**To:** BioElectronics Corporation (mkwhelan@verizon.net)

**Subject:** U.S. TRADEMARK APPLICATION NO. 86222506 - ANTI-INFLAMMATORY VAC - N/A

**Sent:** 7/9/2014 4:54:57 PM

**Sent As:** ECOM119@USPTO.GOV

**Attachments:**
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**UNITED STATES PATENT AND TRADEMARK OFFICE (USPTO)**
**OFFICE ACTION (OFFICIAL LETTER) ABOUT APPLICANT'S TRADEMARK APPLICATION**

**U.S. APPLICATION SERIAL NO.** 86222506

**MARK:** ANTI-INFLAMMATORY VAC

*86222506*

**CLICK HERE TO RESPOND TO THIS LETTER:**
**http://www.uspto.gov/trademarks/teas/response_forms.jsp**

**CORRESPONDENT ADDRESS:**
BIOELECTRONICS CORPORATION
BIOELECTRONICS CORPORATION
4539 METROPOLITAN CT
FREDERICK, MD 21704-9452

**APPLICANT:** BioElectronics Corporation

**CORRESPONDENT'S REFERENCE/DOCKET NO:**
N/A

**CORRESPONDENT E-MAIL ADDRESS:**
mkwhelan@verizon.net

# OFFICE ACTION

## STRICT DEADLINE TO RESPOND TO THIS LETTER

TO AVOID ABANDONMENT OF APPLICANT'S TRADEMARK APPLICATION, THE USPTO MUST RECEIVE APPLICANT'S COMPLETE RESPONSE TO THIS LETTER **WITHIN 6 MONTHS** OF THE ISSUE/MAILING DATE BELOW.

**ISSUE/MAILING DATE: 7/9/2014**

The referenced application has been reviewed by the assigned trademark examining attorney. Applicant must respond timely and completely to the issue(s) below. 15 U.S.C. §1062(b); 37 C.F.R. §§2.62(a), 2.65(a); TMEP §§711, 718.03.

**TEAS PLUS APPLICANTS – TO MAINTAIN REDUCED FEE, ADDITIONAL REQUIREMENTS MUST BE MET, INCLUDING SUBMITTING DOCUMENTS ONLINE:** Applicants who filed their application online using the lower-fee TEAS Plus application form must (1) continue to submit certain documents online using TEAS, including responses to Office actions (see TMEP §819.02(b) for a complete list of these documents); (2) accept correspondence from the USPTO via e-mail throughout the examination process; and (3) maintain a valid e-mail address. *See* 37 C.F.R. §2.23(a)(1), (a)(2); TMEP §§819, 819.02(a). TEAS Plus applicants who do not meet these three requirements must submit an additional fee of $50 per international class of goods and/or services. 37 C.F.R. §2.6(a)(1)(iv); TMEP §819.04. However, in certain situations, authorizing an examiner's amendment by telephone will not incur this additional fee.

SUMMARY OF ISSUES that applicant must address:

- **SECTION 2(d) REFUSAL – LIKELIHOOD OF CONFUSION**
- **DISCLAIMER REQUIRED**
- **IDENTIFICATION OF GOODS – AMEND TO AVOID DECEPTIVENESS**

### SECTION 2(d) REFUSAL – LIKELIHOOD OF CONFUSION

Registration of the applied-for mark **ANTI-INFLAMMATORY VAC** is refused because of a likelihood of confusion with the mark **V.A.C.** in U.S. Registration No. **1982349**. Trademark Act Section 2(d), 15 U.S.C. §1052(d); *see* TMEP §§1207.01 *et seq.* See the enclosed registration.

Trademark Act Section 2(d) bars registration of an applied-for mark that so resembles a registered mark that it is likely a potential consumer would be confused, mistaken, or deceived as to the source of the goods and/or services of the applicant and registrant. *See* 15 U.S.C. §1052(d). A determination of likelihood of confusion under Section 2(d) is made on a case-by case basis and the factors set forth in *In re E. I. du Pont de Nemours & Co.*, 476 F.2d 1357, 177 USPQ 563 (C.C.P.A. 1973) aid in this determination. *Citigroup Inc. v. Capital City Bank Grp., Inc.*, 637 F.3d 1344, 1349, 98 USPQ2d 1253, 1256 (Fed. Cir. 2011) (citing *On-Line Careline, Inc. v. Am. Online, Inc.*, 229 F.3d 1080, 1085, 56 USPQ2d 1471, 1474 (Fed. Cir. 2000)). Not all the *du Pont* factors, however, are necessarily relevant or of equal weight, and any one of the factors may control in a given case, depending upon the evidence of record. *Citigroup Inc. v. Capital City Bank Grp., Inc.*, 637 F.3d at 1355, 98 USPQ2d at 1260; *In re Majestic Distilling Co.*, 315 F.3d 1311, 1315, 65 USPQ2d 1201, 1204 (Fed. Cir. 2003); *see In re E. I. du Pont de Nemours & Co.*, 476 F.2d at 1361-62, 177 USPQ at 567.

In this case, the following factors are the most relevant: similarity of the marks, similarity and nature of the goods, and similarity of the trade channels of the goods. *See In re Viterra Inc.*, 671 F.3d 1358, 1361-62, 101 USPQ2d 1905, 1908 (Fed. Cir. 2012); *In re Dakin's Miniatures Inc.* , 59 USPQ2d 1593, 1595-96 (TTAB 1999); TMEP §§1207.01 *et seq.*

The overriding concern is not only to prevent buyer confusion as to the source of the goods and/or services, but to protect the registrant from adverse commercial impact due to use of a similar mark by a newcomer. *See In re Shell Oil Co.*, 992 F.2d 1204, 1208, 26 USPQ2d 1687, 1690 (Fed. Cir. 1993). Therefore, any doubt regarding a likelihood of confusion determination is resolved in favor of the registrant. TMEP §1207.01(d)(i); *see Hewlett-Packard Co. v. Packard Press, Inc.*, 281 F.3d 1261, 1265, 62 USPQ2d 1001, 1003 (Fed. Cir. 2002); *In re Hyper Shoppes (Ohio), Inc.*, 837 F.2d 463, 464-65, 6 USPQ2d 1025, 1026 (Fed. Cir. 1988).

### COMPARISON OF MARKS

The applicant's mark is **ANTI-INFLAMMATORY VAC.**

The registered mark is **V.A.C.**

The registered mark and the "VAC" portion of the applied-for mark are essentially phonetic equivalents and thus sound similar. Similarity in sound alone may be sufficient to support a finding that the marks are confusingly similar. *In re White Swan Ltd.*, 8 USPQ2d 1534, 1535 (TTAB 1988); *see In re 1st USA Realty Prof'ls, Inc.* , 84 USPQ2d 1581, 1586 (TTAB 2007); TMEP §1207.01(b)(iv).

Although marks are compared in their entireties, one feature of a mark may be more significant or dominant in creating a commercial impression. *See In re Viterra Inc.*, 671 F.3d 1358, 1362, 101 USPQ2d 1905, 1908 (Fed. Cir. 2012); *In re Nat'l Data Corp.* , 753 F.2d 1056, 1058, 224 USPQ 749, 751 (Fed. Cir. 1985); TMEP §1207.01(b)(viii), (c)(ii). Matter that is descriptive of or generic for an applicant's goods and/or services is typically less significant or less dominant in relation to other wording in a mark. *See In re Chatam Int'l Inc.* , 380 F.3d 1340, 1342-43, 71 USPQ2d 1944, 1946 (Fed. Cir. 2004); *In re Binion*, 93 USPQ2d 1531, 1534 (TTAB 2009).

In the present case, the attached evidence shows that the wording " **ANTI-INFLAMMATORY"** in the applied-for mark is merely descriptive of or generic for applicant's goods that are used to reduce inflammation. Thus, this wording is less significant in terms of affecting the mark's commercial impression, and renders the wording "VAC" the more dominant element of the mark.

Adding a term to a registered mark generally does not obviate the similarity between the compared marks, as in the present case, nor does it overcome a likelihood of confusion under Section 2(d). *See Coca-Cola Bottling Co. v. Jos. E. Seagram & Sons, Inc.*, 526 F.2d 556, 557, 188 USPQ 105, 106 (C.C.P.A. 1975) (finding BENGAL and BENGAL LANCER and design confusingly similar); *In re Toshiba Med. Sys. Corp.*, 91 USPQ2d 1266, 1269 (TTAB 2009) (finding TITAN and VANTAGE TITAN confusingly similar); *In re El Torito Rests., Inc.*, 9 USPQ2d 2002, 2004 (TTAB 1988) (finding MACHO and MACHO COMBOS confusingly similar); TMEP §1207.01(b)(iii). In the present case, the VAC and V.A.C. portions of the marks are nearly identical. Therefore the addition of the descriptive wording "ANTI-INFLAMMATORY" does not obviate the similarity of the marks.

In these respects, the literal portions of the applicant's mark and that of the registrant are highly similar in appearance, sound, connotation and commercial impression, and therefore, are likely to cause confusion as to the origin of the goods.

**COMPARISON OF GOODS**

The applicant's goods are identified as "Low frequency electromagnetic therapy apparatus" The goods named in the registration comprise/include "medical devices, namely pump units for promoting wound healing, receptacles for collecting wound drainage, and parts and accessories for the foregoing."

The goods and/or services of the parties need not be identical or even competitive to find a likelihood of confusion. *See On-line Careline Inc. v. Am. Online Inc.*, 229 F.3d 1080, 1086, 56 USPQ2d 1471, 1475 (Fed. Cir. 2000); *Recot, Inc. v. Becton*, 214 F.3d 1322, 1329, 54 USPQ2d 1894, 1898 (Fed. Cir. 2000) ("[E]ven if the goods in question are different from, and thus not related to, one another in kind, the same goods can be related in the mind of the consuming public as to the origin of the goods."); TMEP §1207.01(a)(i).

The respective goods and/or services need only be "related in some manner and/or if the circumstances surrounding their marketing [be] such that they could give rise to the mistaken belief that [the goods and/or services] emanate from the same source." *Coach Servs., Inc. v. Triumph Learning LLC*, 668 F.3d 1356, 1369, 101 USPQ2d 1713, 1722 (Fed. Cir. 2012) (quoting *7-Eleven Inc. v. Wechsler*, 83 USPQ2d 1715, 1724 (TTAB 2007)); *Gen. Mills Inc. v. Fage Dairy Processing Indus. SA*, 100 USPQ2d 1584, 1597 (TTAB 2011); TMEP §1207.01(a)(i). In this case, it is enough that applicant's goods and registrant's goods are both used to promote healing.

The attached Internet evidence consists of excerpts about therapy devices for use in the field of wound healing. This evidence establishes that the applicant's goods and registrant's goods are similar or complementary in terms of purpose or function. Therefore, applicant's and registrant's goods and/or services are considered related for likelihood of confusion purposes. *See, e.g., In re Davey Prods. Pty Ltd.*, 92 USPQ2d 1198, 1202-04 (TTAB 2009); *In re Toshiba Med. Sys. Corp.*, 91 USPQ2d 1266, 1268-69, 1271-72 (TTAB 2009).

Evidence obtained from the Internet may be used to support a determination under Trademark Act Section 2(d) that goods and/or services are related. *See, e.g., In re G.B.I. Tile & Stone, Inc.*, 92 USPQ2d 1366, 1371 (TTAB 2009); *In re Paper Doll Promotions, Inc.*, 84 USPQ2d 1660, 1668 (TTAB 2007).

The marks are used to identify medical devices for use in the field of healing. The same consumers will be exposed to the therapeutic products identified with the marks. The similarities among the marks and the goods of the parties are so great as to create a likelihood of confusion.

**CONCLUSION**

Accordingly, in view of the closely related nature of the goods of the parties and the strong similarity of the marks and their commercial impressions, confusion as to the source of the goods is likely under Section 2(d) of the Trademark Act.

Although the examining attorney has refused registration, the applicant may respond to the refusal to register by submitting evidence and arguments in support of registration. If the applicant chooses to respond to the refusal to register, the applicant must also respond to the

following.

**DISCLAIMER REQUIRED**

Applicant must disclaim the wording "**ANTI-INFLAMMATORY**" because it merely describes an ingredient, quality, characteristic, function, feature, purpose, or use of applicant's goods and/or services, and thus is an unregistrable component of the mark. *See* 15 U.S.C. §§1052(e)(1), 1056(a); *DuoProSS Meditech Corp. v. Inviro Med. Devices, Ltd.*, 695 F.3d 1247, 1251, 103 USPQ2d 1753, 1755 (Fed. Cir. 2012) (quoting *In re Oppedahl & Larson LLP*, 373 F.3d 1171, 1173, 71 USPQ2d 1370, 1371 (Fed. Cir. 2004)); TMEP §§1213, 1213.03(a).

The attached evidence from online dictionaries shows this wording means " used to reduce inflammation" and "counteracting or suppressing inflammation." Therefore, the wording merely describes applicant's therapeutic devices that reduce inflammation.

An applicant may not claim exclusive rights to terms that others may need to use to describe their goods and/or services in the marketplace. *See Dena Corp. v. Belvedere Int'l, Inc.* , 950 F.2d 1555, 1560, 21 USPQ2d 1047, 1051 (Fed. Cir. 1991); *In re Aug. Storck KG*, 218 USPQ 823, 825 (TTAB 1983). A disclaimer of unregistrable matter does not affect the appearance of the mark; that is, a disclaimer does not physically remove the disclaimed matter from the mark. *See Schwarzkopf v. John H. Breck, Inc.*, 340 F.2d 978, 978, 144 USPQ 433, 433 (C.C.P.A. 1965); TMEP §1213.

If applicant does not provide the required disclaimer, the USPTO may refuse to register the entire mark. *See In re Stereotaxis Inc.*, 429 F.3d 1039, 1040-41, 77 USPQ2d 1087, 1088-89 (Fed. Cir. 2005); TMEP §1213.01(b).

Applicant should submit a disclaimer in the following standardized format:

**No claim is made to the exclusive right to use "ANTI-INFLAMMATORY" apart from the mark as shown.**

For an overview of disclaimers and instructions on how to satisfy this disclaimer requirement online using the Trademark Electronic Application System (TEAS) form, please go to http://www.uspto.gov/trademarks/law/disclaimer.jsp.

**IDENTIFICATION OF GOODS – AMEND TO AVOID DECEPTIVENESS**

The use or intended use of the applied-for mark on goods that do not in fact have or exhibit anti-inflammatory properties is or will be deceptive. *See* TMEP §1203.02-.02(b). To avoid a deceptiveness refusal, applicant must amend the identification to indicate that the goods possess this relevant feature or characteristic. *See* TMEP §§1203.02(e)(ii), (f)(i), 1402.05 *et seq*. Merely amending the identification to exclude goods or services with the named feature or characteristic will not avoid a deceptiveness refusal. TMEP §1203.02(f)(i).

Therefore, applicant must amend the identification to the following, if accurate:

Class 10: Low frequency electromagnetic therapy apparatus for reducing or suppressing inflammation

An applicant may only amend an identification to clarify or limit the goods and/or services, but not to add to or broaden the scope of the goods and/or services. 37 C.F.R. §2.71(a); *see* TMEP §§1402.06 *et seq.*, 1402.07.

**RESPONSE GUIDELINES**

To expedite prosecution of the application, applicant is encouraged to file its response to this Office action online via the Trademark Electronic Application System (TEAS), which is available at http://www.uspto.gov/trademarks/teas/index.jsp. If applicant has technical questions about the TEAS response to Office action form, applicant can review the electronic filing tips available online at http://www.uspto.gov/trademarks/teas/e_filing_tips.jsp and email technical questions to TEAS@uspto.gov.

If applicant has questions regarding this Office action, please telephone or e-mail the assigned trademark examining attorney. All relevant e-mail communications will be placed in the official application record; however, an e-mail communication will not be accepted as a response to this Office action and will not extend the deadline for filing a proper response. *See* 37 C.F.R. §2.191; TMEP §§304.01-.02, 709.04-.05. Further, although the trademark examining attorney may provide additional explanation pertaining to the refusal(s) and/or requirement(s) in this Office action, the trademark examining attorney may not provide legal advice or statements about applicant's rights. *See* TMEP §§705.02, 709.06.

/John M. C. Kelly/
United States Patent and Trademark Office
Trademark Examining Attorney
Law Office 119
571-272-9412
john.kelly@uspto.gov

**TO RESPOND TO THIS LETTER:** Go to http://www.uspto.gov/trademarks/teas/response_forms.jsp. Please wait 48-72 hours from the issue/mailing date before using the Trademark Electronic Application System (TEAS), to allow for necessary system updates of the application. For *technical* assistance with online forms, e-mail TEAS@uspto.gov. For questions about the Office action itself, please contact the assigned trademark examining attorney. **E-mail communications will not be accepted as responses to Office actions; therefore, do not respond to this Office action by e-mail.**

**All informal e-mail communications relevant to this application will be placed in the official application record.**

**WHO MUST SIGN THE RESPONSE:** It must be personally signed by an individual applicant or someone with legal authority to bind an applicant (i.e., a corporate officer, a general partner, all joint applicants). If an applicant is represented by an attorney, the attorney must sign the response.

**PERIODICALLY CHECK THE STATUS OF THE APPLICATION:** To ensure that applicant does not miss crucial deadlines or official notices, check the status of the application every three to four months using the Trademark Status and Document Retrieval (TSDR) system at http://tsdr.uspto.gov/. Please keep a copy of the TSDR status screen. If the status shows no change for more than six months, contact the Trademark Assistance Center by e-mail at TrademarkAssistanceCenter@uspto.gov or call 1-800-786-9199. For more information on checking status, see http://www.uspto.gov/trademarks/process/status/.

**TO UPDATE CORRESPONDENCE/E-MAIL ADDRESS:** Use the TEAS form at http://www.uspto.gov/trademarks/teas/correspondence.jsp.

# antiinflammatory

Also found in: Dictionary/thesaurus, Wikipedia



On this page
Word Browser



**antiinflammatory** /an·ti·in·flam·ma·to·ry/ (-in-flam´ah-tor"e) counteracting or suppressing inflammation; also, an agent that so acts.


**antiinflammatory**
[-inflam´ətor"ē]
Etymology: Gk, *anti* + L, *inflammare*, to set afire
**1** pertaining to a substance or procedure that counteracts or reduces inflammation.
**2** an antiinflammatory drug.


**antiinflammatory** [an"te-in-flam´ah-tor-e]
**1.** counteracting or suppressing INFLAMMATION.
**2.** an agent that so acts.


**antiinflammatory,**
*adj/n* serves to relieve inflammation in cases, such as injury or infection; beneficial trait of some essential oils.


**an·ti·in·flam·ma·to·ry** (an'tē-in-flam'ă-tō-rē)
Reducing inflammation by acting on body responses, without directly antagonizing the causative agent; denoting agents such as glucocorticoids and aspirin.


**an·ti·in·flam·ma·to·ry** (an'tē-in-flam'ă-tōr-ē)
Reducing inflammation by acting on body responses, without directly antagonizing the causative agent; denoting agents such as glucocorticoids and aspirin.

Medical Dictionary for the Health Professions and Nursing © Farlex 2012

**an·ti·in·flam·ma·to·ry** (an'tē-in-flam'ă-tōr-ē)
Reducing inflammation by acting on body responses, without directly antagonizing the causative agent; denoting agents such as glucocorticoids and aspirin.

Medical Dictionary for the Dental Professions © Farlex 2012

## Patient discussion about antiinflammatory.

**Q. Can anyone suggest a treatment for plantar fasciitis, apart from ultrasound, physio, anti-inflammatory agents?** My friend has had Plantar Fasciitis for more than 1 year and has persevered with all the ususal treatments above plus lots of rest from weight-bearing and elevation.

**A.** Padded foot splints, silicone heels insert and special shoes (e.g. arch-supporting shoes) may also help. These are usually sold and fitted by a professional. Exercise is another important measure. Some patients benefit from avoiding walking barefoot or in sleepers but rather using shoes from the first step.

More advanced treatments include steroid-local anesthetics injections, botulinum toxin (similar to botox) injections and surgery.

The prognosis is usually favorable, and most patients achieve relief of the pain.

However, all of the above is just for general knowledge - if you have any specific question, you may want to consult a doctor.

You may read more here:
www.nlm.nih.gov/medlineplus/ency/article/007021.htm

Read more or ask a question about antiinflammatory



Want to thank TFD for its existence? Tell a friend about us, add a link to this page, or visit the webmaster's page for free fun content.

Link to this page:

```
<a href="http://medical-
dictionary.thefreedictionary.com/antiinflammatory">anti
inflammatory</a>
```

Please bookmark with social media, your votes are noticed and appreciated:





Mentioned in
-icam
-metacin

References in periodicals archive
recently reported the results of a population-based, case-control study regarding risk factors for pediatric invasive group A streptococcal (GAS) infection (1), noting that the "new" use of nonsteroidal **antiinflammatory**

Medical browser
antiictaric

Full browser
antiidiotype antibody

-profen
17ß-hydroxycorticosterone
acemetacin
Acetaminophen
acetylsalicylic acid
Adrenocorticosteroids
Akebia quinata
anti-inflammatory
anti-inflammatory agents
anti-inflammatory drug
Anti-inflammatory drugs
antiinflammatory agents
antiinflammatory drug
antiinflammatory leukotriene
Antirheumatic Drugs
Ascriptin
aspirin

drugs (NSAIDs), defined as NSAID use <2 weeks before diagnosis, was associated with invasive GAS infection, whereas self-defined "regular" NSAID use was not.
*Nonsteroidal antiinflammatory drugs and group A streptococcal ...* by *Mulla, Zuber D.* / *Emerging Infectious Diseases*

Instead, drug companies have concentrated on aspirin, ibuprofen, cyclo-oxygenase-2 inhibitors, and other **antiinflammatory** drugs that block a single biochemical pathway but don't protect EETs.
*Running interference: fresh approach to fighting inflammation* by *Seppa, N.* / *Science News*

**More results**

antiicteric
antiidiotype antibody
antiimmune
antiinfection vitamin
antiinfective
antiinfective drug
**antiinflammatory**
antiinflammatory agents
antiinflammatory drug
antiinflammatory leukotriene
antiinhibitor coagulant complex
antiinitiator
antiinsulin
antikenotoxin
antiketogenesis
antiketogenic
Antikickback Law

antiidiotype autoantibody
antiimmune
antiinfection vitamin
antiinfective
antiinfective drug
Antiinflamatorio No Esteroideo
**antiinflammatory**
antiinflammatory agent
antiinflammatory agent
antiinflammatory agent
antiinflammatory agent
antiinflammatory agent
antiinflammatory agents
antiinflammatory drug
antiinflammatory drug
antiinflammatory drug
antiinflammatory hormone

Definition of *anti-inflammatory* in English:

# anti-inflammatory

Syllabification: an·ti·in·flam·ma·to·ry

Pronunciation: /ˌantēinˈflamәˌtôrē, ˌantī- /

**ADJECTIVE**

(Chiefly of a drug) used to reduce inflammation.

MORE EXAMPLE SENTENCES

**NOUN (plural anti-inflammatories)** Back to top

An anti-inflammatory drug.

MORE EXAMPLE SENTENCES

MORE EXAMPLE SENTENCES

More definitions of **anti-inflammatory**

Definition of **anti-inflammatory** in:

- The British & World English dictionary

anti-g
anti-infective
**anti-inflammatory**
anti-intellectual
Anti-Lebanon Mountains

More words in this category

amphetamine
anticholinergic
anxiolytic
arsphenamine
bactericide

Translate **anti-inflammatory**

into Italian

WORD OF THE DAY

frowzy

Pronunciation: 'frouzē

ADJECTIVE

scruffy and neglected in appearance

*See full definition*

**TYPED DRAWING**

**Serial Number**
74676320

**Status**
REGISTERED AND RENEWED

**Word Mark**
V.A.C.

**Standard Character Mark**
No

**Registration Number**
1982349

**Date Registered**
1996/06/25

**Type of Mark**
TRADEMARK

**Register**
PRINCIPAL

**Mark Drawing Code**
(1) TYPED DRAWING

**Owner**
KCI LICENSING, INC. CORPORATION DELAWARE 12930 IH-10 West San Antonio TEXAS 782492248

**Goods/Services**
Class Status -- ACTIVE. IC 010. US 026 039 044. G & S: medical devices, namely pump units for promoting wound healing, receptacles for collecting wound drainage, and parts and accessories for the foregoing. First Use: 1995/04/01. First Use In Commerce: 1995/04/01.

**Filing Date**
1995/05/01

**Examining Attorney**
WARD, JOYCE A.

**Attorney of Record**
Pamela B. Huff

**DESIGN MARK**

**Serial Number**
75874141

**Status**
REGISTERED AND RENEWED

**Word Mark**
VACUUM ASSISTED CLOSURE

**Standard Character Mark**
No

**Registration Number**
2657666

**Date Registered**
2002/12/10

**Type of Mark**
TRADEMARK

**Register**
PRINCIPAL

**Mark Drawing Code**
(1) TYPED DRAWING

**Owner**
KCI Licensing, Inc. CORPORATION DELAWARE 12930 IH-10 West San Antonio TEXAS 782492248

**Goods/Services**
Class Status -- ACTIVE. IC 010. US 026 039 044. G & S: [ medical devices, namely, pump units for promoting wound healing, receptacles for collecting wound drainage, and parts and accessories for the foregoing ] * parts and accessories for pump units for promoting wound healing and receptacles for collecting wound drainage*. First Use: 1995/04/01. First Use In Commerce: 1995/04/01.

**Disclaimer Statement**
NO CLAIM IS MADE TO THE EXCLUSIVE RIGHT TO USE "VACUUM ASSISTED" APART FROM THE MARK AS SHOWN.

**Filing Date**
1999/12/15

**Examining Attorney**
SNAPP, TINA L.

**Attorney of Record**
Pamela B. Huff

# VACUUM ASSISTED CLOSURE

# Chronic Wounds

## RecoveryRx® Chronic Wound Studies

### Introduction

**Low-Level Pulsed Radiofrequency Fields and the Treatment of Soft-Tissue Injuries**

The aim of this lecture is to outline the main physiological processes involved in the healing of wounds and to suggest a mechanism by which pulsed radiofrequency (RF) energy, or the currents induced in tissues by the application of that energy, may influence its course.

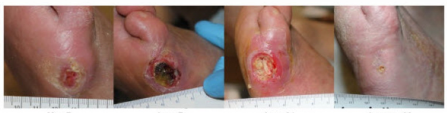
Emphasis is given to the part played by edema in inhibiting the processes of wound healing. Reference is made to the growing evidence that pulsed RF energy affects the time course of wound healing and the hypothesis is proposed that one possible mechanism by which pulsed RF energy accelerates wound healing is by reducing edema.

View Complete Published Paper

Pulsed radiofrequency electromagnetic field therapy is available in various forms. Extensive clinical research has been conducted with a

**BioElectronics Medical Device Chronic Wound Recovery**
Diabetic Foot Ulcer Patient

Clinical research has been conducted with a large number of clinical publications for hard to heal and chronic wounds. Most research; however, has been done with devices that use relatively high power, are large and clinic based. These therapies have been shown to be effective, but due to the frequency of the applications (up to twice daily for 30 min) it has limited potential for widespread use.



May 7 | June 7 | June 21 RecoveryRx™ Introduced | January 22 Ulcer Healed & Pain Controlled

RecoveryRx® technology is the miniaturization of the traditional large equipment used in hospitals and clinics. Advances in microelectronics have made it possible to deliver the clinically proven and superior extended duration therapy in small, convenient and cost-effective applications.

RecoveryRx® is applied to the wound, incorporating into the dressing or on top of the dressing for 24 hours per day. The radiofrequency electromagnetic field from RecoveryRx® passes through the dressing; therefore, the device does not need to be in direct contact with the skin. This makes for a simple application of this powerful technology, which not only promotes wound healing but also reduces chronic wound pain.

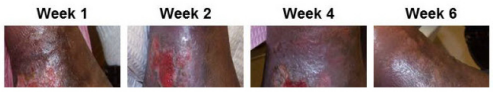
**View our all our case studies, which include patients with venous stasis ulcers, diabetic ulcers and ulcers from pyoderma gangrenosum**

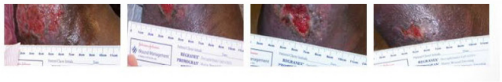
## Published Case Series

In a case series of four patients who were treated with RecoveryRx® at Temple Foot and Ankle Clinic, Philadelphia, all the patients had long standing ulcers that had failed previous therapies. The study period was six weeks. Three patients had diabetic ulcers and one had a venous stasis ulcer. This case series has been published in the *International Wound Journal*.

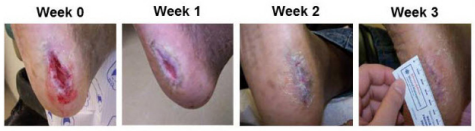
**The use of a portable, wearable form of pulsed radio frequency electromagnetic energy device for the healing of recalcitrant ulcers: A case report**

**Diabetic patient with Venous Stasis Ulcer had undergone compression therapy and no appreciable healing was seen. Compression therapy was continued along with RecoveryRx® therapy.**

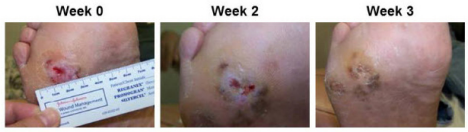




Diabetic patient with a right heel ulcer. Failed therapy included offloading, debridement and application of triple antibiotic ointment. After RecoveryRx® therapy was introduced ulcer healed in 3 weeks.




Diabetic patient with ulcer on right foot, previous failed therapy debridement, use of Promogran dressing. After RecoveryRx® therapy was introduced ulcer healed in 3 weeks.




All four patients healed after the introduction of RecoveryRx® therapy, two in 3 weeks and two patients healed in 8 weeks. The table below documents the rate of healing for the 4 patients in this study.

| Patient | Age | Location | Week 0 | Week 1 | Week 2 | Week 3 | Week 4 | Week 5 | Week 6 |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 66 | right leg | 4 x 2.5 | 4 x 2.3 | 4 x 2 | 3 x 1.5 | 2 x 1.5 | 1 x 0.7 | 0.7 x 0.5 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2 | 60 | right foot | 0.5 x 0.5 | 0.3 x0.3 | 0.2 x 0.1 | ulcer healed | | | |
| 3 | 43 | left heel | 4 x 1 | 2 x 0.5 | 1 x 0.3 | ulcer healed | | | |
| 4 | 74 | right heel | 2.5 x 1.75 | 2 X 2 | 2 X 1.5 | 1.7 X 0.7 | 1 X 1 | 1 X 0.5 | 1 X 0.5 |

## Recent News

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"I use RecoveryRx™ on every facial procedure. It reduces my patients bruising and swelling by 50% following Blepharoplasty, Face Lifts, and Rhinoplasty. As a result of RecoveryRx, two weeks of standard surgical recovery has been reduced to 5-7 days."

Laurie Casas MD, FACS
Northwestern University
Feinberg School of Medicine

See More Testimonials

# Clinical Policy Bulletin: High-Frequency Pulsed Electromagnetic Stimulation



**Number: 0175**

**Policy**

Aetna considers high-frequency pulsed electromagnetic stimulation (also known as therapeutic magnetic resonance) experimental and investigational for all indications, including any of the following (not an all inclusive list) because its effectiveness has not been established:

- Promotion of osteogenesis
- Treatment and prevention of osteoporosis
- Treatment of acute post-operative pain and edema
- Treatment of fibromyalgia
- Treatment of knee osteonecrosis
- Treatment of lateral or medial epicondylalgia/epicondylitis
- Treatment of mechanical neck disorders
- Treatment of neuropathic pain (e.g., painful diabetic peripheral neuropathy)
- Treatment of osteoarthritis
- Treatment of scaphoid fractures
- Treatment of soft tissue injuries
- Treatment of spasticity in multiple sclerosis
- Treatment of subacromial impingement syndrome
- Treatment of wounds.

See also CPB 0680 - Electrical Stimulation for Chronic Ulcers; and CPB 0343 - Bone Growth Stimulators.

**Background**

Various types of electrical stimulation have been examined for soft tissue injuries and wound healing. These include direct electrical stimulation using high voltage pulsed currents or high voltage galvanic currents in which the electrodes are placed directly on the wound site, low voltage pulsed electromagnetic fields, and high frequency pulsed electromagnetic fields, which include Diapulse (Diapulse Corporation of America, Great Neck, NY). Diapulse has been used in the management of chronic wounds, soft tissues injuries, and other indications including migraine, tinnitus, acute head injuries, and pelvic inflammatory disease. Although there are case studies (Duma-Drzewinska and Buczynski, 1978; Itoh et al, 1991; Comorosan et al, 1993; Tung et al, 1995) as well as small randomized controlled trials (Goldin et a., 1981; Salzberg et al, 1995; and Kenkre et al, 1996) that reported beneficial effects of Diapulse in treating refractory wounds, these studies had many drawbacks. Another electromagnetic device for the treatment of refractory wounds and soft tissue injuries is SofPulse. However, there is a lack of published data on its effectiveness for these indications.

Goldin et al (1981) focused on donor site skin graft healing reported positive results, but it is unclear how the positive outcome (90 % healing) was selected, and whether the results were statistically different at other degrees of healing. The statistical analysis involved adding the scores together from 3 different scales. The validity of this type of analysis is very questionable. Furthermore, healing of donor skin graft sites is perhaps physiologically different than the more common situation of pressure ulcer healing, and it is not clear if the results can be extrapolated from one clinical situation to another.

Salzberg et al (1995) examined if non-thermal pulsed electromagnetic energy treatment increases the healing rate of pressure ulcers in patients with spinal cord injuries (n = 30). Subjects consisted of 30 male spinal cord-injured (SCI) patients, 20 with Stage II and 10 with Stage III pressure ulcers. Subjects were given non-thermal pulsed high-frequency electromagnetic energy treatment for 30 mins twice-daily for 12 weeks or until healed. The percentage of pressure ulcers healed was measured at 1 week. Of the 20 patients with Stage II pressure ulcers, the active group had a significantly increased rate of healing with a greater percentage of the ulcer healed at 1 week than the control group. After controlling for the baseline status of the pressure ulcer, active treatment was independently associated with a significantly shorter median time to complete healing of the ulcer. Stage III pressure ulcers healed faster in the treatment group but the sample size was limited. The authors concluded that the results of this study suggested that non-thermal pulsed electromagnetic energy treatment is safe and accelerates wound healing in SCI men with Stage II pressure ulcers.

Diapulse has also been used for the treatment of acute post-operative pain and edema. This application is more difficult to evaluate due to the lack of objective outcome measures. However, randomized controlled trials are still considered critical. Both Wilson (1974) and Barclay (1983) reported positive results in randomized trials looking at ankle and hand injuries, respectively, but the statistical analysis was seriously flawed compromising any evaluation of the results. Pennington et al (1993) reported the use of Diapulse to reduce swelling in association with ankle sprains in an effort to reduce lost training days in the military. Although this randomized trial showed a 4.7 % decrease in ankle volume (compared to 0.95 % decrease in the control group), the clinical significance of this finding is unknown. For example, it is not known if the use of Diapulse actually reduced the morbidity of ankle sprains in terms of lost training days. In addition, the specific statistical test used to evaluate the results is not given. Bentall and Eckstein (1975) studied the use of Diapulse to reduce post-operative ecchymoses and edema in patients undergoing orchidopexy. This randomized double blind study showed a significant improvement in scrotal wound color changes at 6 and 8 days post surgery. The clinical significance of these findings is unknown. Finally, there have been 2 studies on the use of Diapulse after oral surgery (Aronofsky, 1971; Rhodes, 1981). However, both represented case series studies, so the true contribution of Diapulse cannot be determined.

In 1995, the Health Care Financing Administration (HCFA) commissioned the Emergency Care Research Institute (ECRI), an independent, nonprofit health services research agency, to conduct an assessment of electrical stimulation, which included pulsed electromagnetic field stimulation (e.g., Diapulse and SoftPulse devices) for chronic wound healing. In November, 1996, ECRI's Technology Advisory Committee reported its final conclusion stating that electrostimulation does not appear to be markedly superior or inferior to conventional or alternative therapies for chronic wound healing (HCFA, 1996). Based on this assessment on published trials, HCFA (1997) issued a national coverage policy stating "there is insufficient evidence to determine any clinically significant differences in healing rates. Therefore, electrical stimulation cannot be covered by Medicare because its effectiveness has not been adequately demonstrated".

Flemming and Cullum (2003) evaluated the evidence supporting the use of Diapulse electromagnetic therapy for treating pressure sores and reached the following conclusions: "The results suggest no evidence of a benefit in using electromagnetic therapy to treat pressure sores. However the possibility of a beneficial or harmful effect cannot be ruled out due to the fact there were only two trials with methodological limitations and small numbers of patients."

In December 2003, the Centers for Medicare & Medicaid Services (CMS) decided to reverse its initial (July 2002) non-coverage of EMS for the treatment of chronic wounds. Currently, CMS covers the use of ES and electromagnetic stimulation for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers. Chronic ulcers are defined as those that have not healed despite 30 days of treatment with standard wound therapy. In reversing its position, CMS appeared to have classified EMS to be similar to ES and cited the AHCPR Clinical Practice Guideline for the treatment of pressure ulcers, which recommends a course of treatment with ES for Stage III and Stage IV pressure ulcers that are refractory to conventional therapy (Bergstrom et al, 1994). It is interesting to note that the AHCPR recommendation was based on the findings of four studies, none of which used EMS for the treatment of pressure ulcers. CMS also discussed the ECRI report (1996) that there is evidence that pulsed electromagnetic energy (PEE) stimulation improves the normalized healing rates for Stage II decubitus ulcers. However, the ECRI report also stated there is insufficient evidence to determine whether PEE stimulation improves the normalized healing rates of Stage III or Stage IV decubitus ulcers. Furthermore, there is no evidence that PEE stimulation improves the healing rates of chronic venous or diabetic ulcers.

Of note, the ECRI assessment also concluded that there is evidence that pulse electromagnetic field (PEMF) stimulation improves the normalized healing rates of venous ulcers. However, this improvement appears to be small and may not be clinically useful. Furthermore, the report stated that there is no evidence that PEMF stimulation improves the healing rate of chronic decubitus or diabetic ulcers.

The BlueCross BlueShield Association Medical Advisory Panel concluded that electromagnetic therapy for chronic skin wounds does not meet the TEC criteria (BCBSA, 2005). This is in agreement with the assessment on pulsed signal therapy (PST) for musculoskeletal conditions conducted by the British Columbia Office of Health Technology Assessment (Sibley et al, 2001). The assessment focused on PST, which is a type of PEMF. The BCOHTA assessment also summarized the literature on PEMF generally, and concluded that "there are no published controlled, clinical trials showing that PST provides a clinical advantage versus placebo or other PEME devices".

Furthermore, in a systematic review on wound care management, Cullum et al.(2001) concluded that there is generally insufficient reliable evidence to draw conclusions about the contribution of laser therapy, therapeutic ultrasound, electro-therapy and electromagnetic therapy to chronic wound healing. Flemming and Cullum (2001) also concluded that there is currently no reliable evidence of benefit of electromagnetic therapy in the healing of venous leg ulcers.

In a systematic review on treatment of pressure ulcers, Reddy and colleagues (2008) concluded that there is little evidence to support routine nutritional supplementation or adjunctive therapies including electromagnetic therapy compared with standard care.

In a randomized, double-blind, control trial, Gupta and associates (2009) evaluated the effectiveness of PEMF in healing of pressure ulcers in patients with neurological disorders. A total of 12 patients (male:female, 9:3) having neurological disorders, with age between 12 to 50 years and 24 pressure ulcers were enrolled in this study. Six patients with 13 ulcers received PEMF therapy and the remaining 6 patients with 11 ulcers received sham treatment for 30 sessions (45 mins each) using the equipment "Pulsatron". The frequency of PEMF was set at 1 Hz with sine waves and current intensity of 30 mAmp. Whole body exposure was given in both the groups. Bates-Jensen wound assessment tool (BJWAT) score was used as main outcome measure and scores at the end of session were compared with initial scores and analyzed. Similarly, National Pressure Ulcer Advisory Panel (NPUAP) scores were compared and analyzed as secondary outcome measure. Thirteen ulcers were in stage IV and 11 were in stage III at the start of the study. Significant healing of ulcers was noted, BJWAT scores, in both the treatment and sham groups ($p < 0.001$ and $p < 0.003$, respectively) at the completion of the study. However, when comparing between the groups, healing was not significant ($p = 0.361$). Similar trend was noted with NPUAP scores with no significant difference between the treatment and sham groups ($p = 0.649$) at the completion of study. The authors concluded that no significant difference in pressure ulcer healing was observed between PEMF treatment and sham group in this study.

In a Cochrane review, Hulme et al (2002) examined the effectiveness of pulsed electric stimulation in treating patients with osteoarthritis (pulsed electric stimulation has been demonstrated to stimulate cartilage growth on the cellular level). These investigators concluded that current evidence suggests that electrical stimulation therapy may provide significant improvements for knee osteoarthritis, but further studies are needed to confirm whether the statistically significant findings shown in these studies result in important health benefits.

Sutbeyaz et al (2006) assessed the effect of PEMF on pain, range of motion (ROM) and functional status in patients with cervical osteoarthritis (COA). A total of 34 patients with COA were included in a randomized, double-blind study, in which PEMF was administrated to the whole body using a mat 1.8 x 0.6 m in size. During the treatment, the patients lay on the mat for 30 mins per session, twice a day for 3 weeks. Pain levels in the PEMF group decreased significantly after therapy ($p < 0.001$), but no change was observed in the placebo group. The active ROM, paravertebral muscle spasm and neck pain and disability scale scores improved significantly after PEMF therapy ($p < 0.001$) but no change was observed in the sham group. The results of this study are promising, in that PEMF treatment may offer a potential therapeutic adjunct to current COA therapies in the future.

In a Cochrane review on electrotherapy for neck pain, Kroeling et al (2009) noted that the evidence of PEMF as a treatment option is of very low quality. The authors stated that they can not make any definite statements on the efficacy and clinical usefulness of electrotherapy modalities for neck pain. They noted that future trials on these interventions (including PEMF) should have larger patient samples and include more precise standardization and description of all treatment characteristics.

McCarthy and colleagues (2006) noted that the rehabilitation of knee osteoarthritis often includes electrotherapeutic modalities as well as advice and exercise. One commonly used modality is PEMF. Its equivocal benefit over placebo treatment has been previously suggested. However, recently a number of randomized controlled studies have been published that have allowed a systematic review to be conducted. The authors concluded that this systematic review provides further evidence that PEMF has little value in the management of knee osteoarthritis. There appears to be clear evidence for the recommendation that PEMF does not significantly reduce the pain of knee osteoarthritis.

In a randomized, placebo-controlled study, Ay and Evcik (2009) examined the effects of PEMF on pain relief and functional capacity of patients with knee osteoarthritis. A total of 55 patients were included. At the end of treatment, there was statistically significant improvement in pain scores in both groups ($p < 0.05$). On the other hand, no significant difference was observed within the groups ($p > 0.05$). These investigators observed statistically significant improvement in some of the subgroups of Lequesne index (e.g., morning stiffness and activities of daily living) compared to the placebo group. However, these researchers could not observe statistically significant differences in total of the scale between two groups ($p > 0.05$). Applying between-group analysis, the authors were unable to demonstrate a beneficial symptomatic effect of PEMF in the treatment of knee osteoarthritis in all patients. They stated that further studies using different types of magnetic devices, treatment protocols and patient populations are warranted to confirm the general efficacy of PEMF therapy in knee osteoarthritis and other conditions.

Aktas et al (2007) noted that subacromial impingement syndrome (SIS) is a frequent cause of shoulder pain. In a double-blinded, randomized, and controlled study, these rsearchers examined if PEMF provided additional benefit when used with other conservative treatment modalities in acute phase rehabilitation program of SIS. A total of 46 patients with unilateral shoulder pain who had been diagnosed as having SIS were included in this trial. The cases were randomly separated into two groups. All cases received a treatment program for 3 weeks consisting of Codman's pendulum exercises and subsequent cold pack gel application on shoulders with pain 5 times a day, restriction of daily activities that require the hands to be used over the head, and meloxicam tablet 15 mg daily. One group was given PEMF; the other group was given sham PEMF daily, 25 mins per session, 5 days per week for 3 weeks. Shoulder pain during rest and activity and which causes disturbance of sleep was evaluated using a visual analog scale (VAS), and total Constant score investigated shoulder function. Daily living activities were evaluated by shoulder disability questionnaire. Results were assessed before and after treatment. When compared with the baseline values, significant improvements in all these variables were observed at the end of the treatment in both groups ($p < 0.05$). No significant difference between treatments was observed for any of these variables ($p > 0.05$). The authors concluded that there is no convincing evidence that PEMF therapy is of additional benefit in acute phase rehabilitation program of SIS.

In a randomized, controlled, prospective multi-center clinical trial, Foley and associates (2009) examined the safety and effectiveness of PEMF stimulation as an adjunct to arthrodesis following anterior cervical discectomy and fusion (ACDF) in patients with potential risk factors for non-union. A total of 323 patients with radiographical evidence (computed tomography-myelogram [CT-myelo] or magnetic resonance imaging [MRI]) of a compressed cervical nerve root and symptomatic radiculopathy appropriate to the compressed root that had failed to respond to non-operative management were enrolled in the study. Subjects were either smokers (more than 1 pack per day) and/or were undergoing multi-level fusions. All patients underwent ACDF using the Smith-Robinson technique. Allograft bone and an anterior cervical plate were used in all cases. Measurements were obtained pre-operatively and at each post-operative interval and included neurological assessment, VAS scores for shoulder/arm pain at rest and with activity, SF-12 scores, the neck disability index (NDI), and radiographs (antero-posterior, lateral, and flexion-extension views). Two orthopedic surgeons not otherwise affiliated with the study and blinded to treatment group evaluated the radiographs, as did a blinded radiologist. Adverse events were reported by all patients throughout the study to determine device safety. Patients were randomly assigned to one of two groups: (i) those receiving PEMF stimulation after surgery (PEMF group; n = 163), and (ii) those not receiving PEMF stimulation (control group; n = 160). Post-operative care was otherwise identical. Follow-up was carried out at 1, 2, 3, 6, and 12 months post-operatively. The PEMF and control groups were comparable with regard to age, gender, race, past medical history, smoking status, and litigation status. Both groups were also comparable in terms of baseline diagnosis (herniated disc, spondylosis, or both) and number of levels operated (1, 2, 3, or 4). At 6 months post-operatively, the PEMF group had a significantly higher fusion rate than the control group (83.6 % versus 68.6 %, $p = 0.0065$). At 12 months after surgery, the stimulated group had a fusion rate of 92.8 % compared with 86.7 % for the control group ($p = 0.1129$). There were no significant differences between the PEMF and control groups with regard to VAS pain scores, NDI, or SF-12 scores at 6 or 12 months. No significant differences were found in the incidence of adverse events in the groups. This was the first randomized, controlled trial that analyzed the effects of PEMF stimulation on cervical spine fusion. While PEMF stimulation significantly improved the fusion rate at 6 months post-operatively in patients undergoing ACDF with an allograft and an anterior cervical plate, however, the fusion rate for PEMF patients was not significantly different from that of the control group at 12 months post-operatively.

Biering-Sørensen et al (2009) reviewed the literature on non-pharmacological prevention and treatment of osteoporosis following spinal cord injury (SCI). PubMed, EMBASE and the Cochrane Controlled Trials Register were searched. All identified papers were read by title, abstract and full-length article when relevant. Hand search of the articles' sources identified additional papers. For included studies, the level of evidence was determined. No studies conclusively showed an effective intervention. However, there are few randomized controlled trials (RCTs), and those that exist assess interventions and outcome measures that could be improved. Five studies on weight-bearing early post-injury are conflicting, but standing or walking may help retain bone mineral. In the chronic phase, there was no effect of weight-bearing (12 studies). One study found that an early commencement of sports after SCI improved bone mineral, and the longer the period of athletic career, the higher the (leg) bone mineral. Early after SCI, there may be some effects of electrical stimulation (ES) (5 studies). Chronic-phase ES studies vary (14 studies, including mixed periods after injury), but improvement is seen with longer period of training, or higher frequency or stimulus intensity. Improvements correspond to trabecular bone in the distal femur or proximal tibia. Impact vibration and pulsed electromagnetic fields may have some positive effects, whereas pulsed ultrasound does not. Six studies on the influence of spasticity show inconsistent results. The authors concluded that bone mineral should be measured around the knee; the length and intensity of the treatment should be sufficiently long and high, respectively, and should commence early after SCI. If bone mineral is to remain, the stimulation has to be possibly continued for long-term. In addition, these investigators stated that RCTs are necessary.

In a randomized, double-blind, placebo-controlled, parallel study, Weintraub et al (2009) examined if repetitive and cumulative exposure to low-frequency PEMF targeting painful feet can reduce neuropathic pain (NP), influence sleep in symptomatic diabetic peripheral neuropathy (DPN), and influence nerve regeneration. Subjects with DPN stage II or III were randomly assigned to use identical devices generating PEMF or sham (placebo) 2 hrs/day to feet for 3 months. Nerve conduction testing was performed serially. Main outcome measures included pain reduction scores using a VAS, the Neuropathy Pain Scale (NPS), and the Patient's Global Impression of Change (PGIC). A subset of subjects underwent serial 3-mm punch skin biopsies from 3 standard lower limb sites for epidermal nerve fiber density (ENFD) quantification. Subjects (n = 225) were randomized with a drop-out rate of 13.8 %. There was a trend toward reductions in DPN symptoms on the PGIC, favoring the PEMF group (44 % versus 31 %; $p = 0.04$). There were no significant differences between PEMF and sham groups in the NP intensity on NPS or VAS. Twenty-seven subjects completed serial biopsies; 29 % PEMF subjects had an increase in distal leg ENFD of at least 0.5 SDs, while none did in the sham group ($p = 0.04$). Increases in distal thigh ENFD were significantly correlated with decreases in pain scores. The authors concluded that PEMF at this dosimetry was non-effective in reducing NP. However neurobiological effects on ENFD, PGIC and reduced itching scores suggest future studies are indicated with higher dosimetry (3000 to 5000 G), longer duration of exposure, and larger biopsy cohort.

Sutbeyaz and colleagues (2009) evaluated the clinical effectiveness of low-frequency PEMF therapy for women with fibromyalgia (FM). A total of 56 women with FM, aged 18 to 60 years, were randomly assigned to either PEMF or sham therapy. Both the PEMF group (n = 28) and the sham group (n = 28) participated in 30-mins sessions, twice-daily for 3 weeks. Treatment outcomes were assessed by the fibromyalgia Impact questionnaire (FIQ), VAS, patient global assessment of response to therapy, Beck Depression Inventory (BDI), and Short-Form 36 health survey (SF-36), after treatment (at 4 weeks) and follow-up (at 12 weeks). The PEMF group showed significant improvements in FIQ, VAS pain, BDI score, and SF-36 scale in all domains at the end of therapy. These improvements in FIQ, VAS pain, and SF-36 pain score were maintained during follow-up. The sham group also showed improvements and were maintained on all outcome measures except total FIQ scores after treatment. At 12 weeks follow-up, only improvements in the BDI and SF-36 scores were present in the sham group.

Pieber et al (2010) reviewed different types of electrotherapy for the treatment of painful diabetic peripheral neuropathy. A structured search of the electronic database MEDLINE was performed from the time of its initiation to July 2009. Articles in English and German were selected. The efficacy of different types of electrotherapy for painful diabetic peripheral neuropathy has been evaluated in 15 studies; the effects of transcutaneous electrical nerve stimulation are consistent. The beneficial effects of prolonged use have been reported in 3 large studies and 1 small study. The effects of frequency-modulated electromagnetic neural stimulation were assessed in 1 large study, and a significant reduction in pain was reported. Treatment with pulsed and static electromagnetic fields has been investigated in 2 small and 3 large studies, and analgesic benefits have been reported. In 1 large study focusing on pulsed electromagnetic fields, no beneficial effect on pain was registered. Only small studies were found concerning other types of electrotherapy, such as pulsed-dose electrical stimulation, high-frequency external muscle stimulation or high-tone external muscle stimulation. The conclusions drawn in these articles were diverse. Shortcomings and problems, including a poor study design, were observed in some. The authors concluded that further randomized, double-blind, placebo-controlled studies comprising larger sample sizes, a longer duration of treatment, and longer follow-up assessments are needed.

In a multi-center, double-blind, randomized trial, Adie et al (2011) examined if adjuvant PEMF therapy for acute tibial shaft fractures reduces the rate of surgical revision because of delayed union or nonunion. Six metropolitan trauma hospitals, 259 participants with acute tibial shaft fractures (AO/OTA type 42) were randomized by means of external allocation to externally identical active and inactive PEMF devices. Participants were instructed to wear the device for 10 hours daily for 12 weeks. Management was otherwise unaltered. The primary outcome was the proportion of participants requiring a secondary surgical intervention because of delayed union or nonunion within 12 months after the injury. Secondary outcomes included surgical intervention for any reason, radiographic union at 6 months, and the Short Form-36 Physical Component Summary and Lower Extremity Functional Scales at 12 months. Main analyses were by intention-to-treat. A total of 218 participants (84 %) completed the 12-month follow-up; 106 patients were allocated to the active device group, and 112 were allocated to the placebo group. Compliance was moderate, with 6.2 hours of average daily use. Overall, 16 patients in the active group and 15 in the inactive group experienced a primary outcome event (risk ratio, 1.02; 95 % CI: 0.95 to 1.14; p = 0.72). According to per-protocol analysis, there were 6 primary events (12.2 %) in the active, compliant group and 26 primary events (15.1 %) in the combined placebo and active, non-compliant group (risk ratio, 0.97; 95 % CI: 0.86 to 1.10; p = 0.61). No between-group differences were found with regard to surgical intervention for any reason, radiographic union, or functional measures. The authors concluded that adjuvant PEMF stimulation does not prevent secondary surgical interventions for delayed union or nonunion and does not improve radiographic union or patient-reported functional outcomes in patients with acute tibial shaft fractures.

In a preliminary clinical study, Abdelrahim et al (2011) evaluated the effect of PEMF on the healing of mandibular fractures. A total of 12 patients with mandibular fractures were selected for the present study. Each patient was treated by closed reduction using maxillo-mandibular fixation (MMF) and was assigned into 1 of 2 equal groups. The fracture sites of group A only were exposed to PEMF 2 hours daily for 12 days, after 2 weeks post-operatively the MMF was removed. For group B (control group), the MMF was removed at 4 weeks post-operatively. The effectiveness of the 2 treatment modalities was evaluated clinically and radiographically using computerized densitometry. The data were statistically analyzed. After releasing the MMF, a bi-manual mobility test of the fractured segments showed stability of the segments in all cases. An insignificant difference was found between the mean bone density values of the 2 groups at all study intervals. In contrast, the percentage of changes in bone density of the 2 groups revealed that group A had insignificant decreases at the 15th post-operative day and a significant increase 30 days post-operatively compared with group B. The authors concluded that from the present limited series of patients, PEMF stimulation might have a beneficial effect on the healing of mandibular fractures treated with closed reduction. However, additional research, using RCTs, should be conducted to ascertain its effectiveness compared with other treatment modalities.

In a Cochrane review, Griffin et al (2011) evaluated the effects of electromagnetic stimulation for treating delayed union or non-union of long bone fractures in adults. These investigators searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (May 2010), the Cochrane Central Register of Controlled Trials (in The Cochrane Library 2010, Issue 2), MEDLINE (1966 to May 2010) and EMBASE (1980 to 2010 Week 20), trial registers and reference lists of articles. Randomized controlled trials evaluating electromagnetic field stimulation for the treatment of delayed union or non-union of long bones in adults were selected. Two authors independently selected studies and performed data extraction and risk of bias assessment. Treatment effects were assessed using risk ratios and, where appropriate, data were pooled using a random-effects model. A total of 4 studies, involving 125 participants, were included; 3 studies evaluated the effects of PEMF and 1 study, capacitive coupled electric fields. Participants with delayed union and non-union of the long bones were included, but most data related to non-union of the tibia. Although all studies were blinded randomized placebo-controlled trials, each study had limitations. The primary measure of the clinical effectiveness of electromagnetic field stimulation was the proportion of participants whose fractures had united at a fixed time point. The overall pooled effect size was small and not statistically significant (risk ratio 1.96; 95 % confidence interval [CI]: 0.86 to 4.48; 4 trials). There was substantial clinical and statistical heterogeneity in this pooled analysis (I(2) = 58 %). A sensitivity analysis conducted to determine the effect of multiple follow-up time-points on the heterogeneity among the studies showed that the effect size remained non-significant at 24 weeks (risk ratio 1.61; 95 % CI: 0.74 to 3.54; 3 trials), with similar heterogeneity (I(2) = 57 %). There was no reduction in pain found in 2 trials. No study reported functional outcome measures. One trial reported 2 minor complications resulting from treatment. The authors concluded that although the available evidence suggests that electromagnetic field stimulation may offer some benefit in the treatment of delayed union and non-union of long bone fractures, it is inconclusive and insufficient to inform current practice. They stated that more definitive conclusions on treatment effect await further well-conducted RCTs.

Schmidt-Rohlfing et al (2011) performed a systematic review and meta-analysis on the potential effects of electromagnetic fields and high-frequency electric fields on bony healing. Randomized clinical trials were identified and analyzed. Those studies with the primary endpoint "rate of bony healing" were combined in a meta-analysis which was performed with the "random effects" model. These investigators found a total of 14 RCTs, which included a total of 915 patients. The majority of these studies used PEMF. Out of the 14 studies, 9 were suitable for the meta-analysis that revealed a cumulative odds ratio of 3.5 and a 95 % CI of 1.94 to 6.3. When performing a subgroup analysis a statistically significant result could not be confirmed by the studies with a higher methodological quality. In view of the heterogeneous physical parameters with different frequencies, time course, flux densities and in view of the methodological deficits, a general conclusion seems difficult.

The American College of Occupational and Environmental Medicine's clinical practice guideline on "Elbow disorders" (ACOEM, 2012) listed magnets/pulse electromagnetic field as one of the interventions/procedures that are under study and is not specifically recommended for acute, subacute, or chronic lateral epicondylalgia.

In a randomized, double-blind, placebo-controlled, multi-center trial, Hannemann et al (2012) examined the effectiveness of PEMF therapy to stimulate bone growth in patients with acute scaphoid fractures. A total of 53 patients in three different medical centers with a unilateral undisplaced acute scaphoid fracture were randomly assigned to receive either treatment with PEMF (n = 24) or a placebo (n = 29). The clinical and radiological outcomes were assessed at 4, 6, 9, 12, 24 and 52 weeks. A log-rank analysis showed that neither time to clinical and radiological union nor the functional outcome differed significantly between the groups. The clinical assessment of union indicated that at 6 weeks tenderness in the anatomic snuffbox (p = 0.03) as well as tenderness on longitudinal compression of the scaphoid (p = 0.008) differed significantly in favor of the placebo group. The authors concluded that stimulation of bone growth by PEMF has no additional value in the conservative treatment of acute scaphoid fractures.

In a case-series study, Marcheggiani Muccioli et al (2013) examined if PEMF treatment might improve symptoms in the early stage of spontaneous osteonecrosis of the knee. A total of 28 patients (19 males and 9 females, aged 49.8 +/- 16.4 years) suffering from symptomatic (pain) Koshino stage I spontaneous osteonecrosis of the knee, confirmed by MRI were treated with local PEMF therapy (6 hrs daily for 90 days). Clinical evaluation was carried out at baseline, 6- and 24-month follow-up by VAS for pain, knee society score (KSS), Tegner and EQ-5D scales; MRI evaluation was performed at baseline and 6-month follow-up, measuring bone marrow lesion's areas and grading these lesions by WORMS score. Treatment failure was defined as patients undergoing knee arthroplasty. Pain significantly reduced at 6 months (from 73.2 +/- 20.7 to 29.6 +/- 21.3, p < 0.0001), which remained almost unchanged at final follow-up (27.0 +/- 25.1). Knee society score significantly increased in first 6 months (from 34.0 +/- 13.3 to 76.1 +/- 15.9, p < 0.0001) and was slightly reduced at final follow-up (72.5 +/- 13.5, p = 0.0044). Tegner median level increased from baseline to 6 month follow up (1(1 1) and 3(3 4), respectively, p < 0.0001) and remained stable. EQ 5D improved significantly throughout the 24 months (0.32 +/ 0.33, baseline; 0.74 +/ 0.23, 6 month follow up (p < 0.0001); 0.86 +/ 0.15, 24 month follow up (p = 0.0071)). Significant reduction of total WORMS mean score (p < 0.0001) and mean femoral bone marrow lesion's area (p < 0.05) were observed via MRI. This area reduction was present in 85 % and was correlated to WORMS grading both for femur, tibia and total joint (p < 0.05). There were a total of 4 failures (14.3 %) at 24-month follow-up. The authors concluded that PEMF stimulation significantly reduced knee pain and necrosis area in Koshino stage I spontaneous osteonecrosis of the knee already in the first 6 months, preserving 86 % of knees from prosthetic surgery at 24-month follow-up. No correlation was found between MRI and clinical scores. These preliminary findings need to be validated by well-designed studies.

Negm et al (2013) examined if low frequency (less than or equal to 100 Hz) pulsed subsensory threshold electrical stimulation produced either through PEMF or pulsed electrical stimulation (PES) versus sham PEMF/PES intervention is effective in improving pain and physical function at treatment completion in adults with knee OA blinded to treatment. The relevant studies were identified by searching 8 electronic databases and hand-searches of the past systematic reviews on the same topic till April 5, 2012. These researchers included RCTs of people with knee OA comparing the outcomes of interest for those receiving PEMF/PES with those receiving sham PEMF/PES. Two reviewers independently selected studies, extracted relevant data and assessed quality. Pooled analyses were conducted using inverse-variance random effects models and standardized mean difference (SMD) for the primary outcomes. A total of 7 small trials (459 participants/knees) were included. Pulse electromagnetic field/PES improves physical function (SMD = 0.22, 95 % CI: 0.04 to 0.41, p = 0.02, I(2) = 0 %), and does not reduce pain (SMD = 0.08, 95 % CI: -0.17 to 0.32, p = 0.55, I(2) = 43 %). The strength of the body of evidence was low for physical function and very low for pain. The authors concluded that current evidence of low and very low quality suggested that low frequency (less than or equal to 100 Hz) pulsed subsensory threshold electrical stimulation produced either through PEMF/PES versus sham PEMF/PES is effective in improving physical function but not pain intensity at treatment completion in adults with knee OA blinded to treatment. Moreover, they stated that methodologically rigorous and adequately powered RCTs are needed to confirm the findings of this review.

Ryang et al (2013) determined the effectiveness of PEMF as compared with a placebo in the management of knee OA. These investigators reviewed RCTs using electronic databases. They also manually reviewed sources to identify additional relevant studies. A total of 14 trials were analyzed, comprising 482 patients in the treatment group and 448 patients in the placebo group. When the effectiveness of PEMF in treating pain was investigated, no significant effects were observed at any of the time points considered. However, when trials employing high-quality methodology were analyzed, PEMF was significantly more effective at 4 and 8 weeks than the placebo. When the effectiveness of PEMF was evaluated for function, a significant improvement was observed 8 weeks after the treatment initiation, with a standardized mean difference of 0.30 (95 % CI: 0.07 to 0.53). No significant association was found between the use of PEMF and the occurrence of adverse events, as indicated by a relative risk of 1.47 (95 % CI: 0.67 to 3.20). However, 3 (21.4 %) trials applied electromagnetic field intensity over the levels recommended by the International Commission on Non-Ionizing Radiation Protection. The authors concluded that the present study provided suggestive evidence supporting PEMF effectiveness in the management of knee OA. Moreover, they stated that these findings further raised the need for more well-controlled trials, employing adequate methodology, to conclusively evaluate the effectiveness of PEMF.

Maestu and colleagues (2013) examined the effect of very low-intensity transcranial magnetic stimulation (TMS) on symptoms associated with fibromyalgia syndrome. Female fibromyalgia patients (aged 22 to 50 years) were randomly assigned to either a stimulation group or a sham group. The stimulation group (n = 28) was stimulated using 8 Hz pulsed magnetic fields of very low intensity, while the sham group (n = 26) underwent the same protocol without stimulation. Pressure pain thresholds before and after stimulation were determined using an algometer during the 8 consecutive weekly sessions of the trial. In addition, blood serotonin levels were measured and patients completed questionnaires to monitor symptom evolution. A repeated-measures ANOVA indicated statistically significant improvement in the stimulation group compared with the control group with respect to somatosensory pain thresholds, ability to perform daily activities, perceived chronic pain and sleep quality. While improvement in pain thresholds was apparent after the 1st stimulation session, improvement in the other 3 measures occurred after the 6th week. No significant between-group differences were observed in scores of depression, fatigue, severity of headaches or serotonin levels. No adverse side effects were reported in any of the patients. The authors concluded that very low-intensity magnetic stimulation may represent a safe and effective treatment for chronic pain and other symptoms associated with fibromyalgia. This was a small study (treatment group had only 28 subjects0 with a short follow-up (6 weeks); its findings need to be validated by well-designed studies.

In a Cochrane review, Amatya et al (2013) evaluated the effectiveness of various non-pharmacological interventions for the treatment of spasticity in adults with multiple sclerosis (MS). A literature search was performed using the Specialised Register of the Cochrane Multiple Sclerosis and Rare Diseases of the Central Nervous System Review Group on using the Cochrane MS Group Trials Register, which among other sources, contains CENTRAL, Medline, EMBASE, CINAHL, LILACS, PEDRO in June 2012. Manual searching in the relevant journals and screening of the reference lists of identified studies and reviews were carried out. Abstracts published in proceedings of conferences were also scrutinized. Randomized controlled trials that reported non-pharmacological intervention/s for treatment of spasticity in adults with MS and compared them with some form of control intervention (such as sham/placebo interventions or lower level or different types of intervention, minimal intervention, waiting list controls or no treatment; interventions given in different settings), were included. Three review authors independently selected the studies, extracted data and assessed the methodological quality of the studies using the Grades of Recommendation, Assessment, Development and Evaluation (GRADE) tool for best-evidence synthesis. A meta-analysis was not possible due to methodological, clinical and statistical heterogeneity of included studies. A total of 9 RCTs (n = 341 participants, 301 included in analyses) investigated various types and intensities of non-pharmacological interventions for treating spasticity in adults with MS. These interventions included: physical activity programs (such as physiotherapy, structured exercise program, sports climbing); transcranial magnetic stimulation (intermittent theta burst stimulation (iTBS), repetitive TMS (rTMS)); electromagnetic therapy (pulsed electromagnetic therapy; magnetic pulsing device), transcutaneous electrical nerve stimulation (TENS); and whole body vibration (WBV). All studies scored "low" on the methodological quality assessment implying high-risk of bias. There is "low level" evidence for physical activity programs used in isolation or in combination with other interventions (pharmacological or non-pharmacological), and for repetitive magnetic stimulation (iTBS/rTMS) with or without adjuvant exercise therapy in improving spasticity in adults with MS. No evidence of benefit exists to support the use of TENS, sports climbing and vibration therapy for treating spasticity in this population. The authors concluded that there is "low level" evidence for non-pharmacological interventions such as physical activities given in conjunction with other interventions, and for magnetic stimulation and electromagnetic therapies for beneficial effects on spasticity outcomes in people with MS. They stated that a wide range of non-pharmacological interventions are used for the treatment of spasticity in MS, but more robust trials are needed to build evidence about these interventions.

Dingemanse et al (2013) presented an evidence-based overview of the effectiveness of electrophysical modality treatments for both medial and lateral epicondylitis (LE). Searches in PubMed, EMBASE, CINAHL and Pedro were performed to identify relevant RCTs and systematic reviews. Two reviewers independently extracted data and assessed the methodological quality. A best-evidence synthesis was used to summarize the results. A total of 2 reviews and 20 RCTs were included, all of which concerned LE. Different electrophysical regimes were evaluated: ultrasound, laser, electrotherapy, extracorporeal shock-wave therapy (ESWT), TENS and PEMF therapy. Moderate evidence was found for the effectiveness of ultrasound versus placebo on mid-term follow-up. Ultrasound plus friction massage showed moderate evidence of effectiveness versus laser therapy on short-term follow-up. On the contrary, moderate evidence was found in favor of laser therapy over plyometric exercises on short-term follow-up. For all other modalities only limited/conflicting evidence for effectiveness or evidence of no difference in effect was found. The authors concluded that potential effectiveness of ultrasound and laser for the management of LE was found. To draw more definite conclusions high-quality RCTs examining different intensities are needed as well as studies focusing on long-term follow-up results.

Wang et al (2013) stated that PEMF is a promising approach to promote osteogenesis. However, few studies have reported the effects of this technique on the osseo-integration of endosseous implants, especially with regard to different implant topographies. These researchers focused on how

Wang et al (2013) stated that PEMF is a promising approach to promote osteogenesis. However, few studies have reported the effects of this technique on the osseo-integration of endosseous implants, especially with regard to different implant topographies. These researchers focused on how the initial interaction between cells and the titanium surface is enhanced by PEMF and the possible regulatory mechanisms in this study. Rat osteoblasts were cultured on 3 types of titanium surfaces (Flat, Micro and Nano) under PEMF stimulation or control conditions. Protein adsorption was significantly increased by the PEMF. The number of osteoblasts attached to the surfaces in the PEMF group was substantially greater than that in the control group after a 1.5-hr incubation period. Pulsed electromagnetic field stimulation oriented the osteoblasts perpendicular to the electromagnetic field lines and increased the number of microfilaments and pseudopodia formed by the osteoblasts. The cell proliferation on the implant surfaces was significantly promoted by the PEMF. Significantly increased extracellular matrix mineralization nodules were observed under PEMF stimulation. The expression of osteogenesis-related genes, including BMP-2, OCN, Col-1, ALP, Runx2 and OSX, were up-regulated on all the surfaces by PEMF stimulation. The authors concluded that these findings suggested that PEMFs enhance the osteoblast compatibility on titanium surfaces but to different extents with regard to implant surface topographies. They noted that the use of PEMF might be a potential adjuvant treatment for improving the osseo-integration process.

| CPT Codes / HCPCS Codes / ICD-9 Codes | |
|---|---|
| **Other CPT codes related to the CPB:** | |
| 64550 | |
| 97014 | |
| 97024 | |
| 97032 | |
| **HCPCS codes not covered for indications listed in the CPB:** | |
| E0761 | Non thermal pulsed high frequency radiowaves, high peak power electromagnetic energy treatment device |
| 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 |
| **Other HCPCS codes related to the CPB:** | |
| G0281 - G0283 | Electrical stimulation |
| **ICD-9 codes not covered for indications listed in the CPB (not all-inclusive):** | |
| 340 | Multiple sclerosis |
| 354.0 - 355.9 | Mononeuritis |
| 707.00 - 707.9 | Chronic ulcer of skin |
| 715.00 - 715.98 | Osteoarthrosis and allied disorders |
| 722.0 - 722.2 | Displacement of intervertebral disc |
| 722.70 - 722.73 | Intervertebral disc disorder with myelopathy |
| 723.0 - 723.9 | Other disorders of cervical region |
| 724.3 | Sciatica |
| 724.4 | Thoracic or lumbosacral neuritis or radiculitis, unspecified |
| 726.31 | Medial epicondylitis [medial epicondylalgia] |
| 726.32 | Lateral epicondylitis of elbow |
| 727.00 - 727.9 | Other disorders of synovium, tendon, and bursa |
| 728.0 - 728.9 | Disorders of muscle, ligament, and fascia |

| | |
|---|---|
| 729.0 - 729.9 | Disorders of muscle, ligament, and fascia |
| 729.1 | Myalgia and myositis, unspecified |
| 729.2 | Neuralgia, neuritis, and radiculitis, unspecified |
| 733.00 - 733.09 | Osteoporosis |
| 733.49 | Aseptic necrosis of other bone site [ knee] |
| 782.3 | Edema |
| 814.01 | Closed fracture of navicular (scaphoid) bone of wrist |
| 814.11 | Open fracture of navicular (scaphoid) bone of wrist |
| 840.0 - 848.9 | Sprain and strains of joints and adjacent muscles |
| 870.0 - 897.7 | Open wound |
| 996.52 | Mechanical complication due to graft of other tissue, not elsewhere classified |
| 996.55 | Mechanical complications due to artificial skin graft and decellularized allodermis |
| V42.3 | Organ or tissue replaced by transplant, skin |
| **Other ICD-9 codes related to the CPB:** | |
| 806.00 - 806.9 | Fracture of vertebral column with spinal cord injury |
| 952.00 - 952.9 | Spinal cord injury without evidence of spinal bone injury |

**The above policy is based on the following references:**


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Print

# Non-Contact Ultrasound Treatment for Wounds

## DESCRIPTION

Low-frequency ultrasound in the kiloherz range may improve wound healing. Several devices are available, including the MIST Therapy® system, which delivers ultrasonic energy to wounds via a saline mist without direct skin contact.

Ultrasound is defined as a mechanical vibration above the upper threshold of human hearing (> 20 KHz). Ultrasound in the MHz range (1-3 MHz) has been used for the treatment of musculoskeletal disorders, primarily by physical therapists. Although the exact mechanism underlying its clinical effects is not known, therapeutic ultrasound has been shown to have a variety of effects at a cellular level including angiogenesis, leukocyte adhesion, growth factor and collagen production, and increases in macrophage responsiveness, fibrinolysis and nitric oxide levels. More recently, the therapeutic effects of ultrasound energy in the kilohertz range have been examined. It has been proposed that low frequency ultrasound in this range may improve wound healing via the production, vibration and movement of micron-sized bubbles in the coupling medium and tissue.

The mechanical energy from ultrasound is typically transmitted to tissue through a coupling gel. Several high-intensity ultrasound devices with contact probes are currently available for wound debridement. A non-contact low-intensity ultrasound device has been developed that does not require use of a coupling gel or other direct contact. The MIST Therapy™ System (Celleration) delivers a saline mist to the wound with low frequency ultrasound (40 KHz); it includes a generator, a transducer, and a disposable applicator for discharge of prepackaged saline.

In 2004, the U.S. Food and Drug Administration (FDA) reclassified these devices from class III to class II at the request of Celleration (K032378). As part of the reclassification, the FDA named this type of device as a "low energy ultrasound wound cleaner" which they defined as "a device that uses ultrasound energy to vaporize a solution and generate a mist that is used for the cleaning and maintenance debridement of wounds. Low levels of ultrasound energy may be carried to the wound by the saline mist." In 2005, the Celleration MIST therapy device received marketing clearance (K050129) through the FDA's 510(k) process, "to promote wound healing through wound cleansing and maintenance debridement by the removal of yellow slough, fibrin, tissue exudates and bacteria." Several wound drainage and wound vacuum systems were listed as predicate devices.

The FDA's 510(k) process does not require data regarding clinical efficacy; this device was considered essentially equivalent to predicate powered suction pump devices based on the "use of mechanical energy to promote wound healing through means such as the removal of infectious material and other wound exudates."

In 2007, the AR1000 Ultrasonic Wound Therapy System (Arobella Medical) received marketing clearance, listing the Celleration MIST system and several other ultrasonic wound debridement and hydrosurgery systems as predicate devices. The AR1000 system uses a combination of irrigation and ultrasound with a contact probe to debride and cleanse wounds. The indications are similar to that of the MIST system, listed as: "selective dissection and fragmentation of tissue, wound debridement (acute and chronic wounds, burns, diseased or necrotic tissue), and cleansing irrigation of the site for the removal of debris, exudates, fragments, and other matter."

Vacuum-Assisted Closure of Chronic Wounds is addressed in a separate policy.

Electrostimulation and Electromagnetic Therapy for the Treatment of Chronic Wounds is addressed in a separate policy.

## POLICY

Non-contact ultrasound treatment for wounds is considered **investigational**.

## POLICY EXCEPTIONS

Federal Employee Program (FEP) may dictate that all FDA-approved devices, drugs or biologics may not be considered investigational and thus these devices may be assessed only on the basis of their medical necessity.

## POLICY GUIDELINES

Investigative service is defined as the use of any treatment procedure, facility, equipment, drug, device, or supply not yet recognized by certifying boards and/or approving or licensing agencies or published peer review criteria as standard, effective medical practice for the treatment of the condition being treated and as such therefore is not considered medically necessary.

The coverage guidelines outlined in the Medical Policy Manual should not be used in lieu of the Member's specific benefit plan language.

## POLICY HISTORY

1/10/2008: Policy added

3/27/2008: Reviewed and approved by the Medical Policy Advisory Committee (MPAC)

10/7/2008: Policy reviewed, no changes made

12/07/2009: Policy Description revised as follows: Purpose for low-frequency ultrasound added to description. Links added to related policies, Vacuum-Assisted Closure of Chronic Wounds and Electrostimulation and Electromagnetic Therapy for the Treatment fo Chronic Wounds. Policy Exclusion revised to include FEP verbiage. Coding Section revised to add verbiage, "This is **not** an all inclusive list of Non-Covered Procedure Codes". ICD9 Diagnosis section revised to add "Investigational for all codes".

12/29/2010: Policy reviewed; no changes.

11/10/2011: Policy reviewed; no changes.

12/13/2012: Policy reviewed; no changes.

02/26/2014: Policy reviewed; no changes to policy statement. Added the following new 2014 CPT code(s) to the Code Reference section: 97610.

## SOURCE(S)

Blue Cross & Blue Shield Association Policy # 2.01.79

## CODE REFERENCE

**This may not be a comprehensive list of procedure codes applicable to this policy.**

**Investigational Codes**

| Code Number | Description |
|---|---|
| **CPT-4** | |
| 0183T | Low frequency, non-contact, non-thermal ultrasound, including topical application(s) when performed, wound assessment, and instruction(s) for ongoing care, per day (Deleted 12-31-2013) |
| 97610 | Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day (New 01-01-2014) |
| **ICD-9 Procedure** | |
| | |
| **ICD-9 Diagnosis** | |
| | |
| **HCPCS** | |
| | |

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|---|---|
| **To:** | BioElectronics Corporation (mkwhelan@verizon.net) |
| **Subject:** | U.S. TRADEMARK APPLICATION NO. 86222506 - ANTI-INFLAMMATORY VAC - N/A |
| **Sent:** | 7/9/2014 4:54:58 PM |
| **Sent As:** | ECOM119@USPTO.GOV |
| **Attachments:** | |

**UNITED STATES PATENT AND TRADEMARK OFFICE (USPTO)**

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USPTO OFFICE ACTION (OFFICIAL LETTER) HAS ISSUED
ON **7/9/2014** FOR U.S. APPLICATION SERIAL NO. 86222506

Your trademark application has been reviewed. The trademark examining attorney assigned by the USPTO to your application has written an official letter to which you must respond. Please follow these steps:

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/John M. C. Kelly/
United States Patent and Trademark Office
Trademark Examining Attorney
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571-272-9412
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