

# Frequently Asked Questions About Your Colonoscopy And Optical Biopsy

## Why have an optical biopsy as part of your colonoscopy?

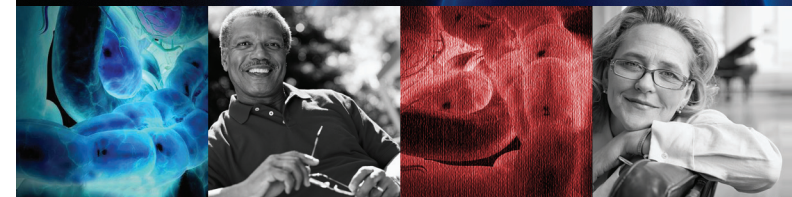
Colonoscopy is a widely recommended procedure that patients and healthcare providers alike have always understood to be a powerful tool when screening for colon cancer. In 2008 however, multiple studies were published demonstrating less effective results than originally thought. A recent Canadian study showed that screening for colon cancer through colonoscopy was only effective 60-70% of the time instead of 90% as originally believed. This has led to increased concerns and the need for additional screening tools. The American Cancer Society estimates that in 2009, 148,000 people in the US will learn they have colon cancer for the first time and 50,000 will die from colon cancer.

One of the most powerful tools being added to traditional colonoscopy procedures around the world today is the optical biopsy. By adding the power of an optical biopsy to a standard colonoscopy procedure, additional areas of concern beyond the removal of large polyps are now being analyzed and identified earlier. In the case of smaller or flat polyps not currently considered for removal or biopsy, your healthcare provider has a new powerful tool to make objective decisions, removing the subjectivity that may have contributed to concerns demonstrated in recent studies.

wavstat<sup>®</sup> optical biopsy system

The advantages of adding optical biopsy to your colonoscopy are offered exclusively at the office of:

# Understanding Your Colonoscopy And Optical Biopsy



The WavSTAT<sup>®</sup>  
Optical Biopsy System



### What is an optical biopsy?

An optical biopsy during a colonoscopy procedure involves the use of a safe low power laser light that shines on an area of suspect tissue or a protruding polyp. After illuminating the targeted tissue, the laser light is then turned off, allowing the WavSTAT System to analyze the light reflected back from the tissue. Since suspect tissue absorbs and reflects light differently than normal tissue, the light signal can be objectively analyzed by the WavSTAT System. In less than three seconds, the light signature is analyzed and provides your healthcare provider with a green light prompt (normal tissue) or a red light prompt (suspect tissue). If the signal is red, biopsy forceps attached to the optical probe can be closed to take an immediate tissue biopsy or simply remove the observed polyp.

### Does the laser light hurt or cause damage to tissue?

No. The WavSTAT Optical Biopsy System operates at a very low level of UV light. Unlike more powerful lasers used for hair removal or other medical procedures, the WavSTAT System does not have the ability to damage tissue or cause pain.

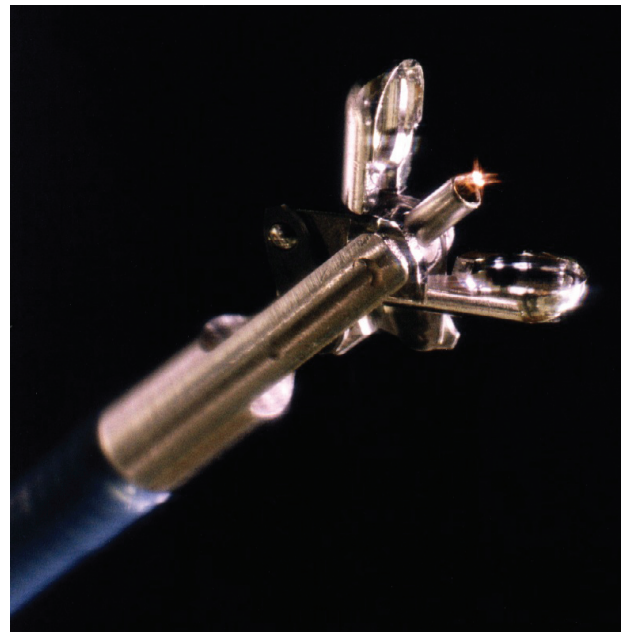
### Does an optical biopsy replace the need for tissue biopsy or polyp removal?

No. The purpose of an optical biopsy during colonoscopy is to help your healthcare professional better evaluate areas of concern that they wouldn't normally evaluate via polyp removal or tissue biopsy. During your procedure, any larger polyps (greater than 1cm) will typically be removed and sent to a lab for pathology analysis. Being able to objectively evaluate smaller or flat polyps not considered for biopsy will help understand future risks of developing colon cancer and lead to earlier intervention.

### What is the benefit of having an optical biopsy performed?

For the healthcare professional, the ability to evaluate smaller or flat polyps is of growing concern. As mentioned, polyps greater than 1cm will be removed and sent to the lab to determine if tissue is abnormal or cancerous. However, the ability to assess smaller or flat polyps is highly subjective, even with the most advanced imaging technology available. With the WavSTAT Optical Biopsy System, your doctor will have greater confidence in understanding future concerns of these smaller or flat polyps.

As a patient, access to the optical biopsy system means having confidence that all areas of concern visualized during your colonoscopy were evaluated objectively. In the past, smaller polyps and flat polyps were only evaluated through visual inspection and enhanced imaging. The WavSTAT Optical Biopsy System provides instant information that was never available before, versus a tissue biopsy that could be collected and later analyzed by a pathologist. The Optical Biopsy System may also lead to a better classification of risk, which can help determine the most appropriate time interval for future screening procedures.



*The WavSTAT System provides physicians two powerful tools by combining an optical fiber within customized forceps.*

### Is the optical biopsy technology FDA approved?

Yes, the WavSTAT Optical Biopsy System has been approved as an adjunct to colonoscopy for the evaluation of certain polyps not previously considered for removal. While larger polyps are likely to be removed without the need for an optical biopsy, smaller or flat polyps need to be evaluated on a case by case basis as recommended by your physician.

### Are there published studies that have validated this technology?

A large multi-center study was performed to receive FDA approval of the WavSTAT Optical Biopsy System. Since that initial study, institutions around the world have validated the use of the WavSTAT Optical Biopsy System and published similar findings.

### Is the WavSTAT Optical Biopsy System only used as an adjunct for colonoscopy?

At the present time, additional studies are being performed to evaluate the potential of the WavSTAT System in other tissue sources. One of the areas currently being investigated is the esophagus. Patients who suffer from acid reflux have the potential of developing Barrett's esophagus, a condition involving a change in the lining of the esophagus due to repeated exposure to stomach acids. Patients with this condition must be followed closely as the potential for developing abnormal tissue that sometimes leads to esophageal cancer is increased. The WavSTAT System is currently being evaluated to assist in improving biopsy selection during the endoscopy screening procedure of patients with Barrett's esophagus.

**wavstat**<sup>®</sup> optical biopsy system