Therakos CellEx™ PHOTOPHERESIS SYSTEM

MDR approved for 5 INDICATIONS

Update

Medical Device Regulation (MDR)

- Medical Device Regulation (MDR) (EU) 2017/745 lays down rules concerning the placing on the market of medical devices for human use and accessories for such devices[1]
- Companies are required to submit a Clinical Evaluation Report (CER) to demonstrate the safety and performance of a medical device in its clinically indicated use[1]
- It demonstrates that the device achieves its intended purpose without exposing users and patients to further risk[1]

The THERAKOS™ CELLEX™ Photopheresis System is MDR approved (independent of software version)

The THERAKOS™ CELLEX™ System is intended to be used in patients who require the administration of photopheresis. This includes patients suffering from:

- Cutaneous T-Cell Lymphoma (CTCL) in patients >18 years of age
- Acute and Chronic Graft versus Host disease (aGvHD, cGvHD) >3 years of age
- Solid Organ Transplant (SOT) rejection (Lung and Heart) >18 years of age

Updates ONLY available after your upgrade to Software 5.6

Introducing ACD-A as an alternative anticoagulant to heparin according to the patient profile[2]

- ACD-A prevents platelet activation and coagulation by binding to free calcium ions in the blood and interrupting the clotting cascade[3]
- With apheresis, ACD-A may be preferred in certain patients where heparin is contraindicated[3-5]

New RoHS3 directive-compliant THERAKOS™ CELLEX™ Photopheresis System Procedural Kit[2,6-8]

- The latest Restriction of Hazardous Substances (RoHS) Standard requires the removal of Di(2-ethylhexyl) phthalate (DEHP) from electrical and electronic equipment[6-8]
- To accommodate this, material changes have been made to the CELLEX™ System Procedural Kit[2]
  - A new RoHS3 directive compliant kit (CLXSP-I) replaces the previous kit (CLXECP)

The benefits (ACD-A option and RoHS3 compliant kit) will be available once upgrade to software v5.6 has been completed.

Please see Important Safety Information on next page.

ACD-A, Anticoagulant Citrate Dextrose Solution A; DEHP, Di(2-ethylhexyl) phthalate; ECP, extracorporeal photopheresis; MDR, medical device regulation; RoHS, Restriction of Hazardous Substances.

Important Safety Information for the THERAKOS™ Photopheresis Procedure[2]

Indications

The THERAKOS™ CELLEX™ Photopheresis System is indicated for patients older than 18 years of age for the administration of photopheresis in the following:

- Cutaneous T Cell Lymphoma (CTCL)
- Solid Organ Transplant (SOT) rejection (heart, lung)

The THERAKOS™ CELLEX™ Photopheresis System is indicated in patients older than 3 years of age for the management of:

- Acute and Chronic Graft versus Host Disease (aGvHD, cGvHD)

Contraindications

THERAKOS™ Photopheresis is contraindicated in:

- Patients possessing a specific history of a light sensitive disease
- Patients who cannot tolerate extracorporeal volume loss or who have white blood cell counts greater than 25,000/mm^3
- Patients who have coagulation disorders or who have previously had a splenectomy

Warnings and Precautions

THERAKOS™ 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.

- Do not expose the device to a magnetic resonance (MR) environment. The device may present a risk of projectile injury, and thermal injury and burns may occur. The device may generate artifacts in the MR image, or may not function properly.
- Thromboembolic events, including pulmonary embolism and deep vein thrombosis, have been reported in the treatment of Graft-versus-Host Disease (GvHD). Special attention to adequate anticoagulation is advised when treating patients with GvHD.
- When prescribing and administering THERAKOS™ 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 Events

- Hypotension may occur during any treatment involving extracorporeal circulation. Closely monitor the patient during the entire treatment for hypotension.
- Transient pyretic reactions, 37.7–38.9°C (100–102°F), have been observed in some patients within six to eight hours of reinfusion of the photoactivated leukocyte-enriched blood. A temporary increase in erythroderma may accompany the pyretic reaction.
- Treatment frequency exceeding labelling recommendations may result in anaemia.
- Venous access carries a small risk of infection and pain.

Please refer to the THERAKOS™ CELLEX™ Photopheresis System Operator's Manual for a complete list of warnings and precautions.

IMPORTANT SAFETY INFORMATION FOR METHOXSALEN USED IN CONJUNCTION WITH THERAKOS™ PHOTOPHERESIS[1]

Consult the 8-methoxypsoralen (Methoxsalen (20 micrograms/mL)) professional leaflet or the oral 8-methoxypsoralen formulation package insert before prescribing or dispensing any medication.

Warnings and Precautions

- Patients exhibiting multiple basal cell carcinomas or having a history of basal cell carcinoma should be diligently observed and treated.
- Methoxsalen may cause fetal harm when given to a pregnant woman. Women undergoing photopheresis should be advised to avoid becoming pregnant.
- Special care should be exercised in treating patients who are receiving concomitant therapy (either topically or systemically) with known photosensitizing agents.
- Oral administration of methoxsalen followed by cutaneous UVA exposure (PUVA therapy) is carcinogenic.
- Patients should be told emphatically to wear UVA absorbing, wrap-around sunglasses for twenty-four (24) hours after methoxsalen treatment. They should wear these glasses any time they are exposed to direct or indirect sunlight, whether they are outdoors or exposed through a window.

Refer to the package insert for methoxsalen sterile solution (20 micrograms/mL) or the oral 8-methoxypsoralen dosage formulation for a list of all warnings and precautions.

For more information about THERAKOS ECP Immunomodulation™ please visit: www.therakos.eu.

References:
1. Official Journal of the European Union. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745. **2.** Operator's Manual. THERAKOS™ CELLEX™ Photopheresis System. For Use with Software 5.6. Therakos. 2024. **3.** Lee G, Arepally GM. J Clin Apher. 2012;27(3):117-125. **4.** Worel N, et al. Transfus Med Hemother. 2019;46:394-406. **5.** Cervantes CE, et al. Am J Kidney Dis. 2023,81(4):475-492. **6.** European Commission. Directive 2015/863. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015L0863&qid=1696579121463. Accessed July 2024. **7.** European Council. Directive 2011//65/EU. Annex II. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02011L0065-20230901. Accessed July 2024. **8.** Data on file - Ref-07742. Therakos LLC.

Therakos™ ECP Immunomodulation