

Rhenium-SCT®

Questions and answers for physicians and medical personnel







FAQs - Doctors and Specialist Staff

1. What is Rhenium and how is it used in medicine?

Rhenium is a chemical element. Its radioisotope Rhenium-188 is used in brachytherapy as a beta emitter. Rhenium-188 is used to treat non-melanoma skin cancer in epidermal radioisotope therapy (as Rhenium-SCT®, Rhenium Skin Cancer Therapy).

A successful study for the treatment of extramammary Paget's disease (EMPD)¹ has already been carried out. In isolated cases, keloids and actinic keratoses have been successfully treated with epidermal radioisotope therapy. There is currently no approval for the treatment of these diseases with Rhenium-SCT®.

Rhenium-188 is also used to treat PAD (peripheral vascular disease), bone², liver metastases³ and arthritis⁴.

2. How does Rhenium-188 work?

The medicinal effect of Rhenium-SCT® is based on the cell-destroying effect of the emitted beta-particles, which have a therapeutic range of up to 3 mm under the skin. The activation of both the mitochondrial apoptosis-inducing factor (AIF) and the protein P53 are responsible for the cell death. Local immune reactions also play a role here⁵.

The half-life of Rhenium-188 is only 17 hours with beta radiation decay energy of 2.12 MeV. Rhenium-188 can be used in all areas of medicine where it is necessary to irradiate tissue therapeutically in a targeted way. The emitted radiation consists of 15.1% gamma radiation (155 keV) and 96.7% beta radiation. Further emissions are not relevant to the application or radiation protection.

3. For which diseases is Rhenium-SCT® approved?

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Since the end of 2014, Rhenium-SCT® has been CE-certified and an approved therapy for the treatment of basal cell and squamous cell carcinoma, including Bowen's disease, in patients with comorbidities when surgical intervention is not possible or conventional therapies cannot be expected to provide a satisfactory cosmetic result due to the anatomical location.

4. Which tumors are particularly suitable for Rhenium-SCT®?

In practice, unfavorably located, small to large tumors are particularly suitable and the treatment can be offered to patients as a supplement or alternative to conventional methods. The Rhenium-188 used in the Rhenium-SCT® is filled into specially developed carpoules and loaded into the applicator to apply the therapy. Rhenium-SCT® is therefore applied individually to each patient depending on the nature of the lesions. Multiple lesions can be treated simultaneously in a single session.

5. What are the contraindications?

Treatment with Rhenium-SCT® is contraindicated in the case of

- Malignant melanomas of the skin
- Skin tumors affecting nerves or bony structures
- Lesions of the eyelids
- Lesions which, owing to the anatomical situation, do not allow the positioning of the radiotherapy source necessary for sufficient coverage
- Confirmed or suspected pregnancy or if a pregnancy cannot be ruled out





- Diseases requiring a medication that significantly suppress either wound healing or affects the immune system
- Patients under the age of 18

6. Are there any other special features or restrictions?

In principle, any tumor size can be treated with Rhenium-SCT®. One Rhenium-SCT® carpoule is sufficient for the treatment of a tumor area of up to 25 cm². The therapeutic range of Rhenium-188 beta radiation in unshielded human tissue is only about 3 mm (92% of the dose in the first 3 mm).

Spinaliomas are often much more sensitive to radiation than basaliomas, so thick spinaliomas (>3 mm) can be treated very successfully.

Direct contact of the Rhenium-188 compound with the skin or wound must be avoided.

7. How is Rhenium-SCT® used?

After the patient is comfortably settled, the lesion to be treated is prepared by the dermatologist. Corneas, crusts and scabs are removed with curettage if necessary. Any bleeding must be stopped. The outlines of the skin area to be treated are then marked with a dermatological pencil and the size is measured. This area should include the entire tumor plus an additional margin of a few millimeters. The tumor is then covered generously with a special transparent foil. Neighboring sensitive and healthy organs, such as the eyes, are protected from the beta and gamma rays of the Rhenium-188 with our special protective goggles and clothing. The activity of the Rhenium-188 compound is then determined by the measuring station. Once these

preparations are complete, the Rhenium-188 compound is applied thinly over the tumor on top of the special foil using the specially designed applicator. The Rhenium-188 compound is designed not to run and quickly forms a sealed, dry but flexible film, which sets in about 10 minutes. The remaining activity of the Rhenium-188 compound in the applicator is subsequently determined by the measuring station. The Rhenium-188 compound now remains on the special film covering the tumor for the specifically calculated time. Depending on the nature of the tumor and the radiation activity of the Rhenium-188, the treatment time ranges between 30 minutes and 3 hours. The tables required to calculate the individual treatment times are provided by OncoBeta®. When the treatment time has ended, the Rhenium-188 compound is removed by simply removing the film and disposed of in a special, shielded disposal container. The protective clothing is then removed and any final safety measures are conducted. Now the patient may leave the treatment room.

8. What should the patient be aware of following their Rhenium-SCT® treatment?

After removal of the Rhenium-coated film, there are no special precautions for the patient associated with the treatment. They will not be contaminated by radioactivity. There is therefore no risk to the patient or other persons.

9. What side effects can occur?

- Erythema
- Swelling

- Bleeding and vascular complications
- · Local infections or fever
- Nausea and vomiting









- Skin necrosis/scarring
- Fatigue/malaise
- · Hair loss at the treatment site
- De-pigmentation of the treatment site
- Local tumors at the treatment site as a later consequence of radiotherapy
- Radiation ulcers
- There is a risk of incorporating the therapeutic beta emitter due to improper handling

10. How is the wound healing process?

Wound healing varies depending on the patient. In most cases, a slight reddening is visible immediately after the treatment. Erythema may occur over the next few days, sometimes in conjunction with the discharge of serum, which then closes with a crust or scab. Sometimes it seems as if the condition of the wound has worsened at first. It may burn or bleed slightly. However, this usually subsides quickly. The erythema fades over a period of 30 – 120 days. A second scab occasionally forms and itching may occur. During this time, the clinical healing process becomes clearly visible. As a rule, wound healing is complete within 60 – 180 days. At the end of the healing process, the treated skin may appear a little lighter and firmer than the untreated skin.

11. What is the level of radiation exposure for the patient and medical staff?

The radiation exposure for the patient due to the gamma levels of Rhenium-188 varies depending on where the tumor is located. It is usually no more than $50-100~\mu\text{Sv}$, with a maximum value of 170 μSv . In comparison, the average natural radiation exposure per year in Germany is 2,100 μSv . When all necessary steps with our protective clothing have been taken, the exposure of medical staff is normally below 0.7 μSv per application.

12. How often can the Rhenium-SCT® treatment be repeated?

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For smaller tumors, one treatment is usually sufficient for permanent removal. It may be necessary to perform epidermal radioisotope therapy multiple times due to the nature of the tumor, as well as its size, depth and localization. In a study of more than 350 patients with more than 1,200 lesions, it was found that in 89% of cases the patients could be adequately treated with a single-session therapy. In 11% of cases, epidermal radioisotope therapy was used 2 or 3 times. Complete remission occurred in 98.5% of all cases.⁶ In a study of 53 patients (37 BCC, 16 SCC), complete remission was observed in all patients during the 20 to 72-month follow-up period.⁷











Bibliography:

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- 3 S. A. Shamim, et al. Nucl Med Comm 31(9) (September 2010): 814 20.
- 4 K. K. Kamaleshwaran, et al. W J Nucl Med 14(3) (December 2015): 216 18.
- 5 D. Eriksson, T. Stigbrand. Tumor Biol 31 (2010): 363 372.
- 6 C. Cipriani, A. F. Sedda: Epidermal Radionuclide Therapy Dermatological High-Dose-Rate Brachytherapy for the Treatment of Basal and Squamous Cell Carcinoma; Therapeutic Nuclear Medicine, Editor: Prof. R. P. Baum, 725 734, © 2014 Springer Verlag, ISBN 978-3-540-36719-2.
- 7 A. F. Sedda, et al. Clin Exp Dermatol (33): 745-749.

Further reading:

A. F. Sedda, C. Cipriani, A. M. Carrozzo: Dermatological Single-Session Beta Emitter Conformational Brachytherapy of Non-Melanocytic Skin Tumours In: Brachytherapy: Types, Dosing and Side Effects, Editor: Leoni M. Fischer © 2009 Nova Science Publishers, Inc, ISBN: 978-1-61728-750-3.





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Rhenium-SCT®

Epidermal Radioisotope Therapy



Painless

The Rhenium-SCT® is a painless therapy with no anaesthesia needed. Especially good for elderly patients, patients with allergies and patients with multiple morbidities or low tolerance to pain.



Personalised

The Rhenium-SCT® is a precise, personalised therapy that is only applied to the area needed to treat. This means that no unnecessary healthy tissue is damaged either in the depth or outside of the safety border.



Single-Session

The Rhenium-SCT® is a single-session treatment in most all cases.



Short Treatment Duration

Easy and practical thank the simple application and short treatment duration.



Non-Invasive

The Rhenium-SCT® is a medical procedure which is non-invasive. A procedure is considered non-invasive when no break or cut in the skin is created. This means no stitches or the possibility of secondary infection.



Aesthetic

Sensational aesthetic results with little or no scarring, considerably fast healing period, no stress treatment, restored functionality.

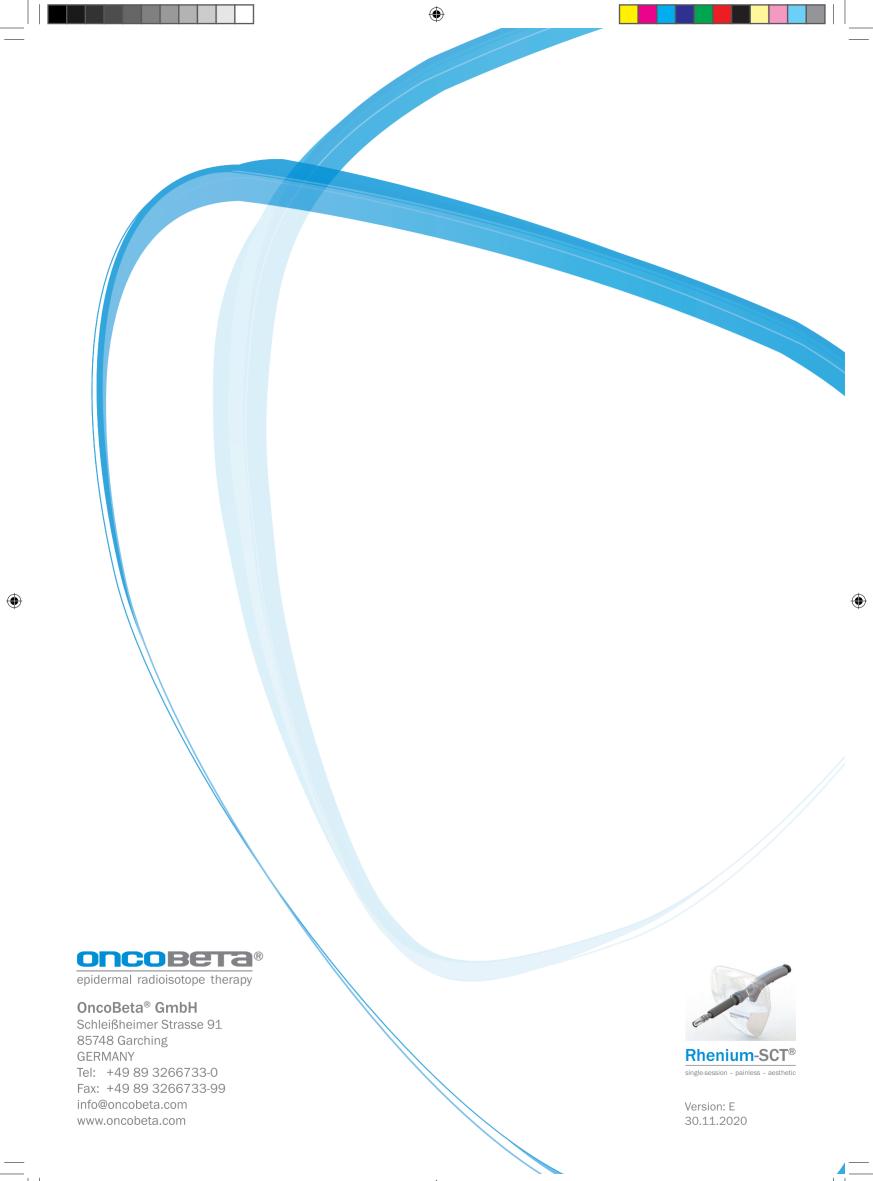






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