MEDICAL DEVICE USER REPORT

Protect Yourself –Traction is NOT Decompression

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Millions of Americans rely on medical devices for basic health and daily living assistance on a routine basis. From the small surgical mesh that a surgeon may use to reinforce your hernia repair to a powered physiotherapy device for rehabilitative care or even an implantable cardioveter-defibrillator, all these medical devices are critical health care devices which are required to go through a review and clearance process with the FDA before they can be sold to doctors or hospitals. So surely, a physician can rest at ease knowing each of these products has gone through some form of device testing for safety and effectiveness, right?

Well, if you concur that's right, then you will probably be shocked to discover, THAT'S WRONG. How is that possible? Before 1976 any manufacturer could sell a medical device without regulatory intervention. When the FDA came into being, it was mandated with the guardianship of America's public health. To do so, besides implementing stringent testing for pharmaceutical approvals, FDA also classified existing devices into three risk categories from Class I for products like say, latex gloves, to the highest risk, Class III category products. But, as long as a manufacturer can show their product is "substantially equivalent" to a device of its type that has already been on the market, the agency routinely clears new devices without any clinical testing at all. Safety studies are not mandatory. Clinical efficacy studies are not mandatory. What is mandatory is that the engineering data and intended use are demonstrably similar in the product documentation submitted to the FDA for clearance to market. If so, then the new device is basically "grandfathered" into the marketplace.

What are my risks as a physician?

Inherent risks of the regulatory system are dangerously varied. In essence, once a particular device has been shown to perform in a particular way, any new device maker can open shop by simply documenting a product that is similar or "substantially equivalent" to another meaning a physician has no way to know if the product does what is claimed. In fact, 510K clearances don't even require the product to have been built, so in reality, an unethical device company can legally make unproven performance claims about it's cleared device- even if its never even been built!

In the case of disc decompression systems- because of their physical similarity in appearance and intended use- ordinary traction equipment can be cleared with language claiming decompression therapy capabilities. But again, because efficacy studies are not *required* by the FDA, how can a physician truly know that it's true? If a company claims that their untested product does the same or better than another tested product is it really true? As a conscientious health care provider, you can't trust claims without any peer-reviewed study data on the actual product you are considering to purchase. Here is a glaring example of why….

"One of the Biggest Disasters in Orthopedic History"- British Medical Journal

Consider the story of Stephen Tower, MD. As a well respected orthopedic surgeon, Dr. Tower performed numerous hip replacement surgeries throughout his career. When DePuy div of J & J introduced a new artificial hip implant for "physically active" candidates, Dr. Tower, an avid biker, took notice. Because the implant design and intended use was basically the same as previously marketed hip implants, *it was grandfathered onto the market without clinical testing.*

The technological advancement was promising: the ball atop the femur and the socket liner inside the pelvis were chrome cobalt metal instead of plastic, which traditionally was known to fail with constant wearing down from active movement. Based on substantial equivalence, the new device was expected to perform at least as well as previously cleared hip implants- with the added technological improvement of high performance materials. So, in 2006 Dr. Tower had a DePuy ASR XL implanted and within six weeks, did a "double century bike race". It took roughly about a year before Tower began to realize something was terribly amiss… besides constant hip pain, he suffered disturbed sleep, severe mood swings, anxiety, hearing loss, and tinnitus. More alarming, high chromium and cobalt levels were found in his blood when tested.

Dr. Tower went on to perform his own research uncovering evidence that metal debris from such implants can cause "profound poisoning". In 2012, DePuy recalled 93,000 ASR XL hips worldwide because the device was failing "far more than average" and causing serious injuries.

Critic's Cry Out: The Lack of Medical Device Testing Requirements Are Tantamount to Clinical Trials on an Unsuspecting American Public!

Choosing A Treatment Device

While the risk of an untested implantable may seem higher than the risk of using an untested decompression device, consider the personal injury suits, one filed by a patient who claimed to have been forced into a wheelchair after being injured [(1)] by the DRX 9000- a device whose makers were found guilty of fraudulent marketing and distributing false advertising- some of which was written to fool the reader into thinking they were reading a legitimate clinical study. Or even more tragic, consider the case where one traction device built with old style traction table scissor lift mechanisms, resulted in the inadvertent death of a toddler. The child crawled under the table while his mother was being treated and triggered a release button that dropped the table crushing the child.[(2)]

Choosing any treatment device for your patients bears significant responsibility on you, the physician, who must weigh saving on initial cost against the potentially higher cost of mistakenly choosing the wrong product for your patients.

How To Protect Yourself- And Your Patients

-**Know the history of the device you are purchasing.** How long has the manufacturer been in business? Do they have a history of excessive product safety failures or patient injury complaints? Even if anecdotal, sometimes a lot of smoke does point to fire.

-Research the device and its studies. Be sure that the outcomes for clinical success you are shown pertain to the device manufacturer from which you are considering to purchase. Many devices designed with mechanical traction technology have actually been claiming to perform to the level of decompression systems. If the studies they show you weren't performed with their device, it's likely their device doesn't achieve the same results. Remember, just as a clinical study done with a hip implant made of plastic versus one made of chromium-cobalt would have alerted users to the true differences in the outcomes regardless of the product similarities and marketing claims, so too is the case with back treatment devices made with mechanical traction technology marketed as equal to studied decompression systems.

-Don't let your patients be human guinea pigs. Choose products that have published study data and long term use with a good reputation in the industry. Remember, clinical studies are a huge financial expenditure that isn't imposed by FDA. So, most device makers aren't likely to expend the time and resources to perform costly product studies unless they are driven by ethics and conviction to excel in patient care.

-Ask for third-party testing validation. Has the product manufacturer undergone *any* independent laboratory testing? Again, the FDA does not require such contract testing because the cost constraint can be highly prohibitive to small device manufacturers. UL testing regimens can easily exceed $100,000 and there is no guarantee for the product to pass. But these independent testing laboratories are staffed with hundreds of engineers specifically trained to identify electrical, emission and design safety standards. By subjecting a product to the most rigorous even destructive testing imaginable, these independent labs can uncover a safety problem long before it becomes an issue in the field. Just remember, ask to see the certificate naming the actual product testing and certification. And don't just trust a label on the cord; some companies have actually been known to claim that because their product uses one or two components that are UL tested and bear the label, that means their device meets the UL standard - which it does not!

KDT +TRACTION = DANGER
The Truth Comes Out

-Research the device. Has it been the subject of any product recall? Sometimes, that information may not be so easy to identify because it means knowing the product clearance number regardless of its marketed name. Consider the case of Kennedy Decompression "Technique". That company claims to teach a technique but they actually sell the Kennedy "decompression table", (KDT) cleared under #K091540 [(3)]. If you research that clearance at the FDA website, the product they market as KDT was actually cleared as "Mettler Traction ME 4000". While there is nothing wrong with the name change, what is wrong is how effectively it hides an important fact about the KDT table: the product is under an "Urgent Recall" FDA warning notice which was issued in June 2011. The FDA website states, "The firm [is] initiating recall because component failure might result in patient

injury. *Use of the device should cease immediately*." How many KDT buyers know about the recall? A recent review of the Kennedy website found no notice of the device recall.

-Study the studies. Some products that claim decompression outcomes have performed studies that clearly showed their technology and patient outcomes were consistent with mechanical traction. Why would a company do that? Simply put, the development costs that go into more advanced decompression technology are higher than the cost to produce a motorized mechanical traction unit. So if you can convince an unsuspecting buyer that it is "just as good" as a more advanced device, there is a significant amount of profit to be made by selling low cost traction tables claiming more costly decompression capabilities. Yet a majority of traction studies since the 1950's have shown that motorized mechanical traction pulling forces (having no specific programmed algorithms) can cause *increases* in disc pressure and typically achieve success rates deemed "not clinically significant"[(5)]. Newer technology decompression distraction studies, alternatively, have consistently documented success rates from 71% of patients studied to 84% and even 92%* success rates [(6)]. So naturally, it would be quite appealing to be able to claim that kind of success even if it's not yours…

Case in point, in 2006 Chattanooga introduced its Triton DTS marketed by Evergreen Marketing as "DTS Spinal Decompression Therapy". Of course by calling it "decompression" there is an implied assumption that the higher study outcomes apply to this product. The DTS website does not post any studies on its device. So is it really capable of performing to the level of an advanced decompression system? According to the European Spine Journal who published a 2009 study[(7)] performed at Alexandria Hospital with the Triton DTS, the study author's conclusion read: "*Interpretation of current available research suggest that traction intervention is not appropriate for the majority of patients with LBP, therefore, traction should not be widely used for patients with LBP. Our pre-predication response rate (of 19.2% in the study) supports this belief*".

Clearly, even newer traction devices, regardless of their marketing claims, continue to yield ordinary traction outcomes.

Method	Rating	RID	Facet arthrosis
Decompression	excellent	7 (50%)	2 (25%)
	good	5 (36%)	4 (50%)
	poor	2 (14%)	2 (25%)
Traction	excellent	0	2 (25%)
	good	5 (55%)	2 (25%)
	poor	4 (45%)	4 (50%)

Excellent = 90 - 100% improved

Good = 50 - 89% improved

Poor = < 50% improved

Patient Assessment of pain relief secondary to spinal decompression and to traction [(8)]

The key to protecting your practice, your patients and yourself, relies on making informed choices. The bibliography references below are provided for you to validate for yourself what you have learned in this report. [(9)] If you would like any additional information or assistance on determining how you can increase your patient services while also increasing your practice revenues and referrals, please contact:

North American Medical Corporation
Call (770) 541-0012
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(1) Lang v. Axiom Worldwide Inc. Case No. 07-4178-CV-C-NKL
(2) *Dynamic Chiropractic*, July 29, 2011, Vol. 29, Issue 16
(3) http://www.accessdata.fda.gov/cdrh_docs/pdf9/K091540.pdf
(4) Class II Recall*: Mettler Traction "Decompression" System Model: ME 4000*, June 17, 2011 http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfres/res.cfm?id=100298
(5) *Cochrane Summaries* "Traction for Low Back Pain with or without Sciatica" May, 12, 2010.
(6) *US Musculoskeletal Review* 2006, Dennis McClure, MD, Neurologist; *Journal of Orthopedic & Sports Physical Therapy*, Vol. 35, No. 1 Jan. 2005; *Journal of Neurological Research*, Vol. 20, No 3, April 1998; Shealy, et al, *American Journal of Pain Management*, Vol. 7 No 2, Apr 1997
(7) *Eur Spine J.* 2009 April; 18(4): 554–561.
(8) *American Journal of Pain Management*, Vol. 7 No 2, Apr 1997
(9) *Consumer Reports* "Dangerous Medical Devices" May 2012, pp. 24-27

*Outcomes achieved on different manufacturers products; studies available on request.