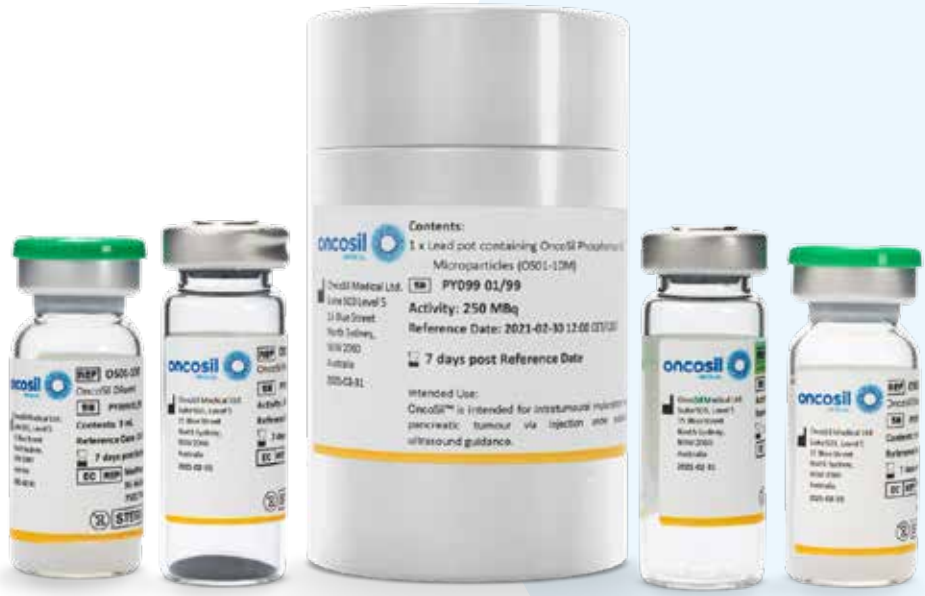
OncoSil™

Intratumoural placement of ^{32}P for locally advanced pancreatic cancer

OncoSil™ is a single-use brachytherapy device that has received breakthrough[1-2] device designation in the European Union, United Kingdom and the United States for the treatment of unresectable locally advanced pancreatic cancer in combination with chemotherapy.

OncoSil™ comprises of Phosphorous-32 (^{32}P) Microparticles suspended in a specially formulated Diluent. The Microparticles are a permanent implant which contain Phosphorous-32 (^{32}P), a pure beta-emitter radioisotope with a physical half-life of 14.27 days. In therapeutic use, 98% of the radiation is delivered within 81 days, which gives an absorbed dose equivalent to 100 Gy.[3]



Intended/Indication 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.

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The half-life, 14.27 days, of the device provides flexibility for dose preparation. Radiation delivered within 81 days gives an absorbed dose equivalent to 100 Gy.[3]

Day of Implantation Relative to Reference Date	Vial Total Radioactivity MBq
–2	276
–1	262
0	250
+1	238
+2	227
+3	216
+4	206
+5	196
+6	187
+7	178

Day of implantation with associated total vial radioactivity in MBq

Storage

The Microparticles and Diluent should be stored at room temperature. Do not freeze the Diluent.

Shelf Life

24 hours from the time of dose preparation, and the patient dose must be implanted within 7 days from the reference day.

Treatment

Generally an OncoSil™ implantation is an outpatient procedure, however the treating clinicians responsible for the patient's care will determine if admission is required.

The predefined Suspension Preparation Protocol of OncoSil™ has a final radioactive concentration of 6.6 MBq per mL.

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REFERENCES: 1. US Food and Drug Administration (FDA) Breakthrough Device Designation for use in combination with systemic chemotherapy. **2.** The British Standards Institute (BSI) designated the device as a breakthrough product under MEDDEV. April 2020 for use in combination with gemcitabine-based chemotherapy. **3.** OncoSil™ System Instructions for Use.

This information is intended for healthcare professionals only. All medical treatments carry benefits and risks. For safety related information, please refer to the OncoSil™ System Instructions for Use.

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