ASX Announcement

9 June 2026

Investor Presentation FDA Update & TRIPP-FFX Initial Results

Sydney, Australia – 9 June 2026: OncoSil Medical Limited (ASX: OSL) is pleased to the release the following investor presentation to the market.

OncoSil Medical will be hosting an investor webinar at 10.30 am AEST today, where the Company's CEO & Managing Director Nigel Lange will provide an update on recent FDA correspondence and discuss the significance of the preliminary results of the TRIPP-FFX trial.

Investors wanting to register to attend this webinar can use the following link**:**

https://us02web.zoom.us/webinar/register/WN_JHEJ453JQe2g1BENlQ47PA

After registering, you will receive a confirmation email containing information about joining the webinar.

Authorisation & Additional Information

This announcement was authorised by the Board of Directors of OncoSil Medical Limited.

For further information, please contact:

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About OncoSil Medical

OncoSil Medical (ASX:OSL) is a global medical device company focused on Interventional Oncology. OncoSil Medical's mission is to improve the outcomes for people living with cancer by utilizing the selected and targeted intratumoural placement of Phosphorus-32 (^{32}P) Microparticles in addition to chemotherapy.

OncoSil Medical has developed OncoSil™ device for the treatment of unresectable locally advanced pancreatic cancer. 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.

Pancreatic cancer is the 12th most common cancer in men and the 11th most common cancer in women across the globe, with 500,000 new cases detected every year[1]. Since pancreatic cancer is generally diagnosed at a later stage, it has a poor prognosis for long-term survival.

OncoSil™ has received CE Marking approval, providing marketing authorisation in both the EU and the UK. OncoSil™ is designated as a breakthrough device in both Europe and the United States. It is currently approved for sale in 30+ countries including European Union, United Kingdom, Australia, Türkiye and Israel, with commercial treatments using the device already undertaken in Spain, Italy, Austria, Germany, Greece, Türkiye, Portugal, Israel and the UK.

To learn more, please visit: www.oncosil.com/

[1] https://gco.iarc.fr/en

OncoSil MEDICAL

Investor Webinar

FDA Update & TRIPP-FFX Initial Results

CEO & Managing Director, Nigel Lange

9 June 2026

Targeted Approach • Positive Impact

FDA Update

OncoSil Reaches Final FDA Review Stage for Humanitarian Device Exemption Application

U.S. Food and Drug Administration (FDA) confirm all outstanding questions relating to OncoSil's Humanitarian Device Exemption (HDE) application for the treatment of distal cholangiocarcinoma (dCCA) in the United States (U.S.) have been satisfactorily addressed

HDE application advances to the final FDA review stage prior to the approval decision, with only final device labelling and any post-market study updates requested

FDA advises it intends to complete its review within 45 days of OncoSil's final submission which will occur within 30 days and grant the HDE

HDE: Accelerating US Market Access for OncoSil™ in dCCA

What is HDE Pathway?

- Designed for medical devices targeting rare diseases affecting fewer than 8,000 individuals annually
- Permits approval based on demonstration of probable benefit outweighing risk, rather than requiring the extensive clinical evidence of a costly Phase III randomised clinical trial needed for a (Pre-market approval) PMA
- Provides shortened market access with a cost-efficient route

Why HDE is Relevant for OncoSil™ in dCCA

- dCCA is a rare and highly aggressive cancer with limited treatment options and poor prognosis
- OncoSil™ is being positioned as a novel, localized radiation treatment that may address a significant unmet need in this patient population
- Under this approval, OncoSil Medical will be authorised to commercially market and sell the OncoSil™ device in the US*

Strategic Benefit for OncoSil™

- ✓ Reduced clinical development burden and cost (no randomised trial)
- ✓ Earlier US commercial entry opportunity
- ✓ Homogeneous reimbursement landscape
- ✓ Shorter regulatory timeline versus PMA
- ✓ Ability to generate real-world evidence and physician adoption post-approval
- ✓ Establishes US market presence in a high-value oncology indication

HDE Eligibility ⟶ FDA Approval ⟶ Coding & Reimbursement ⟶ Initial Commercialisation ⟶ US Adoption

* Subject to oversight conditions standard under the HDE framework

OncoSil™ Advances to Final Administrative Stage Before Potential FDA HDE Approval

Major Regulatory Milestone Achieved

- On 3 June 2026 (U.S. time), the FDA confirmed that all previously raised questions have been satisfactorily addressed.
- Completion of the substantive review process represents the most advanced stage reached in the Company's U.S. regulatory program.

Final FDA Requirements

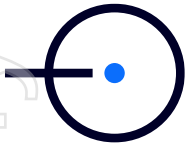
- The FDA has requested submission of:
  - Final device labelling for OncoSil™ device
  - Any updates to the proposed post-market study, if required

Submission deadline: Within 30 days.

Clear Path to Approval

- Following receipt of the requested information, the FDA indicated its intention to complete the review within 45 days and grant the HDE.
- Potential HDE approval would establish OncoSil's first U.S. regulatory approval pathway.

Next Steps & Value Creation Pathway



OncoSil intends to submit the requested information within the FDA's prescribed timeframe of 30 days.

Potential FDA HDE approval will provide a pathway to commercialise OncoSil™ in the US, the world's largest medical device market.

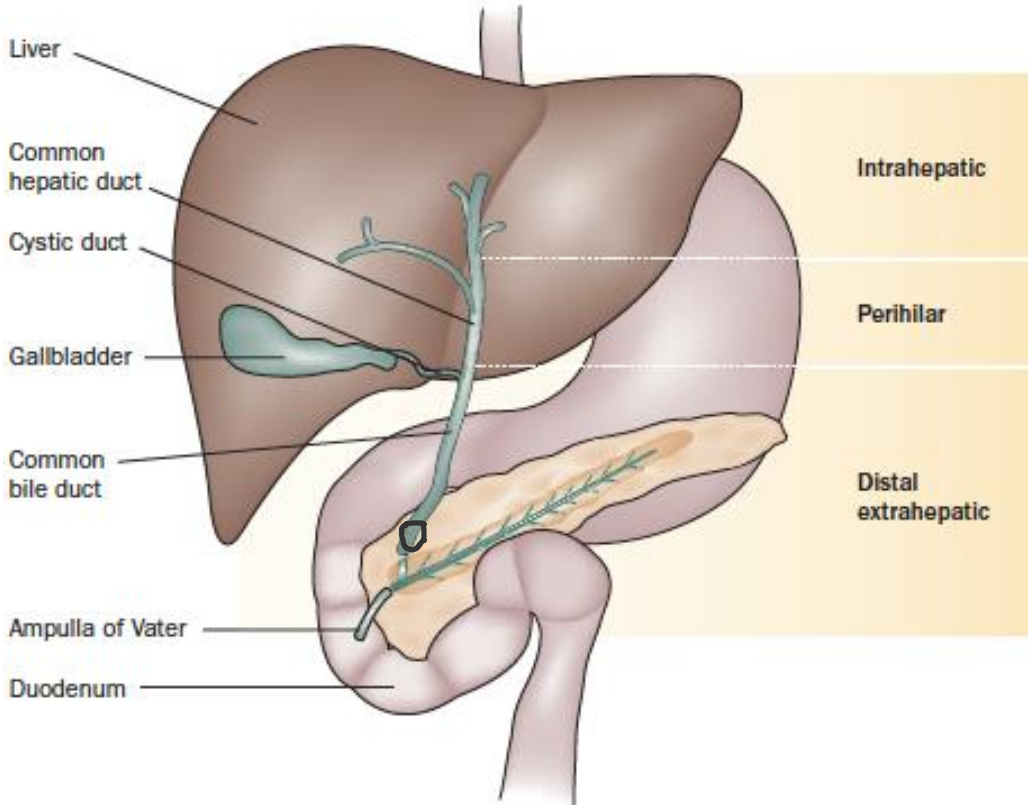
Successful US commercial execution is expected to enhance strategic partnering and acquisition opportunities, consistent with previous transactions (TheraSphere™, Sir-Spheres® etc.) in the oncology sector.

OncoSil is approaching a potentially transformational regulatory milestone, with potential FDA HDE approval providing a pathway to U.S. market entry and creating multiple opportunities for long-term shareholder value creation.

Distal Cholangiocarcinoma (dCCA)

Patients with dCCA have a poor prognosis with limited treatment options and survival

- dCCA develops as a cancerous tumour in the common bile duct within the head of the pancreas.
- Clinical symptoms of the disease are not evident until the tumour has developed to a point that it is difficult to remove with surgery .
- More than 50% of patients who develop dCCA cannot have the tumour removed surgically (the tumour is “unresectable”)[1].
- Treatments for unresectable tumours involve the placement of a stent, chemotherapy, external radiation therapy, or a combination of the two.
- Side effects due to chemotherapy and radiation therapy are considerable and have a negative impact on the quality of life for the patient.
- OncoSil™ has shown considerable promise for dCCA[2] and is the basis for the HDE.
- The advantage of OncoSil™ is the ability to deliver a high radiation dose to the target dCCA tumour with minimal side-effects.



References:
1. Hester CA, Dogeas E, Augustine MM, et al. Incidence and comparative outcomes of periampullary cancer: A population-based analysis demonstrating improved outcomes and increased use of adjuvant therapy from 2004 to 2012. J Surg Oncol 2019; 119:303-317. doi: 10.1002/jso.25336
2. Ross PJ et al. Results of a single-arm pilot study of ^{32}P microparticles in unresectable locally advanced pancreatic adenocarcinoma with gemcitabine/nab-paclitaxel or FOLFIRINOX chemotherapy. *ESMO Open* February 2022; 7 (1): 100356.

Treatment for Unresectable dCCA and Impact on Quality of Life (QOL)

The dCCA disease course has a negative impact on QOL for the patient

- Since most dCCA patients have a stent implanted, the challenge for clinicians is to maintain the patency of the common bile duct.
- Invariably the stent occludes within 4-6 months due to tumour development .
- This results in significant complications including extreme abdominal pain and cholangitis (inflammation and infection) which necessitates admission to hospital:
    - interruption of chemotherapy
    - possible surgery to replace the stent and reopen the bile duct
    - administration of antibiotics to control the infection
- As the disease continues to progress, subsequent re-occlusion of the stent results in repeated admissions to hospital.
- The patient inevitably succumbs to sepsis (systemic infection) and liver or multi-organ failure.

*OncoSil™ has the potential to **control local tumour development** and **maintain bile duct patency**, resulting in **increased quality of life** and **extended survival**.*

TRIPP-FFX Initial Results

TRIPP-FFX Met Both Co-Primary Endpoints

- TRIPP-FFX met both co-primary endpoints, supporting the use of OncoSil™ alongside standard-of-care FOLFIRINOX chemotherapy in patients with unresectable LAPC.
- Investigators concluded that toxicities associated with the addition of OncoSil™ to FOLFIRINOX chemotherapy were limited and manageable.
- Encouraging efficacy outcomes observed, including 82.2% (95%CI 65-90%) Local Disease Control Rate (LDCR) at 16 weeks and 18.3 months of median overall survival in patients treated with OncoSil™ plus FOLFIRINOX chemotherapy.
- Planned Change Notification submission to Notified Body to support expansion of the OncoSil™ label to include FOLFIRINOX chemotherapy in late CY2026.
- Ability to accelerate market penetration through inclusion of the current standard-of-care chemotherapy regimen.

TRIPP-FFX: Evaluating OncoSil™ with Standard-of-Care FOLFIRINOX

An open-label, multi-centre, randomized study of TaRgeted Intratumoural Placement of Phosphorous-32 (OncoSil™) in addition to FOLFIRINOX chemotherapy versus FOLFIRINOX chemotherapy alone in patients with unresectable locally advanced pancreatic adenocarcinoma

Objective:

- To assess the safety and efficacy of OncoSil™ when given in addition to standard FOLFIRINOX chemotherapy for treatment of Locally Advanced Pancreatic Cancer – opportunity to provide **label expansion** into standard of care chemotherapy

Study Sites:

- 15 sites in Australia, Belgium, Italy, Spain and UK
- 88 subjects recruited

Primary Endpoint:

- **Safety and Tolerability** as determined by the Adverse Event profile
- **Local Disease Control Rate** (LDCR) at 16 weeks (H_0 55%; H_1 75%)

Secondary Endpoints:

- Local Progression Free Survival (LPFS)
- Progression Free Survival (PFS)
- Time to Symptomatic Progression
- Clinical Benefit Response
- CA 19-9 Response
- Overall Survival (OS)
- Quality of Life
- EQ-5D-3L
- EORTC QLQ-C30
- EORTC QLQ-PAN26
- Pain Scores
- NRS
- EORTC-PAN26 (pain scores)
- Weight loss
- Tumour response (by RECIST v1.1 and tumour volume assessment by central review)
- Surgical resection rate (R0/R1)

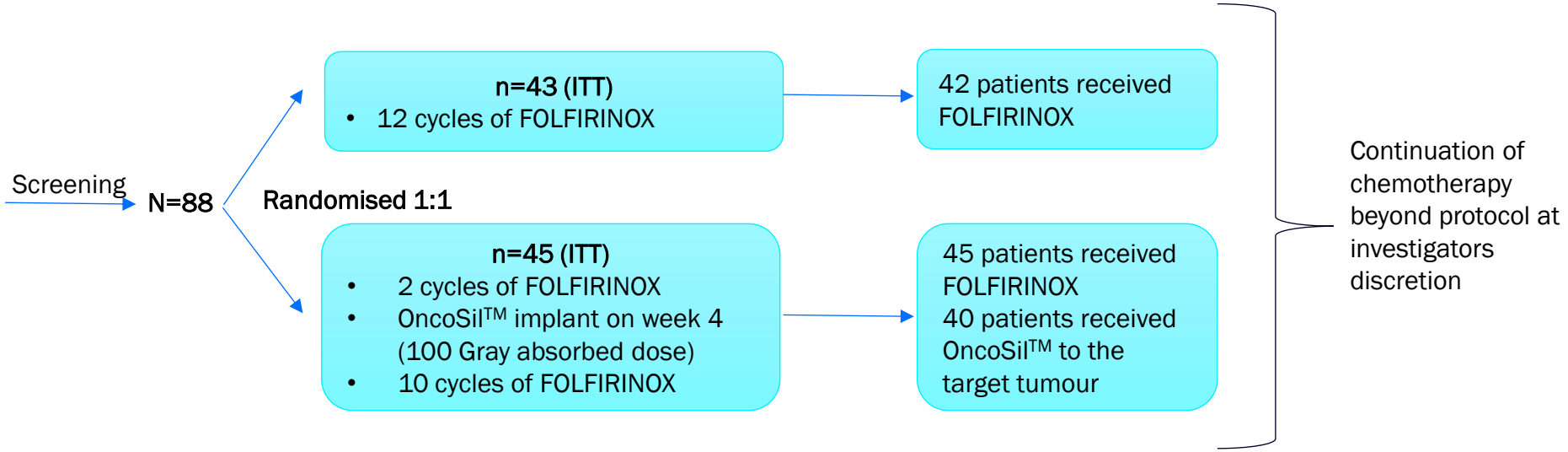
Study Design, Main Eligibility Criteria and Participant Flow

Randomised non-comparative Phase II study design:

- Experimental arm is compared against historical control.
- **The study was not prospectively powered to demonstrate statistically significant differences between study arms – no formal comparison between arms.**
- Control arm functions as a benchmark for validation of historical control.
- **Designed in accordance with the clinical evidence requirements for an existing CE Mark registration under the European Union Medical Device Regulation (EU-MDR).**

Patients with LAPC:

- Written informed consent
- Histologically or cytologically proven pancreatic adenocarcinoma
- Unresectable LAPC (according to NCCN 2023 v2 guidelines)
- Karnofsky Performance Status ≥ 70
- No prior radiotherapy or chemotherapy for pancreatic cancer
- Age 18+
- Considered fit to receive combination chemotherapy



ITT: Intent-to-treat (as randomised)

Growing Body of Evidence - Efficacy*

	PanCO [1]	Meta-Analysis of Phase 2/3 Trials [2]	TRIPP-FFX	
	gemcitabine + nab-paclitaxel or FOLFIRINOX + OncoSil™ (ITT; n=50)	Chemotherapy or Chemo-radiotherapy (n~6,000 across 74 study arms)	FOLFIRINOX (ITT; n=43)	**FOLFIRINOX + OncoSil™ (ITT; n=45)**
LDCR at 16 weeks (95% CI)	82.0% (68.6–91.4%)	not reported	86.0% (72–95%)	**82.2% (68–92%)**
Best Overall Response				
Partial Response	29.8%	19.2%	41.9%	**57.8%**
Stable Disease	66.0%	not reported	48.8%	**33.3%**
Progressive Disease	4.3%	not reported	9.3%	**8.9%**
Disease Control Rate	90.0%	75.6%	90.7%	**91.1%**
Surgical Resection	23.8%	8.0%	14.0%	**11.1%**
R0 margins**	80%	not reported	16.7%	**60%**
Local PFS, median months (95% CI)	9.9 (7.3–12.6)	not reported	11.8 (7.8–nc)	**12.9 (7.8–nc)**
PFS, median months (95% CI)	9.3 (5.7–11.3)	7.8 (7.1–9.1)	9.9 (7.5–nc)	**12.1 (7.8–15.2)**
Overall Survival, median months (95% CI)	15.2 (11.3–18.8)	13.6 (12.7–13.9)	15.9 (10.2–nc)	**18.3 (12.8–22.2)**

References:

1. Ross PJ et al. Results of a single-arm pilot study of ^{32}P microparticles in unresectable locally advanced pancreatic adenocarcinoma with gemcitabine/nab-paclitaxel or FOLFIRINOX chemotherapy. *ESMO Open* February 2022; 7 (1): 100356.
2. OncoSil Medical Ltd. Data on file.

* Data presented are preliminary and based on ongoing analyses. Final results may be updated following database lock and completion of all planned statistical analyses.
** R0 margin: complete microscopic removal of the tumour.

Interpretation of Efficacy Results

- The TRIPP-FFX study **achieved its primary efficacy endpoint**, demonstrating a meaningful improvement in LDCR at 16 weeks compared with the historical benchmark of 55%.
- For LDCR, the pre-specified success criterion for the trial required the lower bound of the 95% confidence interval to exceed the 55% threshold and the interval to reach the 75% target. The observed result of a 95% confidence interval of 68% to 92% satisfied both conditions decisively.
- Results were **sufficiently strong** to confirm that the 16-week LDCR **exceeded the predefined success threshold (H_0)**.
- The study was **not designed** to compare outcomes between treatment groups, so **efficacy results should be interpreted against the historical control** rather than between study arms.
- Any comparisons between study groups will be conducted in future exploratory analyses and may help guide further research.
- The TRIPP-FFX efficacy data is **consistent** with prior published data from the PANCO study.

Growing Body of Evidence - Safety*

	PanCO [1]	TRIPP-FFX	
	gemcitabine + nab-paclitaxel or FOLFIRINOX + OncoSil™ (PP – Safety Cohort)	FOLFIRINOX (Safety Cohort)	**FOLFIRINOX + OncoSil™ (Safety Cohort)**
Grade ≥3 AEs	81.0%	60.9%	**70.7%**

- 40 patients treated with OncoSil™ + FOLFIRINOX are **sufficient** to establish the combination's safety profile.
- The Safety Review Committee (SRC) conducted scheduled safety reviews throughout the trial and approved continuation of the study at each assessment. Following review of the safety data, the Principal Investigators concluded that the addition of OncoSil™ to FOLFIRINOX was safe and demonstrated an acceptable tolerability profile. These findings support the conclusion that the study **met its safety endpoint**.
- The trial was not powered for statistical comparisons between study arms. Outcomes should be evaluated against historical controls.
- The FOLFIRINOX-only arm confirmed the expected adverse event profile associated with standard chemotherapy.

Reference:
1. Ross PJ et al. Results of a single-arm pilot study of ^{32}P microparticles in unresectable locally advanced pancreatic adenocarcinoma with gemcitabine/nab-paclitaxel or FOLFIRINOX chemotherapy. *ESMO Open* February 2022; 7 (1): 100356.

* Data presented are preliminary and based on ongoing analyses. Final results may be updated following database lock and completion of all planned statistical analyses.

Principal Investigators Endorse Clinical Significance of TRIPP-FFX Results

Michele Milella, Professor of Medical Oncology, University of Verona, Italy and Principal Investigator of TRIPP-FFX Study:

"As TRIPP-FFX was designed as a randomized but non-comparative study, the significance of these findings lies in the successful achievement of the predefined clinical endpoints and the consistency of the overall data, with the control arm serving primarily as a benchmark against historical outcomes rather than for direct statistical comparison.
In this context, the results are consistent with previously reported findings from historical datasets, including the PANCO trial and the OSPREY Registry and favourably compare with chemotherapy alone or the combination of chemotherapy and other forms of local treatment commonly used in this difficult-to-treat disease setting."

Giuseppe Malleo, Associate Professor of Surgery at the University of Verona, Italy and Principal Investigator of TRIPP-FFX Study:

"The TRIPP-FFX study marks an important step forward in the treatment of unresectable locally advanced pancreatic cancer, particularly from a multidisciplinary care perspective. The achievement of both primary endpoints supports the continued clinical development of the OncoSil™ device and adds to the growing body of evidence generated through previous studies and real-world experience.
From a surgical standpoint, the study confirms the possibility to downstage selected patients towards surgical resection. Further detailed analysis will help us better understand which patients may benefit the most, and I would like to acknowledge the strong commitment of everyone involved in the study, especially the patients and clinical teams whose contribution made these results possible."

Next Steps & Commercial Implications

TRIPP-FFX study met both primary endpoints, with limited and manageable toxicities and encouraging LDCR and survival endpoints following the addition of OncoSil™ device to FOLFIRINOX chemotherapy.

2H CY2026

Preliminary results will be submitted to a major oncology congress.

A Change Notification to the Company's EU Notified Body will be submitted to add FOLFIRINOX to the OncoSil™ product label.

Commercial Implications	
Regulatory	**Clinical**
Supports label expansion to include FOLFIRINOX	Validates OncoSil™ in the current standard-of-care setting
Market Access	**Commercial**
Accelerates market penetration	Strengthens physician adoption pathway

Upcoming Milestones in CY2026

1H CY2026

- TRIPP-FFX Last Patient Last Visit
- OSPREY interim data accepted at ESGE Days
- OSPREY interim data presented at ESGE Days
- TGA Approval in Australia
- TRIPP-FFX Clinical Trial Results
- HDE Status Update FDA
- OncoSil™ device US label filing to FDA (HDE)

2H CY2026

- FDA HDE approval for distal cholangiocarcinoma (dCCA)
- Completion of Cyclotek manufacturing validation
- G-BA trial commencement
- Presentation of TRIPP-FFX initial results at an upcoming major oncology congress
- EU regulatory submission – percutaneous label change (PANCOSIL)
- EU regulatory submission – FOLFIRINOX label change (TRIPP-FFX)
- Commercial launch from Cyclotek manufacturing facility in Sydney*
- Launch of OncoSil™ device in Australia
- Launch of OncoSil™ device in the United States (1H CY2027)*

* Subject to approvals

OncoSil MEDICAL

INTENDED USE / INDICATIONS FOR USE: The OncoSil™ System is intended to induce prolonged local tumour control and tumour size reduction in patients with locally advanced unresectable pancreatic cancer, in addition to gemcitabine-based chemotherapy, by implantation of radioactive Phosphorous-32 Microparticles into pancreatic tumours under endoscopic ultrasound guidance. OncoSil™ is indicated for the treatment of patients with locally advanced unresectable pancreatic cancer, in addition to gemcitabine-based chemotherapy.

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.

Targeted Approach • Positive Impact

www.oncosil.com