



In early stage cervical and uterine cancers, nearby lymph nodes are removed to help stage cancers and develop your treatment plan. Ask your doctor if you are a candidate for **Lymphatic Mapping with SPY Fluorescence**.

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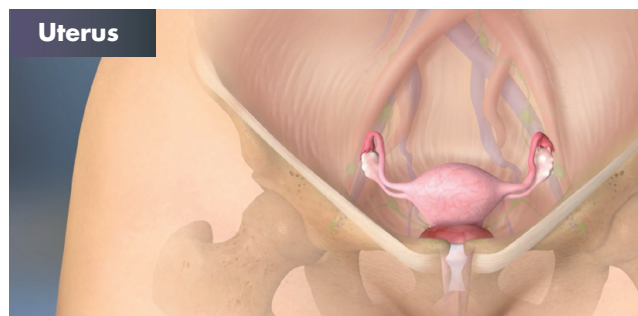
## **Lymphatic Mapping with SPY Fluorescence**

An Option Available for Cervical and Uterine Cancers



## Your Treatment Plan May Include Your Lymph Nodes

**Lymph nodes** are small nodules found throughout the body that play a major role in the immune system. In early stage cervical or uterine cancers, nearby lymph nodes may contain cancer and may be surgically removed. They are evaluated to stage the cancer and guide additional cancer treatment.



## How Lymph Nodes Are Evaluated

Surgeons typically have removed one or more total groups of lymph nodes in a procedure called a total lymphadenectomy. Risks associated with this procedure include lymphedema (fluid accumulation in the legs leading to pain and swelling), longer surgery time, nerve damage, and more blood loss.<sup>3</sup>

Note: Stryker's SPY-PHI, PINPOINT, and 1688 with the Advanced Imaging Modality (AIM) light source and SafeLight Cable are FDA 510(k) cleared for use with SPY AGENT GREEN (indocyanine green for injection, USP) for lymphatic mapping, and Stryker's SPY AGENT GREEN is the only indocyanine green approved for visualization of lymph nodes and lymph vessels during lymphatic mapping in women with cervical and uterine tumors.

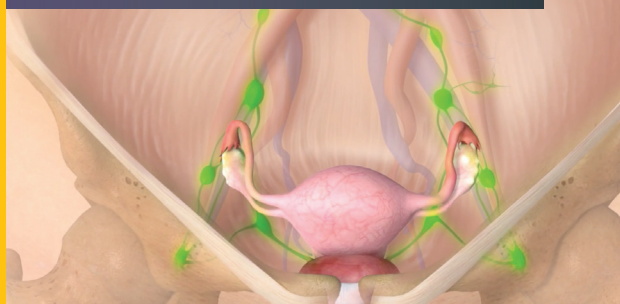
If you have a history of allergy to indocyanine green you should not be given SPY AGENT GREEN. Seek medical attention if, after being given SPY AGENT GREEN, you have reactions such as difficulty breathing, swollen tongue or throat, skin reactions (including hives, itching, flushed or pale skin), low blood pressure, a weak and rapid pulse or other signs or symptoms of an allergic reaction. Do not have a radioactive iodine uptake study (a thyroid function test) for at least a week following use of SPY AGENT GREEN because the iodine in SPY AGENT GREEN may interfere with the study. Information on this pamphlet should not be used as a substitute for talking with your surgeon. All surgery presents risk and women undergoing lymphatic mapping for cervical and uterine cancer might require a lymphadenectomy, which increases the risk of surgical complications and long-term morbidity. These complications include but are not limited to increased risks of bleeding during the course of surgery and swelling in the legs after surgery. Always talk with your doctor about diagnosis. PN 1000903424 Rev C

## Lymphatic mapping with SPY Fluorescence is an Alternative to Total Lymphadenectomy for Early-Stage Low-Risk Patients

**Lymphatic Mapping with SPY Fluorescence** is a procedure which uses near-infrared fluorescence imaging and SPY AGENT GREEN to help surgeons identify the lymph nodes to be removed for evaluation.<sup>1,2</sup> This technique minimizes the risk associated with traditional lymph node removal.

**SPY Fluorescence** is near-infrared fluorescence imaging using Stryker's SPY AGENT GREEN and SPY-PHI System, PINPOINT System, or 1688 System with the Advanced Imaging Modality (AIM) light source and SafeLight Cable.

**SPY AGENT GREEN** will be injected and then fluoresced to help identify the lymph nodes



**Using the surgical technique of lymphatic mapping** may result in the avoidance of unnecessary lymphadenectomy for some early-stage low-risk cancer patients whose disease may be confined to the uterus and cervix. This is important as evidence suggests that only 10% of early-stage patients were determined to have cancer in their lymph nodes requiring total lymphadenectomy.<sup>3</sup>

1. Frumovitz M, et al. Near-infrared fluorescence for detection of sentinel lymph nodes in women with cervical and uterine cancers (FILM): a randomised, phase 3, multicentre, non-inferiority trial. *Lancet Oncol.* 2018 Oct;19(10):1394-1403.

2. Data on File (Document number: RGD12135)

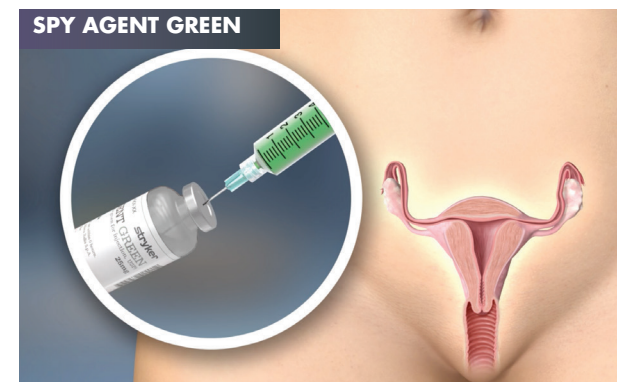
3. Abu-Rustum NR. Sentinel Lymph Node Mapping for Endometrial Cancer: A Modern Approach to Surgical Staging. *Journal of the National Comprehensive Cancer Network.* 2014; 12(2):288-297.

## Questions to Ask Your Doctor about Lymphatic Mapping

### Patient considerations for Lymphatic Mapping using SPY Fluorescence

Compared to blue dye, the FILM\* trial reported that lymphatic mapping using SPY Fluorescence more often successfully<sup>1</sup>:

- Identified at least one lymph node (the closest lymph nodes that would drain the tumor) 96% of the time.
- Mapped lymph nodes on both sides of the pelvis 78% of the time which is important because unsuccessful mapping on both sides of the pelvis may result in the need for a total lymphadenectomy.



### Recommended Conversation with Healthcare Team Member

- Can lymphatic mapping be part of my treatment plan?
- How do you perform the procedure?
- Will my insurance cover lymphatic mapping?
- When would I learn the results of my procedure?
- Who will discuss next steps for my treatment plan with me?

Limitations of the FILM\* study include but are not limited to 1) its inability to determine cancer related outcomes for lymphatic mapping and lymph node biopsy in women with cervical and uterine cancers, and 2) the study reflects the outcomes from surgeons experienced with the procedure and the technology.

\*Near-infrared fluorescence for detection of sentinel lymph nodes in women with cervical and uterine cancers (FILM): a randomised, phase 3, multicentre, non-inferiority trial.