

Blue-Light Cystoscopy with Cysview® is now available at <<Insert Facility Name>>

With an estimated annual bladder cancer incidence of 73,500 and a mortality rate of 14,880 in 2012,1 the medical need to improve detection and resection of all bladder cancer tumors has never been clearer.

To that end, <<Insert Facility name>> is pleased to announce that Blue-Light Cystoscopy with Cysview--which has been proven to significantly increase detection over white-light cystoscopy alone2-8--is now available at our facility.

Cysview (hexaminolevulinate HCl) is an optical imaging agent indicated for use in the cystoscopic detection of nonmuscle invasive papillary cancer of the bladder among patients suspected or known to have lesion(s) on the basis of a prior cystoscopy. It is used with the KARL STORZ D-Light C Photodynamic Diagnostic (PDD) System to perform cystoscopy with the blue-light setting (Mode 2) as an adjunct to the white-light setting (Mode 1). Cysview is not a replacement for random bladder biopsies or other procedures used in the detection of bladder cancer and is not for repetitive use.2



Used as an adjunct to white-light cystoscopy, Blue-Light Cystoscopy with Cysview instills confidence at first sight. It is the **only FDA-approved technology** that:

* Detects more Ta/T1 bladder cancer lesions than does white-light cystoscopy alone2-8
* One or more additional Ta or T1 bladder cancer lesions were detected by Blue-Light Cystoscopy with Cysview in 16.4% of patients compared to white light alone2,7
* Leads to improved tumor resection, since every tumor detected is resected in the same TURB3-8

* Allows for better patient management decisions6

We encourage you to refer your patients with known or suspected bladder cancer to have a Blue-Light Cystoscopy with Cysview at <<Insert Facility Name>>, and to visit our facility to see how this innovative imaging agent is used.

**To learn more about Blue-Light Cystoscopy with Cysview at <<insert Facility name>>, contact <<insert contact urologist's or Department of Urology coordinator's name>> at <<insert phone number>>, or go to** [**www.cysview.com**](http://www.cysview.com)**.**

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Important Risk and Safety Information

Cysview is not a replacement for random bladder biopsies or other procedures used in the detection of bladder cancer and is not for repetitive use.

Anaphylaxis reactions including anaphylactoid shock, hypersensitivity reactions, bladder pain, cystitis, and abnormal urinalysis have been reported after administration of Cysview. The most common adverse reactions seen in clinical trials were bladder spasm, dysuria, hematuria, and bladder pain.

Cysview should not be used in patients with porphyria, gross hematuria, or with known hypersensitivity to hexaminolevulinate, or in patients receiving intravesical chemotherapy or BCG treatment within 3 months of Cysview photodynamic blue-light cystoscopy. There are no known drug interactions with hexaminolevulinate; however, no specific drug interaction studies have been performed. Using Cysview, fluorescence of non-malignant areas may occur, and Cysview may fail to detect some malignant lesions.

Safety and effectiveness have not been established in pediatric patients. Cysview should only be used during pregnancy if the potential benefit justifies the potential risk to the fetus. It is not known whether hexaminolevulinate is excreted in human milk. Because many drugs are excreted in human milk, exercise caution when Cysview is administered to nursing mothers. No clinically important differences in safety or efficacy have been observed between older and younger patients.

Cysview is approved for use with the Karl Storz D-Light C Photodynamic Diagnostic (PDD) system. For system set up and general information for the safe use of the PDD system, please refer to the Karl Storz instruction manuals for each of the components.

Prior to Cysview administration, read the Full Prescribing Information and follow the preparation and reconstitution instructions.

**References: 1.** SEER Stat Fact Sheets: Bladder. Surveillance Epidemiology and End Results (SEER). http://seer.cancer.gov/statfacts/html/urinb.html. Accessed July 27, 2012.  **2.** Cysview [prescribing information]. Princeton, NJ: Photocure ASA; 2011. **3.** Schmidbauer J, Witjes F, Schmeller N, et al. Improved detection of urothelial carcinoma in situ with hexaminolevulinate fluorescence cystoscopy. *J Urol*. 2004;171(1):135-138. **4.** Grossman HB, Gomella L, Fradet Y, et al. A phase III, multicenter comparison of hexaminolevulinate fluorescence cystoscopy and white light cystoscopy for the detection of superficial papillary lesions in patients with bladder cancer. *J Urol*. 2007;178(1):62-67. **5.** Fradet Y, Grossman HB, Gomella L, et al. A comparison of hexaminolevulinate fluorescence cystoscopy and white light cystoscopy for the detection of carcinoma in situ in patients with bladder cancer: a phase III, multicenter study. *J Urol*. 2007;178(1):68-73. **6.** Jocham D, Witjes F, Wagner S, et al. Improved detection and treatment of bladder cancer using hexaminolevulinate imaging: a prospective, phase III multicenter study. *J Urol*. 2005;174(3):862-866. **7**. Stenzl A, Burger M, Fradet Y, et al. Hexaminolevulinate guided fluorescence cystoscopy reduced recurrence in patients with nonmuscle invasive bladder cancer. *J Urol*. 2010;184(5):1907-1913. **8.** Hermann GG, Mogensen K, Carlsson S, Marcussen N, Duun S.. Fluorescence-guided transurethral resection of bladder tumours reduces bladder tumour recurrence due to less residual tumour tissue in Ta/T1 patients: a randomized two-centre study. *BJU Int*. 2011;108(8 pt 2):E297-303.

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