7.9E-03	1.2E-02	1.8E-02	3.0E-02
Other tissue	2.9E-03	3.5E-03	5.3E-03	8.2E-03	1.5E-02
Effective dose equivalent (mSv/MBq)	**5.3E-03**	**6.6E-03**	**9.8E-02**	**1.5E-02**	**2.6E-02**

The effective dose equivalent resulting from an administered activity of 800 MBq sodium pertechnetate (^{99m}Tc) is 10.4 mSv. Following pre-treatment of patients with a blocking agent, administration of 800 MBq sodium pertechnetate (^{99m}Tc) results in an effective dose equivalent of 4.24 mSv.

3) The radiation doses absorbed by a patient following intravenous injection of ^{99m} Tc labelled red blood cells are as follows:

Absorbed dose per unit activity administered (mGy/MBq)

Organ	**Adult**	**15 Year**	**10 Year**	**5 Year**	**1 Year**
Adrenals	8.7E-03	1.1E-02	1.7E-02	2.7E-02	4.9E-02
Bladder wall	9.2E-03	1.2E-02	1.7E-02	2.5E-02	4.6E-02
Bone surfaces	9.2E-03	1.3E-02	2.3E-02	3.9E-02	7.8E-02
Breast	4.3E-03	4.5E-03	7.2E-03	1.1E-02	1.9E-02
GI tract					
Stomach wall	4.8E-03	6.1E-03	9.5E-03	1.4E-02	2.4E-02
Small intestine	4.4E-03	5.3E-03	8.1E-03	1.2E-02	2.2E-02
ULI wall	4.3E-03	5.5E-03	7.9E-03	1.3E-02	2.1E-02
LLI wall	3.9E-03	5.3E-03	8.0E-03	1.1E-02	2.1E-02
Heart	2.3E-02	2.8E-02	4.1E-02	6.2E-02	1.1E-01
Kidneys	1.0E-02	1.2E-02	1.9E-02	3.0E-02	5.5E-02
Liver	7.5E-03	8.8E-03	1.4E-02	2.1E-02	3.8E-02
Lungs	1.4E-02	1.8E-02	2.9E-02	4.5E-02	8.5E-02
Ovaries	4.2E-03	5.4E-03	7.9E-03	1.2E-02	2.1E-02
Pancreas	6.2E-03	7.5E-03	1.1E-02	1.7E-02	2.9E-02
Red marrow	7.3E-03	8.8E-03	1.3E-02	2.0E-02	3.5E-02
Spleen	1.5E-02	1.8E-02	2.8E-02	4.4E-02	8.4E-02
Testes	2.7E-03	3.7E-03	5.4E-03	8.3E-03	1.5E-02
Thyroid	4.9E-03	7.1E-03	1.2E-02	1.9E-02	3.5E-02
Uterus	4.7E-03	5.7E-03	8.5E-03	1.3E-02	2.2E-02
Other tissue	3.7E-03	4.4E-03	6.4E-03	9.8E-03	1.8E-02
Effective dose equivalent (mSv/MBq)	8.5E-03	1.1E-02	1.6E-02	2.5E-02	4.6E-02

The effective dose equivalent resulting from an administration of 925 MBq ^{99m}Tc-labelled red blood cells is 7.86 mSv.

(IV) The radiation dose absorbed by the lens of the eye following administration of sodium pertechnetate (^{99m}Tc) for lacrimal duct scintigraphy is estimated to be 0.038 mGy/MBq. This results in an effective dose equivalent of less than 0.01 mSv for an administered activity of 4 MBq.

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

12.1 ***Instructions for use*****.**
The elution must be carried out in an area capable of maintaining the sterility of the generator.

Preparation
1. Remove the seal, open the lever closing ring and store it together with the top cover.
2. Put the Ultra-TechneKow FM in the Ultra-TechneKow SAFE or behind any other suitable laboratory shielding with the elution station facing forward.
3. NB. The needles are sterile beneath their covers and the generator underneath the top is clean, therefore disinfection with liberal amounts of disinfectants containing alcohol is undesirable and moreover may influence the pertechnetate (^{99m}Tc) yield unfavourably.
4. Remove the flip-off cover from the capsule of the eluent vial, disinfect the stopper, remove (and store) the plastic cover of the inlet needle and lower the eluent vial into its holder.
5. Remove the flip-off cover from the capsule of the sterile vial and put it into the sterile vial shielding.
6. Remove (and store) the rubber needle protection from the outlet needle and lower the shielded sterile vial into the elution station.

Elution
1. Remove the flip-off cover from the capsule of the required TechneVial, disinfect the stopper, let the disinfectant evaporate completely and put the vial into the Ultra Vial Shielding. (The TechneVial contains some residual water as a result of the sterilization process).
2. Replace the shielded sterile vial by the UltraVial shield, ensure the lead glass window faces front.
3. Wait until the TechneVial is filled with at least 3½ millilitres.
4. From this point, the process can be interrupted depending on the required elution volume (Pertechnetate (^{99m}Tc) concentration/ml) Elution is **always** ended by giving the UltraVial Shield a quarter turn, pushing it down and waiting for a few seconds (this causes the TechneVial to be filled with sterile air).
5. Replace the TechneVial Shielding by a shielded unused sterile vial.

NEVER INTERRUPT ELUTION BY LIFTING THE TECHNE VIAL SHIELD WITHOUT THE QUARTER TURN!

ELUATES THAT ARE NOT CLEAR OR COLOURLESS MUST BE REJECTED.

Dispose of and return of the generator
1. Remove and dispose of the used sterile vial and the eluent vial.
2. Replace the original needle cover back on the inlet needles.
3. Elute the remaining millilitres of fluid from the generator (see under elution). The generator is now dry.
4. Replace the original outlet needle cover on the outlet needle.
5. Close the generator system with its top cover and lever closing ring.
6. Store the generator in a suitable place for decay to a level acceptable for disposal.

NB In some countries the possibility exists to return expired generators. Consult the local representative for such a possibility or for details of dismantling.

12.2. The administration of radiopharmaceuticals creates risks for other persons from external radiation or contamination from spills of urine, vomiting etc. Radiation protection precautions in accordance with national regulations must therefore be taken.

12.3. Waste must be disposed of in accordance with National Regulations for radioactive material.