

Targeted Approach • Positive Impact

Intratumoural placement of ³²P for locally advanced pancreatic cancer



We believe our technology will have a truly positive impact in oncology.

OncoSil Medical is a global medical device company focused on Interventional Oncology.

Our mission is to improve the outcomes for people living with cancer by utilising the selected and targeted intratumoural placement of Phosphorous-32 (³²P) Microparticles in combination with chemotherapy.¹

OncoSil[™] is our brachytherapy device. Its targeted approach enables healthcare professionals to deliver a greater radiation dose directly into the tumour compared to external beam radiotherapy, while sparing surrounding critical organs.²

Targeted approach. Positive impact.

OncoSil[™] enables the TaRgeted Intratumoural Placement of Phosporous-32 (³²P) or TRIPP, a single, minimally invasive procedure used in combination with chemotherapy¹ for the treatment of locally advanced pancreatic cancer (LAPC).

OncoSil[™] device treatment pathway*

CHEMOTHERAPY¹ CONTINUATION OF CHEMOTHERAPY¹ ONCOSIL[®] IMPLANTATION

*The above diagram is a treatment pathway recommendation only and is intended to provide guidance on the normal course of patient management when considering the use of OncoSil[®] for the treatment of unresectable locally advanced pancreatic cancer in combination with chemotherapy.¹ Chemotherapy should not be administered within 48 hours either side of the OncoSil[®] implantation.





Targeted approach

During the TRIPP procedure, OncoSil[™] is administered directly into the pancreatic tumour via endoscopic ultrasound (EUS) guidance – an approach which offers:



Maximised dose to tumour – 98% of radiation from one fraction delivered over 81 days



(Per Protocol [PP] Cohort)³

Acceptable side-effect profile - well tolerated by patients

 no evidence of additional risk from combining OncoSil[™] with contemporary systemic chemotherapy regimens³



Targeted radiation delivery to tumour **protects** surrounding organs²



Negligible radiation risk to nuclear medicine staff

Positive impact

The results from the PanCO clinical study demonstrate the benefits of incorporating OncoSil[™] into the treatment strategy for patients with unresectable LAPC.³

High rates of resection

Downstaging to eligibility for

resection with curative intent

33% Patients 14/42

was reached in 33% of patients. Resection was achieved in almost **1 in 4** patients.



Survival of PanCO Study vs. Victoria & NSW (Australia) Pancreatic Cancer Registry^{3,10} Survival Estimates by Resectability in Treated Group (from Diagnosis, 2016-2019)

Comparison vs. PanCO Cohorts (from Study Enrolment, 2017-2018)



Time to event adjusted to day of OncoSil[™] implantation = Day O



Incidence of Treatment-Emergent Adverse Events (TEAEs) over Time by Causality

15.5

Favourable surgical margins



8 out of 10 of those patients who were resected had RO surgical margins. Patients for whom RO margins are achieved have been shown to have improved

survival outcomes vs. those with R1 margins.⁷⁸

Prolonged median overall survival

Months Patients treated with OncoSil[™] in combination with chemotherapy¹ experienced a 20% reduction in risk of death* and median overall survival of 15.5 months

* When compared to CT-only and ICT/CCRT studies⁹

Maximum Change in Tumour Volume from Baseline by Outcome³ **PP Cohort Prior to Surgical Resection**

Tumour Volume, Evaluable Patients	ITT Population, n (%) (N=47/50)	PP Population, n (%) (N=42/42)
Median (range) maximal decrease, %	–51.6% (+72.2% to –89.9%)	-51.9% (+11.1% to -89.9%)
Mean (std dev) maximal decrease, %	-44.0% (34.8)	-49.1% (26.4)
p-value	p<0.0001	p<0.0001



Technical overview

OncoSil[™] is a single-patient, single-use brachytherapy device, comprising Phosphorous-32 (³²P) Microparticles suspended in a specially formulated Diluent. The Microparticles are a permanent implant which contain Phosphorous-32 (³²P), a pure beta-emitter radioisotope.



Technical specifications

- Physical half-life: 14.27 days
- Absorbed dose: In therapeutic use, 98% of the radiation is delivered within 81 days, giving an absorbed dose equivalent to 100 Gy¹⁰
- **Final radioactive concentration: 6.6 Mbq/mL** (following predefined suspension preparation protocol)
- Storage: Room temperature. Do not freeze the Diluent
- Shelf life: 24 hours from the time of dose preparation
- Endoscope flush: Simple saline flush minimises the risk of endoscope contamination

Simple and flexible preparation and dosing

OncoSil[™] has been specifically developed to offer:

24-hour shelf life to enable pre-planning and aid workplace efficiency

(24)

Flexibility in treatment planning due to a wide 10-day treatment window

Confidence in achieving a total dose to tumour of 100 Gy, delivered over the 81-day time period of sustained OncoSil[™] activity

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 Relative to Reference Date -2 -1 0 +1 +2 +3 +4 +5 +6 +7

ay of implantation with associated total vial radioactivity in MBq

Treatment

Generally, an OncoSil[™] implantation is an outpatient procedure. However, the treating clinicians responsible for the patient's care should determine if admission is required.

Certification: Treatment facilities and personnel

The OncoSil[™] System is to be used in a licensed treatment facility. These facilities must hold an appropriate license for the isotope Phosphorous-32 (³²P), which mandates that these institutions will have an appointed Radiation Safety Officer (RSO)/Radiation Protection Officer (RPO) who will be the primary contact for all matters related to radiation safety.

The OncoSil[™] suspension should be prepared within the Nuclear Medicine Department or within a licensed Radiopharmacy. Only appropriately licensed personnel, who have been trained in the preparation of the OncoSil[™] suspension may prepare the product for implantation.

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. The OncoSil[™] System is supplied sterile and is intended for single-patient, single-use.



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References:

1. OncoSil[™] System Instructions for Use.

- 2. Skowronek J. J Current Status of Brachytherapy in Cancer Treatment Short Overview, 2017; 9: 581-589.
- 3. Ross PJ, Wasan HS, Croagh D et al. Results of a Single-Arm Pilot Study of ³²P Microparticles in Unresectable Locally Advanced Pancreatic Adenocarcinoma with Gemcitabine/Nab-Paclitaxel or FOLFIRINOX Chemotherapy. ESMO Open February 2022; 7 (1): 100356.
- 4. OncoPaC-1. ClinicalTrials.gov Identifier: NCTO3076216.
- 5. US Food and Drug Administration (FDA) breakthrough device designation for use in combination with systemic chemotherapy.
- 6. The British Standards Institute (BSI) designated the device as a breakthrough product under MEDDEV, April 2020, for use in combination with gemcitabine-based chemotherapy.
- Balaban EP, Mangu PB and Yee NS. Locally Advanced Unresectable Pancreatic Cancer: American Society of Clinical Oncology Clinical Practice Guideline Summary. J Oncol Pract 13, 265-269, doi:10.1200/jop.2016.017376 (2017).
- 8. Ducreux M, Sa Cuhna A, Caramella C et al. Cancer of the Pancreas: ESMO Clinical Practice Guidelines for Diagnosis, Treatment and Follow-Up. Ann Oncol 26 Suppl 5, v56-68, doi:10.1093/annonc/mdv295 (2015).
- 9. Allerdice, N Wilson, D Turner et al. Indirect Treatment Comparison of PanCO, a Pilot Study of OncoSil P-32. Microparticles Combined with Gemcitabine + Nab-Paclitaxel or FOLFIRINOX Chemotherapy, Versus Standard-of-Care Treatment in Unresectable Locally Advanced Pancreatic Cancer. Presented at ESMO World Congress on Gastrointestinal Cancer, 1-4 July 2020 (Abs. P-260).
- 10. Croagh D. Presented at the E-AHPBA Congress, Sept 2021. Symposium 'Downstaging Unresectable LAPC. Discussion on the Resection Data from the PanCO Study'.

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