

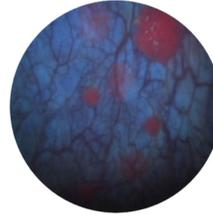


# CYSTOSCOPY FACT SHEET

## Blue Light Cystoscopy (BLC™) with Cysview® (hexaminolevulinate HCl) for Bladder Cancer



Bladder image using white light cystoscopy alone



Same image after using BLC with Cysview as an adjunct to white light

### Bladder Cancer Detection

Cystoscopy is the gold standard diagnostic tool for bladder cancer detection. Doctors who suspect patients may have bladder cancer use this procedure to look inside the bladder. A cystoscope lets the doctor inspect the bladder lining very closely for any abnormal growths or suspicious areas. Historically, cystoscopy was performed using only white light for visualizing suspicious lesions.<sup>1</sup>

Unfortunately, there is a high risk of recurrence in bladder cancer and 30-44% of all patients have evidence of tumor on repeat TURBT upto 8 weeks.<sup>2</sup> This may be due to doctors being unable to detect, and therefore remove, all of the cancer during the initial resection.

### Blue Light Cystoscopy with Cysview®

Blue Light Cystoscopy (BLC™) with Cysview® is a technology that significantly improves the detection of non-muscle invasive bladder cancer compared to traditional White Light Cystoscopy alone.<sup>3</sup>

Cysview is an optical imaging agent indicated for use in the cystoscopic detection of carcinoma of the bladder, including carcinoma in situ (CIS), among patients suspected or known to have lesion(s) on the basis of a prior cystoscopy, or in patients undergoing surveillance cystoscopy for carcinoma of the bladder.<sup>3</sup> Cysview is taken up by cancer cells in the bladder making them glow bright pink under blue light. Because of this, BLC™ with Cysview improves the detection of tumors and therefore can lead to a more complete resection, less residual tumors and better management decisions.<sup>3</sup>

- A solution containing the drug is placed in the bladder using a catheter one hour prior to the cystoscopic procedure. During this time Cysview is absorbed by cancerous tissue.<sup>3</sup>
- The doctor performs the cystoscopy by using both white light and blue light.<sup>3</sup>

### Inclusion of BLC with Cysview in Guidelines

The clinical value of BLC with Cysview has been included in several guidelines. Guidelines and recommendations have been published by the following organizations:<sup>4,5</sup>

- American Urological Association (AUA), Society of Urological Oncology (SUO) (2016) – in the enhanced cystoscopy section, Blue Light Cystoscopy is recommended (Moderate Recommendation; Evidence Strength: Grade B) for use in patients with NMIBC at the time of transurethral resection of bladder cancer tumors (TURBT) to increase detection and decrease recurrence.<sup>4</sup>
- National Comprehensive Cancer Network (NCCN) (2018) – Enhanced (blue light and narrow band imaging) cystoscopy may be useful in identifying lesions not visible using white light cystoscopy.<sup>5</sup>

### Clinical Overview

- Phase III studies using BLC with Cysview demonstrated a statistically significant difference in the detection of:
  - Ta/T1 tumors, with additional tumors detected in 16.4% of patients using BLC with Cysview<sup>3</sup>
  - CIS, with 34.6% patients who recurred with CIS were detected with BLC only<sup>2</sup>
  - recurrence, with 20.6% recurrent patients were found with Cysview alone through flexible cystoscopy<sup>2</sup>

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



## Prescribing Information

Cysview is an optical imaging agent indicated for use in the cystoscopic detection of carcinoma of the bladder, including carcinoma in situ (CIS), among patients suspected or known to have lesion(s) on the basis of a prior cystoscopy, or in patients undergoing surveillance cystoscopy for carcinoma of the bladder. Cysview is used with the KARL STORZ D-Light C Photodynamic Diagnostic (PDD) system to perform Blue Light Cystoscopy (BLC™) as an adjunct to the white light cystoscopy.

## Important risk & safety information

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

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 any derivative of aminolevulinic acid. Cysview may fail to detect some malignant lesions. False positive fluorescence may occur due to inflammation, cystoscopic trauma, scar tissue, previous bladder biopsy and recent BCG therapy or intravesical chemotherapy. No specific drug interaction studies have been performed.

Safety and effectiveness have not been established in pediatric patients. There are no available data on Cysview use in pregnant women. Adequate reproductive and developmental toxicity studies in animals have not been performed. Systemic absorption following administration of Cysview is expected to be minimal. There are no data on the presence of hexaminolevulinate in human or animal milk, the effects on a breastfed infant, or the effects on milk production. The development and health benefits of breastfeeding should be considered along with the mother's clinical need for Cysview and any potential adverse effects on the breastfed infant from Cysview or from the underlying maternal condition.

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. Tanaka MF, Sonpavde G. Diagnosis and management of urothelial carcinoma of the bladder. *Postgrad Med.* 2011; 123(3): 43-55.
2. Daneshmand S, Patel S, Lotan Y, et al. Efficacy and safety of blue light flexible cystoscopy with hexaminolevulinate in the surveillance of bladder cancer: A phase III, comparative, multicenter study. *J Urol.* 2018; 199(5): 1158-1165. doi: 10.1016/j.juro.2017.11.096. *Epub* 2017 Dec 2.
3. Cysview® [prescribing information]. Photocure, Inc. Princeton, NJ; 2018.
4. Chang SS, Boorjian SA, Chou R, et al. Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer: AUA/SUO Guideline. *J Urol.* 2016;196(4):1021-9.
5. NCCN. NCCN Clinical Practice Guidelines- *Bladder Cancer.* 2018; version 4.2018.

Included  
in National  
Urology  
Guidelines<sup>1</sup>

VISIT [CYSVIEW.COM](https://www.cysview.com)

# UNDERSTANDING BLUE LIGHT CYSTOSCOPY WITH CYSVIEW FOR DETECTION OF BLADDER CANCER<sup>2</sup>



## A PATIENT GUIDE

**Cysview can only be  
used by qualified  
healthcare providers.**

**CYSVIEW<sup>®</sup>**  
Hexaminolevulinate HCl



THE  
BLADDER  
CANCER  
COMPANY<sup>™</sup>

## Facts About Bladder Cancer

**81,190** new cases of bladder cancer each year<sup>3</sup>



Over **696,440** bladder cancer survivors in the US<sup>3</sup>

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Cysview should not be used in patients with porphyria, gross hematuria, or with known hypersensitivity to hexaminolevulinate or any derivative of aminolevulinic acid. Cysview may fail to detect some malignant lesions. False positive fluorescence may occur due to inflammation, cystoscopic trauma, scar tissue, previous bladder biopsy and recent BCG therapy or intravesical chemotherapy. No specific drug interaction studies have been performed.

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## What is a cystoscopy?

A cystoscopy is a procedure that your doctor may use to examine your bladder to help find the cause of symptoms, or to treat or monitor conditions. This procedure allows your doctor to look directly inside your bladder and inspect the lining very closely.

If during a cystoscopy any abnormal growths or suspicious areas are seen, your doctor may remove tissue samples (biopsy) and send them to the laboratory to be examined.

A cystoscopy can be done while you are asleep under anesthesia or while you are awake with moderate sedation and/or pain management. Your doctor may instruct you to fast or have a light breakfast depending on whether you will be awake or asleep. Be sure to tell your doctor all the medications you currently take. Ask whether you should take them before your procedure or hold them until after.

## What is a cystoscope?

A cystoscope is a thin, tube-like telescope that is carefully passed up the urethra (the tube through which urine leaves your body) and into the bladder. The cystoscope is a hollow tube that creates a path for surgical instruments to pass through for use in a cystoscopy.



Image of a cystoscope

## **A standard cystoscopy uses white light**

During a cystoscopy procedure, the cystoscope shines light inside the bladder to aid in visibility. In a standard procedure, the light is regular white light—the type we all use every day to light a room.

White light helps your doctor visually assess the general health of your bladder and find irregularities to be further evaluated.



Bladder image under white light

## A cystoscopy can also use blue light with Cysview®

Your doctor also has the option of enhancing a cystoscopy by adding blue light and Cysview to the procedure. Called Blue Light Cystoscopy (BLC™) with Cysview®, this technology significantly improves the detection of non-muscle invasive bladder cancer (NMIBC).

With a standard cystoscopy procedure, your doctor can see some indicators of cancer under white light. With the addition of blue light and Cysview, the procedure offers significantly improved detection of suspicious areas compared to white light.<sup>2</sup> The Cysview causes cancerous cells to glow bright pink under blue light.<sup>2</sup>



Same image using  
blue light and Cysview

## What happens during Blue Light Cystoscopy with Cysview<sup>®2</sup>

- One hour prior to a cystoscopy, a healthcare professional uses a catheter to place about 2 oz of Cysview in the bladder where it is absorbed by cancerous tissue
- For the procedure, your doctor inserts a long, thin tube (a cystoscope) and uses white light to examine the bladder
- When the doctor switches to blue light, the Cysview is taken up by cancerous tumors and glows bright pink—making them more visible and possibly also revealing additional tumors not visible under white light
- With Cysview, all tumors stand out against normal bladder tissue, so they are easier for your doctor to identify and remove completely

**Blue Light Cystoscopy with Cysview has been shown to detect more bladder tumors than White Light Cystoscopy alone.<sup>2</sup>**



## Is BLC™ with Cysview® safe?<sup>2</sup>

Any procedure may have some risks. You should consult your doctor regarding the risks and benefits of this procedure.

- The most common patient complaints include bladder spasm and bladder pain, discomfort when urinating, and frequent urination
- On rare occasions, patients have experienced increased heart rate, chest pain, and fever
- Hypersensitivity reactions may occur in some patients

## Who can have BLC with Cysview?<sup>2</sup>

Anyone who is suspected of having or is known to have bladder cancer (from a previous cystoscopy) can have BLC with Cysview.

**Ask your doctor if BLC with Cysview would be right for you.**

## What to expect after the procedure

Here are some important things to keep in mind for after your cystoscopy:

- Once the procedure is finished, your bladder will be full, so you may need to urinate
- Most people—including those who have just had local anesthesia—feel ready to go home after a short time; once home, you should plan to rest for the remainder of the day
- It is common to have some bladder spasms, which can make you feel like you need to urinate more often than usual
- For a couple days you may feel some pain or discomfort when you urinate
- Blood in the urine is common for several days after the procedure, particularly if you had any bladder tissue removed
- In rare cases, patients may have difficulty urinating after their cystoscopy; if that happens, your doctor may choose to discharge you with a urinary catheter in your bladder to drain excess fluid until any swelling goes down
- Some patients may develop a mild infection after a cystoscopy—watch for fever, chills, unrelieved nausea and/or vomiting, or inability to urinate; an infection may be treated with antibiotics. Consult your doctor if you are concerned
- In some cases your doctor may prescribe additional therapy, including intravesical chemotherapy (placed directly into the bladder)

***Drinking plenty of water can help with many of the common issues experienced after a cystoscopy.***

### When to contact your doctor

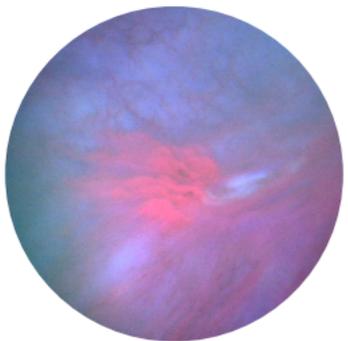
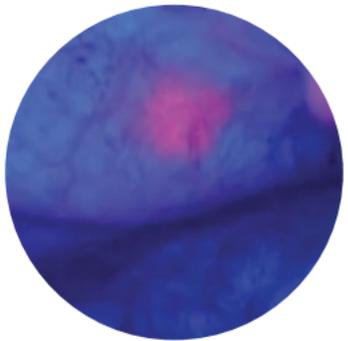
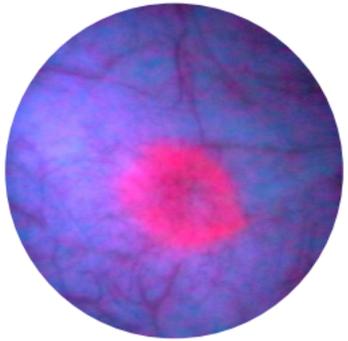
Follow your doctor's discharge instructions carefully. If after 2 or 3 days you still have blood in the urine, you see blood clots after you have urinated several times, or if you have severe symptoms of any kind, please contact your doctor's office immediately.



# Bladder images under white and blue light

**Standard White Light Cystoscopy**

**Blue Light Cystoscopy with Cysview**



## **Additional patient resources**

### **Bladder Cancer Advisory Network (BCAN)**

[www.bcan.org](http://www.bcan.org)

BCAN is the first national advocacy organization dedicated to increasing public awareness about bladder cancer; to advancing bladder cancer research; and to providing educational and support services for the bladder cancer community. Founded in May 2005, BCAN is a cooperative effort among bladder cancer survivors, their families and caregivers, and the medical community.

### **For more information about BLC with Cysview**

[www.Cysview.com](http://www.Cysview.com)

**If you have any questions or concerns about your Blue Light Cystoscopy with Cysview, ask your doctor right away. Your doctor will be able to explain every aspect of the procedure.**