

RECON MEDICAL GEN 4 TRAUMA TOURNIQUET TENSILE STRENGTH QUALITY CONTROL TESTING

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ABSTRACT

In this documentation the methodology and results for tensile strength quality control testing Recon Medical GEN 4 trauma tourniquets will be discussed. 53 GEN 4 trauma tourniquets were tested, and the average ultimate tensile strength was 2319.0 pound-force. The most frequently occurring failure mode was the internal webbing, followed by Velcro delamination, heat weld, and lastly the buckle.

INTRODUCTION

How much pressure or force is required for haemostasis, or occlusion of blood flow, to an extremity? It is dependent upon several variables including, but not limited to, wound location and diameter of extremity. The Recon Medical team has performed a clinical study validating the efficacy of the GEN 4 tourniquet on human volunteers and all tourniquet applications successfully occluded blood flow¹.

With that being said, we have designed and manufactured our tourniquets to carry an arbitrary yet impressive tensile strength which translates into pressure onto extremity, therefore stopping the bleed. The GEN 4 tourniquet has also proven itself with a record of 16 documented lives saved since 2016². An ultra-low temperature study was also performed on the GEN 4 tourniquet proving to be functional in conditions as low as -40 C as well as icy conditions³.

All of this is made possible by an intelligent and sturdy design that includes heavy-duty nylon webbing, Kevlar thread stitching, and an aluminum reinforced buckle. The GEN 3 tourniquet buckle was made from Nylon 6 alone resulting in an average ultimate tensile strength of 700 pound-force therefore the aluminum reinforced buckle is a huge advancement.

TENSILE STRENGTH TESTING METHODOLOGY

1 out of every 500 tourniquets, or 0.2%, of all inventory received from manufacturing facility is tensile strength tested using destructive testing equipment (see figure 1) to determine ultimate tensile strength. It is vitally important when tensile strength testing that the windlass is turned 450 degrees from its initial resting position and then secured in the windlass retainer plate (see figure 2). This activates the internal “floating” webbing which is designed for carrying the tensile load. The piston then moves the lower attachment point downward applying a tensile load to the tourniquet. The ultimate tensile strength is recorded at moment in which the tourniquet fails to

maintain resistance to tensile force. The pound-force at moment of failure is recorded by a Dillon EDjunior dynamometer. The tourniquet can then be removed from equipment, failure mode documented, and the testing is now complete.

Figure 1: Destructive Testing Equipment



DATA

Table 1 presents the high, low, and average ultimate tensile strength of the GEN 4 tourniquet. Table 2 presents all GEN 4 test failure modes.

¹ Recon Medical Clinical Study performed by non-biased third party. Clinical Study protocol and results can be found at <https://reconmedical.com/research/>

² 16 Documented Saved Lives as reported from tourniquet users to Recon Medical as of 11/6/2020

³ Ultra-low temperature study whitepaper can be found at <https://reconmedical.com/research/>

Table 1. Average Ultimate Tensile Strength

Sample	Pound-force (lbf)
Low	2020.0
Average	2319.0
High	2760.0

Table 2. Failure Modes

Failure Mode	Frequency
Internal Webbing	22
Velcro Delamination	18
Heat Weld	12
Buckle	1

Figure 2: Windlass rotated and secured in windlass retainer clip with time strap fastened ready for testing



RESULTS

The GEN 4 tourniquet tensile strength results ranged from 2020.0 to 2725.0 pound-force. The average ultimate tensile strength is 2319.0 pound-force. The most occurring failure mode was the internal webbing followed by the internal webbing, Velcro delamination, heat weld, and then buckle.

DISCUSSION

The GEN trauma tourniquet is designed to withstand immense tensile force. An average ultimate tensile strength of 2319.0 pound-force has proved sufficient to occlude blood flow. If a tourniquet breaks at a tensile force below 2000 pounds, then the tourniquet has failed the quality testing.

The tourniquet is designed so that the internal 1-inch wide nylon webbing will carry the tensile load. A failure at this point is intentional and is no concern unless the failure occurs below the minimum 2000 pound-force threshold.

The 2nd most reoccurring failure mode is Velcro delamination. This failure mode also does not occur below the minimum 2000 pound-force therefore it is not a critical issue. This issue is also under review for root-cause and potential corrective design improvements.

The heat weld failure mode is the 3rd most reoccurring failure mode and is currently under review for root-cause and potential corrective action. This failure does not occur below the minimum 2000 pound-force therefore it is not a critical issue.

Lastly, there was once instance where the buckle was the failure mode, and this occurred at 2725 pound-force. The reasoning for this failure mode is inconclusive and has only ever been documented once. It is not a concern as the failure occurred well beyond the minimum threshold.

Pictures of failure modes can be seen in appendix A.

CONCLUSION

Hundreds of hours have been invested designing and testing the Recon Medical GEN 4 trauma tourniquet. We feel greatly confident in this product and believe it to be reliable in any situation which requires you to stop the bleed. Having thoroughly vetted this product in the lab and in clinical study, and with 16 documented saved lives, we trust the GEN 4 tourniquet to get the job done!

Appendix A

Figure 3: Internal Webbing failure



Figure 4: Internal webbing failure



Figure 5: Detailed view of heat weld



Figure 6: Heat Weld Failure



Figure 7: Velcro Failure

