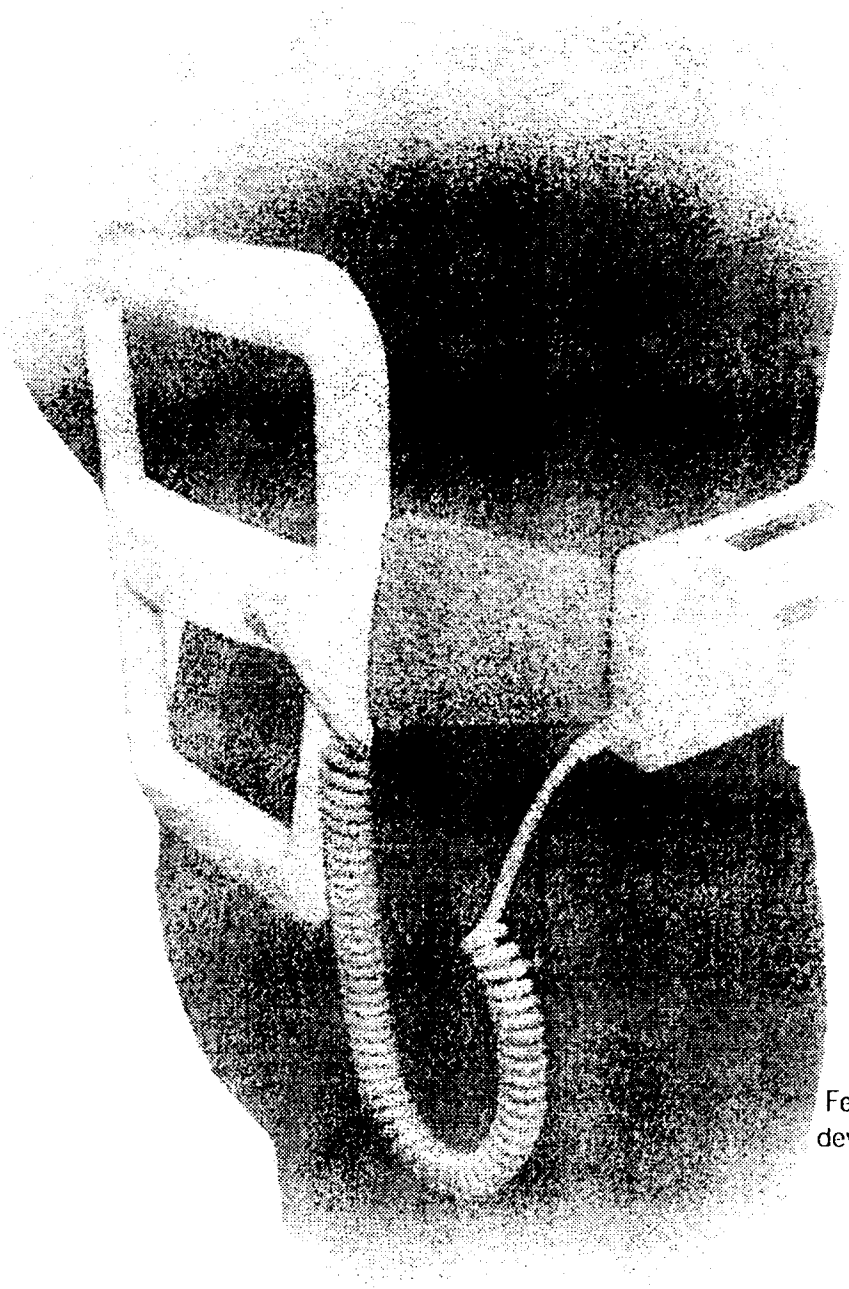

SPINALOGIC®

BONE GROWTH STIMULATOR

Manual and Package Insert

Manufactured and Distributed by

ORTHOLOGIC®

1275 W. Washington Street

Tempe, AZ, 85281-1210

1-800-263-6004

Caution:

Federal Law (USA and Canada) restricts this device to sale, distribution, or use by or on the order of a physician.

SPINALOGIC®

INDICATIONS FOR USE

The SPINALOGIC® is a portable, battery-powered, microcontrolled, noninvasive bone growth stimulator indicated as an adjunct electromagnetic treatment to primary lumbar spinal fusion surgery for one or two levels.

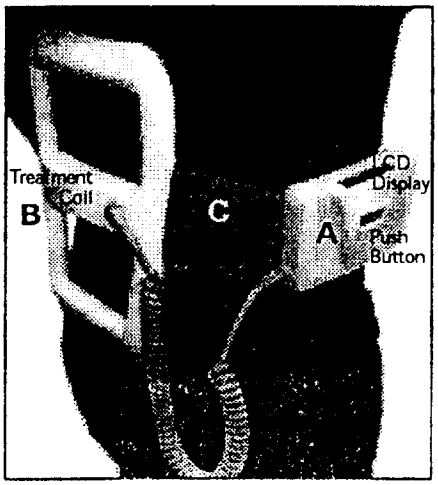

Figure 1

DEVICE DESCRIPTION

The SPINALOGIC® Bone Growth Stimulator (Figure 1) is a portable, battery powered, microprocessor-controlled, noninvasive bone growth stimulator. The device produces very low energy combined static and dynamic magnetic fields on the order of the earth's magnetic field. The device has a push-button that starts the treatment and audible tones to notify the patient that a treatment has started or has ended. A Liquid Crystal Display (LCD) is used to display the device status, e.g., "Time Remaining", "Treatment Completed Today".

There are three major components to the device:

(A) An electronic control module (ECM),

(B) a transducer coil, and

(C) an adjustable waist belt system.

The ECM includes a signal generator that produces an electrical signal which is transmitted to the treatment transducer. The transducer coil is a trapezoidal copper wire coil that converts the electrical signal into a magnetic field. The coil is placed facing the spine so that the magnetic field is directed at the fusion site. The adjustable waist belt system is designed to secure the coil relative to the patient's fusion site during treatment. The standard waist belt system will accommodate patients up to 52 inches (132 centimeters) in circumference and is adjusted for each patient.

The ECM also contains a microprocessor and memory that controls the level of the magnetic field as well as monitors and records the patient use. An LCD is used to display the status of the device. A magnetic field sensor located in the middle of the coil monitors the static magnetic field. Using the sensor data, the ECM maintains the static magnetic field at 200 milligauss (mG). The dynamic field is a sine wave, having a frequency of 76.6 Hz and an amplitude of 400 mG peak to peak, which is superimposed in parallel with the static field. See Table 1 for detailed functional specifications of the SPINALOGIC®.

MODE OF OPERATION

SPINALOGIC® Bone Growth Stimulator treatment is started after the push-button is activated and the micro-controller performs a self-test to verify that no treatment has been administered that day. When completed, the treatment is recorded in the micro-controller's nonvolatile memory and the device turns itself off. The device is powered by four 2/3A batteries. When necessary, a "Replace Battery" message is given on the LCD and the patient is able to replace the batteries. The transducer coil is encased in foam. The batteries and electronic components are housed within the rigid plastic housing of the control module.

The SPINALOGIC® provides treatment by exposing the fusion site to a low-energy magnetic field, which is undetectable during treatment. The patient will typically have no sensation related to the treatment.

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The "push button" (Figure 1) starts the treatment and an audible tone will notify the user that a treatment has started (one beep) or ended (two beeps). The device is designed to give a different tone when it is not providing sufficient magnetic field treatment. The SPINALOGIC® Bone Growth Stimulator has a Liquid Crystal Display (LCD) in addition to the audible tone to display a specific problem. The LCD counts down the time remaining for a treatment and monitors the number of days of proper treatment.

After reading the contraindications, warnings and precautions, please consult your local OrthoLogic Representative or OrthoLogic Customer Service if you have any questions.

TECHNICAL SPECIFICATIONS FOR THE SPINALOGIC®

FUNCTION	PARAMETER AND TOLERANCE	
Treatment	400 mG peak to peak ±80 mG	Alternating magnetic field (AC)
	maximum 2 % harmonic distortion	Alternating magnetic field (AC)
	76.6 Hz ±1.0 Hz	Alternating magnetic field (AC)
	±200 mG ±20 mG	Static magnetic field (DC)
Ambient Magnetic Field Operating Range	± 600 mG	
Treatment Duration	30 minutes + 0 min. -5 min.	
Treatment Frequency	Once a treatment has been dispensed, the patient will not be allowed another treatment until the device's 24 hour clock passes midnight.	
Request Treatment	A push button activates the device.	
Power Source	Four, user-replaceable 2/3 A batteries.	
Circuit Voltage Requirements	Above 9.5 Volts ± 0.1 Volt at start of treatment. Treatment dispensed	
Period of Operation	270 days maximum	
Clock Operation	365 days minimum	
Temperature	Operating Range: +50° F to +100° F (+10° C to +38° C) Storage/Transport Range: +5° F to +140° F (-15° C to +60° C)	

Table 1. Summary of Functional Specifications

Additionally, for ease of use, OrthoLogic has labeled the SPINALOGIC® Bone Growth Stimulator with internationally recognized symbols.

Symbol	Where used	Meaning
	push button	ATTENTION, CONSULT ACCOMPANYING DOCUMENTS
SN	shipping label	SERIAL NUMBER
	device label	BF TYPE EQUIPMENT (IEC 601-1)
CE	device and shipping label	CONFORMITE EUROPEENE

Table 2. International Symbols

CONTRAINDICATIONS

· Demand-type pacemaker and implantable cardiovertor defibrillator (ICD) operation may be adversely affected by exposure to combined static and dynamic magnetic fields. Physicians should not prescribe the SPINALOGIC® for patients with such devices.

· The safety and effectiveness of the SPINALOGIC® in pregnant women have not been studied, and the effects of the device on the mother or the developing fetus are unknown, thus, this device should not be used in pregnant women. If a woman becomes pregnant during treatment with the SPINALOGIC®, treatment should be discontinued immediately.

PRECAUTIONS

· The safety and effectiveness of the SPINALOGIC® has only been studied in those patients having spinal fusion treatment. The safety and effectiveness of this device in patients receiving instrumentation, which may distort the magnetic field generated by the device and thus produce less effective treatment, has not been established.

· The safety and effectiveness of the use of this device on individuals lacking skeletal maturity has not been established.

· The safety and effectiveness of this device in treating patients with the following conditions has not been established and therefore the safety and effectiveness of the device in these individuals is unknown: osseous or ligamentous spinal trauma, spondylitis, Paget's disease, severe osteoporosis, metastatic cancer, renal disease, and uncontrolled diabetes mellitus.

· Animal studies conducted to date do not suggest any long term adverse effects from use of this device. However, long term effects in humans are unknown.

· Compliance with the treatment schedule, timely battery change and proper care of the device are essential. The device will not perform properly and treatment may be unnecessarily prolonged if the patient fails to adhere to the care routine.

· This device should not be used if there are mental or physical conditions which preclude patient compliance with the physician and device instructions.

· The SPINALOGIC® Bone Growth Stimulator was tested for electromagnetic compatibility and was found to comply with the limits for medical devices specified in IEC 601-1-2:1993. These limits are designed to provide reasonable protection against harmful interference in a typical medical or household setting. However, if the SPINALOGIC® Bone Growth Stimulator should appear to affect or be affected by other devices in the vicinity, please try to correct the interference by one or more of the following measures:

- increase the separation between the SPINALOGIC® and other electrical equipment or magnetic (metal) structures or

- call the local OrthoLogic® Representative or Customer Service for help.

· It is not recommended that the SPINALOGIC® Bone Growth Stimulator be used while smoking or near excessive heat or an open flame.

· The following factors will be essential in allowing the SPINALOGIC® Bone Growth Stimulator to be most effective in achieving a successful spinal fusion:

- compliance with physician instructions

- compliance with daily treatment schedule

- proper care of the device

· Components in this system are to be used only with OrthoLogic® components. No attempt should be made to modify or repair this device. If you should experience any problems, please contact your local OrthoLogic Representative or *OrthoLogic Customer Service at 1-800-263-6004.*

ADVERSE EFFECTS

No known significant adverse effects have resulted from the use of this device. Clinical studies, animal studies, and tissue culture experiments conducted with the SPINALOGIC® Bone Growth Stimulator magnetic fields have not indicated any evidence of significant adverse effects.

SUMMARY OF NON-CLINICAL STUDIES

The SPINALOGIC® Bone Growth Stimulator incorporates the same technological features of the OrthoLogic® Bone Growth Stimulator and the treatment signal for the SPINALOGIC® Bone Growth Stimulator is identical to that of the OrthoLogic®. A series of laboratory studies were previously conducted in support of the safety and effectiveness of the OrthoLogic® Bone Growth Stimulator. Toxicological studies on isolated cells, as well as animals, were performed to evaluate the safety of combined static and dynamic magnetic fields. Further, in vitro and in vivo studies were conducted to determine whether the application of these magnetic fields in animal models would stimulate bone healing and other related biological responses. Many of these previous laboratory experiments included whole body exposure to the test animals (and thus included vertebrae and nerve tissue). Additional details of the pre-clinical studies gathered using the OrthoLogic® can be found in the Summary of Safety and Effectiveness for OrthoLogic® Bone Growth Stimulator (P910066).

SUMMARY OF CLINICAL INVESTIGATION

Clinical Protocol Design

The clinical study conducted was a prospective, randomized, double-blind, placebo-controlled trial. The purpose of this clinical study was to investigate the safety and effectiveness of the SPINALOGIC® Bone Growth Stimulator as an adjunct to spinal fusion.

The endpoint for the determination of effectiveness was the status of the fusion after 9 months of treatment as judged by a panel of evaluators. The panel was comprised of the investigator (treating orthopedic surgeon) and two masked reviewers: a musculoskeletal radiologist and an ~~or~~thopedic surgeon. Safety was determined by evaluating all reports of device-related complications and adverse effects.

The patients were seen at enrollment, three, six and nine months post-surgery for imaging of the fusion site and clinical assessment. Additionally, a 3-month post-treatment follow-up visit was conducted to confirm the findings of the 9-month post-surgery follow-up. Imaging techniques included plain radiographs (anteroposterior (AP), lateral and obliques) and CT scans. Lateral flexion-extension radiographs were also taken when clinically indicated.

Patient Inclusion Criteria

Patients meeting the following inclusion criteria and not specifically excluded (see Exclusion Criteria below) were enrolled in this study:

- Over 18 years of age;
- Having undergone a primary intertransverse fusion without internal fixation of one or two vertebral levels between the third lumbar vertebrae (L3) and the sacrum (S1) within the last 30 days;
- Grafted with autograft alone or in combination with allograft.

Exclusion Criteria

Patients who met any of the following exclusion criteria were not eligible for participation in this study:

- Pregnant women shall not participate in this study, and if a patient became pregnant, she was immediately withdrawn from the study. Additionally, female subjects of childbearing potential should have used an acceptable form of birth control, i.e., birth control pills, diaphragm with spermacidal gel or condom;
- Diagnosed as having metastatic cancer, metabolic bone disease, spondylitis, Paget's disease, moderate to severe osteoporosis, renal dysfunction and uncontrolled diabetes mellitus or having an implanted cardiac pacemaker;
- Underwent a spinal fusion for vertebral trauma or scoliosis.

Enrollment, Treatment and Follow-Up Visits

The device was dispensed within 30 days following fusion surgery. The patient used the SPINALOGIC® Bone Growth Stimulator for 30 minutes per day according to the instructions in the patient manual. The device was used for nine months following enrollment (the SPINALOGIC® Bone Growth Stimulator is programmed to cease operation at the end of 270 days).

Radiographic Assessment

The status of the fusion was graded into one of four categories, from no fusion (0) to solid fusion (3). When two levels were involved, the lowest grade at either level was utilized for the fusion assessment. For purposes of outcome and as defined in the protocol, the grades of "0" and "1" were combined into a single category, "No Fusion." Grades "2" and "3" were combined into another category, "Fusion".

The outcome was a combination of the rating assigned by the investigator (masked treating orthopedic surgeon) and two independent masked reviewers: a musculoskeletal radiologist and an orthopedic surgeon. When the radiologist and the investigator agreed, the fusion was assigned their agreed-upon status. When the investigator and radiologist disagreed, the masked orthopedic surgeon's rating was used as a tiebreaker. During the Original assessment, the treating surgeon, had access to all radiographic imaging, clinical, and surgical information. The radiologist utilized only the radiographic imaging information, as stated in the original investigational protocol, and the independent surgeon utilized only radiographic imaging information to make the fusion assessment.

During the Secondary assessment, the two independent panel members were provided all available radiographic information. Consistent with standard clinical practice and medical training the independent orthopedic surgeon was also provided patient information including demographic, clinical and operative information (this did not include follow-up assessments of the fusion status by the treating surgeon). Consistent with clinical practice the radiologist was provided the radiographic data alone.

In both assessments, a patient was considered fused when at least 2 of the 3 panel members agreed on the outcome. Effectiveness was defined by a statistically significant difference between fusion status outcomes in the active and placebo groups.

Pooling Data Across Investigational Sites

The issue of poolability was examined by comparing treatment differences among study sites. The treatment effect difference among sites was examined using all subjects in the following ways: for all sites, pooling the four smallest sites as one, and omitting the four smallest sites. In each case, the statistical test addresses the

difference in success rates between active and placebo interventions. In each case, exact p-values were obtained using the "Exact Test for Homogeneity of Odds Ratios", StatXact-3 for Windows software. The statistical findings indicate that the outcomes at the sites are not significantly different and in fact are poolable.

Patient Disposition

Of the 243 patients, 201 patients were evaluable. All patients are accounted for in this study. Patient adherence with the 3, 6 and 9 month follow-up visit requirement was greater than 94%.

Demographic and Medical and Socioeconomic Characteristics

The statistical test results demonstrate that the randomized assignments of patients to the two treatment arms resulted in a very well balanced distribution of patient characteristics between placebo and active devices. No statistically significant differences were found for the clinical variables cited.

Treatment Compliance

For the majority of both active and placebo patients treatment compliance was greater than 75% compliance for at least 85% of the placebo treated patients and 75% of the active treated patients.

Study Endpoint (9-Month Findings)

Percent Fusion Success as Determined by the Original Panel as proposed within the Investigational Protocol is as follows:

Percent Fusion Success as Determined by the Original Panel at 9 months

	Placebo	Active	p-Value
All Patients	43 (44%)	54 (52%)	0.324
Males Only	22 (55%)	16 (39%)	0.184
Females Only	21 (37%)	38 (60%)	0.011

This data demonstrates a trend towards a positive effect as an adjunctive treatment in the total patient population and the female population, however, there is a trend towards a negative effect in the male population. Additionally, the data demonstrates that this treatment effect is only statistically significant in the female population.

In an effort to provide an analysis which allows the independent surgeon the opportunity to review a patient's clinical background prior to making a determination of the patient's fusion status, a secondary panel analysis (described above) was performed. Provided below is a summary of Fusion Success as determined by the Secondary Panel.

Percent Fusion Success as Determined by the Secondary Panel at 9 months

	Placebo	Active	p-Value
All Patients	42 (43%)	67 (64%)	0.003
Males Only	22 (55%)	25 (61%)	0.656
Females Only	20 (35%)	42 (67%)	0.001

In this instance, the data demonstrate a trend towards a positive effect as an adjunctive treatment in the overall, male and female populations. The data also demonstrates that this treatment effect is statistically significant in the overall population and in women (p-values < 0.05), while the treatment is not statistically significant in the male population.

Provided below is a gender breakdown, by active or placebo status, of those patients whose status changed during the Secondary Panel evaluation.

Comparison of Independent Surgeons Findings - Male Patients

	Not Fused to Fused	Fused to Not Fused	No Change
Active	11	1	29
Placebo	6	4	30
Total	**17**	5	59

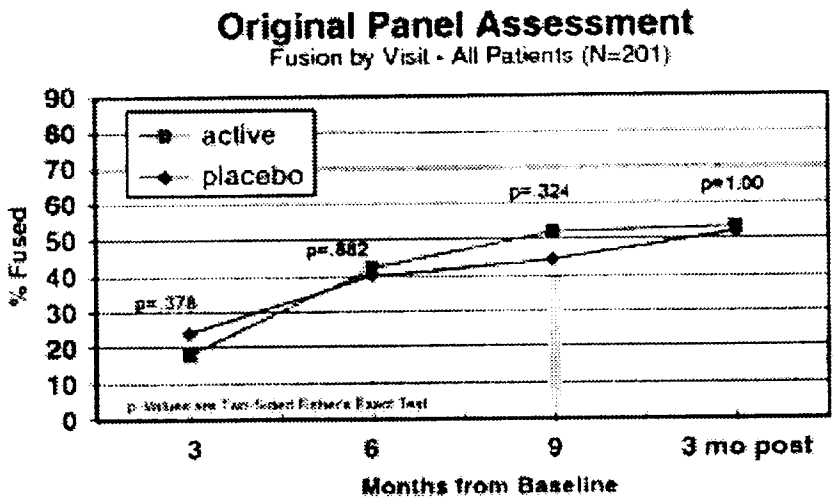
Comparison of Independent Surgeons Findings - Female Patients

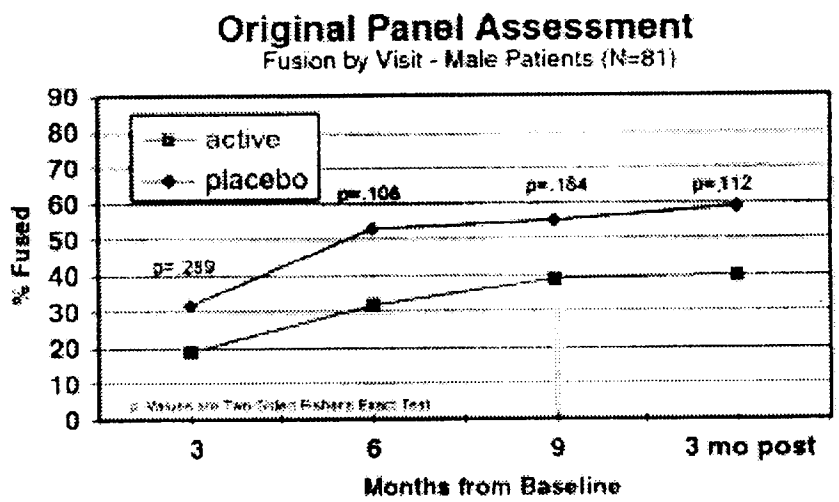
	Not Fused to Fused	Fused to Not Fused	No Change
Active	10	6	47
Placebo	6	11	40
Total	**16**	**17**	**87**

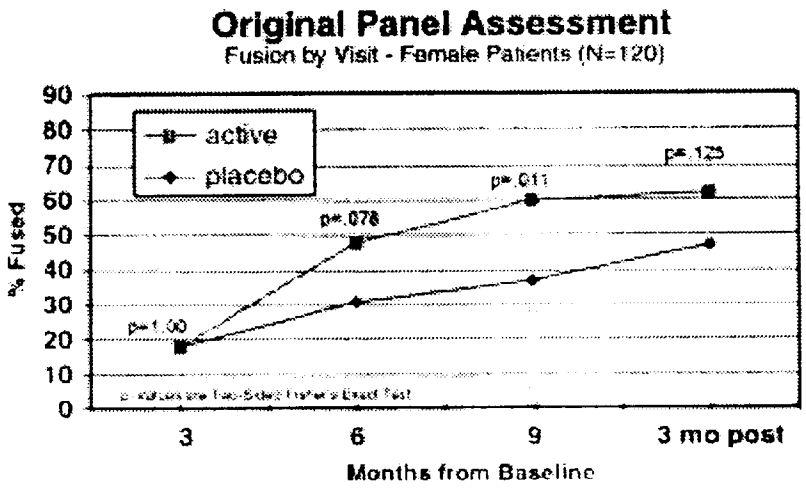
Seventeen (17) men's status' changed from "Not Fused" to "Fused" while 5 had a status change of "Fused" to "Not Fused." Sixteen (16) women's status' changed from "Not Fused" to "Fused" while an almost equal number (17) had a status change of "Fused" to "Not Fused."

Longitudinal Analysis:

The following graphs present longitudinal data gathered from the original panel analysis and the secondary panel analysis.







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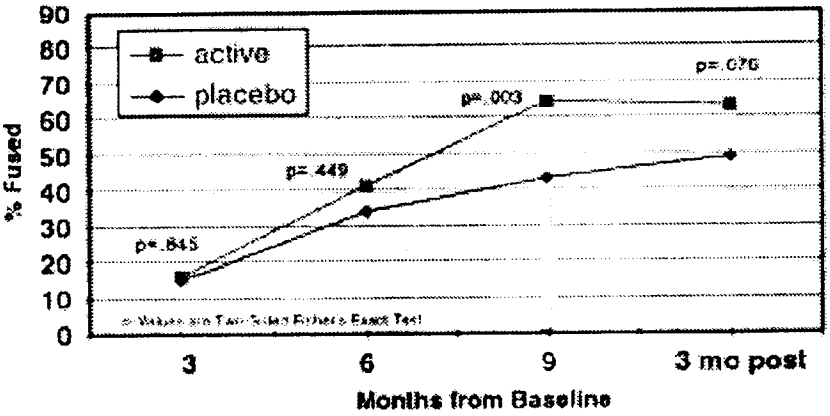
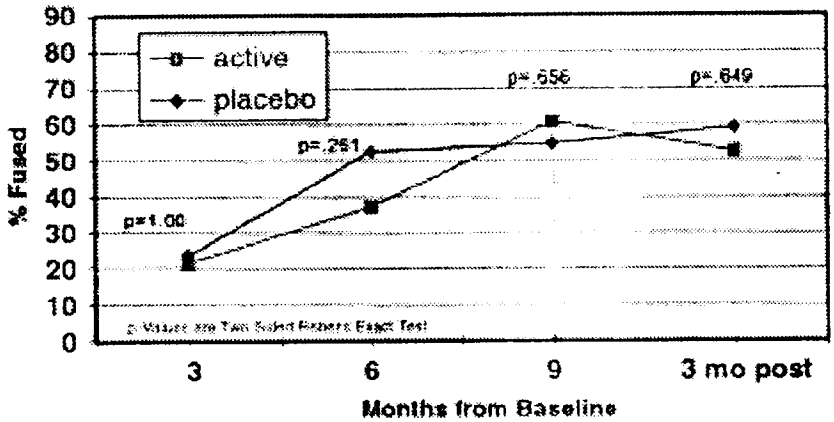
Secondary Assessment

Fusion by Visit - All Patients (N=201)



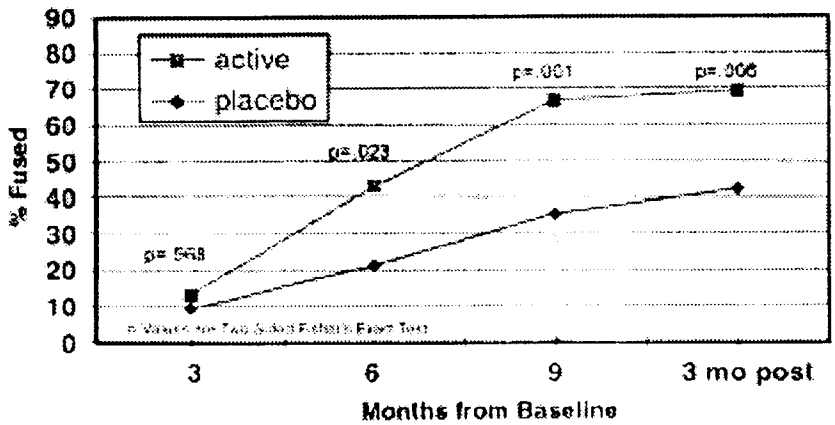
Secondary Assessment

Fusion by Visit - Male Patients (N=81)



Secondary Assessment

Fusion by Visit - Female Patients (N=120)



The original panel analysis shows that, for all patients and male patients there is no statistically significant difference between the active and placebo groups at any timepoint. For the female patients, there is a statistical significance between the active and placebo groups only at the 9 month (study endpoint) timepoint.

The secondary panel analysis shows there is a statistically significant difference for between the active and placebo groups only at the 9 month (study endpoint) timepoint for the overall patient population. For the male population, there is no statistically significant difference between the active and placebo groups at any time point. For the female population, there is a statistically significant difference between the active and placebo groups at the 6-month, 9-month (study endpoint) and 12-month (3 month post-treatment) timepoints.

Logistic Regression

To further examine the effects assessed by the radiographic review panels, an analysis using logistic regression was performed.

The logistic regression findings demonstrate that, in distinct models, the only significant main effects are treatment, gender, and current smoking. The only nearly significant interaction is gender by treatment. There are no significant interactions of treatment with current smoking, number of levels fused, or anatomical levels fused. This justifies dealing in a unified manner with the subsamples of patients with one and two levels fused, and also unifying the data for patients with varying anatomical levels.

Intent-To-Treat Analysis

In order to examine the sensitivity of our findings to missing or excluded values, series of tabular analyses were run to examine 9-month outcomes. When outcomes were missing, in separate analyses, fusion status was imputed as fused, not fused, or assigned its most recent known value (which was seen at later of 3 or 6 months post-entry). Additionally, patients who had been excluded in previous analyses because their 9-month visit was outside the 28-day compliance window were now included and assigned their observed outcome at the visit recorded on the nine-month visit form. Using each of the three imputation schemes, tabulations were done separately for all subjects, males and females.

Using the data from the Secondary Analysis, there was a statistically significant treatment effect in favor of the active device for all patients: p-values were 0.006, 0.015, and 0.007 for imputation as fused, not fused, and "LVCF". For males, there was no statistically significant treatment effect: p-values were 0.521, 0.684, and 0.838 for imputation as fused, not fused, and "LVCF". For females, there was a statistically significant treatment effect in favor of the active device: p-values were 0.004, 0.0005, and 0.0003 for imputation as fused, not fused, and "LVCF".

In conclusion, the effectiveness findings cited above for the SPINALOGIC* device are unaffected by several reasonable imputations of missing data in an intent-to-treat analysis.

DIRECTIONS FOR USE

This device should be operated in a temperature range of +50° F to +100° F (10° C to 38° C).

Waist Belt Adjustment

· First, the SPINALOGIC® waist belt system must be adjusted to accommodate the appropriate waist circumference. Figure 2 demonstrates the method of adjustment:

1. Open connection tabs "A".

2. Detach waist belts "B".

3. Measure patient's circumference around the fusion site.

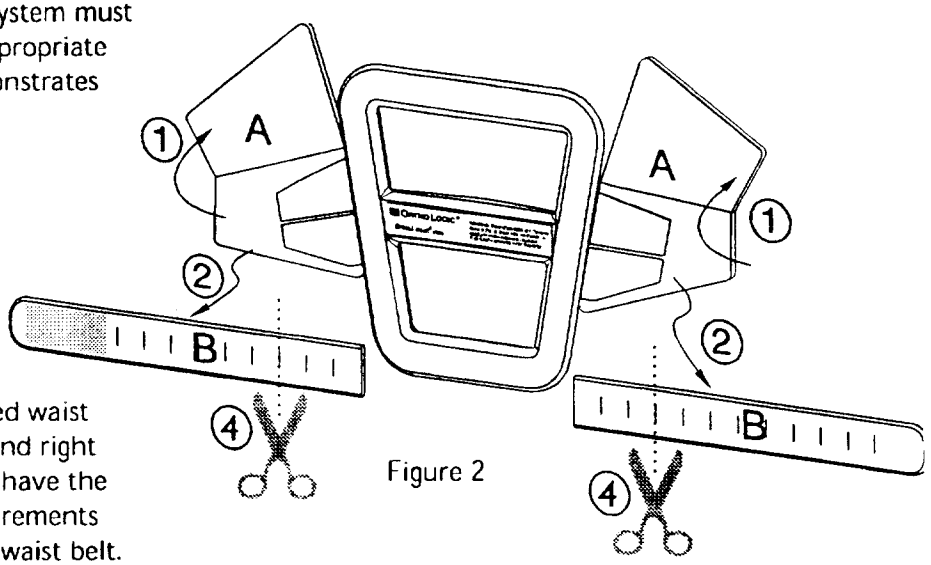


Figure 2

4. Trim waist belt using the measured waist circumference. Trim both the left and right waist belt portions. These portions have the corresponding circumference measurements printed on the inside surface of the waist belt. Trim along the directly corresponding circumference.

· Next, assemble the waist belt by placing the trimmed end portions of the waist belt "B" onto the connector tabs "A" and close the connector tabs.

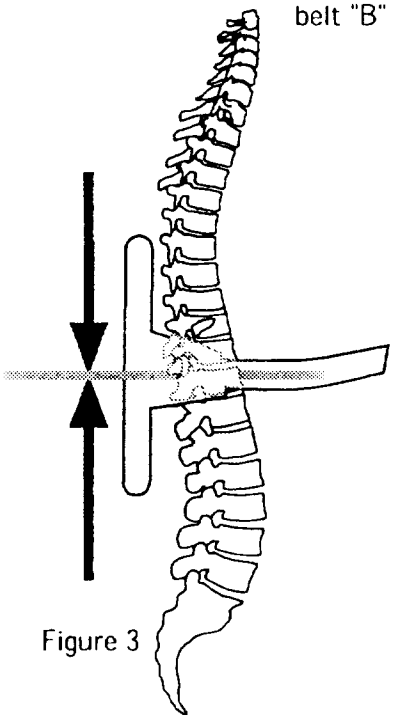


Figure 3

Positioning Treatment Coil

· Open the waist belt and align the center of the coil with the center of the fusion site (Figure 3) and secure the waist belt. NOTE: The waist belt should fit comfortably around the waist and securely hold the transducer coil in place.

Begin Treatment

· Finally, press the "push button" next to the LCD display (Figure 4) to begin a treatment. After briefly displaying the Treatment Record, there will be an audible tone (one beep) and the treatment will begin.

*NOTE: **If the "push button" is accidentally pressed and the device turns on, treatment should be attempted at that time to ensure proper treatment for that day.***

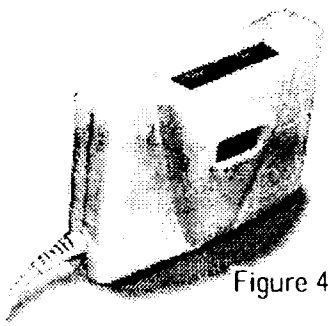


Figure 4

Display Information

During the treatment, the LCD will display the treatment time remaining, starting at 29:59 (29 minutes, 59 seconds) counting down in one second increments to 00:00 (00 minutes, 00 seconds).

During treatment, a typical display may look like the following:

Liquid Crystal Display
Treatment Time Remaining

This example display indicates there are 15 minutes and 41 seconds remaining before treatment will be completed for that day.

The device will automatically shut off at the end of the 30-minute treatment and will give another audible tone (two beeps).

NOTE: Any audible tone given before a 30-minute treatment is completed may indicate that the device needs attention. Look at the LCD display for a message which describes the problem. The messages in Table 3, are examples of what could appear on the LCD.

After the daily treatment is completed, check the treatment history on the LCD by pushing the button. It will display the number of treatments that have been completed during the past thirty days, as well as the total number of completed treatments since the first day treatment began.

NOTE: The device will only permit one treatment per day. The unit will allow treatment for 270 consecutive days from the initial treatment. See "Technical Description" for details.

Liquid Crystal Displays

MESSAGE	DESCRIPTION
LOW BATTERY	This message will appear towards the end of your daily treatment and means that the batteries are getting low. It is not necessary to change the batteries yet.
REPLACE BATTERY!	This message will appear at the beginning of a treatment cycle and means that it is time to replace the batteries with new ones.
TREATMENT RECORD xx/30 yyy/zzz	The number of completed treatments are displayed as follows: **xx = treatments completed in last 30 days,** **yyy = total treatments completed,** **zzz = treatments possible.**
Call for Service	Your device may be experiencing a malfunction, you should call your local OrthoLogic Representative or OrthoLogic at 1-602-263-6004.
Treatment Completed Today	This message is displayed at the end of treatment. It is also displayed if treatment is requested more than once in one day.
Time Remaining mm min., ss sec.	The remaining treatment time is displayed as follows: **mm = minutes, ss = seconds.**

Table 3

Storage

Remove the device and store it in its carrying case until the next day's treatment. Store the unit in a cool dry location. If treatment is attempted again in the same day, the LCD will tell you that a treatment is not available.

Here is an example of a Treatment Record display after completion of a daily treatment:

Liquid Crystal Display
Treatment Record

TREATMENT RECORD	
29/30	079/080

In this example, the numbers in the lower right-hand corner would indicate the ratio between the number of days a proper treatment was completed versus the total number of days since the device was initially activated. The numbers in the lower left-hand corner indicate the ratio for the last 30 days.

TREATMENT SCHEDULE

The treating physician determines how long the patient continues to use the SPINALOGIC®. During treatment, the device is applied every day for 30 minutes per day. Be sure to use the device properly and return promptly for scheduled physician visits. Studies have shown that compliance with these requirements can impact the effectiveness of the treatment.

In addition, bring the device each time there is a physician visit. Always perform a treatment prior to the physician appointment so he or she may obtain the treatment record. Otherwise, a treatment may have to be conducted at the physician's office.

BATTERY REPLACEMENT

The LCD display will indicate when it is time to replace the batteries. The "REPLACE BATTERY" message will be displayed at the beginning of the treatment if the device senses that there is not enough battery power to complete another treatment. HOWEVER, DO NOT CHANGE THE BATTERIES ANYTIME THE UNIT IS STILL RUNNING A TREATMENT. WAIT UNTIL THE DEVICE STOPS OPERATING. After the display turns off, the batteries may then be replaced (Figure 5). It is recommended that only the OrthoLogic® supplied batteries be used for replacement. See specifications for battery information.

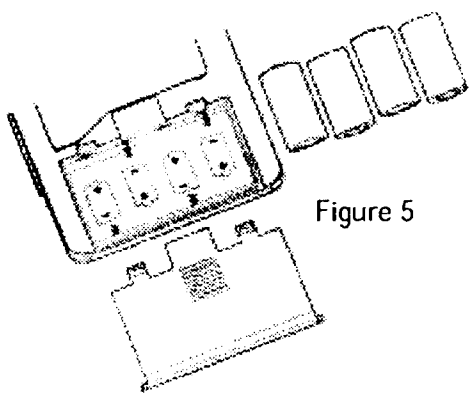


Figure 5

Note: The "LOW BATTERY" message may display towards the end of the treatment which means that the batteries are getting low. IT IS NOT NECESSARY TO CHANGE THE BATTERIES YET.

STORAGE & HANDLING

Battery Self Charging

To minimize battery self charging the battery compartment has mechanical provisions to prevent the incorrect polarity installation of a battery.

Battery Application Labeling

The battery compartment has been clearly labeled with the correct polarity installation configuration for the batteries.

Battery Safety and Handling

- Do not heat or dispose of batteries in a fire.
- Do not charge.
- Avoid shorting or forced discharge.
- Do not damage or use damaged batteries.
- Do not mix old and new batteries together or use batteries other than in their specified polarity.
- Any of the above misuses or abuses may result in swelling, heat generation, leakage, violent rupture, or potential fire.
- Store batteries at room temperature, approximately +70°F (20°C) in less than 80% relative humidity and out of direct sunlight.
- Store batteries to prevent shorting, charging and forced discharge. Ensure that battery ends do not contact each other and avoid contact with metal.
- Use only batteries approved for use by OrthoLogic*.

DEVICE STORAGE, CARE & HANDLING

- Do not submerse the device or any of it's components in any liquid.
- Do not store the device or any of its components in an automobile in extreme cold or hot conditions. The temperature inside an automobile in extreme climates can exceed the recommended operating and storage temperature ranges.
- Do not sterilize the device or any of its components.
- Do not bend, twist or drop the device. These actions may damage the electronics and or the coil.
- It is recommended that the unit be stored in the carrying case provided with the device. The carrying case is designed to protect the unit when not in use and to safely store the additional batteries and device information.

ENVIRONMENTAL CONSIDERATIONS

The following environmental considerations must be respected to ensure safe and proper use of the device.

Table 4
Environmental
Considerations

Operating Temperature Range	+50° F (10°C) to +100° F (38°C) Note: The SpinaLogic® must remain at operating temperature one hour prior to initiating a treatment.
Storage Temperature Range	+5° F (-15°C) to +140° F (60°C)
Storage & Operating Humidity Range	Maximum 80% Relative Humidity
Maximum Ambient Magnetic Field	±600mG

Once treatment has been discontinued, the device should be disposed of properly. The device is programmed to deliver only 270 consecutive days of treatment. The SPINALOGIC® is not reusable and it must be disposed of properly per local governing ordinances and recycling plans regarding disposal or recycling of device components. OrthoLogic® can assist in device disposal.

CUSTOMER SERVICE

For servicing of the device or further information concerning the use of the device, please contact your local OrthoLogic Representative or OrthoLogic Customer Service at 1-800-263-6004.

NOTES:

ORTHOLOGIC

1275 W. Washington Street, Tempe, Arizona 85281 U.S.A.

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PLEASE READ BEFORE USING THIS DEVICE!

SPINALOGIC®

BONE GROWTH STIMULATOR

Patient Manual

Manufactured and Distributed by

ORTHOLOGIC®

1275 W. Washington Street

Tempe, AZ, 85281-1210

1-800-263-6004

Caution:

Federal Law (USA and Canada) restricts this device to sale, distribution, or use by or on the order of a physician.

© January 2000

SPINALOGIC®

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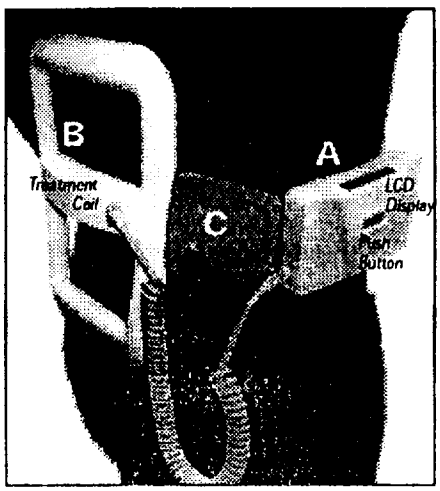

Figure 1
Person wearing a SpinaLogic

DEAR PATIENT:

· Do not use this product before you read this manual very carefully. If you have questions, please contact your doctor or OrthoLogic Customer Service at 1-800-263-6004.

· Words that are written in italics and look like this, "*Words*", are explained in the "Glossary of Medical Terms" on page 6.

PURPOSE OF DEVICE

Your doctor has asked you to use the SpinaLogic® device on your back after your back surgery (primary lumbar *spinal fusion surgery* of one or two levels). This device when used properly will produce magnetic energy over the spot of your back surgery. This energy is meant to help the bones heal. To treat yourself, you must wear the device on the outside of your body for 30 minutes per day.

4/1

SPINALOGIC®

DESCRIPTION OF THE DEVICE

The SpinaLogic® (Figure 1) is very easy to use, comfortable to wear, and safe to use. You will not feel the magnetic energy it produces when using it. The device consists of a control box (A), a treatment coil (B), and a waist belt (C). It has a single "push button" on the control box to start your treatment and will automatically shut-off after 30 minutes. Each day you will hear one beep when you start and two beeps when you stop using it. If something goes wrong when you are using it, a different sound will be heard. If this happens, a message will be shown on the display screen. Each day when using the device, the display screen will show the time you have left to use it that day and the total number of days you have used it.

WHEN THE DEVICE SHOULD NOT BE USED

- Do not use the SpinaLogic® if you have a heart pacemaker or defibrillator.
- Do not use the SpinaLogic® if you are pregnant or if you become pregnant.

RISKS AND BENEFITS

- The safety and benefit of the SpinaLogic® was not studied for patients who also have metal implants at the spot of their back surgery.
- The safety and benefit of the SpinaLogic® is not known for people whose bones are still growing (generally 18 years old or less).
- If you have any of the following medical problems, it is not known if the device will work for you: *osseous or ligamentous spinal trauma, spondylitis, Paget's disease, severe osteoporosis, metastatic cancer, renal disease,* or *uncontrolled diabetes mellitus.*
- Animal testing with this device has not found any safety problems. However, the chance of safety problems with long time use of this device in people is not known.
- The device may not work properly and your treatment may be longer unless you do the following:
    - Always follow your doctor's instructions,
    - Always follow your daily treatment schedule,
    - Always change the batteries when they need it, and
    - Always take proper care of the device.
- Do not use this device if you have any mental or physical conditions that would keep you from following your doctor's orders or the device instructions.
- Do not use the device near products, which may have strong magnetic fields, such as audio speakers. The device may not work right around these products.

If the SpinaLogic® exhibits any error messages on the display screen, try the following:

• Move away from other electrical products or large metal materials, or go to another room while using the device;

• Call OrthoLogic Customer Service for help, 1-800-263-6004.

· Do not use SpinaLogic® while smoking or near heat or fire because the plastic materials used in this device could catch fire.

· Use only OrthoLogic parts with this device because other parts may cause the device not to work right.

· Never try to modify or repair this device because you may damage it.

DIRECTIONS FOR USE

NEVER USE THE DEVICE IF THE TEMPERATURE AROUND YOU IS LESS THAN 50° F OR OVER 100° F (10° C TO 38° C).

1. Putting on the Device

· Your doctor or the OrthoLogic Representative will:

- Cut the belt on the device to fit you;
- Show you how to place the device correctly over the spot of your back surgery;
- Show you how to tighten the belt, and
- Show you how to use the device.

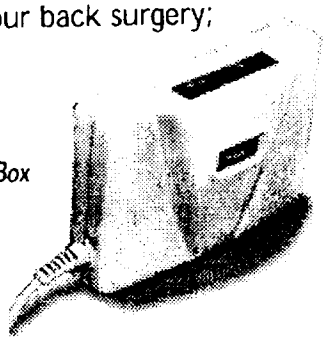

Figure 2
SpinaLogic Control Box

2. Starting Each Day's Use

· Put the device on as you were shown.

· Use the device as you were shown.

Specific directions for operating the device are also given below:

· Press the "push button" next to the screen (see Figure 2) to start each day's use. The device will beep once and the treatment will start.

FOR YOUR INFORMATION!

If by mistake you push the button before using the device that day, you must put the device on and treat yourself right away. The device will only let you use it one time each day.

3. Display Screen

When using the device, the screen will show the time still left for your treatment. The screen will look like this:

Liquid Crystal Display
Treatment Time Remaining

The device will turn off after 30 minutes and will beep two times. NEVER REMOVE THE DEVICE UNTIL 30 MINUTES IS OVER AND YOU HEAR TWO BEEPS.

FOR YOUR INFORMATION!

If you hear beeps before 30 minutes have passed, there may be a problem with your device. Read the display screen for directions. The messages in Table 1 below, may appear on the screen. If you do not understand the message or cannot do what it says, please call OrthoLogic Customer Service at 1-800-263-6004.

Table 1 - Display Messages

MESSAGE	DESCRIPTION
LOW BATTERY	This message will appear toward the end of your daily treatment and means that the batteries are getting low. It is not necessary to change the batteries yet.
REPLACE BATTERY!	This message will appear at the beginning of a treatment cycle and means that it is time to replace the batteries with new ones.
TREATMENT RECORD xx/30 yyy/zzz	The number of completed treatments are displayed as follows: **xx = treatments completed in last 30 days,** **yyy = total treatments completed,** **zzz = treatments possible.**
Call for Service	Your device may be experiencing a malfunction. You should call your local OrthoLogic Representative or OrthoLogic at 1-800-263-6004.
Treatment Completed Today	This message is displayed at the end of treatment. It is also displayed if treatment is requested more than once in one day.
Time Remaining mm min., ss sec.	The remaining treatment time is displayed as follows: **mm = minutes, ss = seconds.**

4. Additional Information

- The device can only be used 270 days in a row (about 9 months). Use the device as long as your doctor tells you to.

- The day you are going to see your doctor, please use the device before going to the doctor's office. If you don't, you may have to use it at the doctor's office.

- Please bring the device with you every time you go to your doctor.

- In a clinical study, the SpinaLogic® was tested on 201 people who had the same type of back surgery that you have just had. 67 of the 104 (64%) people who used the device healed. But only 42 of the 97 (43%) people who did not use the device healed. You have a better chance of your back surgery healing if you use this device than if you do not use this device.

- There are alternatives to using the SpinaLogic®. Some of these are: having physical therapy, taking medications (medicines), seeing a chiropractor, exercising, having surgery, or using other medical devices. Please ask your doctor if you have any questions about other choices for treating your back problem.

REPLACING THE BATTERIES

The display screen will show a message that says "REPLACE BATTERY" when it is time for new batteries. This message will be shown at the start of the use if there is not enough battery power to complete another use.

NEVER CHANGE THE BATTERIES WHEN THE DEVICE IS RUNNING. WAIT UNTIL THE DEVICE STOPS OPERATING.

After the display turns off, the batteries may be replaced as shown in Figure 3 below. Only use the batteries supplied with the SpinaLogic®. They are located in the carry case.

FOR YOUR INFORMATION!

The "LOW BATTERY" message may appear on the display screen at the end of a use. This tells you that the batteries are getting low in power. IT IS NOT NECESSARY TO CHANGE THE BATTERIES YET. Change batteries only when the "REPLACE BATTERY" message appears.

CARING FOR THE BATTERIES

When replacing the batteries you will see the correct way to put them in on the inside of the device (see Figure 3).

Do not misuse the batteries. This could cause a fire, leakage or explosion.

Do not do any of the following:

- Never heat or throw the batteries in a fire;
- Never charge the batteries;
- Never let the battery ends contact each other or other metal. Do not let a piece of metal touch both ends of a battery at the same time;
- Never damage or use damaged batteries;
- Never mix old and new batteries together or use batteries other than in their correct position;
- Always keep batteries at room temperature, about 70°F (20°C) in less than 80% relative humidity and out of direct sunlight;
- Only use the batteries supplied in the carry case with the SpinaLogic®. Enough batteries are provided for the life of the device.

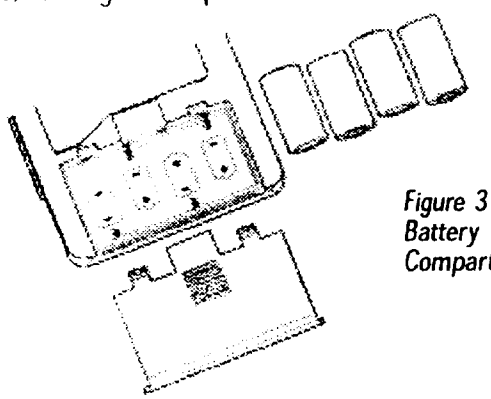

Figure 3
Battery Compartment

DEVICE STORAGE, CARE, AND HANDLING

- Always keep the device in its case in a cool dry place. Never keep it where the temperature is less than 5°F (-15°C) or greater than 140°F (60°C).
- Never put the device or any of its parts in any liquid.
- Never keep the device or any of its parts in an automobile in cold or hot weather.
- Never bend, twist or drop the device. These actions may damage the device or the coil.
- Always keep the SpinaLogic® in the carrying case provided with the device. The carrying case is designed to protect the device when not in use and to safely keep the additional batteries and user information.
- Return your device to your doctor or OrthoLogic Representative when your treatment is completed.

USE WHILE TRAVELING

You should try to use the SpinaLogic® at the same time every day. The clock inside the device counts each day starting at Midnight Mountain Standard Time (MST) and will only allow one treatment every 24 hours. If you travel outside of your normal time zone, you should try to treat at the same time you normally would at home.

USER ASSISTANCE INFORMATION

For servicing of the device or further information concerning the use of the device, please contact your local OrthoLogic Representative or OrthoLogic Customer Service at 1-800-263-6004.

GLOSSARY OF MEDICAL TERMS

Metastatic cancer:	*cancer that has spread to other parts of your body from where it started*
Osseous or ligamentous spinal trauma:	*injury to the bones and/or tissue in your back or spine*
Paget's disease:	*a disease that causes your bones to become more sponge-like*
Renal disease:	*disease of your kidneys*
Severe osteoporosis:	*a serious form of a condition where your bones become much more sponge-like and brittle*
Spinal fusion surgery:	*Surgery which attempts to join together bones in your back*
Spondylitis:	*a condition where you have swelling or irritation of your backbones*
Uncontrolled diabetes mellitus:	*when you are unable to keep control of your insulin level with either diet or insulin shots*

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