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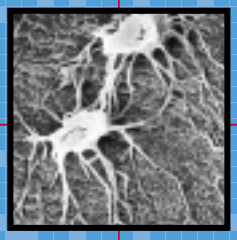
BIOSTIM SPT

NON INVASIVE FRACTURE HEALING SYSTEM



BIOSTIM SPT

NON INVASIVE FRACTURE HEALING SYSTEM

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Bone healing enhancement depends on the properties of the electrical signal

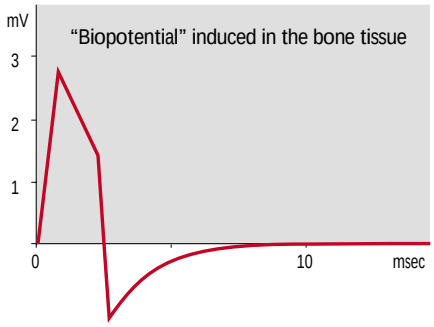
BONE REPAIR AND ELECTRICAL ACTIVITY

The presence of a fracture alters the bioelectrical activity of the bone tissue, giving rise to lesion currents, “biopotentials”, that promote activation and expansion of the osteoprogenitor cells. The characteristics and intensity of the lesion currents are known, and they control the reparatory osteogenetic activity. Exogenous electrical currents with osteogenetic properties are used to enhance bone repair.

FOS: Focused Osteogenetic Signal

An electrical signal is osteogenetic when its frequency, amplitude and wave form characteristics have shown to increase osteoblastic activity. The osteogenetic signal is focused when it can be demonstrated to be capable of maintaining the physical characteristics needed to promote osteogenesis in the treatment site. Clinical experience has shown that not all the devices claiming to promote osteogenesis are really effective: indeed, only few are able to generate a Focused Osteogenetic Signal (FOS). The FOS characteristics of any device underpin safe and effective treatment.

Extensive experimental and clinical experience (over 100,000 patients) shows that Biostim SPT definitely has the FOS properties, in such a way that it can be employed to enhance bone healing, with advantage to both patient and orthopedic surgeon.



CHARACTERISTICS OF THE BIOSTIM SPT SIGNAL*

18-30 Gauss / frequency 75 Hertz / impulse width 1.3 milliseconds / induced electrical field amplitude 3.5±1 millivolt.

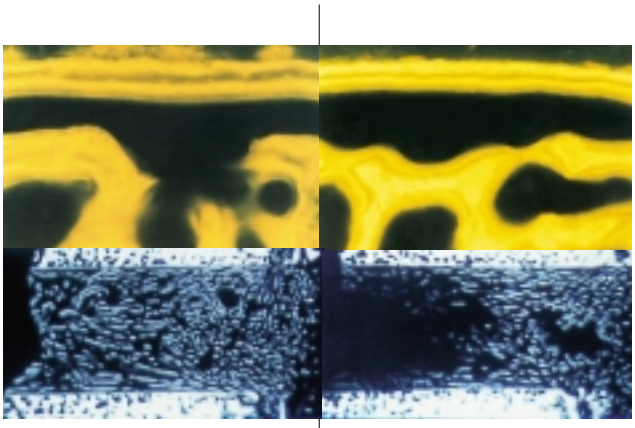
*Patented

Osteogenetic activity of the Biostim SPT signal

Biostim SPT employs a signal that generates, in the site of the lesion, “biopotentials” with high osteogenetic activity. Research *in vivo* has demonstrated that Biostim SPT enhances repair of experimental bone lesions: osteoblast activity (mineral apposition rate) and bone tissue formation are doubled in treated lesions as compared with controls. The osteogenetic effect depends on the length of the treatment: hours per day.

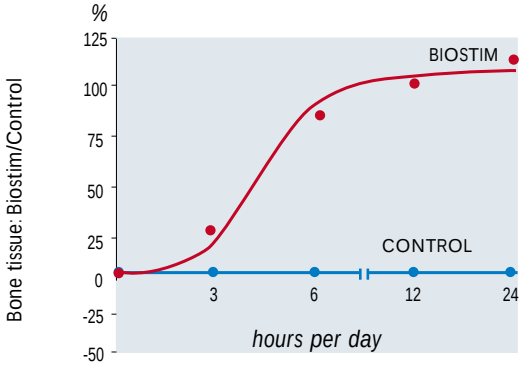
OSTEOGENETIC ACTIVITY *IN VIVO*

Microphotograph in UV light of bone trabeculae (x250) at thirty days. The distance between the two tetracycline labels enables measurement of the mineral apposition rate (MAR): stimulated on the left, control on the right (p<0.0001).



Microphotograph of bone trabeculae (x21) at 60 days. Stimulated on the left, control on the right (p<0.01).

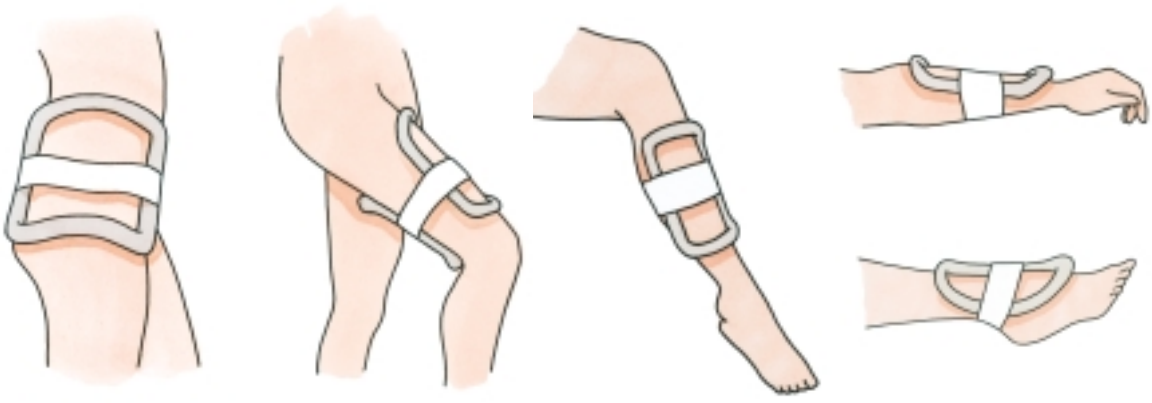
DOSE-RESPONSE CURVE



The effect on the osteogenesis depends on the dosage (hours per day)

Biostim SPT an individualised treatment

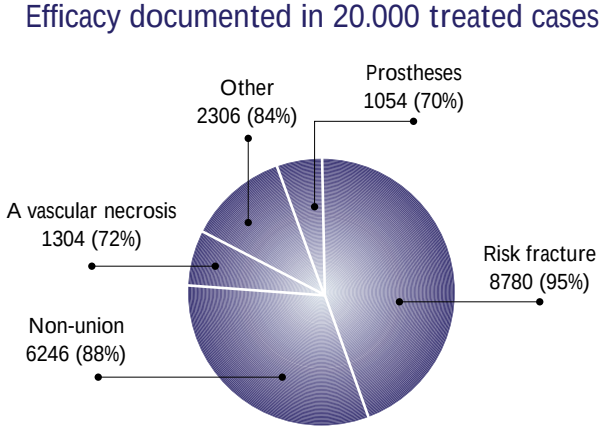
The use of nine different types of coils, each of which can be supplied with 4 different amplitude signals, gives a total of 36 treatment modalities. This ensures that the signal is always focused and osteogenetic on the site to be treated. Biostim SPT has been developed for individual patient treatment. Bone healing enhancement is obtained when Biostim SPT is used for 6 hours per day, not necessarily performed in one session.



Examples of use

Bone growth stimulator widely used through Europe

In twenty years the international clinical experience has confirmed, through multicentre studies, the effectiveness of Biostim SPT in the various orthopedic bone pathologies. This accounts for the favour shown to Biostim SPT not only in Italy but also in Austria, Germany, Spain, The Netherlands and United Kingdom.



The figure shows the distribution of the various pathologies treated. The data are taken from a database of 19,690 subjects (IGEA archive). The values in brackets refer to percentage of successful treatment.

Indications for clinical use of Biostim SPT

NON-UNION

Healing is achieved in 88% of patients treated. Therapy lasts 3-5 months on average. Stimulation is specifically indicated in cases of infected lesions.

Non-union of the humerus before stimulation

After two months of treatment with Biostim SPT

RECENT FRACTURE

Stimulation significantly shortens healing time by 20 to 30%. The therapy is especially indicated in cases of complex fractures that may evolve in a delayed union.

OSTEOTOMY

The therapy is indicated for osteotomies of femur and tibia. It guarantees fast and complete healing of all patients in 60 days.

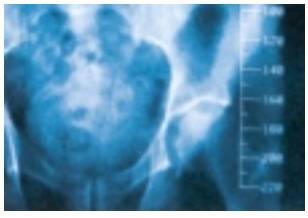
HIP PROSTHESIS REVISION

Treatment with Biostim SPT leads to an early healing. DEXA investigation has shown considerable increase of osteogenesis in patients stimulated as compared with controls; clinical recovery is shortened by 30%.

AVASCULAR NECROSIS OF FEMURAL HEAD

Use of Biostim SPT must be considered the treatment of choice for lesions up to Ficat II. The treatment lasts 6 months.

Avascular necrosis of the femural head before stimulation



Two years follow-up after six months of therapy with Biostim SPT

SPINAL FUSION

Early treatment, within 7 days from surgery, ensures complete healing of bone grafts. Treatment should last 60 days.

The confidence in a choice underpinned by more than twenty years' experience

The medical-scientific reasons for choosing Biostim SPT treatment

- *It can be employed in the presence of plaster.*
- *The presence of internal or external synthesis devices does not represent a contraindication and does not hinder the treatment.*
- *Biological safety is documented.*
- *The highest success rate in literature.*
- *Biostim SPT promotes the periosteal bone callus.*
- *The wide effective area of the signal makes for easy use.*
- *Nine specific coils are available for the different bones to be treated.*
- *Manufactured in conformity with IEC 601- 1.*
- *Electrical safety is homologated by IMQ.*
- *It complies with 93/42/CEE directives and is labeled CE0051.*

New ideas for effective bone healing enhancement: Biostim SPT

- *Favorable cost benefit ratio*
- *Individual treatment*
- *Ready to use*
- *Reduced weight (≅1 kg)*
- *Reduced size (160x95x40 mm)*
- *Battery operated (optional)*