

Kit for the Preparation of Technetium Tc 99m

Sulfur Colloid Injection

For Subcutaneous, Intraperitoneal, Intravenous and Oral Use
For Diagnostic Use by Prescription Only



Indications

- **In adults, indicated to assist in the localization of lymph nodes draining a primary tumor in patients with breast cancer or malignant melanoma when used with a hand-held gamma counter.**
- In adults, to assist in the evaluation of peritoneo-venous (LeVeen) shunt patency.
- Indicated for imaging areas of functioning reticuloendothelial cells in the liver, spleen and bone marrow.
- Indicated for studies of esophageal transit and gastroesophageal reflux, and detection of pulmonary aspiration of gastric contents
- Indicated for subcutaneous, intraperitoneal, intravenous and oral administration.

Fair balance

- **Warnings and Precautions** - Anaphylactic reactions including rare fatalities have occurred following intravenously administered Technetium Tc 99m Sulfur Colloid. Have resuscitation equipment and personnel immediately available.
- **Adverse Reactions** - The most frequently reported adverse reactions include rash, urticaria, anaphylactic shock, and hypotension.
- To view complete prescribing information, visit www.pharmalucence.com

Sulfur Colloid - Proven

In Lymph Node Localization studies for breast cancer using Sulfur Colloid and blue dye, SCI effectively localized in one lymph node in **94%** of all studies performed, while blue dye was shown to localize in only 85%⁽¹⁾

In Lymph Node Localization studies for melanoma using Sulfur Colloid and blue dye, SCI effectively localized in one lymph node in **96%** of all studies performed, while blue dye was shown to localize in only 84%⁽²⁾

(1) In 9,213 procedures using both Sulfur Colloid and blue dye, as cited in FDA approved product labeling for Sulfur Colloid (July 2011).

(2) In 249 patients using both Sulfur Colloid and blue dye, as cited in FDA approved product labeling for Sulfur Colloid (August 2012).

Sulfur Colloid - Trusted

Professional Societies recognize that Lymph Node Localization (LNL) studies performed with Sulfur Colloid Injection (SCI) are the established **standard of care** in breast cancer and melanoma patient management ^(3,4,5)

- ASCO (American Society of Clinical Oncology) guidelines for Breast Cancer and Melanoma
- Joint Clinical Practice Guideline, ASCO and SCO (Society of Surgical Oncology) for Melanoma
- SNM (Society of Nuclear Medicine) guidelines for Melanoma
- EANM and SNMMI guidelines for breast cancer⁽⁶⁾

(3) Sentinel Lymph Node Biopsy in Early-Stage Breast Cancer, American Society of Clinical Oncology Clinical Practice Guideline Update, Vol 32, No 13 (May 1), 2014: pp. 1365-1383.

(4) Sentinel Lymph Node Biopsy for Melanoma: American Society of Clinical Oncology and Society of Surgical Oncology Joint Clinical Practice Guideline, August 2012.

(5) Society of Nuclear Medicine Procedure Guideline for Lymphoscintigraphy and the Use of Intraoperative Gamma Probe for Sentinel Lymph Node Localization in Melanoma of Intermediate Thickness, June 2002.

(6) The EANM and SNMMI practice guideline for lymphoscintigraphy and sentinel node localization in breast cancer, August 2013.

Sulfur Colloid - Safe

In 8730 patients studied in 13 clinical publications evaluated for patient safety in lymph node localization in either breast cancer or melanoma patients, there were **no adverse events** reported attributed to Sulfur Colloid⁽⁷⁾

(7) Pharmalucence Sulfur Colloid s-NDA submissions to FDA (Approved 2011 and 2012).

Outcomes Study - Demonstrated Effectiveness

Krag DN, Anderson SJ, Julian TB, Brown AM, Harlow SP, Ashikaga T, et al.

“Technical outcomes of sentinel-lymph-node resection and conventional axillary-lymph-node dissection in patients with clinically node-negative breast cancer: Results from the NSABP B-32 randomized Phase III trials.”

Lancet Oncology (2007); 8(10) 881-888 ⁽¹⁾

- 5536 patients studied using **Sulfur Colloid**
- Excerpt from the Summary:

“the B-32 trial is the only trial of sufficient size to provide definitive information related to the primary outcome measures of survival and regional control.”

Sulfur Colloid - Summary

- Widely available
- Economically priced
- Well established
- Recognized standard of care
- Decades of use across several indications with proven safety and efficacy profile
- Efficacy in LNL studies supported by vast compendium of literature

For more information

www.sulfurcolloid.com