

Quick Guide

CE 2797

OncoBeta® Rhenium-188 paste

CAUTION:



This product can only be used together with the **OncoBeta® Application System and Measurement Station (MST)**.
Please read the User Manual of **OncoBeta® Application System** before using this product.

1 Introduction

This Quick Guide is addressed only to professionals like **health professionals** and nuclear physicians that have been **trained** by OncoBeta® GmbH or one of its certified representatives are allowed to use this product. The Rhenium-SCT follows all international safety guidelines and regulations such as German Radiation Ordinance (Strahlenschutzverordnung), EU MDR 2017/ 745, Australia's (TGA) Therapeutic Goods Act 1989, TGA MDR 2002, Labelling and packaging regulatory framework and South African regulations made in terms of the medicines and related substances act, 1965.

ATTENTION

National regulations should be considered when selecting the personnel using the product.

Do not use pressure bandages on the lesion after therapy.

Do not slide the mixing wheel mechanism unless the applicator lever with carpoule is fully retracted.

This Quick Guide is applicable for **OncoBeta®s Rhenium-188 paste** as well as its application within the therapeutic procedure named **Rhenium-SCT®**. Before the use of the product, the users need to read the user manuals for accessories that are used with the product.

Before using this Quick Guide, it must be verified if all the pages are available. In case this Quick Guide or the labelling on the product should not be complete, please contact the manufacturer.

1.1 The Rhenium-SCT® Therapy

The Rhenium skin cancer therapy (SCT) using the beta-emitter rhenium-188 (17h half-life, 2.12 MeV max. beta energy, 15% 155 keV gamma emissions) (Rhenium Skin Cancer Therapy = Rhenium-SCT®) is a non-invasive treatment for non-melanocytic cancer types. During the treatment, the area to be treated is covered by a sterile transparent foil. Subsequently, the rhenium-188 paste is applied on the area of the lesion with a certain safety margin. In a worst-case scenario, the radiation burden for a patient due to another patient sitting 1.2 m away is negligible and estimated to be around 1.17 µSv.

The rhenium-188 is bound to a matrix (**OncoBeta® Rhenium-188 paste**). The treatment time (i.e., the time the rhenium-188 must remain on the lesion) is calculated based on the applied radioactivity, the area of the region it was applied. This results in a target dose at a defined depth. After the treatment time is over, the protective foil is removed together with the radioactive paste. The paste dries out during the treatment time and turns into a flexible film.

Given the nature of beta radiation the dose drops rapidly with depth, such that underlying tissue is spared to the radiation of rhenium-188. The lesion and the safety margin around it get however a lethal dose. The high energy electrons from beta emitter isotopes are therapeutically effective only at a short distance and they allow underlying healthy tissue to be spared.

1.2 Intended Use

The Rhenium Skin Cancer Therapy (Rhenium-SCT®) is intended to be used to treat skin cancer lesions and skin tumors using the radioisotope Rhenium-188.

1.2.1 Indication

The Rhenium-SCT® is indicated for:

- Basal cell carcinoma (BCC)
- Squamous cell carcinoma (SCC), incl. Bowen's disease

especially for patients with co-morbidities for which a surgical approach is not indicated, or for lesions which anatomical position may result in a suboptimal cosmetic result using conventional approaches.

1.2.2 Contraindications

The Rhenium-SCT® is contraindicated in the following cases:

- Malignant Melanoma
- Skin tumors that involve nerves or bony structures
- Lesions of the upper lid
- Lesions which anatomical position does not allow a proper application of the Rhenium-188 paste
- Confirmed pregnancy or impossibility to rule out a pregnancy
- Illnesses which require medication which suppresses significantly wound healing or the immune system
- Patients under 18 years
- Existing major circulatory disorders in the region to be treated

1.2.3 Clinical benefits

The treatment of non-melanoma skin cancer with a single session of Rhenium-SCT results in complete remission in 97% of patients within a period of 6 to 24 months after treatment.

This clinical benefit is accompanied by excellent or good cosmetic outcomes in 90% of patients and improvements in quality of life. The treatment has a very low incidence of wound complications and infections, and is considered to be painless.

1.2.4 Safety and performance characteristics

- Secure irradiation of the tumour with beta radiation up to 3mm penetration
- Treatment is possible almost everywhere on the skin
- Non-Invasive and painless
- Single session treatment in most cases
- No anaesthesia necessary; suitable for patients with comorbidities
- Multiple lesions can be treated in same session

1.2.5 Side effects

Within the experience with the device and its preceding investigational version, very few side-effects have been reported beyond the local reaction to the treatment, however, the available data cannot rule out that similar side-effects as conventional brachytherapy may occur. According to the GEC ESTRO Handbook of Brachytherapy such can be:

- Redness of skin and depigmentation
- Inflammation
- Bleedings or vascular complications
- Local infections or fever
- Nausea and vomiting
- Skin necrosis / scars

OncoBeta® Rhenium-188 paste

- Tiredness / Unpleasantness
- Hair loss at the treated area
- Local tumors at the treated area as long-term side effect of radiation therapy
- Radiation ulcer
- Depigmentation

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

2 Safety

2.1 General Safety Information

National regulations for the therapeutic use of open radioactive material must be implemented.

All rooms where the products are meant to be used must fulfil all regulations regarding the handling of open radioactive material for therapeutic use. The required Nuclear Medicine infrastructure must be available and national radiation safety regulations, including labelling, must be followed.

The centre performing the treatment must have a valid permission to handle rhenium-188 (unsealed source). Only personnel that are allowed to handle open radioactive material according to national radiation safety regulations can use the products.

Goods shall not be used prior to receiving the Certificate of Compliance. Acceptance criteria defined in the Certificate of Compliance will allow the customer to accept the goods and use them for their intended purposes.

Handling with radioactive material requires attention and care. Distractions should be minimized in any situation. If necessary, all working steps should be practiced without radioactive material (dry run) before using the products.

Proper transport containers with shielding (e.g., Type A Container, Waste Container with shielding) should be used in order to transport radioactive material to/inside the hospital/institution.

When handling radioactive material this should be shielded at all times unless it must be exposed according to its intended use. Proper shielding should be available for every working step and gloves should be worn when handling the transport containers.

The duration should be minimized, when the personnel is close to products containing rhenium-188 or items contaminated with rhenium-188. The distance to the radioactive material should be maximized at all times.

OncoBeta® GmbH can offer proper waste containers with shielding for disposal of used products or contaminated items. These products have sufficient shielding for safe handling if used according to their intended use. Re-188 waste can be disposed together with normal waste after 3 weeks of decay.

All rooms as well as all devices and accessories used for the treatment should be tested for contamination at the end of each treatment. If anything is found to be contaminated, correct clinic procedure should be followed to decontaminate the device or room.

2.2 Safety during treatment

User manuals for all devices and accessories required for the **Rhenium-SCT®** procedure should be read before beginning the treatment.

The contact between paste and skin or lesion must be avoided at all times. In order to do so, the foil must be selected to cover the region generously (at least 2cm border around the area to be treated). The doctor must inspect the packaging of the foil before opening it to make sure it is not damaged. The paste (which is packed in Carpoules of 0.6 to 2.2 GBq) must be applied in thin homogeneous layers over the foil. The application must be quick and should not be interrupted or paused. The paste must be brushed only over the foil and within the boundaries marked previously on the skin.

The foil must be controlled before use for potential damages or cuts. The foils are meant to be single-use and should not be reutilized.

Special care must be taken when applying the paste close to body cavities and open wounds, as in such places the risk of incorporation is higher.

The content of each Carpoule must be mixed before use, using the **OncoBeta® Application System Base Station** in order to make the paste as homogeneous as possible.

The slider of the **OncoBeta® Application System Applicator** should be reset to fully up until visibly green before loading a carpoule.

After loading the **OncoBeta® Application System Applicator**, it should be ensured there is a capped carpoule in the applicator carpoule holder.

Several Carpoules may be used in case of lesions with an area to be treated >25cm². Use Carpoules of the same LOT in such cases. For multiple use please refer to section 4.7, point 15 in the IFU_APS guidebook.

The treatment can only be applied to the indications stated under 1.2.1. The area to be treated must be defined before treatment and must be marked with a waterproof pen.

The time of the treatment must be measured by at least two (2) independent devices. At least one of them must work without connection to the power mains.

The treatment time must be validated in terms of plausibility (commonly between 45 and 180 minutes). OncoBeta® GmbH can provide tables for calculating it. The recommended target radiation dose to be delivered for the desired clinical effect of the **Rhenium-SCT®** procedure would be 50 Gy at the thickest part of the lesion. The material provided by OncoBeta® GmbH or by its sister company already includes this target radiation dose explicitly.

Personnel and third parties, including the physicians carrying out the treatment, should stay as short as possible inside the treatment rooms. In case a person (personnel or third party) is needed to stay in the treatment room during a treatment, then proper radiation safety measures (protective clothing, eye protection and shielding) must be used and distance to the patient must be maximized. Persons that are not related to the treatment are not allowed to be in the treatment room during treatment.

Long grippers or pliers should be used to remove the Foil with the applied paste at the end of the treatment.

The patient must be positioned in such way that the lesion is horizontal and properly accessible to the treating physician in order to avoid contaminations. Furthermore, body cavities and skin close to the area to be treated must be properly covered.

The eyes of the patient should be protected during the treatment. This can be done e.g., using radiation safety goggles. This is particularly important for treatments in the face.

Contaminated instruments must be packed in a water-tight way and should then be properly shielded.

The product **OncoBeta® Rhenium-188 paste** may only be used within one session. Furthermore, it must be used on additional lesions (if desired) only within a few minutes of activation (risk of drying out).

Only products approved by **OncoBeta® GmbH** may be used for the treatment.

It must be taken care that no contamination of the treatment room takes place once the Foil is removed together with the paste.

Once the treatment is over, a contamination measurement device must be used to verify that the patient is free of radioactivity, as well as the personnel and the treatment room, including all devices.

2.3 Symbols

Carpoule reference number	REF
LOT/charge number	LOT
Serial number	SN

OncoBeta® Rhenium-188 paste

Quantity	
Medical Device	
Unique Device Identifier	
Date of production	
Manufacturer	
To be used before	
Radioactive	
Keep dry	
Keep protected from sun light	
Please read user manual	
Caution	
CE-Mark	

3 Product Description

The **OncoBeta® Rhenium-188 paste** is a rhenium-particle mixed with a viscous polymeric matrix. The product is packed in a Carpoule in order to handle it without risk of contamination.

The **OncoBeta® Rhenium-188 paste** is applied on sterile protective foil covering the area to be treated using the **OncoBeta® Application System**. The Carpoule and the paste meant to be used only during one single session.

4 Complaints / vigilance

Any complaints and vigilance related information shall be reported to OncoBeta GmbH. Vigilance related information shall also be reported to the competent authority of the member state where the user/ patient is established. Information can be shared with OncoBeta by using following email ID: complaints@oncobeta.com

5 Contact Information

Legal Manufacturer: OncoBeta GmbH • Schleißheimer Straße 91.
• 85748, Garching bei München • GERMANY • www.oncobeta.com
Revision: N • Date: 2025-09-18