ADVISORY NOTICE

Abdominal Aortic & Junctional Tourniquet

Date: 7th November 2016

To: All distributors supplying the Abdominal Aortic & Junctional Tourniquet (AAJT)

In the Spring 2016 edition of Journal of Special Operations Medicine (JSOM), pages 36-42, *Testing of Junctional Tourniquets by Medics of the Israeli Defense Force in Control of Simulated Groin Hemorrhage*, it was brought to CompressionWorks attention that Israeli researchers conducted a study to assess military experience in junctional tourniquet use. Testing was conducted in simulated prehospital care, using four different junctional tourniquet models, including the AAJT. Fourteen Special Operation Forces (SOF) medics tested each junctional tourniquet model four times (two times on each side of the body). Three units of each model were subjected to a total of 56 tests (i.e., each unit was used an average of 18.6 times). During the testing, the pressure gauge for all three devices broke. The AAJT had 18 completed tests (between 5 users) in total before the third and final AAJT broke. Despite the device breakages, it was concluded that the AAJT performed best in four categories: safety, effectiveness, time to effectiveness, and user preference.

In 2014, Compression Works identified a potential weakness within the pressure gauge. As a preventive measure, a protective cap (i.e. shroud) was designed to increase the ruggedness of the device. By April 2014 all devices manufactured included this shroud over the end of the gauge. No breakages related to the gauge have been reported since that time.

Compression Works investigated the root cause of the failures during the Israeli study. It was found that the three units used during the study were manufactured in 2012, prior to the addition of the shroud. Furthermore, it was concluded that the breakages were due to excessive stress as a result of repetitive training placement. While the AAJT is intended for single use only and is not a permanent reusable medical device, it was discovered that the current labeling for the AAJT does not alert the user to the single use status.

It is important that users are aware that the AAJT is for single use only, and should never be used on more than one patient. Multiple uses can result in device failure and/or cross-contamination, in the case of multiple users.

REQUIRED ACTION:

Enclosed are satellite labels alerting the user to the Single Use status of the AAJT. Please affix one label to each unit of AAJT still in your possession. Place label on front side, but do not cover the existing label.

Complete the attached form, indicating the number of units relabeled and return to Lorraine@fent-pharm.co.uk. If additional labels are needed, please contact Lorraine@fent-pharm.co.uk.

Compression Works is currently reviewing all labeling to ensure all required information is included in order for the user to use the AAJT safely and effectively. Labels will be updated accordingly. In the meantime, please ensure all units of AAJT within your possession include the satellite label provided.

Kindest regards,

John Croushorn, M.D.
President

Evidence of Corrective Action

Distributor/Company	
Address	
Country	
Contact Person	
Email	
Phone Number:	

This is to certify that _____ number of AAJT devices were labeled with the Single Use satellite label provided with the Advisory Note dated 7th November 2016.

Signed Print Name Date