

## **A recent personal experience with the Hemaclear elastic ring tourniquet, as reported to FDA MedWatch**

*In March of 2009, I attended a meeting of the Association of periOperative Nurses (AORN) in Chicago and saw the Hemaclear non-pneumatic tourniquet being displayed by the manufacturer consisting of an elastic ring wrapped in stockinette, with two application straps. The company representative offered to demonstrate the use of the device on my arm and I agreed. After my experience, as described below, I would urge anyone considering the use of such a device to first consider whether they would use it on themselves, before making a decision on whether to use it on an anesthetized patient. I'm concerned that in an anesthetized patient, who can't feel what is going on, there could be much more residual damage than I experienced.*

*The manufacturer claims that this device is intended to combine exsanguination and tourniquet functions, and was advertised in a booth as allowing much faster initial exsanguination and "no nerval (nerve) injury". The device consisted of an elastic ring of a selected size (in my demonstration, the size was selected by the company representative), which came wrapped in stockinette with two application straps. It was applied (by the company representative) by rapidly pulling the two straps simultaneously so that in a very short period of time (which I would estimate to be less than 5 seconds) the ring was rolled up the limb from distal to a proximal position, where it remained.*

*The rapid rolling exsanguinations and Hemaclear tourniquet application experience was incredibly sudden and felt "violent" to me. The experience was very similar to the feeling I have had by wrapping an elastic band around the middle of a finger and then rolling it toward the tip ... sort of feels like the end of your finger is about to "explode". This was exactly what my entire arm felt like, except that the feeling was compressed into a 1-5 second period. It felt like an IED (improvised explosive device) just went off inside my arm.*

*I had the elastic ring on my arm for no more than 20 seconds before I said, "Please get this thing off me!" Immediately after removal of the ring I noticed "fatigue" in my arm and a slowing of my reaction time (similar to what I feel after typing on a keyboard for a prolonged period).*

*About 12 hours later, and after 3 Tylenol tablets to reduce my pain and discomfort, I applied a cold pack to my arm in an effort to cool down a prominent burning sensation along the inside of my elbow (close to where a blood sample would be taken). I also noticed a similar burning sensation at the back of my arm where the triceps meets the elbow.*

*After 12 hours, I still noticed that my typing performance was slower (with more mistakes) and I was still experiencing some pain in the triceps/biceps region. I also noticed an uncomfortable sensation and fatigue in the region of my deltoid muscle, which I thought was unusual because the location was at least 6 inches above the location where the elastic ring came to rest after the exsanguination. I'm not sure what the source of this discomfort would be related to - muscles, nerves, or just veins and arteries that may have been stretched both in circumference and location within the limb due to such a rapid and violent exsanguination.*

*After 24 hours, I did not have any tingling or numbness in the limb which I assumed was a good thing, but I continued to notice a feeling of muscle fatigue in that arm, a continuing sensation of coldness in my arm, and some slowness in reaction time for a period of 4 days after removal of the Hemaclear tourniquet.*

*In view of my experience, I am submitting this report to the FDA MedWatch Online Reporting and I would urge anyone that is considering the use of the Hemaclear device to consider first whether they would use it on themselves, before making a decision on whether to use it on a patient.*

*Sincerely,*

*KG*