OncoSil™ Calibration System
Instructions for Use

Product Name: OncoSil™ Calibration System

Product Number: OS01-99

Calibration Sample. Not for human use. Do not implant

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⚠ Please read these Instructions for Use in their entirety prior to using OncoSil™.

1. DEVICE DESCRIPTION

OncoSil™, is comprised of **OncoSil Phosphorous-32 Microparticles** (hereafter **Microparticles**) and **OncoSil Diluent** (hereafter **Diluent**).

The **Microparticles** contain Phosphorous-32, a pure beta-emitter radioisotope with a physical half-life of 14.27 days. The maximum energy of the emitted beta particles is 1.711 MeV. The average energy of the emitted beta particles is 0.6950 MeV.

The **Microparticles** are provided in individually crimp-sealed vials, containing 250 ±10% MBq (6.76 mCi) at 12:00 CET (CEST) on the reference date. Each vial is moist heat (autoclave) sterilised. Each individual vial of Microparticles is placed inside a Perspex lined lead pot to shield personnel from radiation during shipping and handling.

The **Diluent** comprises of inactive pharmacopeia grade excipients and performs as a carrier to facilitate implantation of the Microparticles into target treatment tumour.

The **Diluent** is moist heat (autoclave) sterilised and provided in individually crimp-sealed vials each containing approximately 9 mL of Diluent.

Note: OncoSil™ does not incorporate any material or ingredient derived from medicinal, human, animal or recombinant origin.

2. INTENDED USE

OncoSil™ Calibration System is intended for dose activity measurement calibration.

3. CERTIFICATION OF TREATMENT FACILITIES AND PERSONNEL

The OncoSil™ Calibration System is to be used in a licensed treatment facility. These facilities must hold an appropriate license for the isotope Phosphorous-32 (^{32}P), which mandates that these institutions will have an appointed Radiation Safety Officer (RSO) / Radiation Protection Officer (RPO) who will be the primary contact for all matters related to radiation safety.

The OncoSil™ suspension should be prepared within the Nuclear Medicine Department or within a licensed Radiopharmacy. Only appropriately licensed personnel, who have been trained in the preparation of the OncoSil™ suspension may prepare the product for calibration.

OncoSil Medical can only authorise a shipment of the OncoSil™ Calibration System after:

1. The license for the treatment facility to receive and hold ^{32}P has been verified by OncoSil Medical.
2. A training visit has been conducted in which relevant individuals permitted to work as an Authorised Dispenser (AD), have completed the training and experience requirement set out by OncoSil Medical. Please see below:

3.1 Authorised Dispenser

Authorised Dispenser (AD)

- **Definition of Authorised Dispenser (AD)** as defined by OncoSil Medical, is the person preparing the OncoSil™ suspension (i.e. Radiopharmacist, Nuclear Medicine Personnel) and must successfully complete additional training on the OncoSil™ device as described below;

  AD Training: The AD attends the OncoSil Medical Training Programme and performs at least one cold dose (i.e. Microparticles are not radioactive) dilution which is supervised in the physical presence of an OncoSil Medical representative (Authorised Trainer).

  Completion of this training allows the Authorised Dispenser (AD) to:
  a. Order the initial OncoSil™ Calibration System to perform the calibration procedure.
  b. Once the OncoSil™ calibration suspension has been successfully completed, the site will be able to order the OncoSil™ System, to be used during the Authorised Users (AUs) supervised endoscopic ultrasound (EUS) implantation procedure of the first patient at the respective treatment facility.

4. STORAGE AND TRANSPORTATION CONDITIONS

Upon receipt of the OncoSil™ Calibration System and once incoming inspection requirements are fulfilled, the device should be stored inside the Type A packaging and moved to Nuclear Medicine Department/ Radiopharmacy, or other approved location that is able to handle radioactive materials until the OncoSil™ suspension is to be prepared.

The Microparticles and Diluent should be stored at room temperature. **Do not freeze the Diluent.**

5. CALIBRATION SYSTEM PRESENTATION

Each OncoSil™ Calibration System will be labelled with the product code **OS01-99** and will contain the following components:

- 1 sealed can encasing 1 x vial of the Microparticles containing 250 ±10% MBq (6.76 mCi) at 12:00 CET (CEST) on the reference date. The vial is supplied inside a Perspex lined lead pot.
- 2 vials of approximately 9 mL of OncoSil Diluent.
- 1 empty sterilised P6 vial for dilution of suspension of OncoSil™ (identified with a green stripe on the top of the label).
- 1 empty lead pot for dilution of suspension of OncoSil™ (identified with a green stripe on the top of the label).

Shipment documents provided will include a Calibration Certificate, which will be included in the Type A package.

The Calibration Certificate will have the activity, expressed as four significant figures (XXX.X MBq) as measured by the ion chamber at the manufacturing site. This measured activity is quoted on the Calibration Certificate included in the Type A package. Once prepared the activity of the calibration suspension is the activity that the ionisation chamber is to be calibrated / adjusted to, allowing for any decay time from the quoted date and time or reference.

6. ACCESSORIES

A number of accessories routinely available in Nuclear Medicine/Radiopharmacy Departments are used to prepare the OncoSil™ calibration suspension. These accessories are not supplied with the OncoSil™ Calibration System. Examples include:

- Long forceps/tweezers with rubber tips (preferably 20-25 cm (7.87 inches), to minimise radiation finger doses)
- Plastic backed absorbent surface covers
- Sterile Luer lock syringes (3 mL or 5 mL and 10 mL)
- Sterile 16-21 gauge needles, 5-7 cm (2- 2.7 inches) in length
- Sterile aeration / filtered venting needles
- Sterile Isopropyl Alcohol (IPA) Wipes
- Beta radiation syringe shields (3 mL or 5 mL and 10 mL)
- Protective clothing (gloves, coats, goggles etc.)

7. CALIBRATION PROCEDURE

7.1 Background

In order to prepare and verify OncoSil™, it is necessary to be able to measure the activity of the suspension. OncoSil™ contains Phosphorous-32 Microparticles suspended in the OncoSil Diluent. This isotope (^{32}P), is a pure beta emitter and the measurement of such isotopes is highly dependent on the geometry of the source emitting the radiation. This calibration procedure, therefore, is required to ensure that the later patient doses of OncoSil™ suspension are prepared and accurately measured. As ^{32}P standards for finely divided sources, such as the OncoSil Microparticles are not available, it is necessary to assess the performance of the ionisation chamber in facilities using an accurately prepared suspension of the Microparticles.

The hazard of an inaccurate measurement of an OncoSil™ suspension is the possibility of over or under dosing. If an ionisation chamber at a particular facility under reads (underestimates) the activity from the true value, there is a possibility that overdosing of the patient could occur. The effects of this could range from discomfort to serious injury. Alternatively, if the ionisation chamber over reads (over estimates) the activity from the true value, there is a possibility that under dosing of the patient could occur. The effect of this could be administering a sub therapeutic dose to a particular tumour.

7.2 Principle

To perform the calibration, the OncoSil Microparticles are manufactured according to the standard procedure and the activity is determined using an ionisation chamber. The measurements performed are traceable to the USA National Institute of Standards and Technology (NIST) ^{32}P measurement exercise. This NIST traceable ionisation chamber at the OncoSil Microparticles manufacturing site is used to measure the activity of every vial produced and dispatched.

The OncoSil™ Calibration System for the calibration exercise is prepared and shipped with the same components that will accompany OncoSil™ System for patient implantation.

The Authorised Dispenser prepares the first dilution as per the calibration suspension preparation procedure. This suspension / dilution is then measured in the ionisation chamber to be calibrated by taking three separate measurements, calculating and recording the arithmetic mean of the results.

The four significant figure activity on the Calibration Certificate is referenced to 12:00 CET (or CEST) on the date of reference. If the local times zone is not CET (or CEST) then the local time equivalent of the reference date and time needs to be calculated and recorded. Often the equivalent local time for reference will not be a time during normal working hours, and the calibration exercise will not, therefore, be being done at (or very near to) the reference time. The time difference between the local equivalent of reference and the time of measurement has to be calculated, recorded and then factored into the activity on the certificate as a correction higher, if the measurement is being done locally before the reference time, or lower if the measurement is being done locally after reference. The corrected activity on the certificate is then recorded on the calibration form. The corrected activity is then compared to the average measured activity from the local ionisation chamber, and any discrepancy between the two activity values is corrected for by adjusting the ionisation chamber ^{32}P calibration factor (refer to manufacturer's operating manual to perform this procedure).

By performing the procedure in this way the measurement of the OncoSil Microparticles locally is traceable to the calibrated activity in the manufacturing ion chamber, and finally back to the NIST ^{32}P measurement exercise.

The ionisation chamber ^{32}P calibration value is set using the initial dilution of the calibration suspension to avoid any errors that could be introduced by inaccurate dilution, which could result if the second dilution vial was used. If the second aliquot is not exactly 1.7 mL it could result in an error that means the final dilution is not a reliable source for calibration.

For this reason the second dilution of the calibration suspension preparation is only measured to provide an assessment of the linearity of the response.

Note:

- Slight inaccuracies in the volume of the first Diluent aliquot (7.0 mL) are not expected to have any effect on the ionisation chamber ^{32}P calibration value.
- When preparing patient doses a different aliquot of Diluent is added to the first vial depending on which day with respect to the reference day that the implantation is being done. With the calibration suspension this is not the case. To keep the geometry of the calibration suspension constant the procedure is to always add 7.0 mL of Diluent and compensate for any discrepancy from reference in the activity calculations.
- It is important that the calibration suspension is homogenous and is not allowed to settle for more than 5 minutes.
- It is recommended that all measurements must be completed within 5 minutes of mixing.

7.3 Acceptance Criteria

The activity of the OncoSil™ calibration suspension is referenced to 12:00 hours Central European Time - CET (or Central European Summer Time - CEST) on the date of reference.

In the procedure, a minimum of three measurements of the prepared calibration suspension are recorded on the OncoSil™ Calibration Form, and the arithmetic mean (average) value calculated and recorded on the form.

Placing the calibration suspension in the ionisation chamber and using the ionisation chamber ^{32}P calibration factor (refer to manufacturer's operating manual to perform this procedure) the ionisation chamber is then adjusted, to read the value on the Calibration Certificate (this is the value that has

been corrected for time zone differences and decay). This process will provide an ionisation chamber ^{32}P calibration value enabling measurements to be within ±10% of the manufacturer's ionisation chamber.

A second group of measurements, performed during the second stage of the calibration suspension dilution is to provide an assessment of the linearity of the ionisation chamber, and this measurement should ideally be within ±10% of the expected value.

7.4 Procedure Planning

1. Record all the general information (Device model, serial number) for the calibration suspension on OncoSil™ Calibration Form.
2. Determine the difference between the **Local Date and Time** and the OncoSil™ Calibration **System Reference Date and Time (12:00 CET/CEST).**
3. Record on the OncoSil™ Calibration Form**. - Time Zone for Measurement Location**

   Note: The time difference between CET/CEST and the Local Time can be determined by accessing a suitable Time Zone website, such as: http://www.timezoneconverter.com/cgi-bin/tzc.tzc or http://www.worldtimeserver.com/ (note that if CET or CEST is not listed in the time zones then selecting Frankfurt, Germany, will provide the same time zone).

   For example; if the treatment facility where the ionisation chamber to be calibrated is located in New York, USA, then the treatment facility is on **Eastern Standard Time EST (or EDT – Eastern Daylight Time / Eastern Daylight Savings Time)**, which depending on when each location switches to or from summer time is normally -6 hours from CET/CEST.
4. Determine **Local Time Equivalent of Reference Time (CET/CEST + Relative Time Difference)** and record on the OncoSil™ Calibration Form.

   For example; using the time converter and a 24hr clock (08/08/2018 12.00hrs CET = 08/08/2018 06.00hrs; New York EST).
5. Next determine **knowing the local time equivalent of reference, 08/08/18 at 06:00 in our current example, determine the time difference from this time to the time of actual measurement.**

   For example; if the calibration measurement was occurring 11:00 on the 08/08/18 then it would be 5 hours after reference – local time.
6. Select the appropriate decay factor from **Correction Factor Tables** to be applied to the measured initial calibration suspension results.

   For example; the local time of measurement is 5 hours after the local equivalent of the reference time, which results in a decay factor of 0.99 from the tables. An example of the decay factor table is shown below:

HOURS	1	2	3	4	5
0 plus	0.998	0.996	0.994	0.992	0.990

Table 1. Example selected portion of ^{32}P decay table provided.

7. Record the correction factor to be used on the OncoSil™ Calibration Form. The activity to be corrected will be provided on a Calibration Certificate located in the Type-A package.
8. Before commencing the procedure ensure a background activity measurement has been made, and that it will be subtracted – either manually or automatically – from the measurements made. Record the background, if the compensation is done manually, on the OncoSil™ Calibration Form.

8. DETAILED CALIBRATION SUSPENSION PREPARATION PROTOCOL

This section provides a detailed instruction for the preparation of OncoSil™ calibration suspension.

Note:

- The calibration suspension preparation must be performed by the Authorised Dispenser trained by an OncoSil Medical representative.
- Calibration suspension preparation is outside of OncoSil Medical's control and is the responsibility of the treatment facility.
- Before beginning the procedure, the labelling of all components of the OncoSil™ System should be checked to ensure that the correct materials are available for use. Visually inspect the vials for cracks, breakages, and incomplete seal **prior** to use. If there is sign of damage, return the damaged component(s) to the radiation shields and contact OncoSil Medical.
- The calibration suspension procedure is to be performed behind Perspex or Lucite, suitable for shielding from beta particles.
- This calibration suspension procedure should **not** be performed under a laminar flow hood, which directs airflow towards the operator thereby risking exposure to radioactive material.
- All syringes must be used within an appropriate beta-radiation (Perspex/Lucite) syringe shield.
- All vials within the OncoSil™ Calibration System must only be used for a single preparation. All contaminated waste must be placed in a designated radioactive waste container.
- Upon withdrawing needles from vials, be aware of any drips of radioactive suspension from the needle tip that could drop onto the top of the vial or the bench.

Figure 2: The OncoSil™ Calibration System

Contents: 1 sealed can encasing 1 x vial of the Microparticles containing 250 ±10% MBq (6.76 mCi) at 12:00 CET (CEST) on the reference date. The vial is supplied inside a Perspex lined lead pot, 2 vials of approximately 9 mL of OncoSil Diluent, 1 empty sterilised P6 vial for dilution of suspension of OncoSil™ (identified with a green stripe on the top of the label), 1 empty lead pot for dilution of suspension of OncoSil™ (identified with a green stripe on the top of the label).

Step-by-step procedure:

1. Remove the components from the Styrofoam insert in the Type A package.
2. Locate the Calibration Certificate that states the activity at reference for the OncoSil™ Calibration System as 4 significant figures – XXX.X MBq
3. Record this activity on the OncoSil™ Calibration Form next to the decay factor to be applied to the figure to account for the time difference between the time of measurement and the local time of reference.
4. Correct the activity stated on the Calibration Certificate by multiplying by the decay factor selected and record the result on the OncoSil™ Calibration Form. This is the calibration activity figure that the local ion chamber should read once the dilution procedure below is completed.
5. Hold the sealed can securely.
6. Pull ring and remove lid from the can.
7. Remove the packing material and the Perspex lined lead pot containing the Microparticles vial from the tin.
8. Place the can, lid and packing material in appropriate waste after checking for radioactive contamination.

Note: The initial preparation and the dilution to the standardised concentration of 6.6MBq/mL for administration should be done consecutively.

Note: A filtered/aeration venting needle can be used to assist with all steps of the calibration suspension preparation procedure, however as it is not for human implant a filtered/aeration venting needle is not essential. This is only essential when sterility must be maintained for patient implants.

Step 1 – First Dilution

9. **Microparticles Vial:** Take the Perspex lined lead pot that encloses the vial of Microparticles.
10. Remove the tape securing the top and bottom segments of the lead lined pot and CAREFULLY AND SLOWLY remove ONLY the lead lid from the pot.
    Note: that the lid is the larger lead segment.
11. The vial containing the Microparticles is itself contained within a further Perspex shield.
12. Using long forceps/tweezers remove Perspex lid only.
13. If necessary (if not already removed), using long tweezers remove the centre of the Aluminium crimp so that the rubber stopper centre is exposed.
14. Wipe the rubber stopper of the Microparticles vial with a sterile IPA wipe.
15. Using long forceps/tweezers replace Perspex lid.
16. **Diluent Vial:** Invert Diluent vial until the suspension is homogeneous. Remove the plastic cap to expose the rubber stopper and wipe with a sterile IPA wipe.
17. Using a sterile 10 mL syringe with needle, draw up 7.0mL of Diluent and dispense through the small hole in the top of the Perspex lid into the Microparticles vial via the rubber stopper.
18. With the needle tip above the suspension, withdraw the air from the vial containing the calibration suspension, and expel any remaining Diluent remaining in the needle. This step can be repeated if not all the Diluent is cleared from the syringe and needle.
19. With the needle tip above the suspension, pull back the syringe plunger to minimise the risk of drips from the needle tip, before CAREFULLY removing the needle from the vial.
20. Dispose of syringes and needles in appropriate radioactive waste.
21. Replace the lead lid of the pot.
22. **To assist mixing:** Firmly hold the top and bottom segments of the Perspex lined lead pot in a closed position and invert the suspension to obtain a homogeneous mixture. Do this 20-30 times.
23. Remove the lead lid of the pot and using long forceps/tweezers remove the Perspex lid.

24. Using long forceps/tweezers remove the calibration suspension vial from the Perspex lined shield to check if suspension is homogeneous.
25. If the suspension is not homogeneous, replace calibration suspension vial into Perspex lined shield, replace both the Perspex lid and lead lid of pot and repeat the inversion step until the suspension is homogeneous.
26. Again, remove the lead lid from the pot and using long forceps/tweezers remove the Perspex lid and Microparticles vial to re-check if suspension is homogeneous.
27. Once homogeneous, using long forceps/tweezers, place the calibration suspension vial into an ion chamber to commence the measurement process.
28. Once a stable measurement value has been obtained, record the activity on the OncoSil™ Calibration Form after correcting the measurement for background (if required).
29. Repeat the calibration suspension activity measurements twice to record a total of three activity values on the OncoSil™ Calibration Form
    Note: It may be necessary to invert the vial a few times between measurements if there has been any interruptions between the measurements.
30. Return the calibration suspension vial back into the Perspex lined lead shield and replace the Perspex lid using long forceps/tweezers.
31. Replace the lead lid of the pot.
32. Calculate the Average Background Corrected Measurement and record the value of the OncoSil™ Calibration Form.
33. Calculate the Relative Difference (% Diff) between the Average Measured Value and the Decay Corrected Value on the Calibration Certificate and record the result on the OncoSil™ Calibration Form.
    Note: If the Relative Difference is less than 5% adjustment of the ^{32}P measurement factor in the ion chamber is not required, however, it can be performed if the site desires. If the relative difference is between 5% and 10% it is recommended that the response factor be adjusted to the Decay Adjusted Certificate Value. If the relative difference is greater than 10% the response factor must be adjusted to the Decay Adjusted Certificate Value.
34. If adjustment is to be performed set the ionisation chamber ^{32}P calibration value according to the manufacturer's recommendation until the measured value is within 5% of the decay adjusted Calibration Certificate value.
35. Record these values on the OncoSil™ Calibration Form - Ion Chamber Calibration Factor Record.
36. Confirm the calibration adjustment, if applicable, by removing the vial from the ion chamber and then replacing it and re-measuring it.
    Note: The value should be within ±5% of the expected value, which is the value the calibration factor was adjusted to read.
37. Immediately proceed the second stage of the dilution process (see below) for an assessment of the linearity of the response.

Step 2 – Second Dilution

38. Take the empty Perspex lined lead pot.
39. Remove the tape that's securing the top and bottom segments of the lead lined pot and CAREFULLY AND SLOWLY remove ONLY the lead lid from the pot.
    Note: that the lid is the larger lead segment.
40. Remove Perspex lid.
41. Take the empty P6 vial (identified with a green stripe on the top of the label) and place into the Perspex shield within the empty lead pot.

42. Remove the plastic cap of the empty P6 vial to expose the rubber stopper and wipe with a sterile IPA wipe.
43. Replace the Perspex lid.
44. **SECOND Diluent Vial:** Invert second Diluent vial until suspension is homogeneous.
45. Remove the plastic cap of the empty vial to expose the rubber stopper and wipe with a sterile IPA wipe.
46. Using a sterile 10 mL syringe with needle, draw up 7.5 mL of Diluent and dispense into the empty P6 vial (identified with a green stripe on the top of the label) via the Perspex lid and rubber stopper.
47. With the needle tip above the suspension, withdraw the air from the vial, and expel any Diluent remaining in the needle.
    Note: this step can be repeated if not all the Diluent is cleared from the syringe and needle.
48. With the needle tip above the suspension, pull back the syringe plunger to minimise the risk of drips from the needle tip, before CAREFULLY removing the needle from the vial.
49. Dispose the syringes and needles in appropriate waste.
50. **First Dilution:** Ensure suspension is homogeneous. If not, with both the Perspex lid and lead lid in place invert suspension 10-20 times or until homogeneous.
51. CAREFULLY and SLOWLY remove lead lid leaving the Perspex top in place.
52. Using a 3 or 5 mL beta syringe shield with the appropriate syringe, and a 5 cm long needle, remove 1.7 mL of the calibration suspension and transfer into the P6 vial which already contains 7.5 mL of Diluent, through the small hole in the top of the Perspex lid via the rubber stopper.
53. Do not remove the calibration suspension vial from the Perspex lined shield during this addition.
54. With the needle tip above the calibration suspension, withdraw the air from the vial, and expel any suspension remaining in the needle.
    Note: This step can be repeated if not all the calibration suspension is cleared from the syringe and needle.
55. With the needle tip above the suspension, pull back the syringe plunger to minimise the risk of drips from the needle tip, before CAREFULLY removing the needle from the vial.
56. Dispose the syringes and needles as radioactive waste.
57. Replace the lead lid of the pot.
58. **To assist mixing:** Firmly hold the top and bottom segments of the Perspex lined lead pot in a closed position and invert the suspension to obtain an homogeneous mixture. Do this 20-30 times.
59. Remove the lead lid of the pot and using long forceps/tweezers carefully remove the Perspex lid.
60. Using long forceps/tweezers remove the P6 vial containing calibration suspension from the Perspex shield to check if suspension is homogeneous.
61. If the suspension is not homogeneous, replace the P6 vial containing calibration suspension into the Perspex lined shield, replace both the Perspex lid and lead lid of pot and repeat the inversion step until the suspension is homogeneous. Again, remove the lead lid from the pot and using long forceps/tweezers remove the Perspex lid and the P6 vial containing the OncoSil™ to re-check if the suspension is homogeneous.
62. Once homogeneous, using long forceps/tweezers, place the P6 vial containing calibration suspension into an ion chamber, for measurement, ensuring that a suitable background measurement has been determined beforehand.

63. Commence the measurement process for the ionisation chamber and record the calibration suspension activity value on the OncoSil™ Calibration Form, once a stable value has been obtained.
64. Repeat the measurement process twice more to record a total of three values on the OncoSil™ Calibration Form.
65. Return the calibration suspension vial back into the Perspex lined lead pot and replace both the Perspex lid (using long forceps) and lead lid from the pot.
66. Calculate the Average Background Corrected Measurement of the three values and record the result on the OncoSil™ Calibration Form.
67. If the second dilution process on the calibration suspension has been performed within one hour of the first dilution process it is not necessary to select a new correction factor for the local time zone difference and decay from the reference time. If there has been a delay of greater than one hour between these measurements a new factor incorporating the delay between the measurements should be selected.
68. Calculate the expected diluted calibration suspension activity value:

$$\underset{MBq/mCi}{Diluted\ Average\ Activity} = \underset{MBq/mCi}{Calibrated\ Average\ Activity\ Vial\ 1} \times \frac{1.7}{7}$$

69. Next determine if the difference between the diluted average activity and calibrated average activity is within the required range (which is ±10% of the expected diluted activity value).
70. If the value lies outside this range repeat the mixing step for the second vial, and then repeat the measurement. Values outside the ±10% range may be indicative of a non-homogeneous suspension during the measurement.
    Note: If the value is again outside the range, contact OncoSil Medical for advice.
71. If the value lies within the expected range the ionisation chamber response is linear within the range required for the calibration suspension, and it is suitable for use in preparing OncoSil™ doses for implantation.
72. Following dilution, any disposable needles/tubing, syringes with any remaining calibration suspension, gauzes, gloves, aprons and other protective clothing, must be disposed of as radioactive waste and in accordance with treatment facility policies.
73. Forward a copy of the OncoSil™ Calibration Form to OncoSil Medical Customer Service by email to orders@oncosil.com.

9. RADIATION SAFETY GUIDELINES FOR ONCOSIL™

All persons handling and dispensing and implanting OncoSil™ must be familiar with and abide by all Local, State and Federal regulatory requirements governing therapeutic radioactive materials. Standard approved radiation protection techniques should be used to protect staff when handling OncoSil™. For more specific guidance on radiation safety as it relates to the OncoSil™ System, refer to the OncoSil™ System Radiation Safety Guidelines.

9.1 General Precautions

- Adequate shielding from beta radiation must be effected during storage, handling and use of OncoSil™.
- Standard procedures and practices used to minimise occupational radiation doses must be effected during storage, handling and use of OncoSil™.
- Unshielded vials and syringes must be handled with forceps that set the fingers away from the unshielded radioactive source by a minimum of 20 cm (7.9 inches).
- Radiation safety practices must be implemented in accordance with Local, State and Federal, regulatory requirements. Any loss of containment (spills and/or leakages) of OncoSil™ must be isolated, contained and cleaned up immediately. Area contamination monitoring practices should then be followed to ensure the isolation, containment and cleaning has been effective.
- OncoSil™ must be prepared behind a screen suitable for shielding from beta particles e.g. Perspex or Lucite.
- OncoSil™ must be stored inside adequate shielding at all times.
- All contaminated waste must be placed in a designated radioactive waste container and disposed of in accordance with treatment facilities policies.

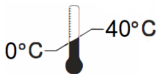
9.2 Staff Precautions

- Individual monitoring of staff in accredited facilities is a general requirement. There are no special requirements for staff handling OncoSil™ in relation to dose monitoring. General film badges or some form of personal dosimeter are acceptable.

10. WARNINGS

- If any signs of damage or ineffective sterile barrier integrity are observed for the OncoSil™ System, DO NOT USE the system and contact OncoSil Medical. Signs of damage and/or ineffective sterile barrier integrity may include, for example, broken vial, cracked vial, broken ring pull, non-intact tamper evident seals, missing vial caps etc.

11. APPLICABLE SYMBOLS

	Do Not Re-Use		Use By Date
	Caution		Sterile Using Steam or Dry Heat
	Radioactive Hazard		This way up
	Do not use if package is damaged		Temperature Limitation (upper and lower)
	Manufacturer combined with Date of Manufacture		Consult Instructions For Use
	Catalogue number		Serial Number

OncoSil™ is a Registered Trademark of OncoSil Medical Ltd

IFU_OS01-99 CAL_GLO (DOC-327) Ver. 1

Approved By:

(CO-168) IFU Revision

Description

IFU's need to be revised in light of a the Indications For Use not matching what we are approved for.

Justification

Labelling should reflect what has been approved by the regulatory body.

Assigned To:	Initiated By:	Priority:	Impact:
Derby Chang	Derby Chang	Urgent	Major

Version History:

Author	Effective Date	CO#	Ver.	Status
John Harvey	February 23, 2023 1:47 PM AEDT	CO-168	1	Published
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