

** KKT mitigates concerns with neck treatments**
KKT's loading patterns are scientifically safe and the most beneficial known to date

Introduction

The KKT spinal treatment device consists of an impulse delivery mechanism, which uses a stylus to deliver waveforms of various frequencies and amplitudes, both linearly and rotationally. These loads, frequencies and amplitudes are deemed safe according to the device approvals granted by the Food and Drug Administration, Health Canada and the European Commission.

Sound Frequency (Load Pattern) Safety

Tissues of the spine and associated musculature are sensitive to the effects of various loading patterns, which include frequency, amplitude, and duration. KKT operates in the audible range of frequencies similar to classical music. KKT purposefully functions within the frequencies most beneficial to spinal tissues by using an amplitude determined to stimulate the healing activation of cells responsible for vertebral disk structure and health. The duration of the vibration that we treat with is also known to positively impact the spinal tissues in a similar pattern. According to ISO 2631, an international standard stating the limits of safe sound wave and vibration exposure, the KKT device falls several orders of magnitude below the stated limits.

Cervical Vertebral Artery Safety

There are several anatomical regions within the neck, most specifically, the vertebral arteries, which are susceptible to injury. The vertebral arteries thread through holes or orifices of the vertebrae so that when you move your neck the arteries twist to conform. It takes 30 degrees of axial neck rotation to place stress on the cervical arteries increasing the risk of injury. Should a vascular compromise be present, the risk of vertebral artery dissection is increased considerably. KKT's unique design treats the upper cervical region without twisting or turning the neck, thus eliminating the tension and reducing the risk of vertebral artery damage.

Over 20,000 KKT treatments are administered annually and KKT has a patient treatment operating record that spans over five years with no recorded adverse events.

Force and Pressure Application Safety

Various human safety organizations such as NHTSA are concerned with impact of human injury and have documented the intolerable load levels of the human body. KKT's scientific and engineering team ensures that we engrain safety features into our design criteria and clinical applications and that we operate well within the stated regulations.

In the worst case scenario, the KKT device has a maximum operational force capability of less than 5 lbs. Should a patient move unexpectedly or a clinician accidentally lower the stylus on to the patient incorrectly, the maximum load averages less than 2.5 lbs. The safety mechanism incorporated in the stylus design is such that the stylus will collapse and automatically turn the device off under this force. As expected, these forces fall well below the stated guidelines.

Comparative Treatment Analysis

While treatment loads from KKT average around 2 lbs, typical neck manipulation performed by specialists from various clinical disciplines places roughly 15 to 25 lbs. Further, KKT is non-invasive, meaning the treatment does not puncture the skin to activate neuromuscular structures. Even the smallest skin break introduces bacteria that place us at risk of infection. This is important to people with immunodeficiency disorders and people who take medication that lowers or suppresses the immune system.

Summary

Safety is an essential component of KKT design and operation. Extensive testing and analysis ensures that any risk or threat of injury is effectively mitigated enabling the patient to benefit from the KKT treatment with minimal concern for their safety or well-being.

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