ICU MEDICAL SUPPORTING EVIDENCE

Measurement of Flow Rates for the Gripper Micro™ and Other Selected Infusion Sets

Report of a study commissioned by ICU Medical, Inc. and conducted by Regulatory and Clinical Research Institute.

Objective

To determine and compare the flow rates of the Gripper Micro safety needle and five other infusion sets.

Methods

Flow testing was performed on six infusion sets. All infusion sets employed a 20-gauge, 1-inch needle and were attached to the same standard titanium port. Flow was collected via a silicone catheter (inner diameter 0.05", outer diameter 0.11", length 15.5") with a container on a digital scale that provided readings in 1-g increments. For each infusion set, three trials were conducted on three needles of each device type under three different pressure conditions (gravity, 4 psi, and 10 psi).

Results

Table 1. Average flow rates under different pressure conditions[1]

	Mean ± Standard Deviation Flow Rate (mL/min)		
Infusion Set	Gravity	4 PSI*	10 PSI
SafeStep Huber Needle Set	16.45 ± 0.25	34.58 ± 0.38	67.87 ± 0.87
Huber Plus Safety Infusion Set	15.05 ± 0.40	32.21 ± 1.63	62.60 ± 0.46
PowerLoc Safety Infusion Set	15.89 ± 0.27	32.68 ± 1.05	63.43 ± 0.76
MiniLoc Safety Infusion Set	16.75 ± 0.30	34.84 ± 1.15	61.53 ± 9.47
Gripper Plus™ Non-coring Safety Needle	16.47 ± 0.20	34.03 ± 1.81	65.66 ± 1.26
Average and Standard Deviation	16.12 ± 0.68	33.67 ± 1.16	64.22 ± 2.54
Gripper Micro Blunt Cannula, Non-coring Safety Needle	23.05 ± 0.18	46.35 ± 0.80	89.12 ± 1.68
Percent Increase in Flow	3.0%	37.7%	38.8%

*Pound-force per square inch

Conclusion

For all six infusion sets, mean flow rates increased as pressure increased. Of the devices tested, the Gripper Micro Blunt Cannula, Non-coring Safety Needle demonstrated the greatest mean flow rate under all three pressure conditions. The device demonstrated approximately 40% greater flow than the other infusion sets.

The blunt cannula design of the Gripper Micro safety needle contributes to its faster flow rate. While the outer diameter (O.D.) is identical to a Huber needle of the same gauge, the blunt cannula has a larger inner diameter (I.D.) due to thinner wall thickness, allowing greater flow through the device (Table 2). The mechanical characteristics of the blunt cannula notably influence the flow rate of fluids through the device.

Table 2. Dimensions of Gripper Needles*

	Inner Diameter (inches)	
Gauge	Gripper Micro Blunt Cannula, Non-coring Safety Needle	GRIPPER PLUS® Non-coring Safety Needle
22	0.0190-0.0205	0.0154-0.0173
20	0.0255-0.0270	0.0220-0.0245

*Needle length 1"

1. Data on file. PE-554 20 Gauge X 1" Gripper Micro Competitive Flow Rate Testing.

icumedical
human connections

800.824.7890 | www.icumed.com