

THERAKOS[®] ECP EDGE

TRANSFORMING
SERVICE INTO
SOLUTIONS

Your complete partner
for >25 years in
optimizing delivery of
ECP immunomodulation
in practice.*



ECP = extracorporeal photopheresis

* First licensed in Canada in 1999 for the palliative treatment of the skin manifestations of CTCL unresponsive to other forms of treatment.



Therakos CellEx
PHOTOPHERESIS SYSTEM

INDICATION

The THERAKOS[®] CELLEX[®] Photopheresis System is indicated for use in the ultraviolet-A (UVA) irradiation, in the presence of the photoactive drug 8-methoxypsoralen (8-MOP), of extracorporeally circulating leukocyte-enriched blood, in the palliative treatment of the skin manifestations of cutaneous T-cell lymphoma (CTCL) and systemic sclerosis (SSc).

See Important Safety Information on back page.

Helping you optimize delivery of ECP immunomodulation in practice

With over 25 years of experience in Canada, our dedicated team focuses solely on photopheresis.*
We provide expert service and streamlined support tailored to this specialized therapy.



THERAKOS® ECP Experience

THERAKOS experience and support services in Canada



THERAKOS® CELLEX® System

Designed with you and your patients in mind



THERAKOS ECP Immunomodulation®

Procedure, mechanism of action, and clinical profile



Accessing THERAKOS ECP

Your dedicated team for onboarding and ongoing support

One Team. One Device.



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Important Safety Information for THERAKOS® CELLEX® Photopheresis Procedure

CONTRAINDICATIONS

Certain underlying medical conditions contraindicate THERAKOS CELLEX Photopheresis, including:

- Patients who cannot tolerate extracorporeal volume loss during the leukocyte enrichment phase
- Patients exhibiting idiosyncratic or hypersensitivity reactions to 8-methoxypsoralen/psoralen compounds
- Patients with coagulation disorders or who have had previous splenectomy

WARNINGS & PRECAUTIONS

THERAKOS CELLEX Photopheresis treatments should always be performed in locations where standard medical emergency equipment is available. Volume replacement fluids and/or volume expanders should be readily available throughout the procedure.

- **MR-Unsafe:** Do not expose the device to a magnetic resonance (MR) environment. The device may present a risk of projective injury, and thermal injury and burns may occur. The device may generate artifacts in the MR image, or may not function properly.
- **Thromboembolic Events:** Thromboembolic events, including pulmonary embolism and deep vein thrombosis, have been reported in the treatment of Graft versus Host Disease (GvHD), an indication not approved in Canada. Special attention to adequate anticoagulation is advised when treating patients with GvHD.
- **Concomitant Therapy:** When prescribing and administering THERAKOS CELLEX Photopheresis for patients receiving concomitant therapy, exercise caution when changing treatment schedules to avoid increased disease activity that may be caused by abrupt withdrawal of previous therapy.

ADVERSE REACTIONS

Hypotension may occur during any treatment involving extracorporeal circulation. Monitor the patient closely during the entire treatment.

Transient pyretic reactions, 37.7-38.9°C (100-102°F), have been observed in some patients within 6-8 hours of reinfusion of the photoactivated leukocyte-enriched blood. A temporary increase in erythroderma may accompany the pyretic reaction.

Treatment frequency exceeding labeling recommendations may result in anemia.

Venous access carries a small risk of infection and pain.

Important Safety Information for Methoxsalen Sterile Solution Used in Conjunction with THERAKOS® CELLEX® Photopheresis System

CONTRAINDICATIONS

Methoxsalen Sterile Solution is contraindicated in:

- Patients exhibiting idiosyncratic reactions to psoralen compounds
- Patients with aphakia
- Patients possessing a specific history of a light-sensitive disease state

SERIOUS WARNINGS & PRECAUTIONS

- **Concomitant Therapy:** Exercise care in treating patients who are receiving concomitant therapy (either topically or systemically) with known photosensitizing agents.
- **Carcinogenicity:** Oral administration of methoxsalen followed by cutaneous UVA exposure (PUVA therapy) is carcinogenic. Patients exhibiting multiple basal cell carcinomas or having a history of basal cell carcinoma should be diligently observed and treated.
- **Teratogenicity:** Methoxsalen may cause fetal harm when given to a pregnant woman. Women undergoing photopheresis should be advised to avoid becoming pregnant.
- **Cataractogenicity:** Patients should be told emphatically to wear UVA absorbing, wrap-around sunglasses for twenty-four (24) hours after methoxsalen treatment, any time they are exposed to direct or indirect sunlight and whether they are outdoors or exposed through a window.
- Safety in children has not been established.

FOR MORE INFORMATION

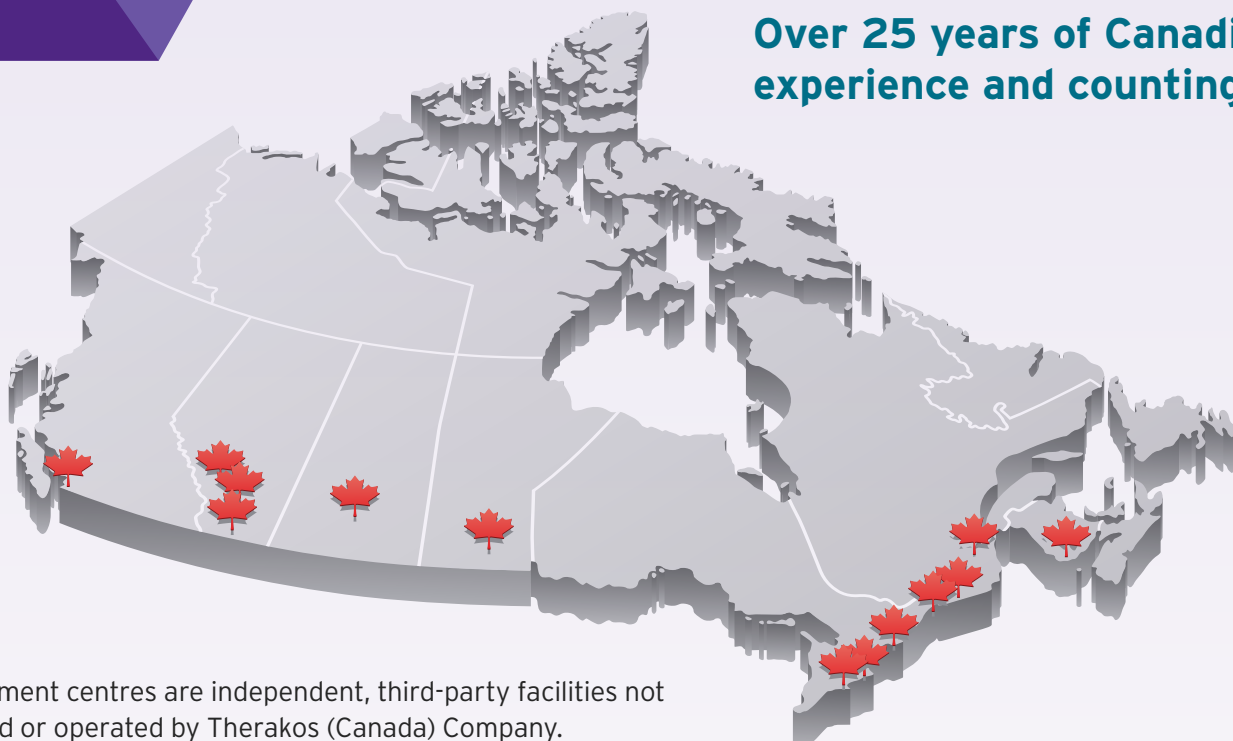
See product monograph for methoxsalen sterile solution (if used in conjunction with the THERAKOS CELLEX Photopheresis System) and the Operator's Manual for the CELLEX system at health-products.canada.ca/dpd-bdpp/ or by calling 1-833-223-4ECP (1-833-223-4327).



THERAKOS ECP EDGE

Where Canadian Photopheresis Care Began

Over 25 years of Canadian experience and counting.*



Treatment centres are independent, third-party facilities not owned or operated by Therakos (Canada) Company.

"The relationships we've built over the years with Therakos have been pertinent to our success as a center. The training provided is invaluable, and the team is always available. It's clear they have a true passion for the work we do."

- Canadian Apheresis Clinical Nurse Educator / Quality Manager[†]

"We have been working with Therakos since 2009 and despite being a small unit, they treat us like we are their only customer. Every year they provide preventative maintenance, and in-person support for Operators to review their practice and to pass on any new information. Our staff feels very supported by Therakos, and it is a pleasure dealing with everyone there."

- Canadian Clinical Resource Nurse[†]

THERAKOS® ECP is used in >300 treatment centres in >30 countries worldwide, with >1.6 million treatments delivered to date.¹

Treatment centre information provided is for informational use only, is subject to change, and may not be comprehensive.

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† Quote from an actual Therakos customer. Individual customer experiences may vary.

Comprehensive Support to Optimize Your Photopheresis Delivery



ON-SITE SUPPORT WHENEVER YOUR CLINIC NEEDS

Complimentary initial training for nurses and other team members

Continuous on-site operator training and troubleshooting to help teams become more confident

Constant procedural support, including device operational learning sessions based on centre-specific needs

Machine repair, servicing and warranty*



ON-DEMAND SUPPORT WHENEVER YOUR TEAM NEEDS

Dedicated hotline for customer, technical, and clinical support

Therakos Institute online training programs and educational activities for practitioners

Educational materials for your patients



ONGOING SUPPORT FROM OUR DEDICATED TEAM

Field engineers provide timely device support and expertise

Clinical specialists deliver personalized operator training

Product support specialists provide remote operator assistance and access to product information

Medical support to address all medical and scientific requests

Business managers offer dedicated product information and support



OTHER LEARNING ACTIVITIES BASED ON CENTRE- SPECIFIC LEARNING NEEDS

Approved activities to suit your specific learning needs, including in-person, virtual, or hybrid sessions

* Applicable only for select service contracts.

Reference: 1. Data on File - Ref-08367. Therakos (Canada) Company.

See Important Safety Information on accompanying material.

THERAKOS ECP EDGE

THERAKOS® CELLEX® Photopheresis System

Purpose-built for photopheresis delivery, and designed to meet the needs of you and your patients

COMPACT DESIGN

The only **all-in-one** device, equipped with four wheels and handle for easy transport within your unit.^{1*}

Dimensions: 163 cm x 58.4 cm x 79 cm
Weight: 166 kg
Required Floor Space: 4614 cm²

STREAMLINED ENGINEERING

Designed for efficiency in ECP administration - **specifically developed to deliver ECP immunomodulation.**¹

One kit for all procedures, helping simplify inventory, training and setup.

One technology interface, with integrated touchscreen monitoring.

FULLY INTEGRATED

Canada's only **fully-integrated ECP system**, designed to enhance ease of use for operators.¹

A single-device workflow that eliminates the need to transfer treatment bags between devices from apheresis to photoactivation.



PATIENT-FOCUSED CARE

Multiple features to help ensure patients receive **safe, adaptable, and well-controlled** treatment.¹

Sterile closed system reduces contamination and reinfusion errors, and automated methoxsalen calculations minimize dosage errors.

EFFICIENT TREATMENT

Treatment can be completed in as little as **75 minutes.**^{1,2}

High cell collection efficiency, and consistent UVA irradiation set automatically based on remaining lamp lifetime, hematocrit of the treatment bag, and treatment volume.

VERSATILE PATIENT MANAGEMENT

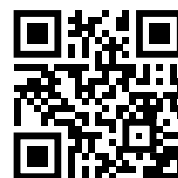
Adaptable features to help optimize treatment for each patient.¹

Choice of single- or double-needle mode based on venous access, with the flexibility to switch at any time during the procedure.

Automated flow rate controls minimize the need for operator intervention.

Bowl optic sensor adapts to abnormal plasma conditions, such as lipemia or hyperbilirubinemia.

See more of the THERAKOS® CELLEX® Photopheresis System



History of Photopheresis

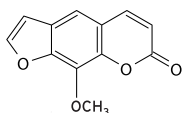
Advances from ancient Egypt to our modern era

>3500
years ago



Origins of phototherapy: Ancient Egyptians use the plant *Ammi majus* in combination with light exposure to help treat vitiligo.^{3,4}

1947



8-methoxypsoralen (8-MOP) identified as one of the active ingredients in *Ammi majus*.⁵

1980's



Dr. Richard Edelson pioneers the process of extracorporeal photopheresis in CTCL.⁶

1987



THERAKOS UVAR

The world's first fully-integrated Photopheresis system.

1999



THERAKOS UVAR XTSTM Photopheresis System

Launch of the second-generation Photopheresis system in Canada.

2009



THERAKOS CELLEX Photopheresis System

Introduction of the third-generation Photopheresis system.

2022
2026



CELLEX PLUS System Upgrade

5.4 Improved notifications and troubleshooting.¹

5.6 The latest generation CELLEX System software.

Future



Future Concepts

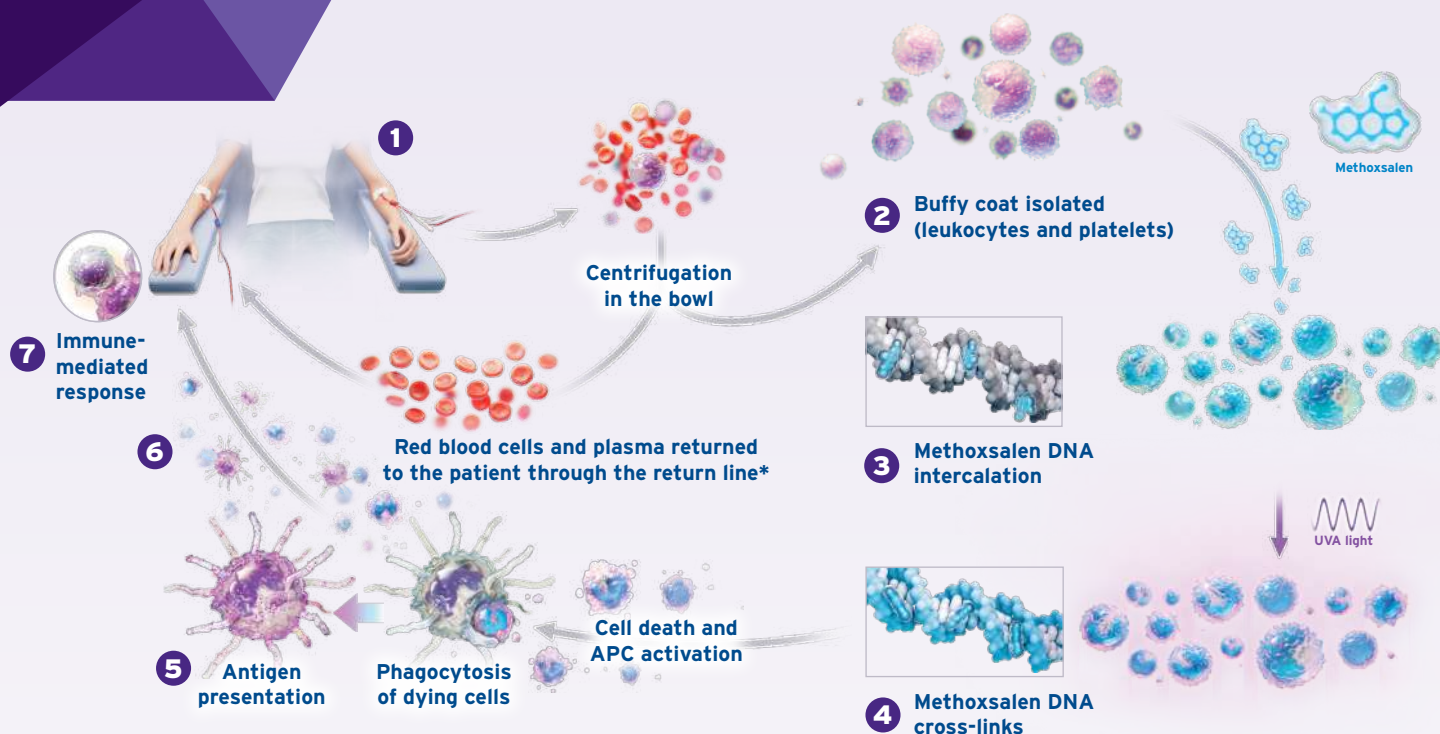
Innovations are being developed with a continued focus on patient safety and user experience.*

* Investigational products are subject to Health Canada clearance.

References: 1. THERAKOS® CELLEX® Photopheresis System Operator's Manual. 2. Data on File - Ref-01420. Therakos (Canada) Company. 3. Jarkowatch T, et al. Light Treatment in Medicine. (edx) Photobiology, 2000, Springer, New York, NY. 4. Honigsmann H. *Photochem Photobiol Sci.* 2013;12:16-21. 5. Campbell J. *Br J Nursing.* 2020;29:547-552. 6. Edelson R, et al. *N Engl J Med.* 1987;316(6):297-303.

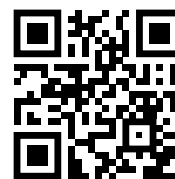
See Important Safety Information on accompanying material.

Procedure and Mechanism of Action



- 1 A small fraction of whole blood is collected from the patient through the collect line.¹
- 2 With the help of the bowl optic sensor, the collection and control software, and the hematocrit sensor, the buffy coat is isolated following centrifugation, while the remaining red blood cells and plasma are returned.^{1,2}
- 3 The buffy coat is transferred to the treatment bag where it is then treated with methoxsalen sterile solution, a photosensitizing agent.^{1,3-5}
- 4 As the buffy coat circulates through the photoactivation module, methoxsalen is photoactivated by UVA light, which triggers cell death.^{1,6,7}
- 5 Antigen-presenting cells (APCs) are activated and start phagocytosing dying lymphocytes.⁸⁻¹⁰
- 6 Once photoactivation is complete, the buffy coat (now containing living, dead, or dying cells, subcellular fragments, and soluble factors) is returned to the patient's bloodstream through the return line.¹
- 7 Translational studies suggest that Photopheresis may activate an immune-mediated response.¹¹⁻¹³

Watch the MOA Video and see THERAKOS® Photopheresis in Action



While much is known about the mechanism of action, the exact mechanism of action is currently being studied.

ECP = extracorporeal photopheresis

* The procedure pictured above illustrates a patient using double-needle mode.

THERAKOS® ECP is an Established Therapy

THERAKOS ECP is backed by 25 years of Canadian experience*

THERAKOS ECP is a well-tolerated therapy that has demonstrated efficacy in treating the skin manifestations of CTCL, and SSc.



Review Clinical Summaries in CTCL and SSc

THERAKOS ECP does not suppress the immune system^{14†}

ECP immunomodulation is not associated with increased risk of infections, and supports patients' ability to respond normally to new antigens.¹⁵⁻²¹



Review the Safety and Tolerability Profile

THERAKOS ECP is recommended in clinical guidelines²²⁻³¹

ECP is backed by evidence-based treatment recommendations in international guidelines.



Review Guideline Recommendations in CTCL and SSc

See Important Safety Information on accompanying material.

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† Incidence of adverse events is <0.003%, and is generally sporadic and mild, consisting of nausea, fever or headache. Serious side effects, such as sepsis, occur infrequently.

References: 1. THERAKOS® CELLEX® Photopheresis System Operator's Manual. 2. Cho A, et al. *Front Med (Lausanne)*. 2018;5:236. 3. UVADEX® (methoxsalen) Sterile Solution [prescribing information]. Therakos, Inc. 4. Smith SI, et al. *Analyst*. 2010;135(5):943-952. 5. Gasparro FP, et al. *Yale J Biol Med*. 1985;58(6):519-534. 6. Bladon J, et al. *Br J Haematol*. 1999;107(4):707-711. 7. Tatsuno K, et al. *Cell Death Dis*. 2019;10(8):578. 8. Berger CL, et al. *Int J Cancer*. 2001;91(4):438-447. 9. Huang MN, et al. *J Clin Invest*. 2020;130(2):774-788. 10. Bladon J, et al. *Photodiagnosis Photodyn Ther*. 2005;2(2):119-127. 11. Shiue LH, et al. *Photodermatol Photoimmunol Photomed*. 2015;31(4):184-194. 12. Quaglino P, et al. *Int J Immunopathol Pharmacol*. 2009;22(2):353-362. 13. Knobler RM, et al. *J Am Acad Dermatol*. 2006;54(5):793-799. 14. Das-Gupta E, et al. *Bone Marrow Transplant*. 2014;49(10):1251-1258. 15. Suchin KR, et al. *J Am Acad Dermatol*. 1999;41:980-986. 16. Hart JW, et al. *Ther Adv Hematol*. 2013;4:320-334. 17. Dignan FL, et al. *Bone Marrow Transplant*. 2014;49(5):704-708. 18. Jaksch P, et al. *J Heart Lung Transplant*. 2012;31:950-957. 19. Martin PJ, et al. *Biol Blood Marrow Transplant*. 2012;18:1150-1163. 20. Pierelli L, et al. *Transfusion*. 2013;53(10):2340-2352. 21. Bruserud O, et al. *Cancer Immunol Immunother*. 2014;63:757-777. 22. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Cutaneous Lymphomas V.3.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed September 18, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org. 23. National Cancer Institute PDQ Guidelines. Mycosis Fungoides and Other Cutaneous T-cell Lymphomas Treatment (PDQ®)-Health Professional Version. Updated February 19, 2025. 24. Knobler R, et al. *J Eur Acad Dermatol Venereol*. 2020;34(12):2693-2716. 25. Connelly-Smith L, et al. *J Clin Apher*. 2023;38(2):77-278. 26. Willemze R, et al. *Ann Oncol*. 2018;29(S4):iv30-iv40. 27. Alfred A, et al. *Br J Haematol*. 2017;177(2):287-310. 28. Latzka J, et al. *Eur J Cancer*. 2023;195:113343. 29. Gilson D, et al. *Br J Dermatol*. 2019;180(3):496-526. 30. AWMF-S2k Guideline (013-072): Extracorporeal Photopheresis. 31. Knobler R, et al. *J Eur Acad Dermatol Venereol*. 2021;35(1):27-49.

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Access and Funding Information

Practical tools and guidance to help support access to THERAKOS® ECP

From budget impact models to tailored pricing, Therakos (Canada) Company offers custom support for your clinic.



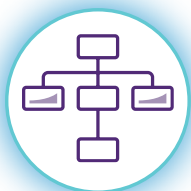
Directly supporting your funding and reimbursement efforts with:

- Comprehensive business cases and financial impact models
- Transferable budget impact data that may demonstrate cost offsets
- Submission information to support coverage requests



Flexible pricing plans created with Canadian hospitals in mind:

- Fixed kit pricing based on prior-year volume
- 12-month pricing with discounts defined by volume thresholds
- Pricing options to support predictable budgeting, even as patient needs grow



Support models designed to fit your environment:

- Four service model options
- Single- and multi-year contracts for added flexibility
- Evaluation program offering a one-year trial of CELLEX® at no additional cost, including full service throughout the trial period

Your Dedicated Canadian Team

One point of contact for all your THERAKOS ECP needs



CUSTOMER SERVICE

Customer Care team to ensure smooth deliveries and aftersales queries



PRODUCT SUPPORT

Product Support team to address alarms or urgent concerns during treatments



TECHNICAL SUPPORT

Service Engineers to help ensure all devices run smoothly



CLINICAL SUPPORT

Clinical specialists to train operators and ensure confident use

"My experience with Therakos has been exceptional - I have yet to work with a company that offers better resources and support. The Therakos team is readily available and highly responsive, consistently finding effective solutions to meet our needs. The telephone support offered by Therakos enables our team to feel comfortable, confident and secure when performing procedures."

*- Canadian Clinical Nurse Educator**



customercare@therakos.com



1-833-223-4ECP (1-833-223-4327)

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