ELECTRICAL STIMULATION OF OSTEOGENESIS

INTEGRATING PART OF MODERN ORTHOPAEDIC AND TRAUMATOLOGIC TREATMENT

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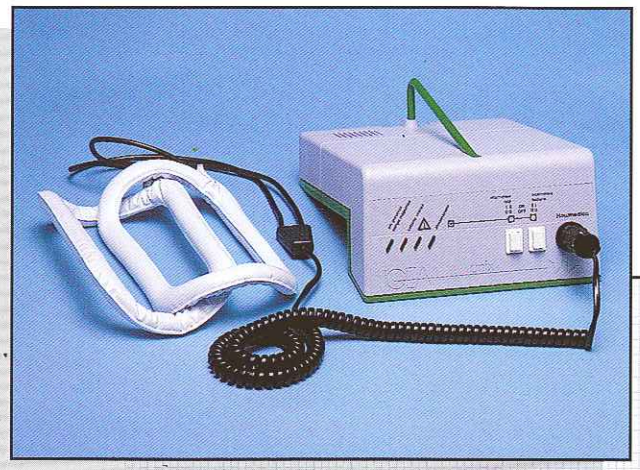


IGEA UNIX/E

BIOSTIM

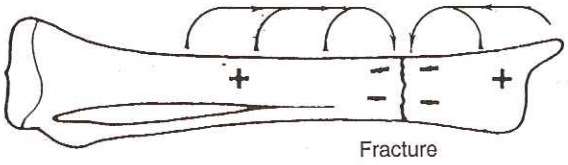
IGEA®

TECHNOLOGY FOR CLINICAL BIOPHYSICS

BIOSTIM and OSTEOGENESIS

The relation between electrical potentials and the repair process of bone tissue has been the subject of detailed studies since 1957 (1).
It has been demonstrated *in vivo* that osteogenetic activity at the fracture site is always associated with the flow of a spontaneous electric current of a few microampères intensity: "lesion current". This activates a complex biological phenomenon known as "regional acceleratory phenomenon", which regulates bone tissue repair (9).

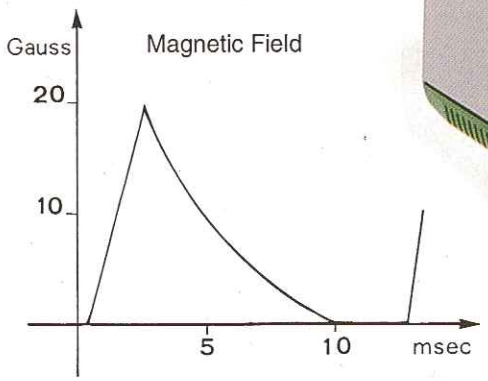
Figure 1
Electrical potentials of bone tissue

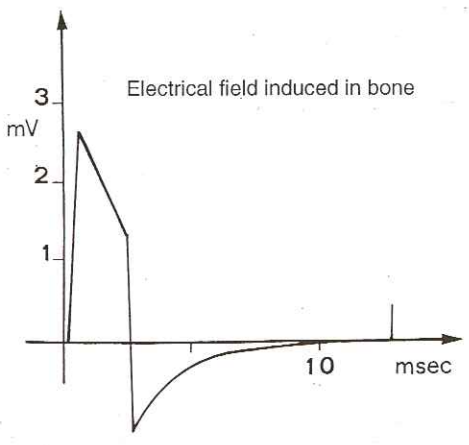


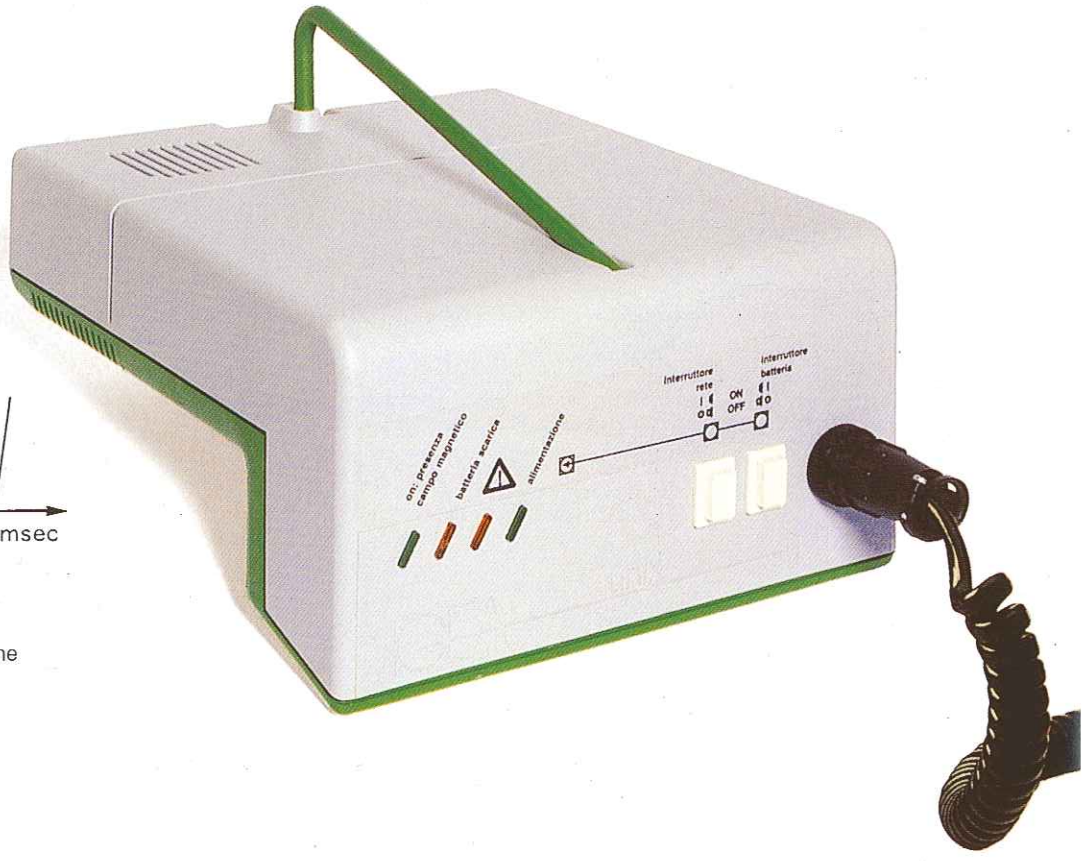
The fracture site is electrically negative and is traversed by a current of a few microapères.

By reproducing the action of the lesion current, the elctrical field induced by BIOSTIM enhances bone tissue repair.
The clinical effectiveness of BIOSTIM is closely linked with the characteristics of the signal employed: 18-30 Gauss, 75 Hertz frequency, duration of impulse 1.3 milliseconds, amplitude of electric field induced 3.5 +/- 1 millivolts (fig.2). If the aforesaid characteristics are not maintained, not only may the therapeutic effect be nullified, but bone reabsorption resulting from increased osteoclast activity may be observed (25). For this reason, the calibration parameters fixed in the BIOSTIM cannot be altered by the patient.

Figure 2
Signal IGEA®
(Patented)







EXPERIMENTAL RESEARCH IN VIVO

The effect of BIOSTIM on osteogenesis has been studied since a long time: both early and late stages of the bone repair process show positive response to stimulation.
Application of BIOSTIM doubles the rate of bone deposition, i.e. osteoblasts activity, and the quantity of bone laid down.

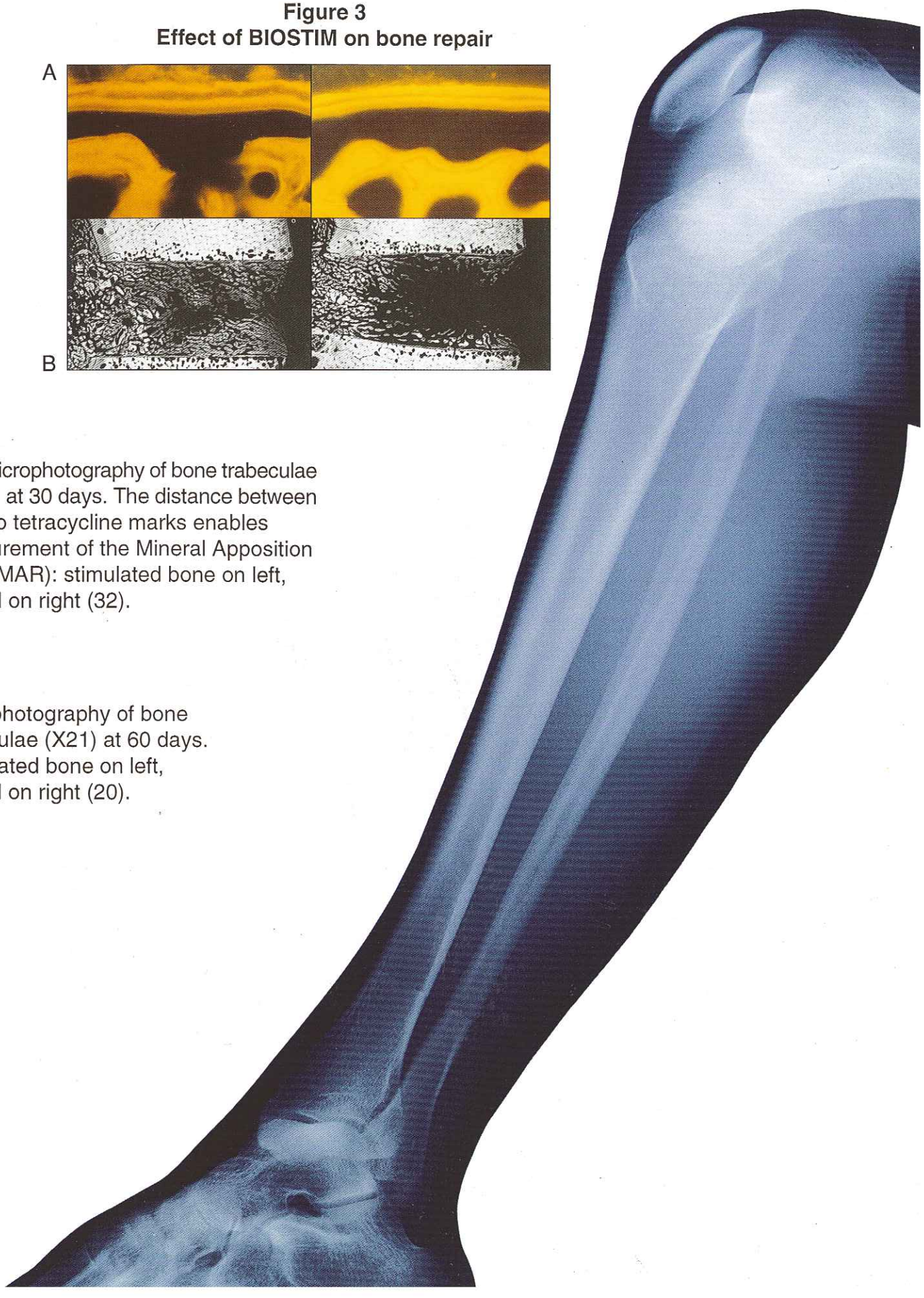
Figure 3
Effect of BIOSTIM on bone repair

A

B

A: U.V. Microphotography of bone trabeculae (X250) at 30 days. The distance between the two tetracycline marks enables measurement of the Mineral Apposition Rate (MAR): stimulated bone on left, control on right (32).

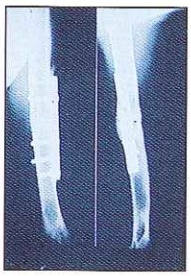
B: Microphotography of bone trabeculae (X21) at 60 days. Stimulated bone on left, control on right (20).



INDICATIONS FOR USING BIOSTIM:

Retarded consolidation and pseudoarthritis: consolidation is obtained in 88% of patients stimulated. Average duration of therapy 3-5 months. Stimulation is particularly indicated with infected lesions.

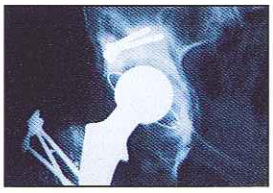
Pseudoarthrosis of humerus *start stimulation*



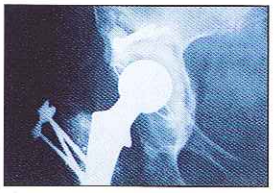
After 2 months **IGEA** *stimulation*

Recent fractures: stimulation significantly shortens consolidation time by 30%. The therapy is especially indicated for "risk fractures" threatening to develop in a non-union.

Osteotomies: the therapy is indicated for osteotomies of femur and tibia. It ensures rapid and complete consolidation of all patients in 60 days.



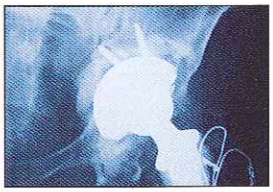
Painful prosthetic implant *start stimulation*



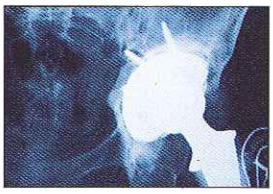
After 6 months **IGEA** *stimulation*

Painful prosthetic implants: stimulation may be used by patients with primary or revision prostheses. Pain symptoms are resolved in 70% of patients with 2-3 months therapy, with full recovery of function.

Vertebral arthrodesis: begin therapy within 7 days from operation: 60 days stimulation ensures formation of solid fusion of grafts.



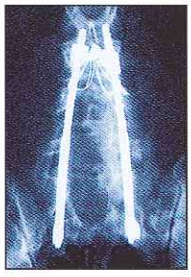
Painful prosthesic implant *start stimulation*



After 4 months **IGEA** *stimulation*

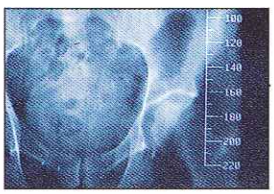
Homoplastic bone grafts: rehabitation of homoplastic bone grafts is accelerated by treatment with BIOSTIM. In case of reimplant, therapy lasts 3 months and leads to rapid fixation of prosthesis and fusion of bone grafts. In case of massive grafts, following resection, therapy reduces consolidation time by 30%.

Vertebral arthrodesis *before operation*

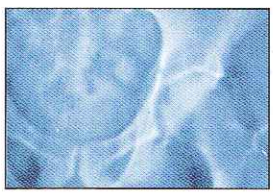


After 2 months **IGEA** *stimulation*

Avascular necrosis of head of femur: the use of BIOSTIM stimulation must be considered the treatment of choice for lesion up to Ficat degree II. Duration of therapy 6 months.



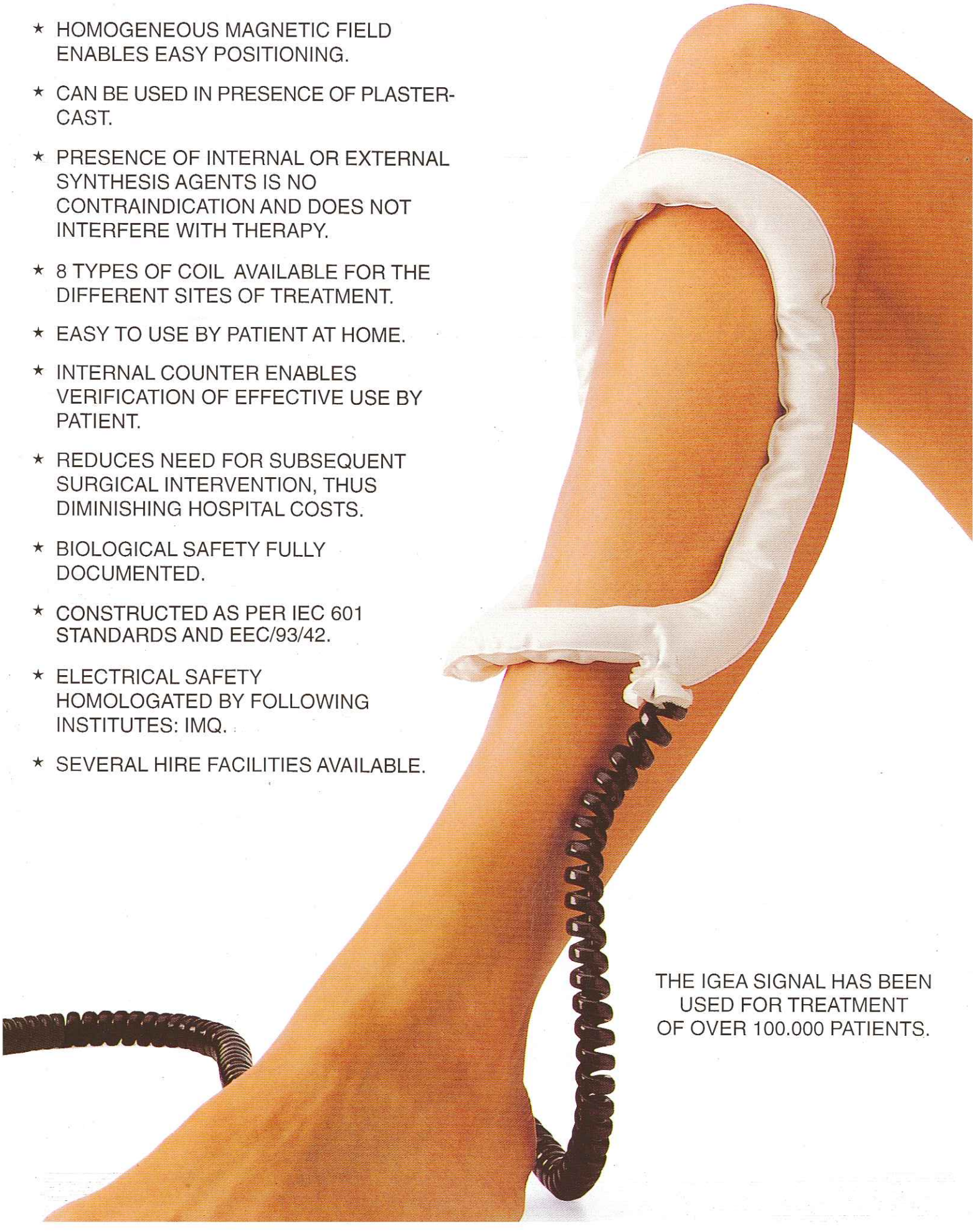
Avascular necrosis of head of femur *start stimulation*



Follow-up at 2 years after 6 months **IGEA**

INFORMATION ABOUT BIOSTIM

- ★ DOUBLES SPEED OF BONE DEPOSITION.
- ★ ONLY FORM OF WAVE (PATENTED) THAT PROMOTES A SOLID PERIOSTAL CALLUS.
- ★ HOMOGENEOUS MAGNETIC FIELD ENABLES EASY POSITIONING.
- ★ CAN BE USED IN PRESENCE OF PLASTER-CAST.
- ★ PRESENCE OF INTERNAL OR EXTERNAL SYNTHESIS AGENTS IS NO CONTRAINDICATION AND DOES NOT INTERFERE WITH THERAPY.
- ★ 8 TYPES OF COIL AVAILABLE FOR THE DIFFERENT SITES OF TREATMENT.
- ★ EASY TO USE BY PATIENT AT HOME.
- ★ INTERNAL COUNTER ENABLES VERIFICATION OF EFFECTIVE USE BY PATIENT.
- ★ REDUCES NEED FOR SUBSEQUENT SURGICAL INTERVENTION, THUS DIMINISHING HOSPITAL COSTS.
- ★ BIOLOGICAL SAFETY FULLY DOCUMENTED.
- ★ CONSTRUCTED AS PER IEC 601 STANDARDS AND EEC/93/42.
- ★ ELECTRICAL SAFETY HOMOLOGATED BY FOLLOWING INSTITUTES: IMQ.
- ★ SEVERAL HIRE FACILITIES AVAILABLE.



THE IGEA SIGNAL HAS BEEN USED FOR TREATMENT OF OVER 100.000 PATIENTS.

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