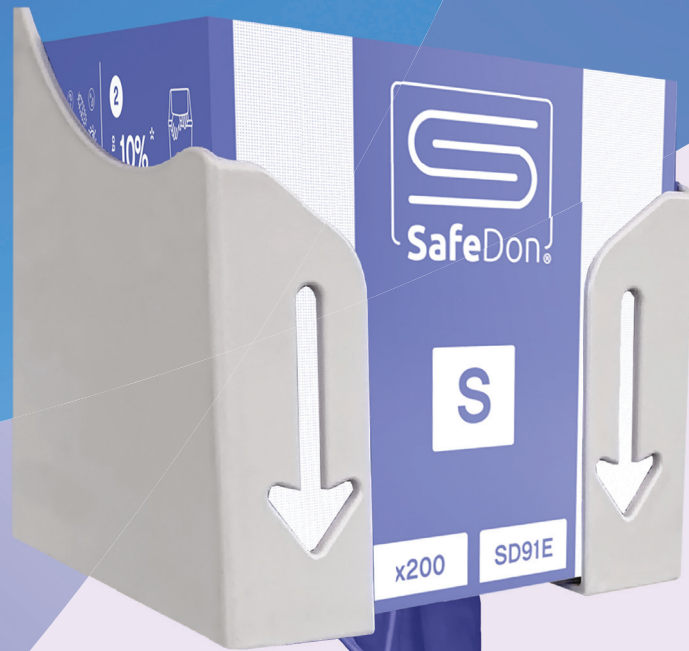




BIOBURDEN COMPARISON STUDY



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In summary

This report summarises work undertaken by Swann Morton Microbiological Laboratory Services to determine whether gloves in the SafeDon packaging system are less prone to becoming contaminated than gloves packed in the traditional packaging systems.

The gloves evaluated were a typical nitrile and latex disposable examination glove.

Over a course of 6 weeks gloves were used by a selection of end users. Samples were taken from each site every week and evaluated for bioburden in an accredited laboratory. The results were then compared to establish whether the SafeDon packaging system helped prevent contamination occurring on gloves compared to traditional packaging systems.

Contact plates were used to directly compare the cleanliness of the packaging and aperture.

Testing showed that the gloves in SafeDon packaging were less contaminated than the gloves in standard packaging. This was confirmed in all seven sites evaluated.



Introduction

The SafeDon packing system has been developed to dispense gloves one at a time, cuff first. The first glove is donned on the hand and this donned hand then used to remove the next glove reducing cross contamination.

In traditional packing the gloves dispense in a more random orientation and often more than one glove is dispensed at a time, leading to them becoming contaminated as they come in to contact with other surfaces before being donned.

In addition, the SafeDon packaging system is wall mounted with the aperture facing downwards which should help prevent contaminants settling on the exposed gloves.

- Testing sites were selected, and each customer was provided with SafeDon packaged gloves and traditionally packaged gloves
- Validation work was undertaken on unopened boxes of gloves in order to establish pre-existing background levels of contamination
- Testing sites were visited on a weekly basis over a period of six weeks and samples of gloves from each packaging system were taken
- Gloves were tested for mould and bacteria bioburden. Average background contamination was subtracted from the results
- Contact plates were used at each site to test for amounts of contamination on the surface of the glove box, particularly around the aperture area
- Results analysed



EXAMPLE SHOWN SafeDon
CUFF 1st™ GLOVE
DISPENSING SYSTEM.

DISPENSES ONE
GLOVE AT A TIME.

Bioburden Method Validation

The gloves in the Safedon and traditional packaging were sampled and tested as shown below:



No of Samples

6 lots of 3

Media

Tryptone Soya Agar



Test Method

Samples were automatically agitated in 100 ml sterile Ringer solution for a period of 2 minutes.

10mls of the fluid was then inoculated into a petri dish and mixed with molten agar and allowed to set.

Recovery efficiency was determined by repeating the extraction process in triplicate.

All plates were incubated at 30 °C +/- 2 °C for a minimum of 4 days.

Following incubation, the number of colony forming units on each plate was determined.



Background Bioburden

Carried out to calculate the background bioburden on gloves in order to calculate an average which can be subtracted from the comparison samples.

Note: Background levels of mould were found to be insignificant. Therefore, no subtraction of background bioburden was conducted for mould.



Determination of Glove Bioburden

To find amounts of bioburden on Safedon and traditional packaged gloves from various sites were sampled over a period of six weeks in order to compare bioburden levels between the two packaging systems.

The glove bioburden was assessed on Tryptone Soya Agar & Sabouraud Dextrose Agar and the surfaces of the Safedon packaging and traditional packaging were also evaluated for contamination.

Results

The results are summarised in the tables below:

SITE	OVERALL % IMPROVEMENT OVER THE SIX-WEEK PERIOD	
	BACTERIA	MOULD
Cartridge World	55.52%	61.97%
Anston Medical	13.2%	10.1%
Thornberry Animal Sanctuary	91.7%	100.0%
Killamarsh Care Home	83.7%	28.8%
Peace Funerals	96.2%	94.1%
Minto Road Dental	57.4%	52.6%
Thou Art Tattoo	255.0%	-14.1%

	OVERALL AVERAGE COUNT FOR ALL SITES OVER 6 WEEKS	
	BACTERIA	MOULD
SafeDon	39.8	4.7
Traditional	529.8	41.2
% improvement SafeDon compared to traditional packaging	92.5%	88.6%



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Second Study

Following the initial study a second study was carried out at Glan Clwyd Hospital HSDU department in North Wales. This was carried out to compare the SafeDon packaging against traditional packaging in a specific health care environment.

The same methodology was used as in the initial study but the gloves were placed in a clean room gowning area and a wash room reception. Samples were taken from each packing type at each location each week for six weeks and analysed for bioburden.

The gloves were compared each week for the percentage Bioburden improvement as shown in the table below:

	PERCENTAGE IMPROVEMENT USING SafeDon COMPARED TO TRADITIONAL PACKING AT EACH SITE					
	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6
Clean room gowning	75.5	100	100	100	100	0
Wash room reception	86.6	0	0	100	0	100

The average colony forming units at all sites is shown below together with the percentage improvement:

PACKING SYSTEM	AVERAGE COLONY FORMING UNITS FROM BOTH SITES					
	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6
SafeDon	26.9	0	0	0	0	0
Traditional	136.8	29.4	143.3	166.8	17.4	155.4
% improvement with SafeDon	80.3%	100%	100%	100%	100%	100%

The overall improvement for SafeDon packing over traditional packing over the 6 weeks for % bioburden and reduction in percentage bacteria count are shown in the tables below:

HOSPITAL AREA	AVERAGE IMPROVEMENT FOR SafeDon OVER THE 6 WEEKS (%)
Clean room gowning	79.3%
Wash room reception	47.8%

	AVERAGE BACTERIA COUNT OVER THE 6 WEEKS
SafeDon	4.5cfu
Traditional	108.2cfu
Percentage improvement	95.9%

Conclusion

At all seven sites and for each glove type (Nitrile and Latex) there was a significant reduction in bacteria bioburden, and in six sites a reduction in mould count with the SafeDon packaging system compared to the traditional style packaging.

The overall contamination was reduced in all sites and showed the benefits of this packaging system in terms of bioburden reduction.

Significantly less contamination was found on SafeDon packaged gloves as opposed to traditional packaged gloves in all six weeks. Comparing all sites over the entire six-week period, SafeDon packaged gloves had 92.5% less bacterial contamination and 88.6% less mould contamination compared with traditional gloves.

The 2nd study carried out in Glan Clywd hospital showed a significant improvement when comparing the Bioburden of SafeDon compared to traditionally packed gloves with gloves from both the clean room gowning area and the wash room reception showing less bioburden (79.3% and 47.8% respectively). It would be expected to have less effect in the wash room reception as this area is kept very clean to reduce contamination transferring to other areas of the hospital.

The results show the clear benefits of SafeDon packaging over traditional packaging systems in reducing the bacterial and mould contamination, with an average 92.5% improvement for reduction in bacterial contamination and 88.6% for mould in the first study and in the 2nd study the overall average bacterial count 95.9% lower for SafeDon over traditionally packed gloves.



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