

PLUG PREVENT PROTECT

BIOSENTRY
TRACT SEALANT SYSTEM



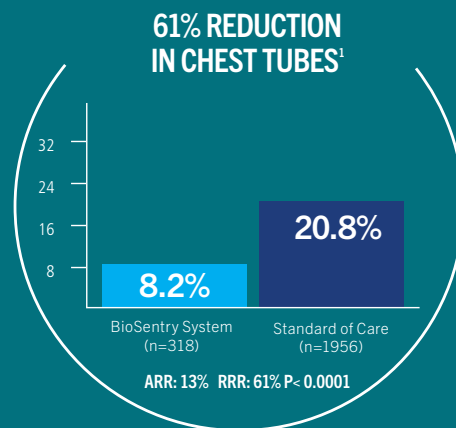
BIOSENTRY TRACT SEALANT SYSTEM IS THE FIRST BIOPSY SEALANT SYSTEM OF ITS KIND DESIGNED SPECIFICALLY TO ADDRESS THE ISSUES OF BIOPSY-RELATED PNEUMOTHORAX.

Clinical study from MD Anderson Cancer Center denotes a 61% reduction in chest tubes¹

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



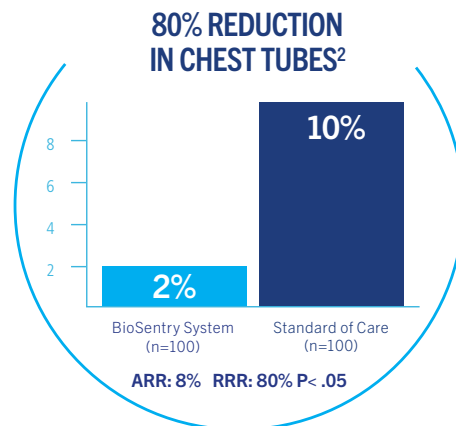
STUDY DESIGN:

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 the BioSentry System²

HIGHLIGHTS:

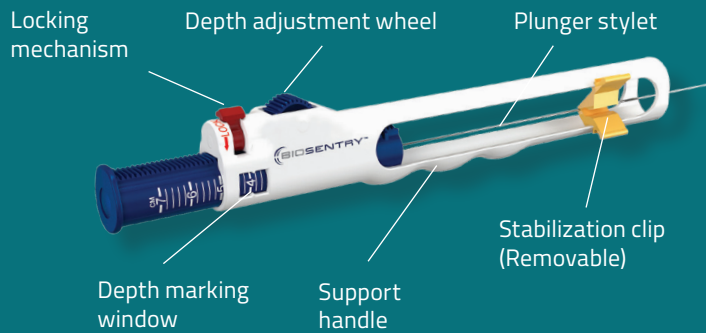
- The treatment group demonstrated a significant reduction in chest tube placements
- With the BioSentry System, patients experienced an 83% reduction in average time of hospital stay post CT-guided percutaneous transthoracic needle biopsy



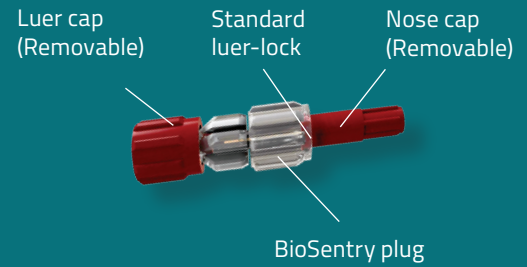
STUDY DESIGN:

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).

Delivery Device



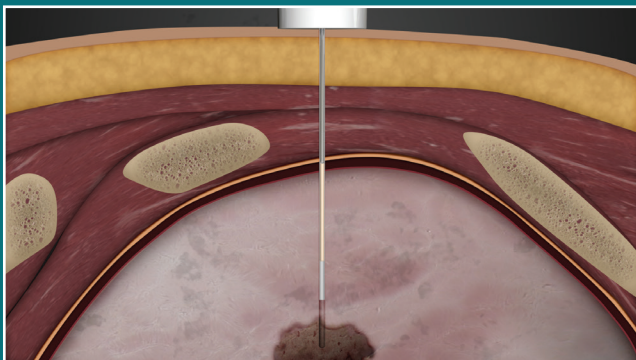
Co-Axial Adapter



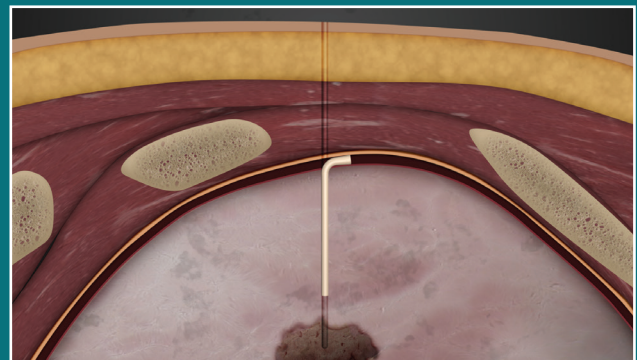
The BioSentry tract sealant system deploys a self-expanding hydrogel plug into the pleural space following a percutaneous lung biopsy. This creates an airtight seal that closes the pleural puncture and provides accuracy in marking a biopsy location for visualization during surgical resection.

BENEFITS

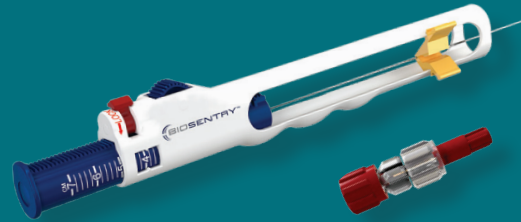
- Hydrogel plug **fully resorbs**[†]
- During this time it is **visible and marks the biopsy location** for surgery
- The applicator **standardizes the method** how the plug is placed¹
- Usable with **17 & 19 Gauge** coaxial introducer needles
- **No clinically significant complications** associated with use²



Dehydrated plug is deployed with 0.5cm extending into the pleural space



Plug swells, creating an airtight seal that closes the pleural puncture



SKU	DESCRIPTION	PACKAGING
H78776822019S1	BIOSENTRY TRACT SEALANT SYSTEM	5/BOX

† Data on File

REFERENCES

- ¹ Ahrar JU, Gupta S, Ensor JE 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; Feb 40(2):270-276. doi: 10.1007/s00270-016-1489-9.
- ² Grage RA, Naveed MA, MD, Keogh S, Wang D. Efficacy of a Dehydrated Hydrogel Plug to Reduce Complications Associated With Computed Tomography–guided Percutaneous Transthoracic Needle Biopsy. *J Thorac Imaging.* 2017; Jan 32(1):57-62, doi: 10.1097/RTI.0000000000000247.

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.

Warnings: 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 anti-coagulant 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.



USA > 14 Plaza Drive, Latham, NY 12110 > tel: 800-772-6446 or 518-798-1215 > fax: 518-798-1360
International > Haaksbergweg 75 (Margietoren), 1101 BR Amsterdam Z-O > The Netherlands
tel: +31 (0)20 753 2949 > fax: +31 (0)20 753 2939

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