

## **Important Safety Information for the THERAKOS® CELLEX® Photopheresis Procedure**

### **Indications**

The THERAKOS® CELLEX® Photopheresis Systems is indicated for the administration of photopheresis. Please refer to the THERAKOS® CELLEX® Operator's Manual for a complete list of warnings and precautions.

### **Contraindications**

THERAKOS® Photopheresis is contraindicated in patients possessing a specific history of a light sensitive disease. THERAKOS® Photopheresis is contraindicated in patients who cannot tolerate extracorporeal volume loss or who have white blood cell counts greater than 25,000 mm<sup>3</sup>. THERAKOS® Photopheresis is contraindicated in 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. Safety in children has not been established. Both men and women should take adequate contraceptive precautions both during and after completion of photopheresis 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.

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.

Also refer to the THERAKOS® CELLEX® Photopheresis System Operator's Manual.

**Important Safety Information for UVADEX (methoxsalen) used in conjunction with THERAKOS® CELLEX® Photopheresis is provided in the Full Prescribing Information for UVADEX (methoxsalen) available at [www.therakos.com.au](http://www.therakos.com.au)**