MERIT MEDICAL®

BIOSENTRY® TRACT SEALANT SYSTEM

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your sales representative. Inspect prior to use to verify that no damage has occurred during shipping.

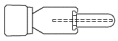
For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

KIT CONTAINS:

- 1X *BioSentry®* delivery system

- 1X Coaxial Adapter with *Bio-Seal®* plug



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, indications 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.

CAUTION:

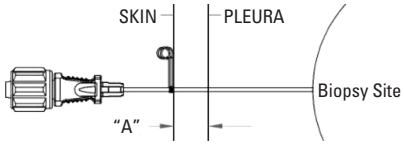
- Verify BioSentry plug is loaded in coaxial adapter prior to use.
- Do not use this device if the skin to pleura distance of the biopsy path is less than 1cm or exceeds 7cm.
- Do not use multiple plugs in the same needle tract
- Store in a cool, dark, dry place.

NOTE:

- The coaxial introducer needles may have working lengths which will differ from the working lengths of the biopsy devices used.
- The individual practitioner is responsible for the proper procedure and techniques to be used with this device.
- Performance has not been studied with a biopsy that crosses a pulmonary fissure or with multiple plural punctures.

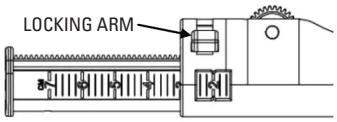
INSTRUCTIONS FOR USE

1. Using a coaxial introducer needle, perform the biopsy per the Directions for Use supplied with the biopsy instrument selected.



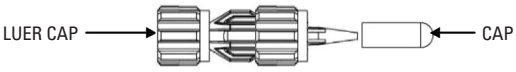
2. After the biopsy sample has been taken, compute distance "A" (in cm) from the skin to the pleural surface using appropriate imaging technique.

NOTE: The coaxial cannula depth stop is optional and may be removed prior to using the coaxial introducer needle.



3. Unlock the red lock arm on the BioSentry delivery system by moving it to the unlocked position.
4. Adjust the depth until the white arrows in the marking window match the skin to pleura distance computed in the Step 2.
5. Relock the device by moving the red lock arm to the locked position.
6. Remove the tip protector from the distal tip of the plunger.

NOTES: The small graduations on the BioSentry delivery system are 2 mm (0.2 cm) apart.



7. Remove the red cap from the adapter and verify that the BioSentry plug is visible in the coaxial adapter.

NOTE: Hold the adapter horizontal to prevent the BioSentry plug from falling out.

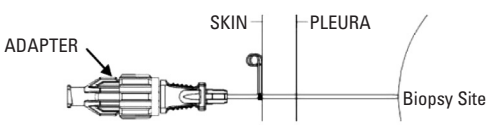
8. Ensure that the stylet has been removed from the coaxial introducer needle and fill the coaxial introducer needle hub with drops of saline to prehydrate the plug. Saline is not necessary if fluid is already present in the introducer hub.

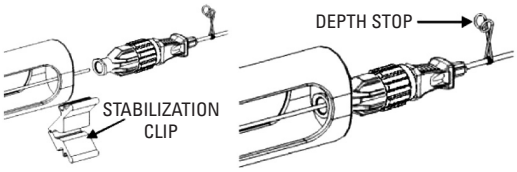
NOTE: The BioSentry plug should be deployed within fifteen (15) seconds of securing the adapter assembly to the coaxial introducer needle. Hydration and swelling of the BioSentry plug begins upon exposure to fluid; delays may lead to difficulties or inability to deploy.

9. Attach the coaxial adapter to the end of the coaxial introducer needle hub and tighten.

NOTE: Avoid over tightening to ensure smooth release of plug from the coaxial adapter into the coaxial introducer needle.

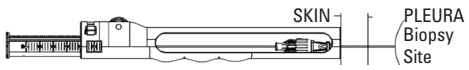
10. Remove the red luer cap from the coaxial adapter.



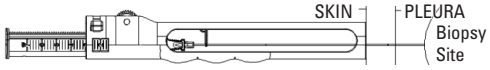


11. Remove the yellow stabilization clip as shown.
12. Position the BioSentry delivery system such that the plunger stylet begins to pass through the coaxial adapter.

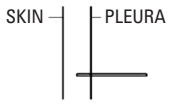
NOTE: The stabilization clip must be removed to properly deploy the BioSentry plug.



13. Advance the BioSentry delivery system until it contacts the patient's skin. If the depth stop is used, it must be properly aligned inside the housing. This positions the BioSentry plug within the coaxial introducer needle to the correct depth as determined in Step 2.
14. If the introducer needle is inserted into the skin at an angle, the BioSentry delivery system may still be used so long as one edge of the delivery system makes contact with the patient's skin, and the skin to pleura distance does not exceed 7cm.



15. Retract the coaxial introducer needle by reaching through the oval windows of the BioSentry delivery system and pulling the coaxial introducer needle away from the skin until the entire coaxial adapter fully enters the distal end of the blue plunger. While retracting the introducer needle, the spring clip, if used, must be oriented within the housing. Maintain slight downward pressure on the BioSentry delivery system.



16. Remove the coaxial introducer needle and the delivery system together in one motion to complete the procedure. The BioSentry plug is deployed across the visceral pleura as shown.

CLINICAL TRIAL

The efficacy and safety of BioSentry Tract Sealant System was demonstrated in a randomized, multicenter clinical trial of 339 patients undergoing percutaneous transthoracic needle aspiration biopsy for non-calcified lung masses. Subjects with bullous emphysema at or near the biopsy site, multiple pleural punctures, or a biopsy crossing a fissure were excluded.

The group treated with BioSentry Tract Sealant System and the control group were comparable in age, gender, ethnicity, height, and weight respectively. Both groups also had comparable percentages of patients with a history of smoking.

Treatment success was defined as the absence of a pneumothorax at each of the three follow-up time periods (0-60 minutes, 24 hours and 30 days).

Treatment Success - Per Protocol Population

BioSentry n (%) N = 150	Control n (%) N = 137	p-value
126 (84%)	94 (69%)	0.0021

Fewer patients treated with BioSentry Tract Sealant System were admitted to the hospital for pneumothoraces than controls (5% vs. 8%) and for all causes (9% vs. 14%). Patients treated with BioSentry had fewer chest tubes placed than controls (4% vs. 11%) with fewer placed for large (1% vs. 5%) or non-resolving (1% vs. 5%) pneumothoraces.

Adverse Events – Intent to Treat Population

	BioSentry N = 170		Control N = 169	
AE Category	**Number of Events**	**Number (%) of Patients**	**Number of Events**	**Number (%) of Patients**
Any Device AE	61	43 (25%)	96	74 (44%)
AE other than pneumothorax	23	6 (4%)	30	8 (5%)
Non-device AE	53	31 (18%)	59	36 (21%)
AE's that were more common in the group treated with BioSentry than in the Control group and were > 1%				
Coughing with Blood	5	3 (2%)	2	2 (1%)
Infections	3	3 (2%)	2	2 (1%)

Any Device AE includes all procedure related AE including pneumothoraces, AE's other than pneumothorax includes procedure-related AE that might reasonably be attributed to the device or procedure. Non-device AE's are those not reasonably attributable to the procedure. Adverse device effects were comparable between the treatment and control groups, with the exception of reported pneumothoraces (including chest pain with pneumothorax) and pleural fluid which were higher in the control group. The percentages of non-device related adverse events were similar between the control and treatment arms (21% vs. 18%).

Symbol	Reference Number	Title of Symbol	Meaning of Symbol
℞ ONLY	NA	Rx only	Caution: (US) Federal law restricts this device to sale by or on the order of a licensed practitioner.[a]
	3082	Manufacturer	Indicates the medical device manufacturer.[b]
	2607	Use-by date	Indicates the date after which the medical device is not to be used.[b]
LOT	2492	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.[b]
REF	2493	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified.[b]
STERILE EO	2501	Sterilized using ethylene oxide	Indicates the medical device has been sterilized using ethylene oxide.[b]
	2608	Do not resterilize	Indicates a medical device that is not to be resterilized.[b]
	2606	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.[b]
	1051	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.[b]
	1641	Consult instructions for use	Indicates the need for the user to consult the instruction for use.[b]
	0434A	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot for a variety of reasons be presented on the medical device itself.[b]
UPN	NA	Universal Product Number	A Universal Product Number (UPN) code represents the manufacturer's number for an item
	NA	Quantity in package	To indicate that the adjacent number reflects the number of units contained in the package.
		Recyclable Package	To indicate that packaging is recyclable.[c]
		Non-Pyrogenic	Indicates a medical device is non-pyrogenic.[b]

a. 21 CFR 801.109 - Code of Federal Regulations.

b. ISO 15223-1: 2016 - Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied.

c. EN ISO 14021 Environmental labels and declarations. Self-declared environmental claims (Type II environmental labeling)

MERITMEDICAL® www.merit.com

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407956002_001 ID 2024-01-31

Recyclable Package