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Air Barrier System™

For Hip and Posterior Spine Procedures

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30031 Ahern Avenue
Union City, CA 94587-1234 USA
Telephone: 510-429-1500
Toll Free: 800-777-4674
Fax: 510-429-8500
Outside USA: +1-510-429-1500
mizuhosi.com
newhipnews.com

Mizuho OSI

Note: Mizuho OSI is constantly improving its products. All specifications are subject to change without notice. Mizuho OSI is a Delaware Corporation. Manufactured in the USA.

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The air emitted by the nozzle is HEPA filtered and 99.97% free of particles 0.3 µm or larger.

Cleaner Air At The Incision

The **Air Barrier System**™ provides surgeons and risk managers a targeted tool to help mitigate surgical site infections. Complementary to existing systems used today, the Air Barrier System provides an additional layer of infection control for hip arthroplasty and posterior spine surgeries. Featuring a low-profile footprint in the operating room and a sterile disposable component that integrates easily into the standard workflow, the Air Barrier System has been clinically shown to help reduce airborne levels of bacteria at the surgical site.[1]

Factors That Contribute to Airborne Bacterial Concentrations

The Air Barrier System helps to address elevated bacterial levels found at or near the surgical site. A number of factors may contribute to these higher levels of bacterial concentrations in the air in the operating room.[1]

- Number of door openings during a procedure
- Number of individuals in the room
- Type of procedure taking place

How It Works

A disposable sterile nozzle is placed near the surgical site and emits ultraclean, nonturbulent air. The air envelops the incision with an air barrier of positive pressure. As a result, particles that may carry bacteria, that would normally land in the surgical site are deflected by the air barrier.

Optimizing Performance

The performance of whole room ventilation systems, including advanced systems such as HEPA filtered Laminar Air Flow, can suffer due to obstacles such as lights, booms, pendants and individuals that come between the source of clean air and the surgical site.

The Air Barrier System overcomes these obstacles by emitting HEPA filtered ultra clean air directly to the surgical site during procedures. The device also maintains a positive pressure barrier around the surgical site when the ambient OR air pressure changes.

Increased Airborne Bacteria Lead to Surgical Site Infections

In a randomized 300 patient study published by Infection Control & Hospital Epidemiology, increased airborne bacterial concentrations at the incision site were shown to increase the incidence of implant surgical site infections after hip arthroplasty and instrumented posterior spine surgery.[2]

In that same study the control group (N = 146) had 4 implant SSIs while the Air Barrier System group (N = 148) had 0 implant SSIs.

AORN Recommendation

Citing two randomized clinical studies using the Air Barrier System, the AORN Guideline for Sterile Technique recommends the use of portable ultraclean unidirectional air delivery systems delivered to the surgical incision when a fixed unidirectional (laminar air flow) ultraclean air delivery system is not available or is not large enough to cover the entire sterile field.[2]

“High quality evidence supports the use of portable unidirectional ultraclean air delivery systems at the surgical site.”[2]

“Two RCTs showed that the use of sterile hose to deliver unidirectional ultraclean airflow over the surgical wound decreased bacterial contamination.” [1,2,3]

Surgical Site Infection Concerns

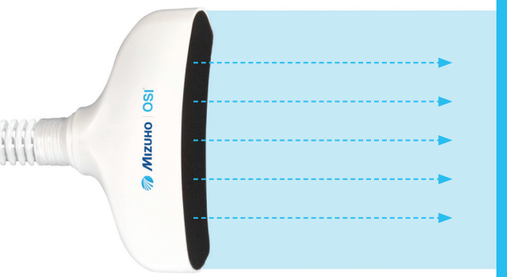
- Procedure duration, implant use, and pre-existing conditions are contributing factors to SSI risk.[4,5]
- SSIs resulting from Posterior Spine Surgery can result in charges of **over $40,000 per additional required surgery**.[6]
- Among 311 US residents over 45 surveyed, **74%** would select a hospital that uses new technology for surgical infection prevention over others.[7]
- 60% to 70% of respondents would **drive an additional 50 miles** and pay an additional $500 out of pocket to go to a hospital with new infection prevention technology.[6]

$3.3B

According to the CDC, Surgical Site Infections (SSI) are the most costly hospital acquired infection with an estimated annual cost of $3.3 billion.[8]

Safe & Simple Intraoperative Adjustments

The Air Barrier System is attached to the patient via a sterile, single-use adhesive fastener pad interface. The sterile, single-use nozzle can easily be adjusted intraoperatively along the fastener pad.



Minimal Device Interference

As the positive pressure barrier created by the device is made up entirely of air, it results in minimal interference with surgeons, staff, and instruments. With an effective range of 20” (50.8 cm), the system is designed to allow for placement of the nozzle near the incision, maintaining coverage and minimizing interference.

Radiolucent
Nozzle & Hose

Specifications & Components

Specifications

Blower

Footprint	12 in. (30.5 cm) x 12.5 in. (31.8 cm)
Height	24 in. (61 cm)
Weight	<45 lbs (20.4 kg)
2 wheels	
Telescoping Handle	

Nozzle

Dimensions	8.5 in. (18.7 cm) width x 3 in. (6.6 cm) height x 5.5 in. (12.1 cm) depth
Hose Length	72 in. (158.7 cm)

Electrical

Device Ratings	120 VAC, 60 Hz, 5 Amp Max.
Power Consumption	<50 Watts
Leakage Current	<0.1 mA
Power Cord	10’, 125 VAC, 10 A
Power Supply Fuse Rating	Two (2) 5 x 20 mm, 5A, 250V, T (time-lag)
Enclosure Water Protection	IPX2

Supported Procedures

- Hip arthroplasty[9]
- Posterior spinal fusion[9]
- Laminectomy[9]

Ordering Information

REF	600-0017	Air Barrier System Blower
	600-0015	Air Barrier System Nozzle* (5/cs)
	600-0016	ABS Hook and Loop Pad* (10/cs)

*Sterile, single-use component