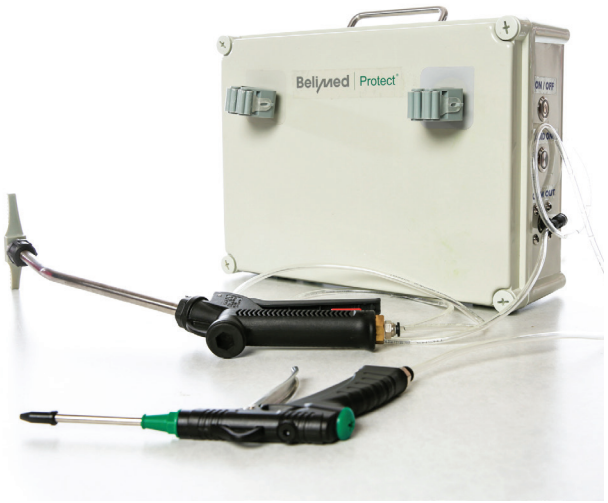
Importance of Pretreating Surgical Instruments with Minimal Aerosolization

Belimed Protect® Pretreatment Product

SECTION 1: Surgical procedure statistics and importance of precleaning surgical instruments after the medical procedure.

"The number of outpatient surgical procedures in the U.S. is expected to climb to 144 million per year by 2023. Additionally, more than 48 million inpatient surgical procedures are performed in hospitals annually. The tremendous growth in surgical cases may be associated with an increased risk of Surgical Site Infections (SSI's) if hospitals and surgery centers are not carefully following all of the guidelines to reduce the risks of SSI's, including instrument cleaning and transport recommendations set forth by the Centers For Disease Control and Prevention (CDC) and The Association for the Advancement of Medical Instrumentation® (AAMI").
[Infection Control Results, 04/26/2011]



It is essential to ensure optimized cleaning processes such as pretreating instruments used in surgical procedures to reduce this risk.

The instrument reprocessing cycle starts in the Operating Room (OR), with the pretreating of instruments with enzymatic or non-enzymatic detergent applied either manually or using an automated machine. The detergent (in the form of foam, liquid, or gel) covers the dirty instruments and keeps them moist to avoid concentrations of bio-soil residue on surgical instruments' surfaces after use. This practice is crucial to improving surgical instrument first-time cleaning pass rates.

Close attention should be paid to how the process is performed and the many benefits of pretreating surgical instruments.

The most common method of pretreating instruments is manual spraying of the solution onto the instruments. Although this process allows for flexibility and mobility, automated foamer machines have started gaining popularity.

A pretreatment foamer machine assures more ergonomic application and better compliance in pretreating surgical instruments and medical machines, as is outlined later in Section 5.

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SECTION 2: Pretreatment product application aerosolization properties.

When the pretreatment product is applied in the OR and other healthcare settings, the liquid droplets can aerosolize and become airborne and inhaled in the environment.

When you aerosolize the product, you raise the carbon footprint and potentially "contaminate" the surrounding air.

The American Lung Association reports that "the respirable particles are the particles that reach lower airways in the gas exchange region of the lungs, and they are equal or less 4 microns."

Keeping the "air pollution" to a minimum in the operating room benefits patients and healthcare workers. Examples of common pollutants found in the Operating room, which should be avoided, are shown in Table 1 below.

Table 1.

TERM	MEANING
Aerosol	Colloidal-sized atmospheric particle solids or liquids less than 100mm in diameter
Condensation Aerosol	Formed by condensation of vapors or reactions of gases
Dispersion Aerosol	Formed by grinding of solids, atomization of liquids, or dispersion of dusts
Fog	Term denoting high level of water droplets
Haze	Denotes decreased visibility due to the presence of particles
Mists	Liquid particles
Smoke	Particles formed by incomplete combination of fuel

["Inorganic Air Pollutants", Manahan, Stanley E.]

When applying the pretreatment solution, it should be assured the application method is safe and does not aerosolize the product:

- Applying the product as a mixture of liquid/foam will aerosolize the product.
- Applying the product as a foam will minimize aerosolization of the product. This could be done either manually or by use of an automated machine.

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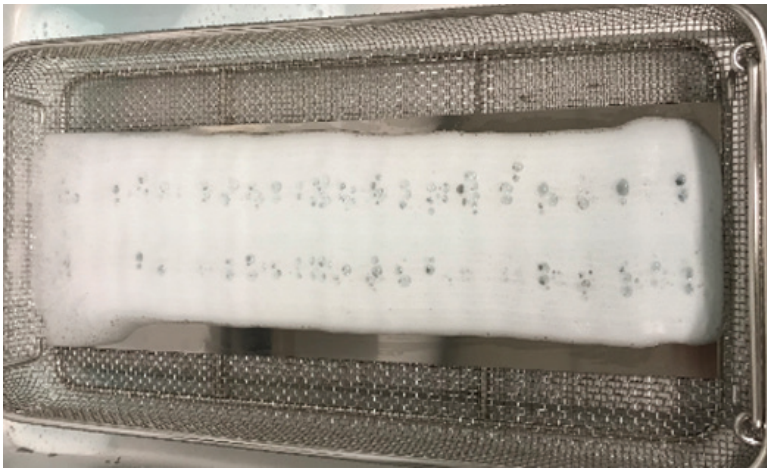
SECTION 3: The Protect® Pretreatment aerosolization properties.

A. Protect® Pretreatment Product – manual application with Trigger sprayer nozzle in foam mode.
The Belimed Protect® Pretreatment product was applied with the bottle trigger position in spray foam mode, as shown in Figure 2.

Figure 2.



The data was collected from four trials using an Air Particle Counter, Model VPC300 and summarized into average values.

This data summary is shown in Figure 3.

Figure 3.

Belimed Protect Pretreatment Foam Spray	Testing Date 10/14/2021	Particle Size	Air before application CONTROL				Control Avg.	Std Dev.	Air after application Belimed Protect Pretreatment applied manually Trigger in Foam Spray Mode				Foam Spray Avg.	Std Dev.
	Particle Size	0.3 µm	29235	35171	49913	38197	**38129**	**8693**	31112	45877	44158	43048	**41049**	**6726**
		0.5 µm	6553	7560	9825	7907	**7961**	**8554**	7143	10196	10605	9201	**9286**	**1546**
		1.0 µm	755	1124	1599	1266	**1186**	**350**	1185	1571	1568	1101	**1356**	**249**
		2.5 µm	136	148	214	134	**158**	**38**	217	226	239	161	**211**	**34**
	Environment	AT (°C)	19	20	23	22	21	2	19	19	23	22	21	2
		RH (%)	70	84	78	69	75	7	69	73	76	69	72	4

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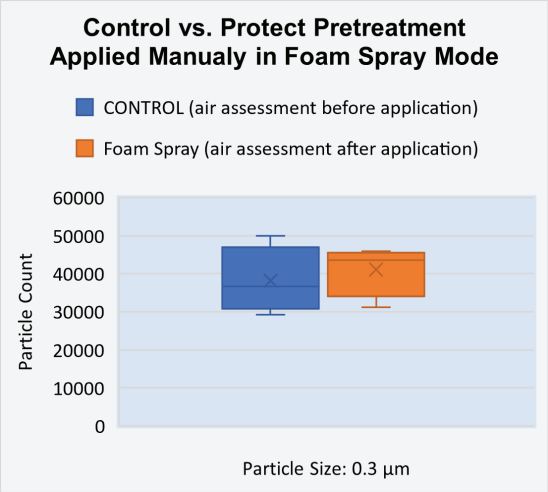
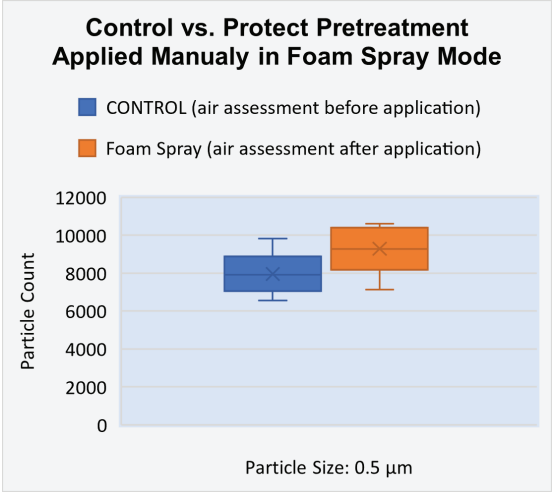
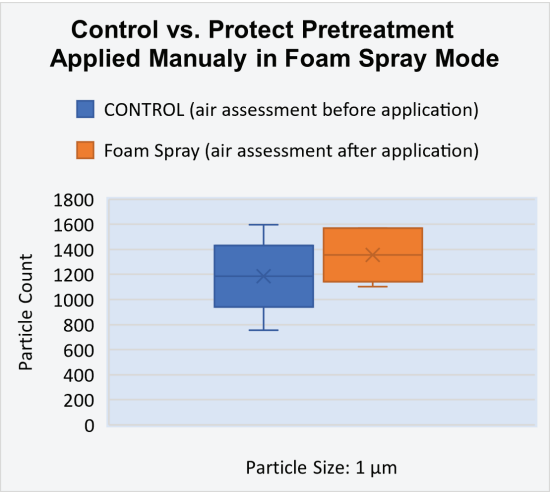
The graphical representation of the particle size aerosolization averages test values is shown in Figure 4.

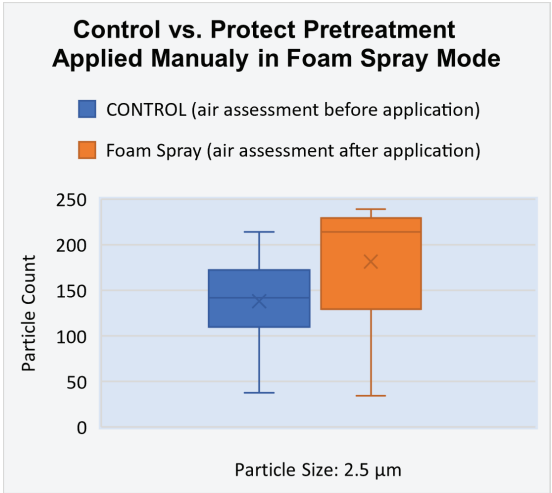
Figure 4.
- Distribution for 0.3 and 0.5 micrometer particles





- Distribution for 1 and 2.5 micrometer particles





Testing Conclusion
The particle count distribution between the tested subject, manual application of Pretreat foam, and the surrounding atmosphere is similar for all particle sizes. Therefore, there is minimal introduction of particles into the surrounding air, when pretreatment is applied using a manual foam application.

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B. Protect® Pretreatment Product – automated application with Protect Pretreatment Foamer.
The Belimed Protect Pretreatment Product was applied uniformly over the surgical instruments, as demonstrated in Figure 5, using the machine shown in Figure 5.

Figure 5.

The data was collected from four trials using the Air Particle Counter, Model VPC300 and summarized into average values.

This data summary is shown in Figure 6.

Figure 6.

Belimed Protect Pretreatment Foamer Machine	Testing Date 10/14/2021	Particle Size	Air before application – CONTROL				Control Avg.	Std Dev.	Air after application – Belimed Protect Pretreatment Foamer Machine				Foamer Avg.	Std Dev.
	Particle Size	0.3 µm	14431	39707	49830	27900	**32967**	**15265**	16668	40710	52668	33131	**35794**	**15075**
		0.5 µm	3815	9266	10918	6371	**7593**	**3142**	4156	10145	11031	7822	**8289**	**3069**
		1.0 µm	607	1328	1815	885	**1159**	**529**	806	1827	1848	1293	**1444**	**497**
		2.5 µm	70	214	186	141	**153**	**63**	132	232	265	160	**197**	**62**
	Environment	AT (ºC)	21	20	20	19	20	1	19	20	20	19	19	1
		RH (%)	56	76	74	69	69	9	59	76	75	68	69	8

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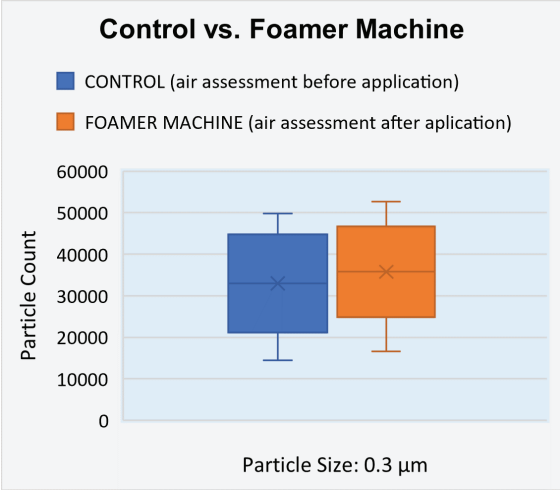
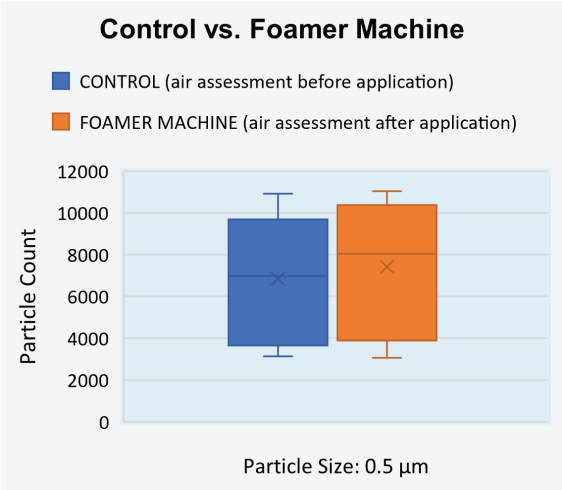
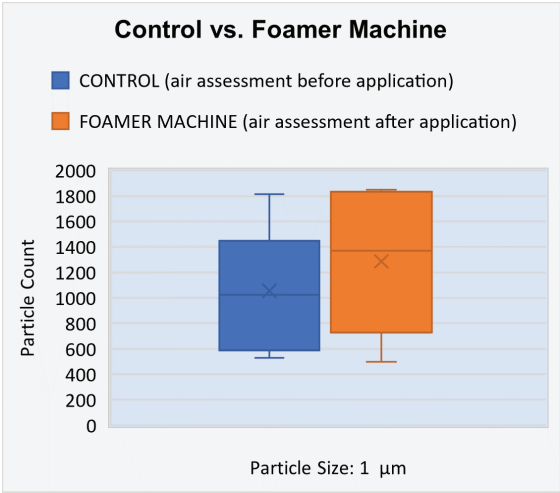
The graphical representation of the particle size aerosolization distribution test values are shown in Figure 7.

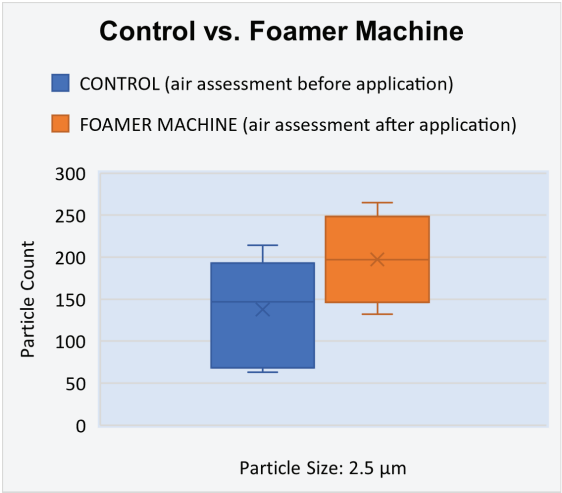
Figure 7.
- Distribution for 0.3 and 0.5 micrometer particles





- Distribution for 1 and 2.5 micrometer particles





Testing Conclusion
Overall, the particle count difference between the tested subject, the Pretreatment Foamer application, and the surrounding test atmosphere is similar for all particle sizes. Therefore, there is minimal introduction of particles into the surrounding air, when pretreatment is applied using an automated foaming application.

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SECTION 4: The benefits of pretreating surgical instruments with Belimed Protect Pretreatment using foam application are as follows:

- Assuring the product does not aerosolize, therefore, allowing for pretreatment in the operating room
- Producing heavy and thick foam, which provides complete coverage of the instruments
- Compliance with the Joint Commission requirement to keep the soiled instruments moist until they reach the Sterile Processing Department
- Removing much of the blood and bio-soil from the instruments, which helps with the following:
  - Reducing time and effort for the manual process of cleaning
  - Increasing the work satisfaction of surgical technicians due to reduced hand fatigue
  - Preventing damage to the instruments' passivation layer and therefore avoiding their pitting and corrosion
  - Protecting the hospital's biggest financial investment, surgical instruments, by prolonging their life span
- Inhibiting the formation of biofilm
- Improving the decontamination processes of surgical instruments, ensuring smooth operation of the CSPD and OR
- Complying with OSHA requirements on ergonomics

SECTION 5: Summary Statement

The use of pretreatment cleaning products is one of the critical steps in the instrument reprocessing cycle.

Belimed tested manual spray in foam mode and automated foam spraying applications. Both showed air particulates emission trends comparable to the number of particulates present in the tested room before pretreatment application.

To reduce the risk of potential aerosolization of Pretreatment Products, Belimed recommends the use of foaming machines or hand spray foam application.

In addition, automated foaming machines are great tools for implementing and reinforcing compliance with the pretreatment of surgical instruments due to ease of operation, ergonomic benefits, application time, and surface coverage.

Disclaimer: The information provided is specific to the Belimed testing condition and can't be directly reproduced. The content of air particulates is unique to the geographic location and off-gassing of the materials present at the testing site and can change based on air patterns and movement. Therefore, the measurement of the particulates before and after may vary.

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