

A patient's guide to **OncoSil™**



For people with
unresectable locally
advanced pancreatic cancer



For people with
unresectable locally
advanced pancreatic cancer

Contents

Introduction

What is OncoSil™?	4
How does OncoSil™ work?	5
Who performs the OncoSil™ treatment?	5
Who is OncoSil™ suitable for?	5

OncoSil™ treatment

What happens during the OncoSil™ procedure	6
Will I have to stop my chemotherapy to receive OncoSil™?	6
Should I stay at the hospital after the OncoSil™ treatment?	6
What are the possible side effects related to any part of this treatment?	7
What are the possible side effects related to interactions with other medicines I am taking at the same time?	9
What are the radiation considerations following the OncoSil™ implantation?	11
What are the other considerations following the OncoSil™ implantation?	11





How does **OncoSil™** work?

- OncoSil™ is injected directly into the pancreatic tumour under endoscopic ultrasound image guidance
- The purpose of the OncoSil™ device is to deliver radiation from Phosphorous-32 (P-32) directly into your tumour to destroy cancer cells
- Once implanted, 98% of the radiation will be delivered in 81 days and the OncoSil™ microparticles will remain permanently in your tumour; they have been tested to ensure long-term safety
- The beta radiation emitted by the OncoSil™ travels a short distance to the tumour tissue causing direct damage to the cancer cell DNA
- This damage makes the cancer cells incapable of further cell division and proliferation
- By stopping cell division and proliferation, OncoSil™ can prevent the cancer cells from multiplying and may ultimately shrink the tumour mass as the cancer cells eventually die

What is **OncoSil™**?

OncoSil™ is a single-use brachytherapy (internal radiation) device used to deliver a pre-determined dose of beta radiation directly into cancerous tissue.

OncoSil™ carries the active component radioactive Phosphorous (P-32) microparticles. These microparticles are tiny, and range in diameter from 28 to 32 micrometres, which is smaller than the width of a human hair. Once implanted, the OncoSil™ microparticles will remain permanently in your tumour.

Who performs the OncoSil™ treatment?

The OncoSil™ implantation procedure is performed in a licensed treatment facility by an endoscopist and a nuclear medicine physician.

Who is OncoSil™ suitable for?

OncoSil™ is intended for the treatment of patients with locally advanced unresectable pancreatic cancer, in combination with gemcitabine-based chemotherapy.



OncoSil™ treatment



What happens during the OncoSil™ procedure?

The OncoSil™ implantation procedure is performed in a licensed treatment facility by an endoscopist and a nuclear medicine physician.

- OncoSil™ Microparticles are suspended in a specially formulated Diluent for implantation
- An endoscope is guided into the upper intestine using ultrasound imaging
- A needle is then guided through the endoscope and into the target tumour
- Once there, the OncoSil™ Microparticle suspension, containing a pre-determined amount of radiation, is injected directly into the tumour
- 98% of the radiation is delivered within 81 days and the Microparticles remain in the tumour permanently

Will I have to stop my chemotherapy to receive OncoSil™?

Generally, the OncoSil™ treatment is performed in the resting week of chemotherapy cycles, so there is no need to interrupt the chemotherapy. However, chemotherapy should not be administered within 48 hours either side of OncoSil™ implantation.

Should I stay at the hospital after the OncoSil™ treatment?

OncoSil™ implantation is an outpatient procedure, although some patients may be required to stay overnight depending on the treating clinician's assessment or local regulations.

What are the possible side effects related to any part of this treatment?

Medical treatments often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or if you would like more information about side effects and risks of this treatment, please ask your doctor.

Side effects related to the implantation procedure

Like other endoscopy procedures, endoscopic ultrasound is typically well tolerated. However, potential risks include:

- Pain, fever, feeling sick and dizzy or faint, bloating and/or a sore throat, however these symptoms are usually short-lived and easily treated
- Side effects related to medicines used as part of the procedure such as the sedative or anaesthetic
- Incorrect placement of OncoSil™ Microparticles
- Uncommon or rare complications of an endoscopic procedure include bleeding or a tear of the stomach or duodenum. In addition, with needle insertion into the pancreas, there is a small risk of bleeding, infection or inflammation (known as pancreatitis)
- Following treatment with OncoSil™, some radioactivity may be detected in faeces (stools) or in the blood and urine. These amounts are small and have not been associated with any harm



OncoSil™ treatment

Possible side effects (cont'd)

Side effects related to the OncoSil™ treatment

In a clinical trial looking at the safety and efficacy of OncoSil™, the majority of side effects were believed to be due to either chemotherapy or cancer. However, those side effects that were possibly or probably related to OncoSil™ treatment and/or the endoscopy procedure included:

- Fatigue or tiredness
- Abdominal pain or discomfort
- Gastrointestinal effects – in particular, nausea, indigestion and reflux
- Abnormal blood results – in particular, reduced white blood cells and platelets in the blood



Side effects related to chemotherapy

OncoSil™ is used in combination with chemotherapy. Like other medicines that treat cancer, the chemotherapy you receive may have unwanted side effects, some of which may be severe. You may need medical treatment if you get some of the side effects. For more information about side effects and risks of chemotherapy, please ask your doctor.

What are the possible side effects related to interactions with other medicines you are taking at the same time?

The safety of OncoSil™ has not been established in the presence of other medicines, with the exception of certain chemotherapy drugs (gemcitabine + nab-paclitaxel). If you are taking other medicines at the same time you are to receive OncoSil™, you should discuss this with your doctor.

What are the radiation safety considerations following the OncoSil™ implantation?

The radiation will only travel a short distance (i.e. 2.76 mm on average) inside your tumour and therefore very little radiation will leave your body.

Whilst this does not represent a radiation hazard to your family or members of the public, there may be a small amount of radiation present in your urine, blood and/or faeces, and therefore you should follow some important safety practices – these are listed overleaf.



OncoSil™ treatment

Radiation safety considerations (cont'd)

Follow this guidance for two weeks after your OncoSil™ treatment:

General interactions

Groups vulnerable to radiation exposure, such as pregnant women, infants and children, should avoid unnecessary contact with the patient for two weeks.

Bathroom use

- Flush the toilet twice after use
- Wipe toilet seat and handle with a disinfecting wipe (Clorox or similar) folding it inside itself, so that used sections are covered
- Wash hands thoroughly with soap and warm water

General clean up

- If any spills of bodily fluids occur, promptly clean up, wearing disposable gloves
- Place gloves and all articles used in the clean-up in a bag and dispose of them in normal household waste
- If any bodily fluids transfer to clothing or bottom of shoes, promptly wash them separately



What are the other considerations following the OncoSil™ implantation?

Intimacy

The safety of OncoSil™ has not been established in patients who are pregnant or who, within 12 months of implantation, become pregnant, nor has the safety of OncoSil™ been established for future children of patients who are pregnant at the time of implantation, or who, within 12 months of implantation, become pregnant. Therefore, the use of contraceptives by both female and male patients is recommended for a period of 12 months following the OncoSil™ treatment.

Breastfeeding

The safety of OncoSil™ has not been established in children being breastfed by patients at the time of implantation or subsequent to implantation. Therefore, it is recommended that patients do not breastfeed for a period of at least 12 months following an OncoSil™ treatment.

Other medical procedures

Upon discharge, you will be provided with a small card outlining your OncoSil™ treatment, which you should carry with you for three months to explain your procedure to any other healthcare professional who may need this information.

For subsequent appointments (e.g. imaging, dental or any invasive procedures) made within three months of OncoSil™ treatment, please ensure you inform the healthcare professional of your OncoSil™ implant when booking your appointment.



INTENDED USE / INDICATIONS FOR USE:

OncoSil™ is intended for intratumoural implantation into a pancreatic tumour via injection under endoscopic ultrasound guidance. OncoSil™ is indicated for the treatment of patients with locally advanced unresectable pancreatic cancer, in combination with gemcitabine-based chemotherapy.

OncoSil™ is a registered trademark of OncoSil Medical Ltd. COMM 23-011.