

Take-Home Information for OncoSil™-Treated Patients and Families

You are being released from this hospital after having received treatment with OncoSil™. OncoSil™ carries the active treatment “radioactive Phosphorous (P-32)” particles. These particles are tiny, and range in diameter from 28 to 32 micrometres, which is smaller than the width of a human hair (which typically ranges in width from 40 to 120 micrometres). The Microparticles are manufactured by combining highly pure silicon with phosphorous, to produce grey-black Microparticles. Once implanted, the OncoSil™ particles will remain permanently in your tumour and have been tested to ensure long-term safety.

The purpose of the OncoSil™ device is to deliver radiation from Phosphorous-32 (P-32) directly into your tumour to destroy cancer cells.

The Diluent comprises of inactive pharmacopeia grade excipients and performs as a carrier to facilitate implantation of the Microparticles into target treatment tumour.

1. 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 side 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.

1.1 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 may occur, 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™ particles.
- 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.

1.2 OncoSil™ Treatment

OncoSil™ has been tested in combination with chemotherapy in clinical studies in patients with pancreatic cancer. The majority of side effects were believed by the researchers 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.

The researchers noted that two-thirds (66%) of these side effects could also have been caused by chemotherapy, therefore it is not easy to know whether or not such complications were directly related to OncoSil™ treatment.

There is also the very small risk of unintentional radiation damage to nearby normal tissue, such as the pancreas, the stomach, small intestine and large intestine, due to the OncoSil™ implant. Potential late radiation side effects could include: bowel ulceration, irritation of the lining of the stomach or

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intestines (enteritis), inflammation of the lining of the lungs (pleurisy), inflammation of the lungs (radiation pneumonitis), gastrointestinal bleed, abnormal passage within body tissue (fistula) and abnormal narrowing of a bodily passage (stricture).

Treatment with OncoSil™ will add to your overall lifetime exposure to radiation. Exposure to radiation over a long time may be associated with an increased risk of cancer. The information gained from clinical studies suggests that the risk of this happening is very small.

There is also a risk of receiving lower doses of the standard chemotherapy regimen, should unforeseen complications related to the OncoSil™ radiation treatment arise.

There may be other side effects or discomforts from the OncoSil™ implantation which are not yet known.

1.3 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 serious. 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.

2. What are the possible side effects related to interactions with other medicines you are taking at the same time (concomitant medicines)?

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

3. What are the radiation considerations following OncoSil™ implantation?

The radiation will only travel a short distance (i.e. 0.11 inches or 2.76 mm) 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 there are important safety practices listed below that you should follow:

3.1 General Interactions (for 2 weeks following OncoSil™ treatment)

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

3.2 Bathroom Use (for 2 weeks following OncoSil™ treatment)

- 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.

3.3 General Clean Up (for 2 weeks following OncoSil™ treatment)

- 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.
- Continue these practices for a period of two weeks after an OncoSil™ treatment.

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4. What are the other considerations following OncoSil™ implantation?

4.1 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™ procedure.

4.2 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™ procedure.

4.3 Other Medical Procedures

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

For subsequent appointments (i.e. pathology, imaging, dental, etc. 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.

If you require extra care or support with your day-to-day activities, following your OncoSil™ implantation, then please discuss this with your physician.

The device is MR Safe – the implanted device does not contain any metallic component.

5. What to do in the event of death within 3 months of the OncoSil™ implant?

In the event of death within three months of your OncoSil™ treatment, please ensure that a family member advises your doctor. Your doctor is advised to contact the Coroner and provide contact details of the Radiation Safety Officer at the hospital. The Radiation Safety Officer's contact details for your doctor are listed below:

Questions or Concerns

Radiation Safety Officer		Treating Physician (your doctor)	
Name		Name	
Phone (Incl. after hours)		Phone (Incl. after hours)	
Email		Email	

Please contact the Radiation Safety Officer for any radiation questions you or your family members may have.

For any other queries, please contact your doctor for any medical-related questions.