



Supporting Documentation
On Wound Irrigation Methods

Combiport-Summary Of Literature Findings To Date

COMBIPORT-SUMMARY OF LITERATURE FINDINGS TO DATE

The following represent the 3 FDA allowed uses of the Combiport device:

I. WOUND IRRIGATION APPLICATION

A. Human clinical and laboratory study:

Morse JW, Babson TF, Camasso C., et al: Wound Infection Rate and Irrigation pressure of Two Potential New Wound Irrigation Devices: The Port and the Cap. Am J Emerg Med 1998;16:37-42

Clinical study summary: Study of 207 emergency department patients with traumatic wounds randomized to CAP and PORT device irrigation of traumatic wounds. 99.5% follow-up rate, one wound infection (facial dog bite) in Port irrigation group (1%). High volume (mean 749 cc), rapid irrigation (97% completed in <4 minutes), and high operator preference (92%) preferred over traditional syringe and catheter method was observed in this study.

Laboratory study summary: Study of 17 medical staff experience with daily wound care who evaluated the PORT against 3 other irrigation techniques, The Cap, traditional syringe and catheter, and traditional syringe and needle. The Port was found to irrigate 10 times faster at moderate mean psi than the Syringe and catheter, and 16 times faster than the Syringe and needle. 11 seconds is required to pass 250 cc through the Port.

Conclusion: In this study, infection rate of Port of 1% compared very favorably with the National reported infection rate for all wounds presenting to ED (5-10% depending on the study quoted). The Port demonstrated high volume, rapid irrigation at moderate mean psi.

B. Animal and Bench Laboratory Study:

Pronchik D, Barber C, Rittenhouse S: Low Versus High-Pressure Irrigation Techniques In Staphylococcus aureus-Inoculated Wounds. Amer J Emerg Med 1997;17:121-124.

Study won first prize in Basic Science Division at PA-ACEP Scientific Assembly, 1998

Rat study summary: Study of 15 rats with bilateral wounds (one on each side), inoculated with equal numbers of Staph bacteria, with Port irrigation on one side at Lower Pressure, Higher Volume, and Syringe and Catheter irrigation with Higher Pressure, Lower Volume on the other side. Wounds were allowed to incubate for 1-5 hours after inoculation, depending on the group of rats being studied, to approximate the 1-5 hours time interval seen frequently from onset of wound to presentation to the ED. There was no statistical difference between the two methods with regard to the number of bacteria washed out by the two methods—each was equally efficacious at washing out the bacteria.

Bench laboratory phase study: Ten time and volume trials each with the syringe and catheter and bag and PORT methods were performed to calculate the mean irrigation time, mean irrigation pressure, and Peak pressures for the two methods. Port method was 3.3 times faster to deliver 3 times the amount of fluid as the syringe method. Port mean irrigation pressure was 1.6 psi with peak of 2.9 psi versus syringe mean of 8.8 with a peak of 14 psi.

Conclusion: In this study, there was no difference in the bacterial irrigation efficacy of the traditional syringe and catheter versus the new Port method. The Port method is over 3 times faster than the syringe method even though the port is using 3 times as much fluid as the syringe. The syringe method reached very high peak pressures (which may be damaging to tissue), as compared to the Port method in this study. Range of mean irrigation pressures was significantly broader (less consistent) with the syringe as compared with the Port method.

II. RAPID INFUSION OF IV FLUID APPLICATION USING THE PORT

A. Human study:

Franklin WE, Patterson J, Kulick M, et al: A New method for Rapid Fluid Bolus Infusion into a Peripheral Vein. Prehosp Emerg Care 1997; 1(4): 273-276.

Summary: In this study in 10 paramedic volunteers, flow rates using the conventional 280 cm IV tubing were compared with a new method using the PORT device and short IV extension tubing of 18 cm in length. Driving pressure for flow into the antecubital vein was created by 1. Gravity dependent flow 2. Squeezing the IV bag 3. Pneumatic pressure cuff at 300 mm HG. Flow of crystalloid was 1.7 times faster with the Port method when fluid was placed under pressure versus the conventional method under equal pressures.

Conclusion: In this study, the Port method was significantly faster than the conventional setup used by paramedics in the field and in the ED. This study was not designed to

develop conclusions about the utility or usefulness of rapid infusion of crystalloid in the hypotensive patient. Rather, the study was simply interested in determining the feasibility of rapid IV infusion of crystalloid in a normovolemic volunteer. Possible applications using the Port with rapid infusion of crystalloid or other products include, among others:

1. As a temporizing measure in cases dealing with identifiable hemorrhage, in which the bleeding may be controlled directly by direct pressure (i.e. amputations)
2. When the patient requires volume resuscitation in the field or ED due to fluid losses (i.e. severe infectious A.G.E., as seen in third world NATO missions)
3. When used with a Y port in the short extension tubing to give cardiac drugs such as adenosine, atropine, and epinephrine in cardiac codes, in much the same manner as a large (500 cc) saline lock. This would allow the drug to be given, unclamp the extension tubing, and, by simply squeezing the crystalloid bag after giving the drug, run the drug rapidly into the central circulation (without using another sharp needle and syringe to draw up a 30 cc saline bolus to chase the drug into the central circulation.)

III. NASOGASTRIC LAVAGE APPLICATION

Although allowed by the FDA for this purpose on the basis of comparable prior art and substantial equivalence, no controlled studies have been done to date using a Port and nasogastric tube for rapid stomach lavage for:

1. evaluation of upper gastrointestinal hemorrhage
2. overdose lavage
3. instillation of crystalloid or activated charcoal.

The Port has been modified already in such a way so the annular rings on its male nozzle end will accept a nasogastric tube in a secure fashion for gastric lavage applications.