



EXPERIENCE THE

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 next page.

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

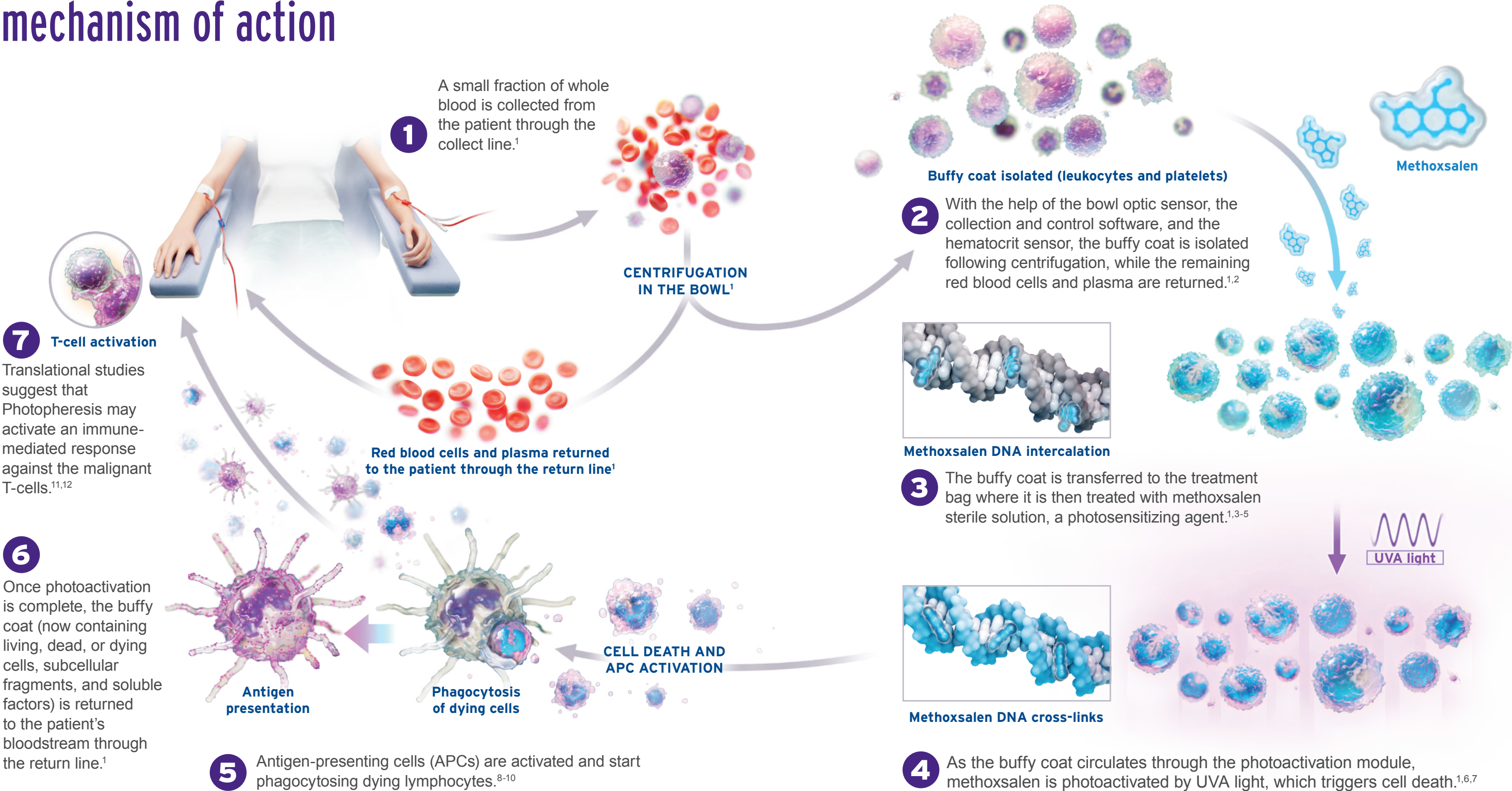
SERIOUS WARNINGS & PRECAUTIONS

- **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).

Procedure and mechanism of action



While much is known about the mechanism of action, the exact mechanism of action is currently being studied. The procedure pictured above illustrates a patient using double-needle mode.¹
UVA, ultraviolet A.

Key device components and features

OPERATOR INTERFACE¹

Displays treatment status, treatment data, and any alarm information.

Key device components

- Integrated touch screen (where treatment operations and alarms are managed)
- Smart Card (records treatment data from each treatment for diagnostic use)

Important features

An intelligent and prioritized alarm system

- Alarms are numbered for quick reference, and each has a pop-up message, alert, and recommended action
- 3 types of alarm signals: LOW Priority, MEDIUM Priority (Operator Correctable), and MEDIUM Priority (Technical)

PHOTOACTIVATION & REINFUSION¹

Following the addition of methoxsalen, the leukocyte-enriched blood fraction is exposed to a prescribed amount of UVA light and subsequently returned to the patient.

Key device components

- Photoactivation module
- Treatment bag
- Return bag

Important features

Automated methoxsalen dosage calculation

- Helps minimize dosage errors

Specific algorithm for consistent UVA irradiation

- Photoactivation time automatically calculated and set according to remaining lamp life time, percentage of hematocrit of the leukocyte-enriched blood fraction, and treatment volume



The THERAKOS[®] CELLEX[®] Photopheresis System is a fully integrated closed-loop device¹

- Single, uninterrupted sterile fluid path to reduce the risk of cross-contamination and infection^{1,13-15}
- One kit for all procedures (single-needle or double-needle mode)¹
- Single-operator management^{1,13}

DEVICE SPECIFICATIONS¹

Dimensions (Height x Width x Depth)	163 cm x 58.4 cm x 79 cm (64 in x 23 in x 31 in)
Working Height	84 cm (33 in) from floor to pump deck surface
Weight	166 kg (366 lb)
Recommended Operating Space	50 cm (18 in) clearing on all sides
Electrical	Frequency: 50/60 Hz Nominal Voltages: 100, 115, 230, 240 volts AC power (±10%, respectively) Current: 7, 6.3, 3.9, 3.8 amps, respectively
Room Operating Temperature	15°C-27.5°C (59°F-81°F) BTU/hour: 2390
Operating Humidity	10%-75% relative humidity, non-condensing
Full Mobility	Enabling use in both inpatient and outpatient settings
Single-Use Procedural Kits*	A preconnected and sterile unit for easy setup and minimal waste Kit dimensions: 59.7 cm x 36.2 cm x 13.7 cm (23.5 in x 14.25 in x 5.38 in) Case dimensions: 61 cm x 37.4 cm x 42 cm (24 in x 14.74 in x 16.5 in; 3 kits per case) *Additional ancillary supplies including saline and anticoagulant are required to perform the procedure.

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FLUID MANAGEMENT SYSTEM¹

Controls all pump and valve functions, directs fluid routing through the Pump Tubing Organizer (where whole blood, saline, and anticoagulant are routed), and maintains flow rates during all phases of the treatment.

Key device components

- Single-harvest, continuous-flow centrifuge
- Peristaltic pumps (5)
- Tubing guides
- Centrifuge bowl pressure sensor
- Air detectors
- Collect and return pressure sensors

Important features

Built-in fluid balance calculator

- Helps estimate blood volume and set fluid balance limits prior to the procedure
- “Whole Blood Processed” and “Fluid Balance” are displayed in real time

Extracorporeal volume is dependent on patient hematocrit as well as the needle configuration.

Centrifuge bowl optic sensor technology

- Features innovative software-directed pumping mechanisms
- Delivers a consistent buffy coat by automatically identifying red cell layer and can adjust the cell separation process to help compensate for abnormal plasma conditions

Hematocrit sensor technology

- Automatically determines when buffy coat collection should end

Automatic interface and isolation of treated fraction

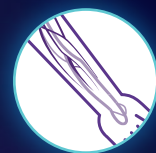
- Centrifuge separation for precision based on individual component mass
- Clean separation with constant centrifuge spinning

Automated collect and return flow rates

- May reduce pressure alarms and the associated treatment interruptions
- Decreases the need for operator interventions

Patient management

The THERAKOS® CELLEX® Photopheresis System is adaptable based on physiologic and medical considerations



Vascular access

The system offers a choice of single-needle (SNM) or double-needle mode (DNM) and the ability to switch between the two according to venous access conditions.^{1,14} Flexible configuration allows operators to adjust smoothly to **individual vascular access needs** in real time.¹

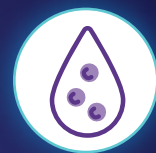
- **With DNM, extracorporeal volume is reduced** compared with SNM, and the continuous fluid return may reduce treatment time¹

The option to use DNM is dependent on vascular access and other patient factors, such as hematocrit.



Hemodynamic instability and low body weight

Blood priming and reduced extracorporeal volume using DNM enable treatment of **patients with low body weight and hemodynamic instability**.¹



No lower limit for leukocyte levels

Regardless of the needle mode, centrifuge bowl continuously harvests 1 concentrated buffy coat.¹



Abnormal lipid and bilirubin in plasma

Bowl optic sensor allows customization of the system to the needs of patients with **abnormal plasma conditions**, such as lipemia or hyperbilirubinemia.¹



Reduced flow rates

Collect, return, and reinfusion flow rate limits may be adjusted for patients with **medical conditions warranting lower flow rates**, such as cardiac, renal, or pulmonary insufficiency, diabetes, hypertension, hypotension, edema, low body weight, or fragile veins.¹



On average, the total treatment time* with the CELLEX system is 99.27 minutes.¹⁶

*Accounts for the buffy coat collection and handling time, the irradiation time, and the handling time after treatment.¹⁶

Dedicated support with the THERAKOS® CELLEX® Photopheresis System

**ON-DEMAND
SUPPORT
AVAILABLE
WHEN
YOU NEED IT**

Customer Care available at 1-833-223-4327

Therakos Institute, which offers training programs and educational activities for practitioners

Educational materials for your patients and practice

**ONGOING
SUPPORT FROM
OUR INTERNAL
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

Business managers offer dedicated product information and support

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