Clinical Indications

- DELAYED UNIONS
- NON-UNIONS
- RECENT FRACTURES
- STRESS FRACTURES
- BONE GRAFTS
- OSTEOTOMIES
- OPEN FRACTURES
- WOUND HEALING

Dosage/Treatment time: 6 - 8 hours a day for 30 - 90 days.
The Therapy can be repeated.

REFERENCES

- Fontanesi G, et al.Treatment of delayed union and pseudarthrosis by low frequency pulsing electromagnetic stimulation. Study of 35 cases. Ital J Orthop Traumatol. 1983 Sep;9(3):305-18.
- Dal Monte A, et al. Treatment of congenital pseudarthrosis and acquired non-union with pulsing electromagnetic fields (PEMFS). Orthop. Trans. J. Bone Joint Surg. 1986;10(3):452.
- Fontanesi G, et al. La lenta evoluzione del processo riparativo di una frattura può essere prevenuta? G.I.O.T. 1986;389-404.
- Borsalino G, et al. Electrical stimulation of human femoral intertrochanteric osteotomies. Double-blind study. Clin Orthop Relat Res. 1988;(237):256-63.
- Ieran M. et al. Effect of low frequency pulsing electromagnetic fields on skin ulcers of venous origin in humans: a double-blind study. J Orthop Res. 1990 Mar;8(2):276-82.
- Traina GC, et al. Effect of electromagnetic stimulation on patients suffering from non-union. A retrospective study with a control group. J of Bioelectricity.1991;10:101-117.
- Cane V, et al. Pulsed magnetic fields improve osteoblast activity during the repair of an experimental osseous defect. J Orthop Res. 1993;11(5):664-70.
- Mammi GI, et al. The electrical stimulation of tibial osteotomies. Double-blind study. Clin Orthop Relat Res. 1993;(288):246-53.
- Capanna R, etal Effect of electromagnetic fields on patients undergoing massive bone graft following bone tumor resection. A double blind study. Clin Orthop Relat Res. 1994;(306):213-21.
- "Consensus Conferenceï Impiego della Stimolazione Elettrica e Magnetica in Ortopedia e Traumatologia, Italian Journal of Orthopaedics and Traumatology. 1998;24(1):13-31.
- Fini M, et al. The effect of pulsed electromagnetic fields on the osteointegration of hydroxyapatite implants in cancellous bone: a morphologic and microstructural in vivo study. J Orthop Res. 2002 Jul;20(4):756-63. doi: 10.1016/S0736-0266(01)00158-9. PMID: 12168664.
- De Mattei M, et al. Changes in polyamines, c-myc and c-fos gene expression in osteoblast-like cells exposed to pulsed electromagnetic fields. Bioelectromagnetics. 2005;26(3):207-14.
- Cadossi R, et al. Electric and magnetic stimulation of bone repair: review of the European experience. In: Roy K. Aaron, Mark E. Bolander, editors. Symposium of Physical Regulation of Skeletal Repair. American Academy of Orthopaedic Surgeons. Rosemont, Illinois; 2005. p. 37-51.
- Luna Gonzalez F, et al. Pulsed electromagnetic stimulation of regenerate bone in lengthening procedures. Acta Orthop Belg. 2005 Oct;71(5):571-6.
- Cadossi R, et al. Fattori fisici di stimolazione ossea. Physical forces in bone stimulation. G.I.O.T. 2007;33(suppl. 1):S255-S261.
- Massari M, et al. Pulsed electromagnetic fields and low intensity pulsed ultrasound in bone tissue. Clinical Cases in Mineral and Bone Metabolism 2009; 6(2): 149-154.
- Sollazzo V, et al. Effects of Pulsed Electromagnetic Fields on Human Osteoblastlike Cells (MG-63): A Pilot Study. Clin Orthop Relat Res. 2010; 468:2260–2277.
- Cebrian JL, et al. Comparative study of the use of electromagnetic fields in patients with pseudoarthrosis of tibia treated by intramedullary nailing. International Orthopaedics (SICOT) (2010) 34:437-440.
- Massari L. Algorithm for employing physical forces in metabolic bone diseases Aging Clin Exp Res 2011; 23 (Suppl. to No. 2): 52-53.
- Massari L, et al. Stimolazione elettrica dell'osteogenesi: efficacia e tecnologie a confronto. GIOT, dic 2011; 37:1-8.
- Martinelli N, et al. Pseudarthrosis after percutaneous distal osteotomy in hallux valgus surgery: a case report. J Am Podiatr Med Assoc. 2012 Jan-Feb;102(1):78-82.
- Esposito M, et al. Differentiation of human osteoprogenitor cells increases after treatment with pulsed electromagnetic fields. In Vivo. 2012 Mar-Apr;26(2):299-304.
- Cadossi M, et al. Utilizzo della stimolazione biofisica nel tessuto osseo osteoporotico. AITOG OGGI - Ottobre/Novembre 2012;1-8.
- Fassina L, et al. Electromagnetic stimulation to optimize the bone regeneration capacity of gelatin-based cryogels. Int J Immunopathol Pharmacol. 2012;25(1):165-74.
- Vincenzi F, et al. Pulsed Electromagnetic Fields Increased the Anti-inflammatory Effect of A2A and A3 Adenosine Receptors in Human T/C-28a2 Chondrocytes and hFOB 1.19 Osteoblasts. PLoS One. 2013 May 31;8(5):e65561. doi: 10.1371/journal.pone.0065561. Print 2013. PMID: 23741498.
- Cadossi R, et al. Trattamenti di supporto: campi elettromagnetici. Adjuvant treatments: electromagnetic fields. GIOT AGOSTO 2013;39(suppl.1):155-160.
- Ongaro A., et al. Pulsed electromagnetic fields stimulate osteogenic differentiation in human bone marrow and adipose tissue derived mesenchymal stem cells. Bioelectromagnetics. 2014 Sep;35(6):426-36.
- Cadossi M, et al. Clinical Application of Biophysical Stimulation on Bone in Europe. In: Paul J. Rosch, ed. Bioelectromagnetic and Subtle Energy Medicine, Second Edition. December 19, 2014 by CRC Press. (24) p. 267-78
- Cadossi R, et al. Physical Regulation in Cartilage and Bone Repair. In: Marko S. Markov, ed. Electromagnetic Fields in Biology and Medicine. March 2, 2015 by CRC Press. (16) p. 253-72.
- Moretti B. Biofisica Ortopedica e traumatologica nella pratica clinica. Edizioni CIC, Nov 2015.
- Massari L, et al. Focus Group Ortopedia. Impiego clinico della stimolazione elettrica in ortopedia e traumatologia. The use of electrical stimulation in traumatology and orthopaedic practice. Giornale Italiano di Ortopedia e Traumatologia. 2017;43:105-106.
- Borelli P.P. Aspetti di riabilitazione nelle fratture di polso: ruolo dellavstimolazione biofisica e del tutore modulare. Chirurgia della Mano - Vol. 54 (3) 2017.
- Breccia M, et al. The Effect of Pulsed Electromagnetic Fields Stimulation in Percutaneous Surgery for Hallux valgus and Metatarsalgia. Orthop Muscular Syst. 2019,8: 270. doi:10.4172/2161-0533.1000270.
- Martini F, et al. Bone Morphogenetic Protein-2 Signaling in the Osteogenic Differentiation of Human Bone Marrow Mesenchymal Stem Cells Induced by Pulsed Electromagnetic Fields. Int J Mol Sci. 2020 Mar 19;21(6):2104. doi: 10.3390/ijms21062104. PMID: 32204349; PMCID: PMC7139765.
- Bloise N, et al. In Vitro Production of Calcified Bone Matrix onto Wool Keratin Scaffolds via Osteogenic Factors and Electromagnetic Stimulus. Materials (Basel). 2020 Jul 8;13(14):3052. doi: 10.3390/ma13143052. PMID: 32650489; PMCID: PMC7411850.
- De Francesco F, et al. Biophysical Stimulation in Delayed Fracture Healing of Hand Phalanx: A Radiographic Evaluation. Biomedicines 2022, 10, 2519. https://doi.org/ 10.3390/biomedicines10102519.

IGEA/E011/02/24

This brochure is intended for the BIOSTIM mod. BB02, brand name IGEA.
The device complies with the MDR, Medical Device Regulation (EU) 2017/745 and is identified as CE 0051.
It complies with IEC 60601-1 for safety and essential performance of medical devices and the technical standards referred to there.
It complies with IEC 60601-1-11 for safety of medical devices for home use.

IGEA CLINICAL BIOPHYSICS

IGEA MEDICAL UK
Suites 1 & 2, Parkhill Business Centre Annexe,
Walton Road Wetherby
LS22 5DZ West Yorkshire (UK)
www.igeamedical.com

CUSTOMER SERVICE
+44 01937 547065 customerservicesuk@igeamedical.com

BioStim® Therapy

The new Biophysical Stimulation Device for Bone Healing

MEDICAL DEVICE MDR COMPLIANT

IGEA CLINICAL BIOPHYSICS

BioStim® Therapy

The new Biophysical Stimulation Device to promote and accelerate fracture Bone Healing

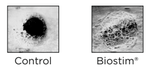
The Efficacy of Biostim® Therapy depends on:

Signal Characteristics

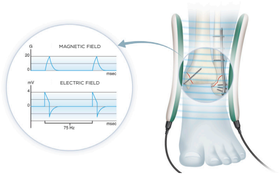
Biostim® Therapy employs a signal capable of increasing the synthesis of the main anabolic growth factors of bone tissue, such as BMP-2, BMP-6, BMP-7, TGF-β1, promoting high osteogenetic activity at the site of injury (Martini F. et al. 2020, Massari L. et al. 2019)

Biostim® Therapy may help to double new bone production

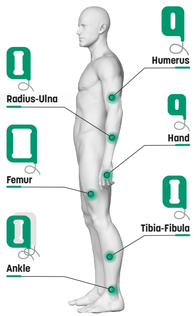
Canè V. et al. J Orthop Res. 1993



Signal Targeting



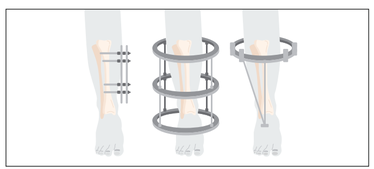
The option of 6 different types of coils, single or double, all highly comfortable, ensures that the signal is always focused on the site of the lesion regardless of the site to be treated.



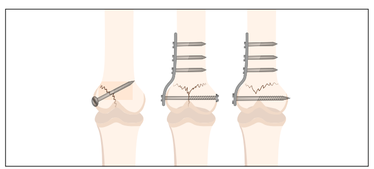
Biostim® Therapy can be used with:

Type of Osteosynthesis

EXTERNAL FIXATION



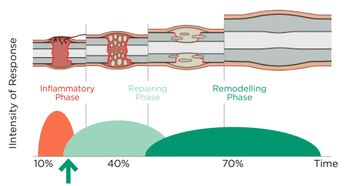
INTERNAL FIXATION



Starting time for stimulation

TIMING FOR STIMULATION

It is recommanded to undertake biophysical stimulation at the end of the initial inflammatory phase



BioStim® Therapy

Cutting-edge technology, totally new design with the same effectiveness, quality and safety as always

Interface

Visual Communication clear and effective which guarantees ease of use and high treatment compliance

Therapy session Countdown coaching of the user for optimal use of the device and compliance with daily therapy times

Patient Assistance Wizard

Stand-by Fucntion with the possibility to interrupt the daily treatment cycle for several hours

Technology

- TFT display with high-definition touch function
- Advanced electronics and firmware
- High-performance, long-life lithium polymer batteries
- Extremely light and thin coils for high user comfort

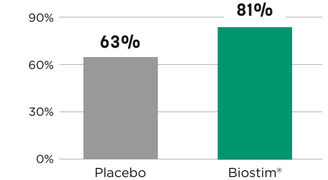
BioStim® Therapy

Promoting the Healing of hIgh-risk fractures, non-unions, delayed unions, osteotomies

- **Accelerating Bone Growth Process**
- **Reducing Recovery time**
- **Avoiding Complications**
- **Usable with every kind of osteosynthesis**

FEMORAL FRACTURES

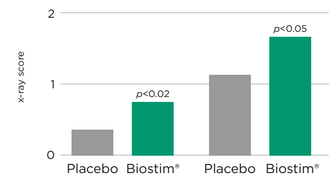
INCREASED HEALING RATE



Faldini C. et al. Current Orthop Practice 2010

FEMORAL OSTEOTOMIES

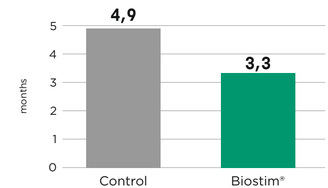
INCREASED CALLUS BONE QUANTITY



Borsalino G. et al. CORR, 1988

TIBIAL NON-UNIONS

DECREASED HEALING TIME BY 2 MONTHS

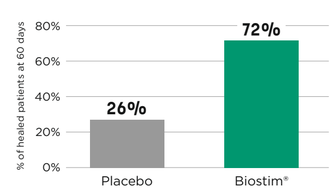


Cebrian JL et al. International Orthopaedics 2010

TIBIAL OSTEOTOMIES

Percentage of Bone Healing at 60 days

INCREASED BONE HEALING BY 46%



Mammi GI et al. CORR 1993