Rhenium-SCT®

Skin Cancer Therapy

Guide for **Referring Clinicians**

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At OncoBeta, we are committed to advancing innovative, non-invasive treatments for non-melanoma skin cancer (NMSC), providing patients with access to therapies that not only reduce the burden of disease and treatment, but also enhance their overall quality of life.

Rhenium-SCT® (Skin Cancer Therapy) is an innovative single-session treatment for patients when other options are unsuitable or have failed.[1]

Objectives of this guide

This guide has been developed to answer questions that referring clinicians may have about Rhenium-SCT.
If you have any additional queries or require further information, please don't hesitate to contact our team at medical@oncobeta.com.

Contents

Rhenium-SCT is an innovative, non-surgical treatment for NMSC

Rhenium-SCT utilises a radioactive isotope, rhenium-188, in the form of a paste to painlessly treat NMSC in a single session.†[2,3,5,6]

Rhenium-SCT is indicated for basal cell carcinoma (BCC) and squamous cell carcinoma (SCC) in patients with co-morbidities where surgery is contraindicated, or for lesions in anatomical positions that may result in suboptimal cosmetic outcomes using conventional approaches.[1]

There are four components to the medical device:

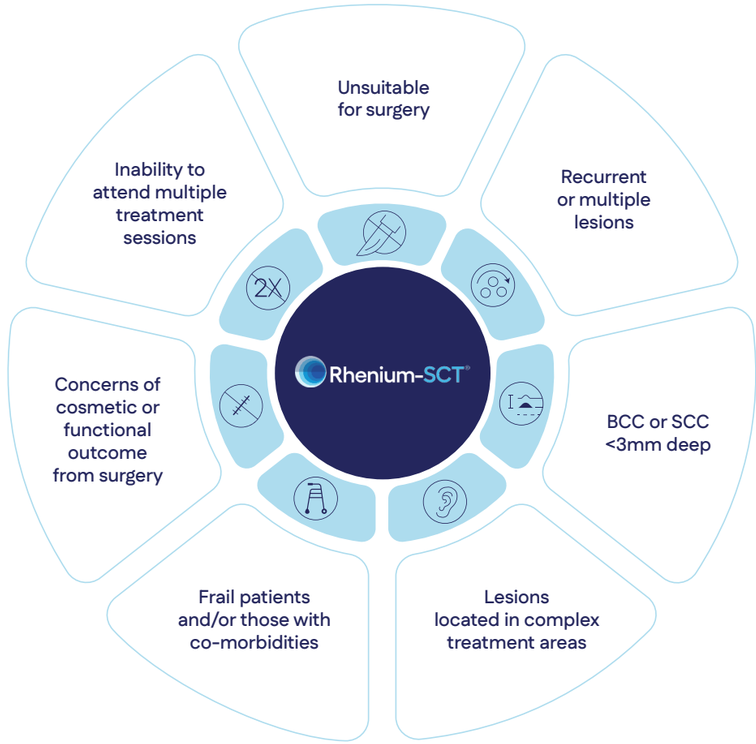
1. The **OncoBeta® Carpoule** is a patented device that contains the rhenium-188 paste, and has a brush to allow for precise treatment application,
2. The **OncoBeta® Applicator** is specially designed to safely apply the paste in a homogenic manner,
3. The **OncoBeta® Base Station** is used to store, mix, and load the carpoules, whilst providing shielding for maximum radiation protection, and
4. The **OncoBeta® Measurement Station** is a specially designed portable dose calibrator to allow for accurate radiation activity measurement to calculate patient treatment times.

Carpoules filled with the rhenium-188 paste.

OncoBeta® Applicator containing the carpoule for treatment.

The OncoBeta® Base and Measurement stations.

Use Rhenium-SCT for biopsy-proven lesions when standard therapies may not be suitable



Rhenium-SCT offers a precise, painless, and personalised treatment for NMSC.†[2,3,5,6]

Precise[2-4]

Accurate application to skin without spreading beyond the tumour area.

Painless*[2,3]

No pain reported during the procedure in clinical trials.

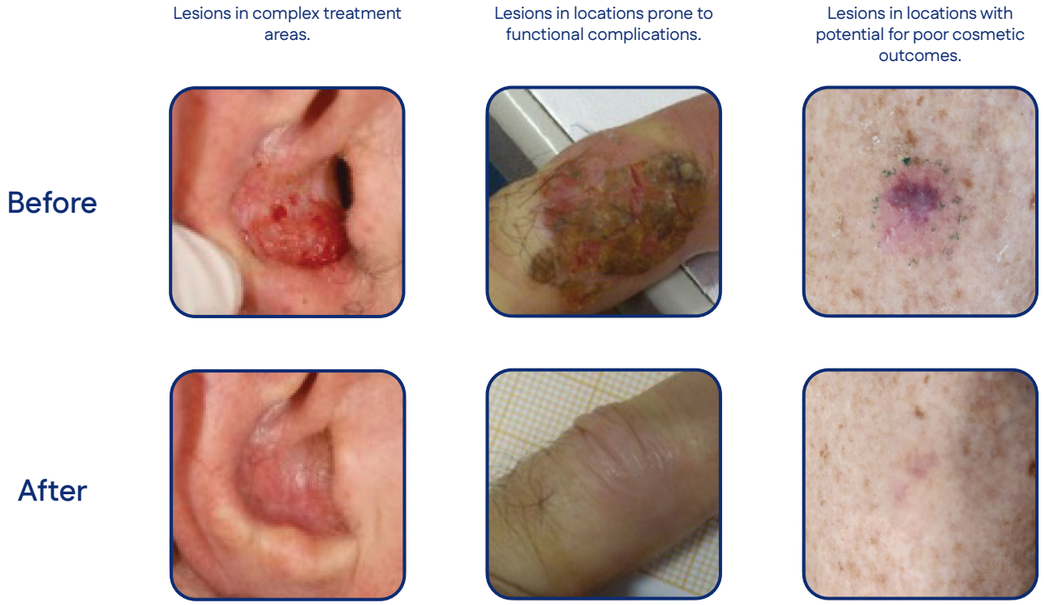
Single treatment†[3,4]

One application (30-180 minutes per treatment).

Non-invasive[1,2]

No cut or break in the skin is created.

When to consider Rhenium-SCT for your patients



Rhenium-SCT has successfully treated:[2,3,5]

- BCC and SCC lesions, including:
  - Superficial and nodular tumours
  - Infiltrative and ulcerated tumours, and
  - Recurrent tumours.

Complex treatment areas treatable with Rhenium-SCT include:[2,3,5,6]

- Face (including nose, ear, and lip)
- Digits
- Genitals
- Locations where wound closure may be challenging.[2]

Rhenium-SCT is contraindicated in:[1]

- Malignant melanoma
- Skin tumours affecting nerves or bony structures
- Lesions of the upper eyelid
- Lesions which anatomical position does not allow a proper application of the Rhenium-SCT resin/paste
- Confirmed pregnancy or impossibility to rule out a pregnancy
- Illnesses which require medication which significantly suppresses wound healing or the immune system
- Patients under 18 years
- Existing major circulatory disorders in the region to be treated.

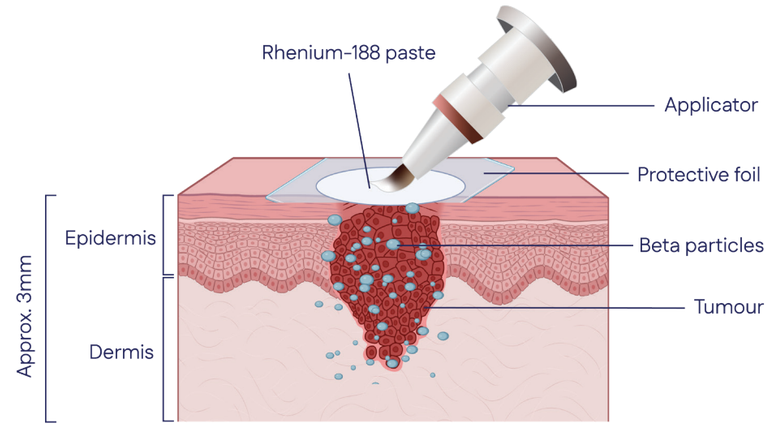
The scientific foundation of Rhenium-SCT

Rhenium-SCT utilises the beta particles emitted from the radioactive isotope, rhenium-188, which destroy cancer cells.[2] Beta particles induce direct local cytotoxic effects, such as apoptosis, as well as an immune reaction.[2]

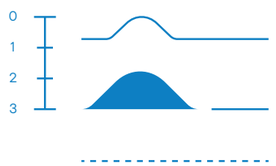
Rhenium-188 is a beta-emitting therapeutic radioisotope that deposits 92% of its energy up to a depth of 3 mm from the surface of the skin lesion[1,6]

Rhenium-188 has a 17-hour half-life, 2.12 MeV maximum beta energy and 15% 155 keV gamma emissions[1,6]

The main gamma component does not contribute significantly to the radiation dose[1,6]

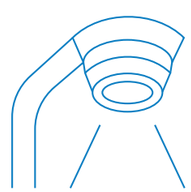


Rhenium-SCT single-session 50 Gy treatment



Rhenium-SCT skin dose penetration of 3 mm spares underlying tissue.*[6]

*~92% absorbed by the top 3 mm of tissue.[6]



The dose halving rate in skin is 2-3x greater than Grenz rays.[10,11]

Clinical studies and research outcomes demonstrate the efficacy and safety of Rhenium-SCT

95–96%

treated lesions achieved a complete response out to two years.*[3,5]

*12-month and 24-month complete response rates of 95% (n=40)[3] and 96% (n=24)[5], respectively, after one application.

92%

of treated lesions assessed by an independent panel of dermatologists reported as yielding a superior or comparable cosmetic outcome to surgery.[3]

2,050

patients have been treated with Rhenium-SCT in clinical studies between 2005–2024[1,7]

Rhenium-SCT is non-invasive and well-tolerated[2,5,6]

- Localised radiodermatitis (mostly Grade 1 and 2) is common (97.5%) following Rhenium-SCT and is an expected reaction to all cutaneous radiation treatments[3]
- The most common adverse event at Day 14 was itchiness (20%)[3*]

*The available data cannot rule out that similar side effects as conventional brachytherapy may occur.[1]

Rhenium-SCT does not require anaesthesia[1]

No special precautions for patients following treatment with Rhenium-SCT[1]

Patient preparation prior to referral

Rhenium-SCT requires collaboration between referring clinicians and the administering nuclear medicine physician or radiation oncologist.

Dermatologists, plastic surgeons and GPs are usually the first point of contact for patients presenting with suspected NMSC. These clinicians diagnose and discuss treatment options with the patient. They can also assist in the preparation of the patient for Rhenium-SCT and facilitate any follow-up. Radiation oncologists and nuclear medicine physicians administer the therapy and are responsible for the treatment process itself.[1]

Clinical information to include when referring a patient

- Patient history
- Punch skin biopsy (with depth noted in report)
- Photographs of demarcated lesions with scale and borders identified by dermoscopy if possible.

Diagnosis and referral

Referring Clinician:

- Diagnoses BCC or SCC
- Performs a punch skin biopsy requesting the depth of the skin cancer from the pathologist
- Discusses treatment options with the patient
- Refers the patient to a nuclear medicine physician or radiation oncologist at a specialist treatment centre if the preferred decision is to treat with Rhenium-SCT[1]

Lesion preparation and measurement

Accurate lesion demarcation is essential to ensure precise treatment, avoiding unnecessary exposure of the surrounding healthy tissue.

This may be performed up to three times: once by the referring clinic, the second during the consult by the treating clinician and the third on the day of treatment.

Preparing the lesion

Measurement of the lesion is used to calculate the surface area and to plan treatment session.

- Preparation of the treatment area is typically done by the treating clinician prior to the treatment day.
- Prior to treatment, the tumour needs to be prepared and cleansed (this may require hair removal, and curettage to remove crusts and scabs). Any bleeding must be stopped prior to treatment.
- The margins of the lesion are demarcated with a dermatological pen and the size is measured. This area should include the entire tumour plus a safety margin of 5 mm. The entirety of the lesion plus safety margin is treated to ensure the complete dosing of the tumour.
- The treating clinician may take further photos in preparation for treatment day.

Treatment day

Treatment is performed by a nuclear medicine physician or radiation oncologist at a specialist treatment centre.

Applying protective foil to the treatment area

- The treating clinician covers the area with a clear plastic film (foil) that prevents the rhenium-188 paste from coming into direct contact with the skin.
- The patient will be shielded from unnecessary radiation exposure as deemed appropriate by the treating clinician.

Applying the paste

- After loading the applicator with the carpoule, the rhenium-188 paste is applied in a thin layer onto the foil.
- The paste will quickly dry, retaining flexibility over the foil but will not run.

Calculating treatment time

The treating clinician calculates the treatment time using a dosimetry program, based on:

- Lesion depth and area including safety margin
- Target radiation dose to the deepest point of the lesion
- Treatment duration is typically 30–180 minutes.[1,3]

Removing and disposing of the foil

- When the treatment is complete, the foil with the rhenium-188 paste is removed.
- The foil is disposed of in a lead-shielded waste container.
- The patient can return to regular activities immediately. Clinic staff will have informed them of appropriate after-care measures and any follow-up visits.

Treatment aftercare

- There are no special precautions for the patient associated with the treatment.[1]
- There is no risk of the patient becoming radioactive, and as a result, neither the patient nor others are at risk.[1]
- Follow up appointments should be planned in agreement with the patient and their referring clinician. It is recommended that wound healing is assessed after 3, 6 and 12–16 weeks.
- In the event of an adverse event, immediately notify the treating clinician for advice on escalating care as required. It is essential to report any adverse events to OncoBeta®.

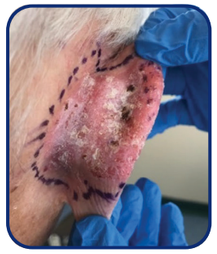
Wound healing typically takes 30–90 days after treatment, but may take up to 180 days depending on factors such as lesion size, depth, location and patient factors.[3,5,6]

Initial follow-up is provided by the treating clinicians and then the patient is returned to the referring clinician for ongoing care or surveillance as necessary. In general, no special aftercare is needed.

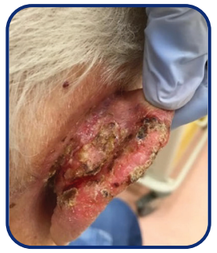
- The dead tumour cells are gradually replaced with new healthy cells.
- The most common side effects of Rhenium-SCT are redness, scabbing, itching and burning. These may occur in the days and weeks following treatment.[1,2]
- The area is expected to look worse in the weeks following treatment, however patients are encouraged to contact their healthcare provider if they have any concerns.

Wound healing and possible side effects

The stages of wound healing after Rhenium-SCT[1-3,5,6]

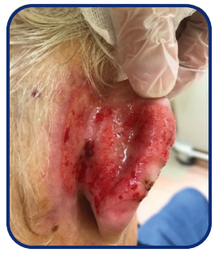


Before treatment



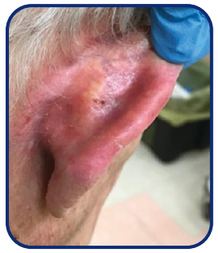
Week 1

- Slight reddening in the first few days.
- Redness increases and a crust or scab forms over the next few days.
- Possible itching and/or slight bleeding may occur.



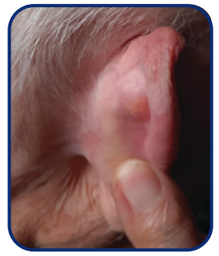
Weeks 2-3

- Lesion may look worse, but this is part of the normal healing process.
- Dead and dying cancer cells are replaced with healthy tissue.



Weeks 3-6

- Redness fades.
- Itching and bleeding subsides.



Weeks 6+

- The healing process is complete.
- The treated area may appear a slightly lighter.

Possible side-effects

Possible treatment-induced toxicity from skin brachytherapy include:[1,3]

- Redness of skin
- Hypopigmentation
- Inflammation
- Bleeding or vascular complications
- Local infections, fever, or pain
- Nausea and vomiting
- Skin necrosis/scars
- Hair loss at the treatment area
- Local tumours at the treatment area as a long-term side effect of radiotherapy
- Radiation ulcer
- Fibrosis

The risk of incorporation (entry of radioactive material in body) of the therapeutic beta-emitter exists only if products are used improperly.[1]

In the event of an adverse event, immediately notify the treating clinician for advice on escalating care as required.

It is essential to report any adverse events to OncoBeta®.

4-months after single application of Rhenium-SCT for lower lip BCC.

John, 91 years old

- Previous history of multiple excisions with graft/flap repairs
- Initial surgical consult for 3cm lower lip BCC
- Inability to attend multiple treatment sessions

Before Rhenium-SCT

How can we help?

- Connect you with your closest treating clinician
- Answer any specific questions you may have
- Address the next steps to accessing Rhenium-SCT
- Send additional clinical or patient resources

For more information, contact OncoBeta® at **medical@oncobeta.com.**

References: 1. OncoBeta® Rhenium-188-Compound Instructions For Use. **2.** Cipriani C et al. J Dermatol Treat 2022;33:969–75. **3.** Tietze JK et al. Clin Nucl Med 2023;48:869–76. **4.** Yosefof E et al. Cancers (Basel) 2023;15(9):2408. **5.** Castellucci P et al. Eur J Nucl Med Mol Imaging 2021;48:1511–21. **6.** Cipriani C et al. Int J Nucl Med 2017;114–22. **7.** Sedda AF et al. Clin Exp Dermatol 2008;33:745–9. **8.** Australian Therapeutic Goods Administration. Acronym and glossary of terms. Available at: https://www.tga.gov.au/resources/acronyms-and-glossary-terms. Accessed April 2024. **9.** Carrozzo AM et al. Eur J Dermatol 2013;23:183–88. **10.** Harley NH et al. J Am Acad Dermatol 1982;7:328–32. **11.** Webster M. 2015. Grenz Ray and Ultrasoft X-Ray Therapy. In Radiation Treatment and Radiation Reactions in Dermatology, edited by R.G. Panizzon and M.H. Seegenschmiedt; Springer-Verlag; pp. 73–87. **12.** Data on file. OncoBeta Garching, Germany.

Rhenium-SCT® is an epidermal radioisotope therapy certified medical device (ARTG number 400142; SAHPRA approved; CE certified).[1]

OncoBeta Therapeutics Pty Ltd, Level 1, Suite 355, 241 Adelaide Street, Brisbane, QLD, 4000.
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