Health Technology Assessment Brief: Ctrac™ Splint

December 7, 2005

Department of Labor and Industries

Office of the Medical Director

Company: MeDevice Corp.

Product: Ctrac for CTS

Purpose: Ctrac for CTS is a pneumatic splint designed to treat symptoms of carpal tunnel syndrome (CTS) by elongating or stretching the transverse carpal ligament (TCL). CTS is a condition resulting from pressure within the carpal tunnel acting on the median nerve which can produce symptoms including pain, tingling, numbness and weakness of the hand. As a result of these symptoms, CTS can interfere with work and non-work activities including sleep.

Common treatments for CTS include splinting, anti-inflammatory medications, occupational therapy and surgery.

FDA Status: Class I, registered and classified as "Apparatus, traction, non-powered"

Evidence: No studies on CTrac have been published.

Porrata H, et al. "New Splint for Carpal Tunnel Syndrome Unresponsive to Conservative Therapy." Unpublished. 2000.

Table 1: Study description.

Rating	Primary Outcome	Inclusion	Exclusion	Baseline Pop Char	Assessor Blinded	Intention to Treat
Class IV – controlled trial, w/o blinding, independent assessment, objective outcome measurement.	Assessment of change in pain, tingling, numbness graded on VAS (0 is none to 10 most intense sensation). Satisfaction of patients graded as poor, fair, good, excellent at end of week 4. Assessed at initial visit and by telephone at weeks 1, 2, 3, 4 and at month 7.	Referred to Saint Vincent's Hospital of New York City. Failed conservative therapy defined as persistence of symptoms of CTS and VAS of 5 or more out of 10, at least 4 months of treatment.	VAS score <5/10, previous CTS surgery, history of osteoporosis, gout, hypothyroidism, osteoarthritis of the hand, septic or rheumatoid arthritis of the hand, renal disease, wrist fracture, pregnancy, 'ongoing involvement in compensation cases', contact allergy to rubber or plastics	31 subjects: average age treated group (n=19) 51.3, average age control group (n=12) 60.8 years, average 24.3 weeks from index surgery to use of device.	No	No

Table 2: Results from Porrata study.

Results		
VAS scores	Treated Group N=19	Control Group N=12
Pain Baseline	8.52	8.41
4 weeks	1.05*	7.75
Tingling Baseline	8.15	8.08
4 weeks	0.95	7.75
Numbness Baseline	8.47	8.16
4 weeks	0.95	8.00
Patient Satisfaction	Treated Group N=19	Control Group N=12
Excellent	15 (79%)	0
Good	4(21%)	0
Fair	0	3(25%)
Poor	0	9(75%)

Costs: Ctrac purchase price is $295.

Insurers:

According to the product representative, approximately 12 workers compensation insurers in California have authorized the individual purchases of Ctrac on a total of approximately 12 claims.