

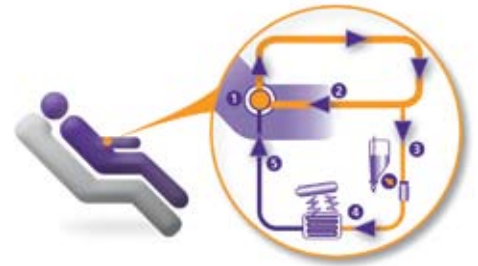
THE ORTHO CLINICAL DIAGNOSTICS FRANCHISE



Immune Cell Therapy: Extracorporeal Photopheresis

Harnessing a combination of expertise in medical devices and pharmaceuticals, Therakos, Inc., pioneered an innovative procedure called extracorporeal photopheresis (ECP). Therakos, now a part of the Ortho Clinical Diagnostics franchise, currently markets the world's only approved integrated systems for ECP.

ECP, which Therakos markets as THERAKOS™ Photopheresis, is a procedure typically performed in a hospital or large community cancer center. During the treatment, a small amount of whole blood is withdrawn from the patient and the white blood cells are separated from the red blood cells and plasma. The red blood cells and plasma are immediately reinfused into the patient. The separated white blood cells are treated with a medicine that is then activated by brief exposure to ultraviolet-A (UVA) light. The treated white blood cells are then promptly returned to the patient's bloodstream. Although the exact effects of photopheresis are still being studied, it appears that when the treated white blood cells are reinfused into the body, its natural ability to maintain a balanced immune system is restored.



Introduced in 2009 (CE marked in 2008), the THERAKOS™ CELLEX™ Photopheresis System is the latest-generation instrument incorporating innovative and advanced technologies to provide a new level of patient-focused care. It is a single, integrated, automated, closed system, designed to enhance the patient treatment experience. Benefits of the THERAKOS™ CELLEX™ Photopheresis System include shorter treatment times and reduced extracorporeal (outside the body) blood volume, allowing for a wider range of Cutaneous T-Cell Lymphoma (CTCL) patients to be treated while maintaining the many benefits of the existing THERAKOS™ UVAR™ XTS™ Photopheresis System.

In the United States the THERAKOS™ UVAR™ XTS™ and CELLEX™ Photopheresis Systems are indicated for the palliative treatment of the skin manifestations of CTCL that are unresponsive to other forms of treatment. CTCL, a type of non-Hodgkin's lymphoma, is a rare cancer that affects certain white blood cells (T lymphocytes). CTCL causes visible skin symptoms as mild as a small rash or as severe as tumors or extensive redness, peeling, burning, soreness, and itchiness all over the body. CTCL falls into different categories based on the severity of the disease and symptoms. The two most common types of CTCL are mycosis fungoides and



Sèzary syndrome. For many patients, treatment with ECP may result in decreased itching and redness, while others may have noticeable or complete clearing of the skin. It is estimated that CTCL affects 16,000 to 20,000 people across the United States.¹

For 20 years, physicians have been using THERAKOS™ Photopheresis Systems to treat their patients, with more than half a million treatments worldwide* performed safely and effectively.

*THERAKOS™ UVAR™ XTS™ and CELLEX™ Systems are also available in Canada and the European Union.

Important Safety Information

UVADEX™ (methoxsalen) Sterile Solution is indicated for extracorporeal administration with the THERAKOS™ UVAR™ XTS or THERAKOS™ CELLEX™ Photopheresis System in the palliative treatment of the skin manifestations of cutaneous T-cell lymphoma (CTCL) that is unresponsive to other forms of treatment.

Methoxsalen is not appropriate for patients who have had a reaction to psoralen compounds, patients who have had a light sensitive disease, or patient with an absence of one or both lenses of the eye.

THERAKOS™ Photopheresis is not appropriate for patients who cannot tolerate blood volume changes or patients with blood clotting disorders. The most commonly reported adverse event is transient non-serious hypotension (a drop in blood pressure) due to minor changes in blood volume during treatment. Other potential side effects such as fever or skin redness usually go away within one day. For more information visit www.therakos.com.

¹ Cutaneous Lymphoma Foundation. *CTCL-MG Fast Facts*, p.2