ONCOBETA®

# Basic Information for Patients

Treatment of non-melanoma skin cancer with

## Rhenium-SCT®

Bringing back
**Quality of Life.**

1x **single-session** **painless** **aesthetic**

>> I did not go to the doctor for a long time since I was afraid of the diagnosis and the therapy. The lesion on my cheek looked simply terrible. It was a hard time for my husband and me. Today I am healed and I enjoy life again. <<

*Francesca Bianchi, Rome, Italy*

**Rhenium-SCT®**
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Dear Patient,

your treating physician has diagnosed you a non-melanoma skin cancer.

First, the good news: these types of skin cancers can be very well treated if they are detected early. Your doctor has already explained the origin of the disease and the different therapy options, as well as their advantages and disadvantages. If you still have questions, reach back out to your doctor to ask him/her directly. Do not let any questions go unanswered.

We also, offer an online patient information service in addition to this brochure. You can find it at: **www.nonmelanomaskincancer.info**

You received this brochure, because your doctor wanted you to have additional information regarding the **Rhenium-SCT®** (SCT = Skin Cancer Therapy).

In the coming pages, we will provide you further information about this therapy.

We wish you a quick recovery!

Your,
OncoBeta® Patient-Service-Team

Bringing back the quality of life to skin cancer patients

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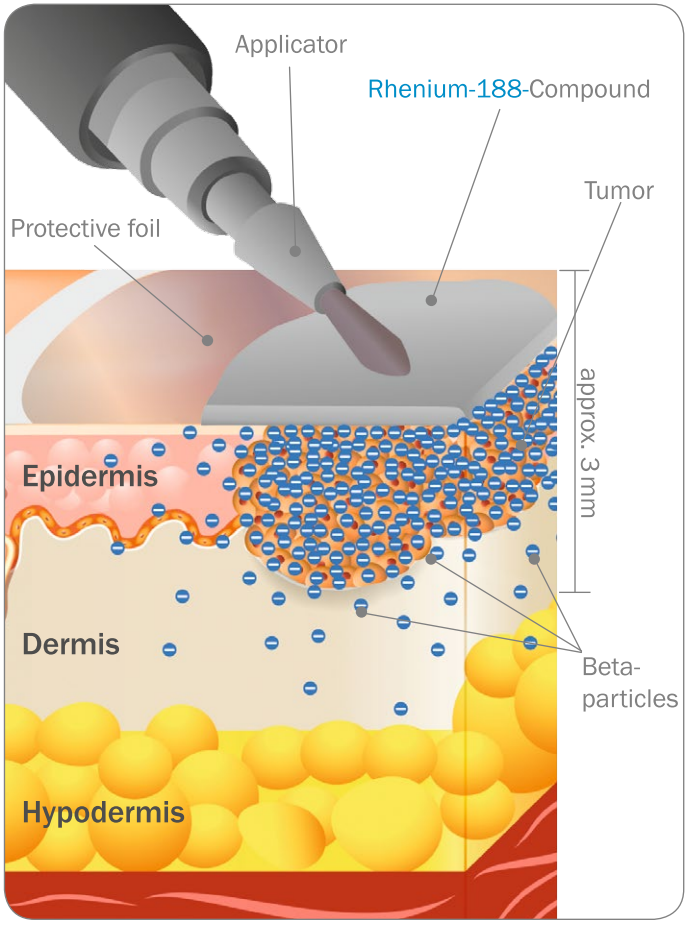
## What is **Rhenium-188?**

**Rhenium-188** is an isotope that decays continuously while emitting beta-radiation.

The penetration range of its beta-radiation is very shallow in human tissue (2 – 3 mm). This makes **Rhenium-188** ideal for the targeted local treatment of superficial skin cancer types, like most non-melanoma skin cancers.

The aim of the **Rhenium-SCT®** is to kill cancerous cells in a targeted and painless manner.

Medically, the working principle of the **Rhenium-SCT®** is based on a local, direct cell-killing effect via beta radiation, which triggers local cell death and a local reaction of the immune system of the body, resulting in the healing of the lesion.

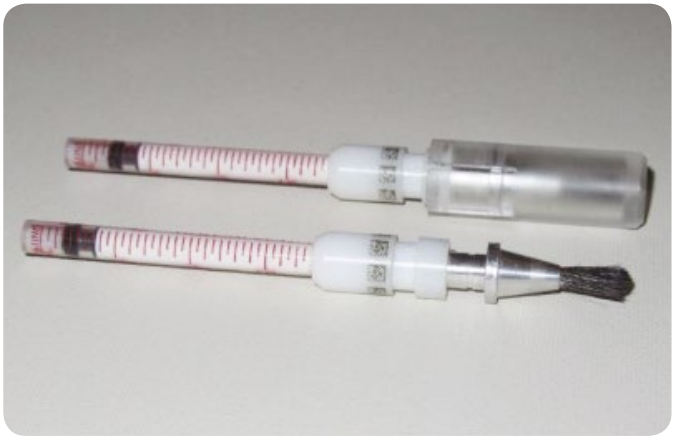



Transversal cut of the skin

Before After

**Rhenium-SCT®**

single-session – painless – aesthetic



Carpoules filled with **Rhenium-188-Compound**


Applicator loaded with a Carpoule

Application of **Rhenium-188-Compound** with the Applicator

## How does the **Rhenium-SCT®** work?

**Rhenium-188** is bound to a fluid matrix (compound) in order to enable its application precisely over the tumor.

The **Rhenium-188-Compound** is filled in so called carpoules which include a brush.

Carpoules are loaded in a special applicator for safely handling.

The area to be treated is covered with a special protective foil.

During the **Rhenium-SCT®** the physician can accurately dose the amount of **Rhenium-188-Compound** by using a mechanical control. This way, the compound is homogeneously applied only above the tumor.

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## Step 1:

The Skin Cancer Specialist marks the area to be treated with the **Rhenium-SCT®** with a dermatological pen.

## Step 2:

The area for treatment is covered with a protective foil.

The **Rhenium-188-Compound** is applied over the area of treatment. Later this foil will be removed together with the dry compound.

The **Rhenium-188-Compound** is applied over the marked area to be treated with help of the Applicator.

## Step 3:

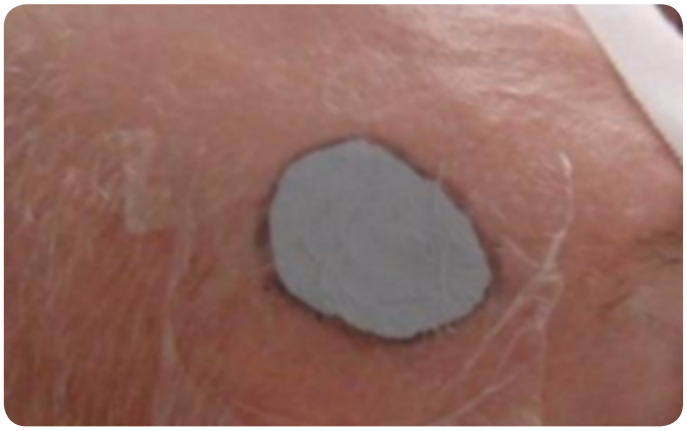
Starting from this point the treatment takes 45 to 180 minutes.

The protective foil and the dry **Rhenium-188-Compound** are removed after the treatment.

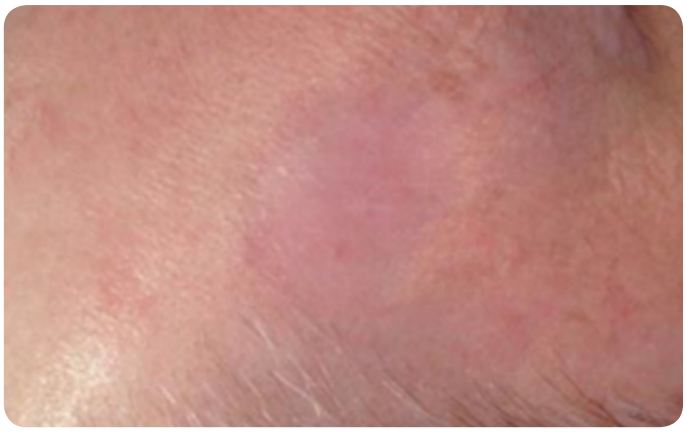
In general, no special aftercare is needed.

The dead tumor cells are disposed by the body and replaced with new healthy cells.

Area: Size of the lesion plus a security margin of up to 5 mm.



Treatment time: aprox. 45 – 180 min
(depending on position, size and depth of lesion)



In most cases, only a single session is required.
Wound healing takes aprox. 30 to 180 days.

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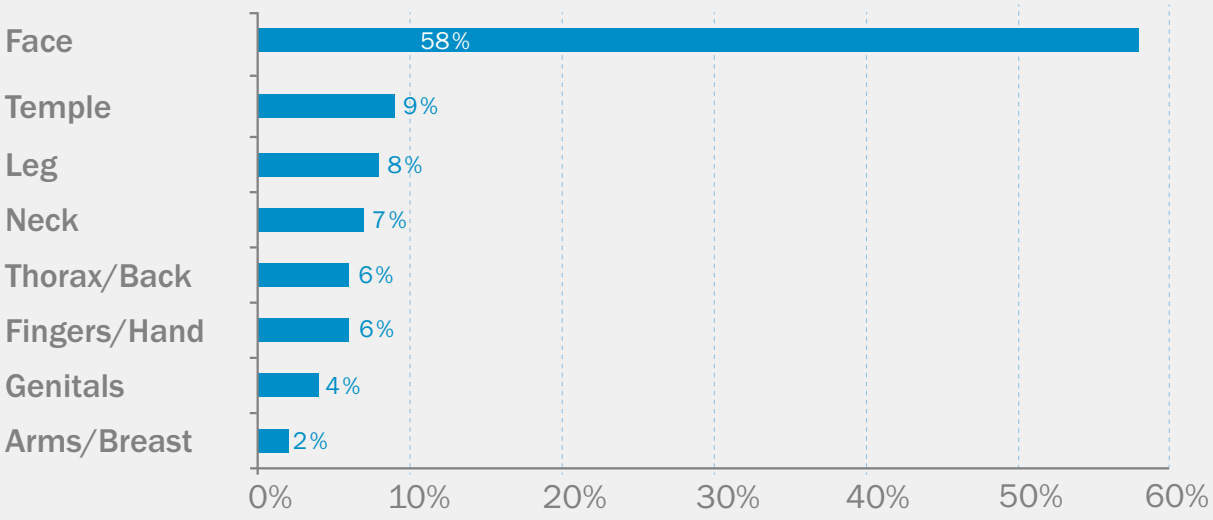
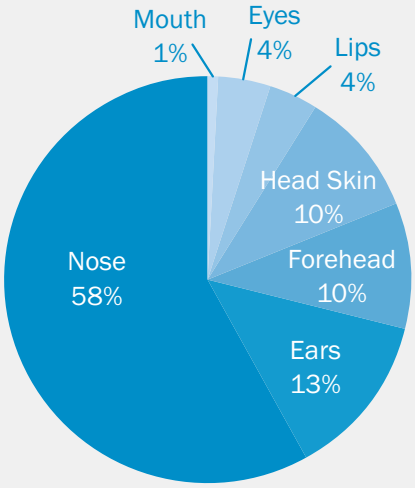
# Experiences with the Epidermal Radioisotope Therapy in the treatment center in Rome (Italy).

| | |
|---|---|
| • Number of treated lesions | > 1300 (2003 – 2017, > 460 patients) |
| • Single-treatment needed for complete remission | > 85 % of the cases |
| • Number of treatments needed for complete remission | 1–3 |
| • Largest treated lesion to-date | 150 $cm^2$ |
| • Reported secondary effects to date | none |
| • Largest number of lesions treated simultaneously to-date | 27 |
| • Oldest patient treated to-date | 105 years |

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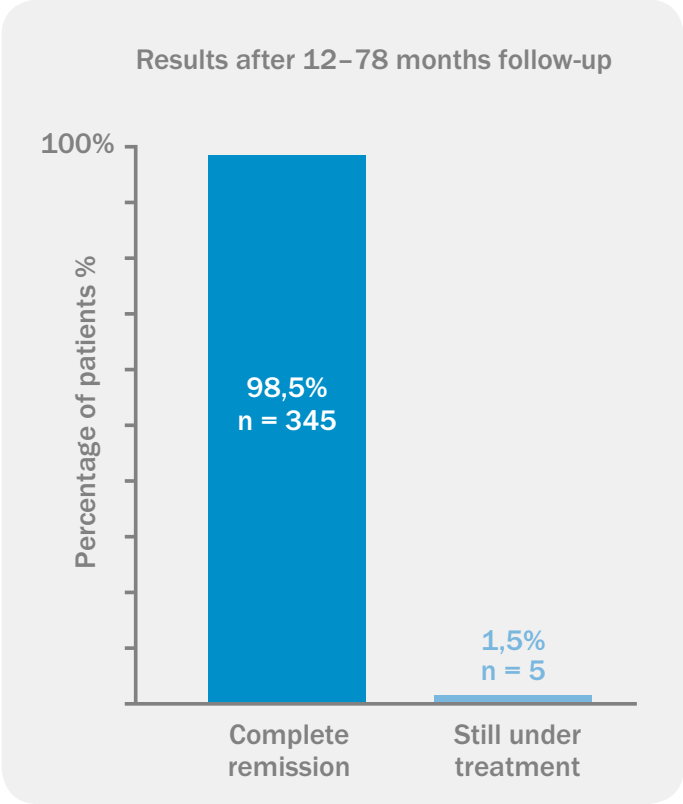
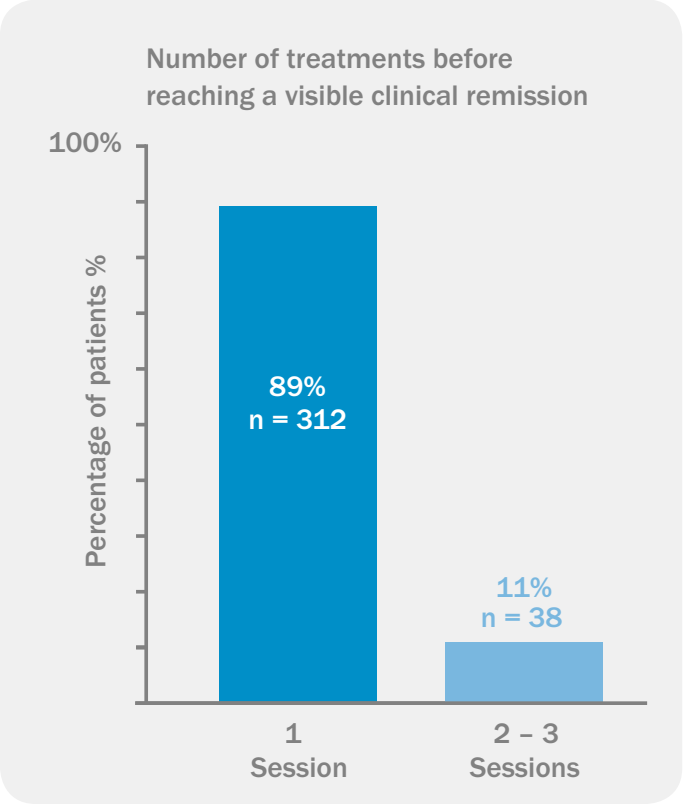
Source: Prof. Cesidio Cipriani, Ospedale St. Eugenio, Rome (Italy)

## Study results from Ospedale St. Eugenio, Rome (Italy)

## Over **350** patients treated with Epidermal Radioisotope Therapy
## More than **1200** treated lesions (basal and squamous cell carcinoma, incl. Bowen's disease)




Almost all patients treated with epidermal radioisotope therapy could achieve a long term remission* of the treated lesions.

A great majority of the patients required a single epidermal radioisotope therapy session.

*Remission = a temporary or long-term diminution of symptoms of a disease.

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Source: Cipriani, C., and Sedda, A. F. "Epidermal Radionuclide Therapy - Dermatological High-Dose-Rate Brachytherapy for the Treatment of Basal and Squamous Cell Carcinoma." In Therapeutic Nuclear Medicine, edited by Baum, R. P. New York: Springer, 2014. ISBN 978-3-540-36719-2

# Questions and Answers for Patients

## 1. Rhenium-188

### 1.1 What is Rhenium-188?

Rhenium-188 is an isotope which continuously decays emitting beta-radiation and a small portion of gamma radiation. The penetration of the beta-particles of Rhenium-188 in human tissue reaches a depth of 2 – 3 mm. Rhenium-188 is ideal in treating superficial tissue, as the skin, because of its high energy beta-radiation.

### 1.2 Where does the Rhenium-188 come from?

The Rhenium-188 used in the Rhenium-SCT® is produced at the facilities in EU.

### 1.3 Does Rhenium-188 harm my body?

During the Rhenium-SCT® the Rhenium-188 is applied on top of a protective foil which has been placed over the treatment area. As a result, if the procedure is performed according to the intended use there will not be any contact between your body and the Rhenium-188. It is only the first 2 – 3 mm of the skin (upper and middle layers, epidermis and dermis) that are affected by the beta-radiation. This only applies to the skin or lesion located directly underneath the Rhenium-188-Compound. The beta-radiation does not affect deeper lying tissue or any other part of your body. The Rhenium-188-Compound only has an effect locally to the area it was applied.

Rhenium-188 also contains a small amount of gamma-emissions (15 %). Gamma radiation can penetrate several centimeters of human tissue. In our case however the amount is so low that it will not produce radiation damage to the rest of your body. The radiation burden due to the gamma-radiation of Rhenium-188 is 0.05 – 0.1 mSv, with a maximum of 0.17 mSv (mSv = milli-Sievert). This dose is equivalent to 2.5 – 5 %, maximum 8 %, of the yearly dose coming from nature (mainly from the sun and the earth). Should the Rhenium-188 be applied in an area of the body close to sensitive organs (for example the eyes), then these will be shielded from potential radiation with lead protections.

### 1.4 Which other medical applications does Rhenium-188 have?

Theoretically, Rhenium-188 can be applied anywhere in the body, where a superficial tissue needs to be therapeutically treated. Beyond its use for non-melanoma skin cancer, Rhenium-188 is also currently used for the treatment of vascular diseases (e.g. stenoses in peripheric vessels), liver and bone metastases, as well as, arthritis.

### 1.5 What is the medical effect of Rhenium-188?

The objective of the therapy is the elimination of tumor tissue.

The medical effect of the Rhenium-SCT® bases on the direct cell destruction caused by the beta-radiation, which both kills cells locally and triggers a reaction of the body's immune system. The treated tissue first dieds, which gives the impression that the lesion got worse. However, the body begins promptly to replace the dead cells with healthy new cells. Thus, the area commonly heals leaving no scars behind.

Compared to the radiation therapy with gamma- or x-rays, or electron-beams, the Rhenium-SCT® does not harm surrounding tissue outside the treatment area (neither around the lesion nor deeper layers).

In the Rhenium-SCT® the Rhenium-188 is embedded in a special synthetic material (Compound) which can be applied precisely on the protective foil over the tumor.

This means that only the tissue in the treatment area gets irradiated, while healthy tissue around it remains untouched.

## 2. Rhenium-SCT®

### 2.1 What is Rhenium-SCT®?

The abbreviation SCT stands for „Skin Cancer Therapy“.
Rhenium-SCT® means treatment of Skin Cancer using Rhenium-188.

### 2.2 What is the Rhenium-188-Compound?

A particular consistency is needed in order to apply the Rhenium-188 directly over the tumor. The Rhenium-188-Compound is accordingly a substance to which the Rhenium-188 is bound. Alternatively the Compound can be thought of as a carrier material for the Rhenium-188. This synthetic material is first fluid, but solidifies once it is applied. The dry Rhenium-188-Compound keeps its flexibilty as a film over the tumor.

### 2.3 Which types of skin cancer can be treated with the Rhenium-SCT®?

The Rhenium-SCT® is intended for the treatment of non-melanoma skin cancers. The most common among them are basal cell carcinomas (BCCs) and squamous cell carcinomas (SCCs). Bowen‘s disease is also part of them (subtype of SCC).

### 2.4 Which types of skin cancer cannot be treated with the Rhenium-SCT®?

Malignant Melanomas, which are typically insensitive to radiation have not been investigated to date and have not been approved for treatment with the Rhenium-SCT®. Skin cancers that have invaded nerves or bone structure are not to be treated with the Rhenium-SCT®.

### 2.5 May the Rhenium-SCT® be used together with other skin cancer therapies?

In most cases, the Rhenium-SCT® is a standalone therapy that treats skin cancer locally with no additional therapies needed. Your doctor must decide if there is a need for other therapies parallel to a Rhenium-SCT®.

### 2.6 What does the healing process look like?

In most cases, redness occurs in the skin nearby the treated lesion directly after treatment of the treated area. It may occur in the days following the Rhenium-SCT® treatment that the treated area of skin will develop a strong red color (erythema) and the lesion will develop a wound. In some cases, a serum will emerge from the wound, later forming a crust or scab. Additionally, it may appear the condition of the lesion has worsened. It is also, possible that the wound may burn or in some rare cases, bleed. The bleeding, however, is often present prior to the treatment and disappears in a few short days. During a period, post treatment, of ca. 30 – 120 days the redness of the skin gradually disappears. In certain cases, a second scab can occur and the wound may also itch. These are indications that the wound is healing, which will be clearly visible. For most people the process is complete within aprox. 60 – 180 days. Scabs may still, however, be present for some time thereafter. At the end of the treatment cycle, your skin will look lighter and firmer (younger) than your untreated skin.

### 2.7 Which side-effects may occur?

Within the data collected in previous years on epidermal radioisotope therapy (> 460 Patients) no side effects have been recorded. Nevertheless, it is feasible that side effects may occur from the application of Rhenium-188.
Possible side effects: Skin redness, inflammation, bleeding, superficial vascular complications, local infections, skin necrosis and scar tissue.
There is no risk of introduction to the body of Rhenium-188 if the therapy Rhenium-SCT® is performed to protocol.

## 2.8 Are there other skin conditions that can be treated with the Rhenium-SCT®?

Rhenium-SCT® has been successfully evaluated in clinical studies for the treatment of Extramammary Paget's Disease (EMPD), Keloids (increased scar tissue generation), and Actinic Keratosis (pre-stage of non-melanoma skin cancer).

To date, there is no clearance for the use of Rhenium-SCT® towards these indications.

## 2.9 Which preparations should I make before the Rhenium-SCT® treatment?

The Rhenium-SCT® is a completely painless local epidermal radioisotope therapy. It is applied when the patient is fully conscious, without need for anesthesia or any other drugs. Accordingly, patients can eat and drink what they desire leading up to administration of the therapy.

Please do not use any cosmetic product (cream, make-up, ... ) nor any skin care products on the day of the treatment.

In cases where a surgical procedure is necessary before the administration of Rhenium-SCT®, due to the size and or depth of the tumor, your treating physician will inform you of all necessary preparations you will need to make. In cases where surgery takes place before the Rhenium-SCT®, it is possible that some portion of the tumor will be removed (flattening the lesion) before treatment. All aspects of special care and or aftercare will be explained by your physician.

## 2.10 What are the steps of the Rhenium-SCT®?

First, your Skin Cancer Specialist will mark the borders of the area to be treated with a dermatologic pen. This area includes the lesion and few millimeters of security margin.

Afterwards, the complete area will be covered by a transparent protective foil.

In cases where the lesion is close to sensitive organs, for example the eyes, those organs will at this stage in the therapy, be shielded from radiation by protective accessories. Protective accessories used to shield vital organs have been specially designed to be used alongside the Rhenium-SCT® therapy.

As soon as all preparation steps are complete, your nuclear medicine physician/technician will apply the Rhenium-188-Compound in a thin, homogeneous layer over the protective foil, using the applicator device. The Rhenium-188-Compound will only be applied over the area marked explicitly by the derma-oncologist. The Rhenium-188-Compound is designed specifically to solidify swiftly, forming a flexible film over the foil. The Rhenium-188-Compound will remain, for a precisely calculated amount of time, on your skin. The amount of time necessary to treat the lesion, depends on its size, depth, the targeted dose volume and the applied radioactivity of the Rhenium-188 in question. The treatment time typically runs on a case by case basis, anywhere between a few minutes, up to a maximum time of 3 hours (average treatment time is 1 hour long).

After the required treatment time is over, the Rhenium-188-Coumpound and the protective foil is removed from your person and disposed of.

## 2.11 What should I take particular care of during the Rhenium-SCT® treatment?

There are only two important aspects to be aware of during the Rhenium-SCT® treatment:

1. Never touch the Rhenium-188-Compound.

2. Stay calm, and relax while seated or standing, to ensure that the Rhenium-188-Compound and the protective foil do not fall from your skin.

In order to make the waiting time more pleasant during the treatment, you may read, watch TV, listen to music or simply relax and enjoy the quietness.

### 2.12 What should I take particular care of after the treatment with the Rhenium-SCT®?

There are no special precautions related to the Rhenium-SCT® after the treatment.

The treated area will change dramatically in the days following your treatment. You may get the impression that the lesion has worsened. This development is completely normal (for description of the typical changes in your skin, see “2.6 What does the healing process look like?”). The wound will heal within the next 30 – 180 days.

Take care to ensure the wound is kept clean during the healing period. Special wound healing care is not expected to be necessary.

Your Skin Cancer Specialist may track your healing progress regularly during the 30 – 180 day dealing period. He/She will also, document the healing process with pictures.

### 2.13 How often is the Rhenium-SCT® applied?

In most cases, only a single session is required for complete remission. In rare cases, two to three treatments will be necessary to achieve remission. This depends almost solely on the depth of the lesion and its anatomical localization.

### 2.14 Can several lesions be treated in the same session?

Almost all non-melanoma skin cancers do not manifest as a single lesion. The Rhenium-SCT® makes it possible to treat all of a patient’s lesions in a single session. This is a strong advantage of the Rhenium-SCT® over other therapies. The most lesions treated in a single session to-date is 27 lesions.

### 2.15 Are there any constraints regarding which areas can be treated?

Non-melanoma skin cancers vary greatly in size, from very small to very large sized lesions. The Rhenium-SCT® can treat arbitrary shapes and sizes. The largest lesion treated with Rhenium-SCT® to-date was 150 $cm^2$.

### 2.16 Are there any other constraints?

At the moment, performing the Rhenium-SCT® on minors, pregnant women, and women where pregnancy cannot be ruled out, is not allowed.

## Do you have more questions?

Contact us directly:

**+49 89 3266733-0**

or per e-mail under

**info@oncobeta.com**

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# Rhenium-SCT®


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epidermal radioisotope therapy

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