

BIOSENTRY
TRACT SEALANT SYSTEM

BIOSENTRY TRACT SEALANT SYSTEM

PLUG. PREVENT. PROTECT



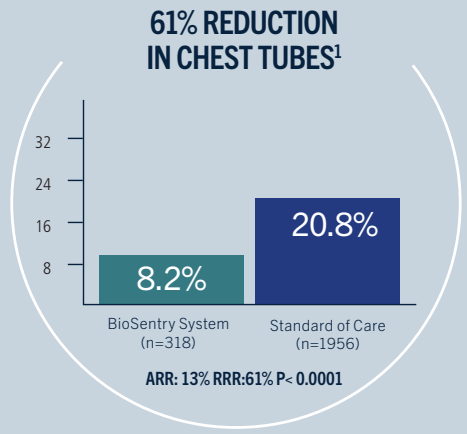
angiodynamics

Clinical study from MD Anderson Cancer Center denotes a 61% reduction in chest tubes

HIGHLIGHTS:

- 37% reduction of pneumothorax and 61% reduction of chest tube placement
- Although the BioSentry System was more frequently used in high-risk patients in the unmatched group, it still demonstrated reduced risk of pneumothorax
- Use of BioSentry System presents a standardized method for mitigating complications post CT-guided lung biopsy for clinicians

ARR = Absolute Risk Reduction RRR = Relative Risk Reduction



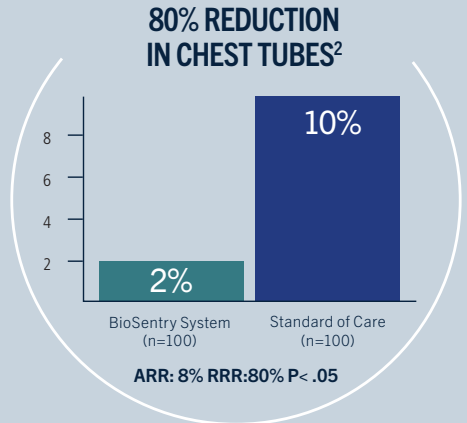
STUDY DESIGN:

Retrospective study, comparing patients receiving BioSentry device (318) vs control arm (1956) during percutaneous lung biopsy. To adjust for potential selection bias, patients in the treated group were matched 1:1 to patients in the control group using propensity score matching.

All-comers study demonstrates 80% reduction in chest tube insertion rates when using BioSentry

HIGHLIGHTS:

- The treatment group demonstrated a significant reduction in chest tube placements
- With the BioSentry System, patients experienced an 83% reduction in average time of hospital stay post CT-guided percutaneous transthoracic needle biopsy



STUDY DESIGN:

Retrospective review of 200 consecutive patients (100 consecutive biopsies were done without any intervention and the next 100 consecutive biopsies done with the BioSentry System).

INDICATIONS FOR USE: The BioSentry TRACT SEALANT SYSTEM is indicated for sealing pleural punctures to significantly reduce the risk of pneumothoraces (air leaks) associated with percutaneous, transthoracic needle lung biopsies and to provide accuracy in marking a biopsy location for visualization during surgical resection.

Warning: The BioSentry TRACT SEALANT SYSTEM can only be used with a 17 and 19 gauge coaxial introducer needle.

This instrument should only be used by a physician familiar with the possible side effects, typical findings, limitations and contraindications of lung biopsies. Physician judgment is required when considering biopsy on patients with bleeding disorders, receiving anticoagulant medications, or with bullous emphysema at or near the biopsy site.

Please refer to Directions for Use for further information pertaining to risks/contraindications. CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.



¹Ahrar, J.U., Gupta, S., Ensor, J.E. et al. Efficacy of a Self-expanding Tract Sealant Device in the Reduction of Pneumothorax and Chest Tube Placement Rates After Percutaneous Lung Biopsy: A Matched Controlled Study Using Propensity Score Analysis. Cardiovasc Intervent Radiol. 2017. 40(2):270-276.

²Grage RA, Naveed MA, Keogh S, Wang D. Efficacy of a Dehydrated Hydrogel Plug to Reduce Complications Associated With Computed Tomography-guided Percutaneous Transthoracic Needle Biopsy. J Thoracic Imaging. 2017 Jan; 32(1):57-62.

USA > 14 Plaza Drive, Latham, NY 12110 > tel: 800-772-6446 or 518-798-1215 > fax: 518-798-1360

International > Haaksbergweg 75 (Margrietoren), 1101 BR, Amsterdam Z-O > The Netherlands > tel: +31 (0)20 753 2949 > fax: +31 (0)20 753 2939

www.angiodynamics.com

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