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FDA FIRST FOR CHIROPRACTIC

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The Food & Drug Administration (FDA) has granted a 510K medical device designation to an instrument whose sole purpose is designed to correct the vertebral subluxation. FDA 510K clearance allows for the legal sale of an instrument and its particular indication of use. The Integrator is chiropractic's first adjusting instrument to receive an FDA 510K that has gone through a funded, independent randomized, clinical trial. Designed by Dr. Jay M. Holder, the Integrator is manufactured by Moyco/Union Broach, one of the oldest and largest surgical instrument manufacturers in North America.

According to Lonnie Graybill, vice president of Moyco: "Unlike some of the other adjusting instruments found on the market we have followed federal regulations; protecting ourselves and the chiropractors that use the Integrator, we're in compliance."

Not only is the Integrator's FDA clearance exceptional, but more so is its history.

Originally created from scratch, borrowing nothing from any current adjusting instrument, the Integrator was designed to reproduce what the hands of a chiropractor were intended to deliver: recoil, torque and dynamic thrust. No other instrument in chiropractic has ever had that in mind.

The Integrator would never have been invented at all, but for the demands required to conduct a human population research study designed by Robert Duncan, Ph.D., of the University of Miami School of Medicine and funded in part by the Florida Chiropractic Society. A totally new chiropractic adjusting instrument (the Integrator) and a technique (Torque Release Technique) were born out of this study by accident and without intention.

The purpose of the study -- a 1-1/2 year-long randomized clinical trial with 98 human subjects, blinded and with placebo control -- was conducted to determine the outcomes that subluxation-based chiropractic had in affecting state of well being (quality of life) in the human population.

The project, conceived by Dr. Holder, was performed at Exodus, a residential addiction treatment facility in Miami. According to Holder, medical director/founder of Exodus, the addicted population best serves as a proving ground for chiropractic for several reasons:

Chemicals are one of the major causes of subluxations. Twenty- percent of the American population suffer from addiction. Up to 83% of all crime is drug-related. The nation's leading cause of death is drug-related. And the addicted population is identified as suffering from RDS (Reward Deficiency Syndrome), an inability to express a normal state of well being or maintain a quality of life equal to the rest of the general population.

Says Holder, "The last thing chiropractic needs is another neck or low back study Today chiropractic needs studies on human potential, state of well being and quality of life."

However, in designing this study, a major hurdle had to be overcome: consistency and reproductability in the application of delivering the chiropractic adjustment and some way to measure its outcome.

To accomplish this, it was necessary to adjust by instrument. Yet, all chiropractic adjusting instruments tested were not reproducible when applied to the patient. A major flaw in the studies and claims attesting to the reproductability of adjusting instruments is that they test their instruments while clamped in devices that fire the instrument against a measurement device (piezo-electric transducers). Any instrument tested in this fashion is claimed reproducible.

Unfortunately, instruments held by hand against the skin of the patient and fired by hand, are not reproducible, concludes Holder. If the pressure against the tip of any adjusting instrument varies as much as 1/8 of an ounce, the dynamic forces, frequency (Hz), and kinetic energy characteristics will vary as much

as three-hundred percent!

To guarantee reproducibility, the development of an automatic trip sensor mechanism had to be made. This would assure that the instrument would fire when an exact predetermined pressure was reached when placed against the skin of the patient and at specific line of drive desired.

Further, this guarantees that a correct and specific frequency (Hertz) is delivered and now allows for a more stable line of drive, often sabotaged in instruments that must be squeezed to fire. Since the purpose of the study was to determine the outcome of traditional chiropractic, an instrument had to be developed that delivered what the hands were intended to.

Up to now, all adjusting instruments provided only axial force. However, the hands provide, at the option of the chiropractor, two more dimensions: recoil and torque (right or left), as in the most traditional application of the chiropractic adjustment, toggle recoil. Torque allows for a line of drive that remains more stable with deeper penetration and recoil allows for greater thrust outcome with less force.

"Less is more," according to Holder. B.J. Palmer demonstrated a nail being hammered into a wood beam. The nail was driven into the wood after the hammer left the head of the nail, not when it was struck (recoil). Speed is also a factor, in that $force = mass \times acceleration$. The Integrator fires at 1/10,000th of a second, making it the fastest hand held adjusting instrument.

Unlike other instruments, that use metal caps and weights to mediate or compensate for their inability to allow the doctor to adjust force, the Integrator has true force adjustment capability.

In a rare interview for Drs. Patrick Gentempo and Christopher Kent's "On Purpose" subscription tape service, Holder discussed the objective outcome measurements of this study that clearly validated the effectiveness of both the Integrator and Torque Release Technique.

These results assessed by Dr. Duncan revealed a retention rate of 100%, a significant reduction in nursing station visits, an improvement in depression that four weeks of chiropractic surpassed what normally takes one year to achieve with standard medical model treatment, and an improvement in anxiety that four weeks of chiropractic surpassed what normally takes six months to achieve with the standard medical model.

Dr. Marvin Talsky, co-developer of Torque Release Technique, says, "TRT is a non-linear vitalistic model and is the first technique in chiropractic to be born out of randomized clinical trial research first, instead of the other way around." TRT training takes one weekend (14 hrs.) and doesn't require the use of an instrument.

Dr. Frank Sovinsky, founder of Chiropractic Mentoring Experience states, "The Integrator is a remarkable innovation in a hand held instrument. TRT has opened up a whole new window in which to view the tonal model of the vertebral subluxation complex." Whether or not we wish to accept Torque Release Technique and the Integrator, the research is in.

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