

Needle-Pro® EDGE™ Safety Device Deadspace

White Paper

INTRODUCTION

Needles are the most widely used medical device with an estimated 16 billion injections administered each year, often used for drug delivery, vaccinations, and injections¹. Exposure of blood borne pathogens, including Hepatitis B virus (HBV), Hepatitis C virus (HCV), and Human Immunodeficiency Virus (HIV), by needle stick injuries (NSI) is a risk to health care professionals (HCP). This exposure risk was a driving force for legislation in the United States mandating needle safety devices. Prior to legislation, 385,000 NSIs were estimated with only 60% reported². The total residual volume of medication in the cannula, hub, or Luer of the needle following injection is termed the “dead space” of the needle and syringe combination. This dead space may be increased as a result of the safety features added to minimize NSIs.

Increased dead space has been associated with inaccurate medication dilution and mixtures, increased risk of blood borne illness spread³, and may lead to increased drug waste, especially when using multi-dose vials or for pediatric centers preparing multiple smaller doses out of adult vials. Thus, minimizing this dead space is critical to maximizing safety and reducing costs.

The objective of this study was to compare the amount of retained volume, or dead space, in six (6) commercially available hypodermic safety needles. An independent laboratory study was performed to assess the average dead space volume in these hypodermic safety needles:



Smiths Medical
Needle-Pro® EDGE™



BD
SafetyGlide™



Covidien™
Magellan™



SOL-MILLENIUM®
Sol-Care™



BD
Eclipse™



TERUMO®
SurGuard® 3

METHODS

Smiths Medical commissioned an independent test from a third party lab. Syringes and 23 gauge needles were assembled using hand tightening, and the mass of the assembly was measured. The syringe was then filled with approximately 1cc distilled water through the needle and any residual air was removed in the syringe and needle was expelled. After all visible air bubbles were expelled, the water was dispensed into a beaker, taking care not to splatter water back into the unit. The mass of the syringe needle combination was then measured again, and the residual volume of water was calculated. A new needle was used for each replicate test, for a total of 10 tests per sample. The average retained volume was then calculated.

RESULTS

The average retained volume was calculated for each sample group (Table 1). The Smiths Medical Needle-Pro® EDGE™ Safety Device had the smallest average dead space volume, 50.33 µl. The Sol-Care™ Needle contained 57% more dead space, the BD Eclipse™ Needle had 37% more dead space, the TERUMO® SurGuard®3 had 34% more dead space, and the BD SafetyGlide™ Needle and Covidien™ Magellan™ Needle had 9% more dead space than the Needle-Pro® EDGE™ Safety Device (Table 1).

TABLE 1

Average retained volume (dead space), for each sample group and percent increase from Needle-Pro® EDGE™ Safety Device		
Sample	Mean Dead Space, µl (Std Dev)	% increase in dead space compared to Needle-Pro® EDGE™ Safety Device
Needle-Pro® EDGE™	50.33 (4.07)	NA
Covidien™ Magellan™	54.68 (10.70)	9%
BD SafetyGlide™	54.67 (7.89)	9%
TERUMO® Surguard™	67.44 (7.44)	34%
BD Eclipse™	68.33 (20.15)	37%
Sol-Millennium® Sol-Care™	79.05 (8.93)	57%

DISCUSSION

This decrease in dead space in the Needle-Pro® EDGE™ Safety Device can lead to considerable cost savings for healthcare providers. When injecting the flu vaccine, a 5.0mL multi-dose vial is often used to administer 0.5mL doses. If the dead space typical to each 23g needle is taken into consideration, the vials containing 5mL (10 doses) can only administer a full 8 doses in the BD Eclipse™, TERUMO® Surguard® 3 and the Sol-Care™. The Needle-Pro® EDGE™ Safety Device can inject a full 9 doses using the same vial and dose.

TABLE 2

Vaccine Waste: Total vaccine waste with various safety needles						
	Needle-Pro® EDGE™	Covidien™ Magellan™	BD Eclipse™	BD Safety Glide™	SOL-MILLENNIUM® Sol-Care®	TERUMO® Surguard® 3
Mean Dead Space (mL)	.05033	.05468	.06833	.05467	.07905	.06744
Vaccine Dose (mL)	0.5	0.5	0.5	0.5	0.5	0.5
Total Dose (mL)	0.55033	0.55468	0.56883	0.55467	0.57905	0.56744
Vial Size (mL)	5	5	5	5	5	5
Doses per Vial	9	9	8	9	8	8

DISCUSSION

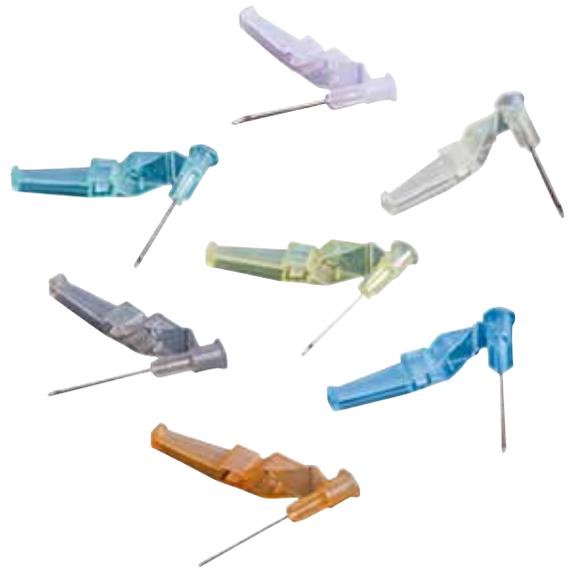
The economic impacts of dead space are particularly significant when dispensing high priced medications or in times of drug shortage to preserve supply. Many drugs, including vaccines, oncologic agents, and medications provided to the end stage renal disease (ESRD) patients would apply to this principle, especially those prepared from multi-dose vials. Situations that would involve not only expensive medications but also those with direct nursing preparation and administration may be of the highest value such as a dialysis clinic for epoetin administration or a Synagis clinic for Respiratory syncytial virus (RSV) prevention in at risk pediatric patients. In these situations, multi-dose vials may be shared between patients and minimizing dead space can allow the facility to provide the needed therapy while minimizing costs incurred through drug waste⁴. In the example below, the use of Smiths Medical's Needle-Pro® EDGE™ device would allow 4 doses of epoetin for an average adult sized patient following dialysis versus only three doses using competitive needles. This would provide a significant savings to the dialysis provider secondary to the ESRD payment bundle.⁵

TABLE 3

Epoetin dose calculation: Total doses per vial with various safety needles						
	Smiths Medical Needle-Pro® EDGE™	Kendall Monoject™ Magellan™	BD Eclipse™	BD Safety Glide™	SOL-MILLENIUM® Sol-Care®	TERUMO® Surguard® 3
Mean Dead Space (mL)	.05033	.05468	.06833	.05467	.07905	.06744
Prescribed Dose (50 units/kg)	50	50	50	50	50	50
Avg patient weight (kg)	80	80	80	80	80	80
Administered dose (units)	4000	4000	4000	4000	4000	4000
Dose (20,000/1mL)	0.20	0.20	0.20	0.20	0.20	0.20
Actual Dose (Dose + Deadspace)	0.25	0.25	0.25	0.25	0.25	0.25
Doses per 1 mL Vial	4.0	3.9	3.7	3.9	3.6	3.7

CONCLUSION

The Needle-Pro® EDGE™ Safety Device retains the least amount of residual volume, or dead space, compared to five other hypodermic safety needle devices. These results suggest that by using the Needle-Pro® EDGE™ Safety Device, hospitals can reduce medication waste in commonly injected medications, expensive drugs and certain vaccinations by increasing the number of doses extracted per vial².



REFERENCES

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