

# Cigna Medical Coverage Policy



**Subject** Pulsed Electromagnetic Therapy

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[Negative-Pressure Wound Therapy/Vacuum-Assisted Closure \(VAC\) for Nonhealing Wounds](#)  
[Tissue-Engineered Skin Substitutes and Platelet-Derived Growth Factors](#)

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## Coverage Policy

**Cigna does not cover pulsed electromagnetic therapy (e.g., Diapulse®, SofPulse®, Provant® Wound Closure System) for any indication, including wound care management, because it is considered experimental, investigational or unproven.**

## General Background

Electromagnetic therapy, often termed pulsed electromagnetic field (PEMF), has been proposed as a treatment for various conditions. Although similar to electrical stimulation, electromagnetic therapy uses an electromagnet to generate electrical current and uses nonthermal pulsed electromagnetic energy to deliver the current. This modality of treatment has been shown to induce various responses (e.g., increased blood flow, collagen formation, granulocyte infiltration) in both in vitro and animal models, primarily to induce wound healing (Blue Cross and Blue Shield Association Technology Evaluation Center [BCBSA TEC], 2005).

In contrast to electrical stimulation, electromagnetic therapy does not involve the use of current, leads, or electrodes. Pulsed electromagnetic devices that are used for wound therapy utilize generators designed to create radiofrequency signals that are typically delivered through coils which do not directly contact the skin. In relation to chronic wound treatment, electromagnetic therapy primarily refers to pulsed electromagnetic fields in the radiofrequency band without thermal effects. It has been suggested that pulsed electromagnetic therapy stimulates blood flow by a rapid peristaltic mechanism on the vessel walls, rather than a heating action or by secondary vasodilatation, and promotes cell proliferation for wound healing.

Pulsed electromagnetic therapy (PEMF) has also been recommended for treatment of painful injuries or inflammation. When used for these indications evidence in the scientific literature suggests that PEMF results in

vasodilatation, modification of the inflammatory process, reduction of edema, and enhanced tissue repair. Several devices are available for management of these conditions and utilize varying frequencies, field strength, and pulse widths although there is little published data to support selection of any of these devices (Fernandez, et al. (2007). One type of electromagnetic therapy, shortwave diathermy (continuous pulsed), is often used for the treatment of pain. It uses radiofrequency electromagnetic fields for therapeutic heating of tissue. Frequency related electromagnetic stimulation (FREMS) uses a short-wave diathermy (continuous or pulsed) which heats tissues and has also been proposed for the treatment of pain.

### **U.S. Food and Drug Administration (FDA)**

A number of devices used for electromagnetic therapy have been approved by the FDA through the 510(k) approval process. In particular when used to treat wounds the FDA considers these devices as Class III devices which require a premarket approval. Some of these devices have been cleared by the FDA more specifically as short-wave diathermy devices or radiofrequency stimulation devices (e.g., Provant Wound Closure System [Regenesis® Biomedical, Scottsdale, AZ]); Diapulse® [Diapulse Corporation of America, Great Neck, NY]; SofPulse® [Electropharmacology, Inc., Alachua, FL]). Several of the devices are intended for the treatment of postoperative pain and edema in superficial tissue and not specifically for wound treatment. Approval for the use of these devices specifically for the treatment of chronic wounds was not found on the FDA site.

### **Literature Review**

#### **Wound Care Management**

Studies in the published medical literature comparing electromagnetic therapy devices with established wound care management are lacking. The clinical studies evaluating the devices and clinical outcomes have been few, are limited in sample size with poorly-defined patient selection criteria, and have limited reporting of methodological details (Ravaghi, et al., 2006; Olyae Manesh, et al., 2006; Ritz, et al., 2003). There is little consensus among authors regarding duration of treatment or technique of application. Two published Cochrane reviews assessed the effects of electromagnetic therapy on wounds, one evaluated venous leg ulcers (Ravaghi, et al., 2006; Aziz, et al., 2011 [update]) and a second evaluated the healing of pressure ulcers (Olyae Manesh, et al., 2006; Aziz, et al., 2010 [update]). The results of both reports provide no evidence of benefit to electromagnetic therapy when used for wound healing. In addition, a systematic review (Reddy, et al., 2008) found minimal data to support therapies such as electromagnetic therapy for the treatment of pressure ulcers.

In one study, the Provant Wound Closure System was specifically evaluated. Ritz et al. (2003) published the results of a randomized trial involving 49 patients with pressure ulcers who received standard wound therapy combined with the Provant Wound Closure System. The results indicate that when compared to a placebo (modified Provant device), Stage II wounds treated with Provant healed faster (26 days versus 66 days, respectively). The authors also reported that Provant-treated wounds showed an average 87% reduction in surface area compared to a 56% reduction for placebo; however no time period was specified. Furthermore, the authors did not compare outcomes with other effective, established wound closure devices or treatments making comparisons difficult.

In an earlier publication, George et al. (2002) reported on a series of in-vitro studies that evaluated cellular mechanisms involved in cell proliferation induction (CPI). CPI theoretically employs sensation-free radiofrequency (RF) stimuli to stimulate dormant cells in damaged wound tissue, and is a technique associated with the Provant Wound Closure System. The authors confirmed that CPI-induced proliferation of fibroblasts and epithelial cells varies as a function of both the treatment dose and the duration of treatment; the author's further hypothesized CPI treatment may accelerate wound closure.

In August 2005, the BCBSA TEC (2005) reviewed the available evidence for electrical stimulation and electromagnetic therapy for chronic wounds. A total of five studies involving 155 patients were reviewed. The panel concluded that the available evidence did not convincingly demonstrate electrical stimulation or electromagnetic therapy led to significant health outcome benefits on the most important clinical outcome, (i.e., number of patients who heal completely). BCBSA TEC concluded that the evidence was not sufficient to permit conclusions regarding the efficacy of electromagnetic therapy or electrical stimulation as an adjunctive treatment for wound healing.

The results of a randomized controlled trial by Czyz et al. (2012) investigated the benefits of electromagnetic energy in eyelid wound healing using an electromagnetic energy patch (n=57) for subjects who underwent blepharoplasty. In comparison to a placebo the authors reported no difference in pain. The difference in

physician graded erythema was statistically significant in favor of the electromagnetic energy patch although the authors concluded there was no effect on postoperative pain, edema or ecchymosis. Limitations of this study included small sample size therefore results cannot be generalized to a larger population.

### **Other Indications**

Evidence in the published peer-reviewed scientific literature evaluating PEMF for conditions other than wound management consists mainly of case series with few randomized controlled trials. PEMF theoretically offers some potential benefit and has been utilized for the treatment of numerous conditions, such as subacromial impingement syndrome, lateral epicondylitis, tinnitus, soft tissue injuries, fibromyalgia, diabetic peripheral neuropathy, plantar fasciitis and for various other conditions related to pain (Ogilvie-Harris, et al., 1995; Ghossaini, et al., 2004; Uzunca, et al., 2007; Fernandez, et al., 2007; Aktas, et al., 2007; Thomas, et al., 2007; Heden and Pilla, 2008, Ay and Evcik 2009; Sutbeyaz, et al., 2010, Omar, et al., 2012; Brook, et al., 2012; Bosi, et al., 2013). When employed for the treatment of pain, study results are mixed, some authors report no difference in pain among study groups (Aktas, et al., 2007; Fernandez, et al., 2007, Ay and Evcik, 2009) while others report improvement in various pain parameters after PEMF therapy (Uzunca, et al., 2007; Thomas, et al., 2007; Heden and Pilla, 2008, Omar, et al., 2012). In some studies, despite improvement in pain, other treatment modalities were used making study interpretations and comparisons difficult (Ay and Evcik, 2009, Omar, et al., 2012).

**Diabetic Neuropathy:** The effects of PEMF on diabetic neuropathy have also been investigated. Wrobel, et al. (2009) published the results of a randomized placebo-controlled double blind study to determine whether low frequency magnetic field can influence pain intensity, quality of life and sleep, and glycemic control in patients with painful diabetic polyneuropathy (n=61). The authors noted that both treatment and control groups demonstrated a significant reduction in pain intensity after the first week of treatment that persisted until the end of the follow-up period (five weeks), with no significant differences between groups. Similar improvements were noted in quality of life values, with no significant differences between groups. In the authors opinion there was no advantage to low frequency pulsed electromagnetic field stimulation compared to sham therapy for the outcomes measured. Weintraub et al. (2009) reported the results of a randomized double-blind controlled trial evaluating the effects of PEMF therapy in reducing diabetic neuropathic pain, influencing sleep, and for nerve regeneration. The study group involved 225 individuals randomly assigned to receive either PEMF or sham treatment. Outcomes were measured using a visual analog score (VAS), Neuropathy Pain Score (NPS), and the Patients Global Impression of Change (PGIC). There was a trend to a reduction in the PGIC score in favor of the PEMF group, however there were no significant differences between groups in neuropathic pain intensity or VAS. PEMF was not effective in reducing diabetic neuropathic pain. Pieber et al. (2010) reviewed the evidence evaluating different types of electrotherapy for the treatment of diabetic peripheral neuropathy and noted conflicting results for pulsed and static electromagnetic therapy; some studies reported the treatment was not effective and some studies reported a short-term analgesic effect (Pieber, et al., 2010). The authors noted differences in study designs, the use of various stimulating patterns, and inconsistent outcomes made comparisons across studies difficult. Bosi et al. (2013) reported the results of a randomized trial evaluating the efficacy of FREMS as a treatment of symptomatic peripheral neuropathy in patients with diabetes mellitus. Patients (n = 110) with symptomatic neuropathy were randomized to FREMS (n = 54) or placebo (n = 56). The primary endpoint was change in nerve conduction velocity (NCV) of the deep peroneal, tibial and sural nerves; secondary endpoints included the effects of treatment on pain, tactile, thermal, and vibratory sensations. In the intention to treat group NCV results were not different between FREMS and placebo. There was a decrease in day and night pain in the FREMS group which was significant initially but not at three months after treatment. Investigators concluded FREMS proved to be a safe treatment for symptomatic diabetic neuropathy; there no effect on NCV and a transient improvement in pain. The results of the study are limited by short term outcomes, further trials evaluating long-term outcomes are needed to support clinical efficacy.

Evidence based guidelines published by the American Academy of Neurology (Bril, et al., 2011) do not support electromagnetic field therapy as a treatment for peripheral diabetic neuropathy; after reviewing one Class I study (randomized controlled clinical trial) the authors noted electromagnetic field treatment is probably not effective for the treatment of peripheral neuropathy.

**Knee Osteoarthritis:** Vavken, et al (2009) published a meta-analysis evaluating the effectiveness of pulsed electromagnetic fields for the management of osteoarthritis of the knee. In all, nine randomized controlled trials were reviewed reporting on a total of 483 patients. Although there was a significant effect of PEMF six weeks after treatment in activities of daily living, there was no significant difference in pain between treatment group

and controls. The authors acknowledged PEMF may be useful and effective in addition to conservative management of osteoarthritis of the knee, although future studies are needed to confirm their findings.

**Post-operative and Non Post-operative Pain:** Omar et al., (2012) published the results of a randomized controlled trial (N=40) evaluating the effectiveness of PEMF as a conservative form of treatment for low back pain with radicular symptoms. The study group consisted of subjects over age 25 years with unilateral radicular pain with or without low back pain and diagnosed with lumbar disc prolapse by magnetic resonance imaging. The experimental group received standard medical treatment in addition to PEMF; the control group received standard medical treatment in addition to placebo treatment with the machine turned off. Clinical outcome measures included visual analog scale (VAS), modified Oswestry Low Back Pain Disability Questionnaire (OSW) for determining impact on activities of daily living and somatosensory evoked potentials for dermatomes. Statistical significance was reported for both groups for VAS and OSW scores after PEMF therapy. A significant decrease of hypoesthesia, improvement of ankle hyporeflexia and improvement of positive straight leg-raising test between groups was reported. Adverse events were not reported and standard medical treatment was not defined. The authors concluded PEMF therapy was an effective modality for treatment of low back pain and radicular symptoms, however further research is needed involving large numbers of subjects to support recommendation as a routine conservative form of treatment.

Guo et al. (2012) reported the results of a meta-analysis evaluating clinical efficacy of PEMF related to post-operative pain, non-post-operative pain and wound healing. A total of 25 controlled trials met inclusion criteria (N=1332) for the analysis. Sixteen trials reported pain outcomes (N=936 treated with PEMF, N=962 control group) for which the authors noted a clinically and statistically significant improvement for patients receiving active treatment (PO:  $P < 0.0001$ , NPO:  $P < 0.0001$ ). The authors reported that variables related to pathology, anatomy, duration of symptoms, duration of therapy, and technologies were examined for relevance to study outcome. Regarding anatomical and pathological variables, the authors concluded there wasn't enough evidence to draw conclusions regarding efficacy for the treatment of degenerative diseases; a majority of the studies involved treatment of subjects with pain and edema arising from soft-tissue injury. For duration of therapy the response of PEMF was independent of the duration of symptoms prior to treatment. When examining device variability it was not clear whether the type of device used or the minutes of therapy were the driving factor for a positive outcome. In the author's opinion, it was the duration of therapy overall that was the most probable predictor of clinical effectiveness.

**Use Outside of the US:** Pulsed electromagnetic therapy devices have been approved for use by one other health authority, the Australian Register of Therapeutic Goods (ARTG 213222), as medical therapy for treatment of chronic and acute pain, blood circulation and general well-being; however, formal guidelines regarding indications for use were not found.

## Summary

There is insufficient evidence in the published, scientific literature to support the effectiveness of pulsed electromagnetic field therapy devices (e.g., Diapulse, SofPulse, Provant Wound Closure System) for wound care management. Studies comparing these devices with established wound care management modalities are lacking and do not support improvement in net health outcomes. Additionally, data are limited evaluating electromagnetic field therapy devices for other indications including but not limited to pain or soft tissue injuries. As a result conclusions cannot be made regarding clinical efficacy when used for these indications and clinical utility has yet to be proven.

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## Coding/Billing Information

**Note:** 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

## Experimental/Investigational/Unproven/Not Covered:

HCPCS	Description
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Codes	
E0761	Non-thermal pulsed high frequency radiowaves, high peak power electromagnetic energy treatment device
E0769	Electrical stimulation or electromagnetic wound treatment device, not otherwise classified
G0295	Electromagnetic therapy, to one or more areas, for wound care other than described in G0329 or for other use
G0329	Electromagnetic therapy, to one or more areas for chronic stage III and stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care as part of a therapy plan of care

**\*Current Procedural Terminology (CPT®) © 2012 American Medical Association: Chicago, IL.**

## References

1. Abdelrahim A, Hassanein HR, Dahaba M. Effect of pulsed electromagnetic field on healing of mandibular fracture: a preliminary clinical study. J Oral Maxillofac Surg. 2011 Jun;69(6):1708-17. Epub 2011 Feb 1.
2. Adie S, Harris IA, Naylor JM, Rae H, Dao A, Yong S, Ying V. Pulsed electromagnetic field stimulation for acute tibial shaft fractures: a multicenter, double-blind, randomized trial. J Bone Joint Surg Am. 2011 Sep 7;93(17):1569-76.
3. Aktas I, Akgun K, Cakmak B. Therapeutic effect of pulsed electromagnetic field in conservative treatment of subacromial impingement syndrome. Clin Rheumatol. 2007 Aug;26(8):1234-9. Epub 2006 Nov 4.
4. Ay S, Evcik D. The effects of pulsed electromagnetic fields in the treatment of knee osteoarthritis: a randomized, placebo-controlled trial. Rheumatol Int. 2009 Apr;29(6):663-6.
5. Australian Register of Therapeutic Goods (ARTG). 213222. Public ARTG summary. Accessed October 9, 2013. Available at URL address: [https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs%2FPublicHTML%2FpdfStore.nsf&docid=1B3EA80AAC6C5E3ACA257BC8004239AC&agid=\(PrintDetailsPublic\)&actionid=1](https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs%2FPublicHTML%2FpdfStore.nsf&docid=1B3EA80AAC6C5E3ACA257BC8004239AC&agid=(PrintDetailsPublic)&actionid=1)
6. Aziz Z, Cullum NA, Flemming K. Electromagnetic therapy for treating venous leg ulcers. Cochrane Database of Systematic Reviews 2011, Issue 3. Art. No.: CD002933. DOI: 10.1002/14651858.CD002933.pub4
7. Aziz Z, Flemming K, Cullum NA, Olyaei Manesh A. Electromagnetic therapy for treating pressure ulcers. Cochrane Database of Systematic Reviews 2010, Issue 11. Art. No.: CD002930. DOI: 10.1002/14651858.CD002930.pub4
8. Blue Cross and Blue Shield Association (BCBSA). Technology Evaluation Center (TEC). Electrical stimulation or electromagnetic therapy as adjunctive treatments for chronic skin wounds. (TEC). Assessment Program Volume 20, No 2. August 2005. Accessed September 27, 2007. Available at URL address: [http://www.bcbs.com/betterknowledge/tec/vols/20/20\\_02.html](http://www.bcbs.com/betterknowledge/tec/vols/20/20_02.html)
9. Bókkon I, Till A, Grass F, Erdöfi Szabó A. Phantom pain reduction by low-frequency and low-intensity electromagnetic fields. Electromagn Biol Med. 2011 Sep;30(3):115-27.
10. Bosi E, Bax G, Scionti L, Spallone V, Tesfaye S, Valensi P, Ziegler D; FREMS European Trial Study Group. Frequency-modulated electromagnetic neural stimulation (FREMS) as a treatment for symptomatic diabetic neuropathy: results from a double-blind, randomised, multicentre, long-term, placebo-controlled clinical trial. Diabetologia. 2013 Mar;56(3):467-75.

11. Bril V, England J, Franklin GM, Backonja M, Cohen J, Del Toro D, et al. Evidence-based guideline: Treatment of painful diabetic neuropathy: report of the American Academy of Neurology, the American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation. *PM R*. 2011 Apr;3(4):345-52, 352 .
12. Bronfort G, Nilsson N, Haas M, Evans R, Goldsmith CH, Assendelft WJJ, Bouter LM. Noninvasive physical treatments for chronic recurrent headache. *The Cochrane Review*. In: *The Cochrane Library*, Issue 1, 2004. Oxford: Update software.
13. Brook J, Dauphinee DM, Korpinen J, Rawe IM. Pulsed Radiofrequency Electromagnetic Field Therapy: A Potential Novel Treatment of Plantar Fasciitis. *J Foot Ankle Surg*. 2012 May-Jun;51(3):312-6.
14. Centers for Medicare and Medicaid Services (CMS). Electrical stimulation and electromagnetic therapy for the treatment of wounds. Change Request 3149. Effective date July 1, 2004. Implementation date July 6, 2004. Accessed September 26, 2012. Available at URL address: <http://www.cms.hhs.gov/MLN MattersArticles/downloads/MM3149.pdf#search=%22Electrical%20stimulation%20and%20electromagnetic%20therapy%20for%20the%20treatment%20of%20wounds.%20Change%20Request%203149%22>
15. ECRI Institute. Hotline Response [database online], Plymouth Meeting (PA): ECRI Institute 2009 Jul 6. Updated 12/15/2010. Electrical Stimulation and Electromagnetic Therapy for the Treatment of Chronic Wounds. Available at URL address: <http://www.ecri.org>
16. Fernandez MI, Watson PJ, Rowbotham DJ. Effect of pulsed magnetic field therapy on pain reported by human volunteers in a laboratory model of acute pain. *Br J Anaesth*. 2007 Aug;99(2):266-9. Epub 2007 May 22.
17. Flemming K, Cullum N. Electromagnetic therapy for the treatment of venous leg ulcers. *Cochrane Database of Systematic Reviews*. In: *The Cochrane Library*, 2001(a), Issue 3. Copyright ©2001 The Cochrane Collaboration.
18. Flemming K, Cullum N. Electromagnetic therapy for treating pressure sores. (Review). *Cochrane Database of Systematic Reviews*. In: *The Cochrane Library*, 2001(b), Issue 3. Copyright ©2001 The Cochrane Collaboration.
19. Foley KT, Mroz TE, Arnold PM, Chandler HC Jr, Dixon RA, Girasole GJ, et al. Randomized, prospective, and controlled clinical trial of pulsed electromagnetic field stimulation for cervical fusion. *Spine J*. 2008 May-Jun;18(3):436-42.
20. Ghossaini S, Spitzer J, Maackens C, Zschommler A, Diamond B, Wazen J. High-frequency pulsed electromagnetic energy in tinnitus treatment. *Laryngoscope*. 2004 Mar;114(3):495-500.
21. George FR, Lukas RJ, Moffett J, Ritz MC. In-vitro mechanisms of cell proliferation induction: a novel bioactive treatment for accelerating wound healing. *Wounds*. 2002;14(3):107-15.
22. Gilbert TL, Griffin N, Moffett J, Ritz MC, George FR. The Provant® Wound Closure System induces activation of p44/42 MAP kinase in normal cultured human fibroblasts. *Ann N Y Acad Sci*. 2002 Jun;961:168-71.
23. Goldstein C, Sprague S, Petrisor BA. Electrical stimulation for fracture healing: current evidence. *J Orthop Trauma*. 2010 Mar;24 Suppl 1:S62-5.
24. Green S, Buchbinder R, Hetrick SE. Physiotherapy interventions for shoulder pain. *Cochrane Database of Systematic Reviews* 2003, Issue 2. Copyright © 2008 The Cochrane Collaboration.
25. Griffin XL, Costa ML, Parsons N, Smith N. Electromagnetic field stimulation for treating delayed union or non-union of long bone fractures in adults. *Cochrane Database Syst Rev*. 2011 Apr 13;(4):CD008471.

26. Hannemann P, Göttgens KW, van Wely BJ, Kolkman KA, Werre AJ, Poeze M, Brink PR. Pulsed Electromagnetic Fields in the treatment of fresh scaphoid fractures. A multicenter, prospective, double blind, placebo controlled, randomized trial. *BMC Musculoskelet Disord*. 2011 May 6;12:90.
27. Hedén P, Pilla AA. Effects of pulsed electromagnetic fields on postoperative pain: a double-blind randomized pilot study in breast augmentation patients. *Aesthetic Plast Surg*. 2008 Jul;32(4):660-6. Epub 2008 May 28.
28. McGaughey, H, Dhamija, S, Oliver, L, Porter, AA, and McDonough, S. Pulsed electromagnetic energy in management of chronic wounds: a systematic review. *Physical Therapy Reviews*. 2009;14(2):132-146. Cochrane Library.
29. Ogilvie-Harris D, Gilbert M. Treatment modalities for soft tissue injuries of ankle: a critical review. *Clin J Sport Med*. 1995;5(3):173-86.
30. Olyaei Manesh A, Flemming K, Cullum NA, Ravaghi H. Electromagnetic therapy for treating pressure ulcers. *Cochrane Database of Systematic Reviews*. In: The Cochrane Library, 2006, Issue 3. Copyright ©2008 The Cochrane Collaboration. First published 19 April, 2006.
31. Omar AS, Awadalla MA, El-Latif MA. Evaluation of pulsed electromagnetic field therapy in the management of patients with discogenic lumbar radiculopathy. *Int J Rheum Dis*. 2012 Oct;15(5):e101-8.
32. Özgüçlü E, Cetin A, Cetin M, Calp E . Additional effect of pulsed electromagnetic field therapy on knee osteoarthritis treatment: a randomized, placebo-controlled study. *Clin Rheumatol*. 2010 Aug;29(8):927-31.
33. Pieber K, Herceg M, Paternostro-Sluga T. Electrotherapy for the treatment of painful diabetic peripheral neuropathy: a review. *J Rehabil Med*. 2010 Apr;42(4):289-95.
34. Ravaghi H, Flemming K, Cullum N, Olyaei Manesh A. Electromagnetic therapy for treating venous leg ulcers. *Cochrane Database of Systematic Reviews* 2005, Issue 4. In: The Cochrane Library, 2006, Issue 3. Copyright ©2008 The Cochrane Collaboration. First published 19 April, 2006.
35. Reddy M, Gill SS, Kalkar SR, Wu W, Anderson PJ, Rochon PA. Treatment of pressure ulcers: a systematic review. *JAMA*. 2008 Dec 10;300(22):2647-62.
36. Regenesi<sup>®</sup> Biomedical, Scottsdale, Arizona. Discover Provant Wound Closure System. Accessed September 26, 2012. Available at URL address: <http://www.regenesisiomedical.com/>
37. Ritz MC, Gallegos R, Canham MB, Eskalai M, George FR. Provant<sup>®</sup> Wound Closure System accelerates closure of pressure wounds in a randomized, double-blind placebo-controlled trial. *Ann N Y Acad Sci*. 2002 Jun;961:356-9.
38. Sutbeyaz ST, Sezer N, Koseoglu F, Kibar S. Low-frequency pulsed electromagnetic field therapy in fibromyalgia: a randomized, double-blind, sham-controlled clinical study. *Clin J Pain*. 2009 Oct;25(8):722-8.
39. Thomas AW, Graham K, Prato FS, McKay J, Forster PM, Moulin DE, Chari S. A randomized, double-blind, placebo-controlled clinical trial using a low-frequency magnetic field in the treatment of musculoskeletal chronic pain. *Pain Res Manag*. 2007 Winter;12(4):249-58.
40. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. Device Listing Database. Regenesi Model 4201. Accessed October 9, 2007. Available at URL address: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm>
41. U.S. Food and Drug Administration (FDA). 510(k) Premarket Notification Database. Regenesi Model 42. K972093. 10/21/97. Accessed October 9, 2013. Available at URL address:

[http://google2.fda.gov/search?q=K972093&client=FDAgov&site=FDAgov&lr=&proxystylesheet=FDAgov&output=xml\\_no\\_dtd&getfields=\\*](http://google2.fda.gov/search?q=K972093&client=FDAgov&site=FDAgov&lr=&proxystylesheet=FDAgov&output=xml_no_dtd&getfields=*)

42. U.S. Food and Drug Administration (FDA). 510(k) Premarket Notification Database. Magnetic Resonance Therapy Device K903675. 1/17/91. Accessed October 9, 2013. Available at URL address: [http://google2.fda.gov/search?q=K903675&client=FDAgov&site=FDAgov&lr=&proxystylesheet=FDAgov&output=xml\\_no\\_dtd&getfields=\\*](http://google2.fda.gov/search?q=K903675&client=FDAgov&site=FDAgov&lr=&proxystylesheet=FDAgov&output=xml_no_dtd&getfields=*)
43. Uzunca K, Birtane M, Taştekin N. Effectiveness of pulsed electromagnetic field therapy in lateral epicondylitis. *Clin Rheumatol*. 2007 Jan;26(1):69-74. Epub 2006 Apr 22.
44. Vavken P, Arrich F, Schuhfried O, Dorotka R. Effectiveness of pulsed electromagnetic field therapy in the management of osteoarthritis of the knee: a meta-analysis of randomized controlled trials. *J Rehabil Med*. 2009 May;41(6):406-11.
45. Vincent W, Andrasik F, Sherman R. Headache treatment with pulsing electromagnetic fields: a literature review. *Appl Psychophysiol Biofeedback*. 2007 Dec;32(3-4):191-207. Epub 2007 Nov 2.
46. Weintraub MI, Herrmann DN, Smith AG, Backonja MM, Cole SP. Pulsed electromagnetic fields to reduce diabetic neuropathic pain and stimulate neuronal repair: a randomized controlled trial. *Arch Phys Med Rehabil*. 2009 Jul;90(7):1102-9.
47. Wróbel MP, Szymborska-Kajanek A, Wystrychowski G, Biniszkiewicz T, Sieroń-Stożny K, Sieroń A, Pierzchała K, Grzeszczak W, Strojek K. Impact of low frequency pulsed magnetic fields on pain intensity, quality of life and sleep disturbances in patients with painful diabetic polyneuropathy. *Diabetes Metab*. 2008 Sep;34(4 Pt 1):349-54.

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