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*Save this manual for future reference.*
This Instruction Manual is intended to assist you in using the Provant® Therapy System. Provant is a pulsed electromagnetic field (PEMF) device. Please read this entire instruction manual carefully before using Provant. If you have any questions, please contact Regenesis Biomedical:

Phone: 1-877-970-4970
Website: www.regenesisbio.com
Email: info@regenesisbio.com

Provant is indicated for adjunctive use in the palliative treatment of postoperative pain and edema of soft tissue. Pain and edema (i.e., swelling) can be significant obstacles to postoperative recovery. By helping reduce pain and swelling, Provant plays an important role in your postoperative care.
INDICATIONS FOR USE

- The Provant Therapy System is indicated for adjunctive use in the palliative treatment of postoperative pain and edema of soft tissue.

CONTRAINDICATIONS

- DO NOT USE Provant Therapy if you have a pacemaker or defibrillator.
- DO NOT USE Provant Therapy if you are or may be pregnant.
- DO NOT USE Provant Therapy to treat over bony growth areas in children.
- DO NOT USE provant Therapy over active or previously treated cancer, either solid or blood-related in origin.

WARNINGS AND PRECAUTIONS

- DO NOT USE Provant Therapy over implanted metal lead wires. Closely follow any directions published by the manufacturer’s information for use (IFU).
- The long-term health effects of Provant Therapy are not known.
- The long-term biologic effects of exposure to Provant Therapy beyond the manufacturer’s recommended dosing are not known.
- The effect of Provant Therapy on topical medicated dermal applications has not been evaluated. Consult your physician prior to use of Provant Therapy over topical medicated dermal applications.
- DO NOT USE Provant Therapy if you are using another electronic medical device without first consulting your physician.
- The effect of Provant Therapy on cancer, either solid or blood-related, and precancerous lesions is not known.
- In some patients, pain (hyperalgesia) with use of Provant Therapy has been reported.
The Provant Therapy Device may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to mitigation measures such as:

- Ensuring that the active side of the Treatment Applicator Pad is not near or pointing toward other electronic devices or cabling while the Provant Therapy Device is in ongoing treatment mode.
- Reorient or relocate the other electronic device(s).
- Increase the separation between the Treatment Applicator Pad and other electronic device(s).
- Reposition cables so that they are not on or near each other.
- Connect the equipment into an outlet on a circuit different from that to which the other electronic device(s) are connected.

⚠️ DO NOT USE this System if it has a damaged cable or Treatment Applicator.
⚠️ DO NOT USE this System in the presence of flammable anesthetic mixtures.
⚠️ DO NOT allow water or other liquids to be spilled into the System Case.

**ADVISORIES**

There are important operating, maintenance and service instructions in the literature accompanying the product.

There is a presence of un-insulated “dangerous voltage” within the product’s enclosure that may be of sufficient magnitude to constitute a risk of electric shock.

Provant intentionally applies pulsed electromagnetic field (PEMF) energy to cells for medical treatment.

Provant is a type BF applied part. This means the Treatment Applicator Pad is safe to place against a living body.

Provant is MR unsafe – keep away from magnetic resonance imaging (MRI) equipment.
SUMMARY OF CLINICAL PERFORMANCE
The clinical performance of Provant Therapy has been evaluated in a number of post-operative conditions including lumbar surgery, total knee arthroplasty, and bunionectomies. These studies point out the safe use of the Provant Therapy and while the studies were not powered, trends were observed to be consistent with the indication of pain and edema reduction in soft tissue.

Clinical Performance in Randomized, Blinded, Sham-Controlled Studies
Three studies have been conducted to evaluate the clinical performance of Provant.

Study 1 evaluated subjects with chronic post-operative pain 3 to 36 months after a lumbar decompression surgery. Subjects were randomized to receive Provant (N=13) or a sham control (N=14) and treated twice daily for 60 days.

Study 2 evaluated subjects with chronic post-operative pain 3 to 36 months after a total knee arthroplasty (TKA). Subjects were randomized to receive Provant (N=24) or a sham control (N=11) and treated twice daily for 60 days.

Study 3 evaluated subjects with acute pain directly following bunionectomy surgery. Subjects received treatment with the Provant device (N=71) or a sham control (N=68) for 7 days directly following surgery.

An additional open-label study in subjects (N=41) with chronic post-operative pain after low back surgery was also conducted.
Safety of Provant Therapy
The safety of Provant Therapy has been evaluated in 225 subjects in controlled clinical studies. The overall rate of adverse events with Provant Therapy was similar to a matched sham control. Adverse events that occurred more with a higher frequency with Provant Therapy was increased pain (hyperalgesia).

Regenesis Biomedical maintains a post-market surveillance program to monitor the safety of the Provant Therapy following prescription of the device. Regenesis has received reports of adverse events of greater than 1 per 1000 patients in pain (hyperalgesia) (2.3% of patients) and skin reaction (0.2% of patients). A subset of hyperalgesia patients was instructed by their prescribers to temporarily discontinue therapy until hyperalgesia improved followed by reintroduction at a lower dose with a gradual dose increase over time were able to tolerate Provant Therapy.

Reports received at a rate of 0.1% or less generally related to pre-existing pain, the underlying condition being treated, or to the surgical procedures that preceded the use of Provant Therapy. Regenesis does not consider these latter reports as being associated with use of Provant Therapy.

Expected Adverse Events
Based on a survey where all patients treated with Provant Therapy were asked to report any symptoms and signs, 2.3% reported increased pain and 0.2% reported rash while using Provant Therapy. Infrequent reports of increased pain have also been reported by patients in clinical trials.
Provant includes the following:
1  Provant System Case (yellow)
2  Power Switch (lighted rocker switch)
3  Control Panel (with indicator lights)
4  Start/Stop Button
5  Usage Meter (available on certain models)
6  A/C Power Cable (three-prong)
7  Yellow Cable
8  Treatment Applicator Pad
9  Disposable Applicator Covers
10 Guidelines for Use
11 Countdown Timer

If any items are missing or appear damaged, contact Regenesis Customer Service at 1-877-970-4970 toll free
• Provant must be prescribed by a licensed healthcare provider.
• This device is intended to be used solely by the patient for whom it is prescribed.
• Provant Therapy has SAFE-T-Energetics™ (self-adjusting feedback technology). Provant automatically regulates and controls the delivered dose, adjusting to meet each patient’s unique body characteristics.
• In order to achieve desired results, it is recommended to treat twice a day, about 8 to 12 hours apart, for the full pre-timed 30 minute treatment; however, it is important to treat as your prescribing clinician has directed.
• Provant treatments are pre-timed and can be administered through clothing, dressings, etc. There is no need to remove these items for treatment.
• Provant is an electrical device, so access to an electric outlet is required for use.
• By following the instructions in this manual, you can administer your own treatments. Alternatively, a family member or care provider may administer the treatments.
• During prolonged use, the Control Panel surface may become slightly warm to the touch.
• The Disposable Applicator Covers are designed to serve as a barrier, keeping the Treatment Applicator Pad clean, and to provide a comfortable contact surface. Provant will not operate without a new Disposable Applicator Cover in place for each treatment session.
• The Provant Therapy System contains a radiofrequency identification (RFID) function which transmits and receives at the 13.56 MHz frequency. This functionality may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.
SETTING UP PROVANT
- Read Safety Information before using Provant.
- Place Provant in a nearby convenient, stable location.
- Open Provant by lifting up the two latches on the outside of the System Case. A hinge will hold the lid open.
- Make sure you can see and reach the Provant Control Panel before you start treating.
- Make sure the Yellow Cable and Treatment Applicator Pad can reach to the part of your body being treated.
- Plug A/C Power Cable into an adjacent three prong power outlet.
- Make sure no one will trip on the Yellow Cable or A/C Power Cable during your treatment.
- Please save the original Provant shipping box so you can use it to return the device after your treatment has ended.

TURNING ON PROVANT
- Turn Provant “On” by pressing the Power Switch on the side of the Control Panel. The green light on the Power Switch will turn on.

PLACING THE DISPOSABLE APPLICATOR COVER
IMPORTANT: Each Disposable Applicator Cover is to be used only once.
- Open the silver pack of Disposable Applicator Covers provided with the device and remove one Disposable Applicator Cover.
- Identify the side of the Disposable Applicator Cover which has a clear window and yellow starburst image.
- Identify the side of Treatment Applicator Pad which says “This side towards patient.”
- Gently insert the Treatment Applicator Pad into the Disposable Applicator Cover so that the words “This side towards patient” are visible through the clear Disposable Applicator Cover window.
- Press locking strips at the top of the Cover together to seal the Disposable Applicator Cover on the Treatment Applicator Pad.
- If the Disposable Applicator Cover has been used previously or is not correctly oriented, Provant will beep three times and treatment will not start when the Start/Stop button is pressed.
- Additional Disposable Applicator Covers are available from Regenesis Customer Service and may be ordered by calling 1-877-970-4970.
POSITIONING THE TREATMENT APPLICATOR PAD

**IMPORTANT:** The body part being treated and the Treatment Applicator Pad should rest lightly together. Excess pressure or weight on the Treatment Applicator Pad may trigger the “Service Required” light and stop treatment.

**IMPORTANT:** Do not push or force the Treatment Applicator Pad underneath you when positioning it, as this may cause friction and injury to your skin.

- Find a comfortable position sitting or lying down. If you are sitting or lying on a metallic surface, make sure comfortable padding, such as a mattress or cushion, is between the treatment applicator pad and the metal, so as not to interfere with the delivery of the therapeutic PEMF energy.

- Make sure you are positioned such that the site to be treated is easily reached.

- It is not necessary to remove any clothing or dressings because Provant PEMF energy penetrates from the Treatment Applicator Pad through clothing and dressings.

- Position the Treatment Applicator Pad directly against the treatment site. The words “This side towards patient” should be facing the area you are treating. Center the starburst symbol over the treatment site.

- You may support the Treatment Applicator Pad next to the treatment site using a pillow or rolled towel to ensure it stays in contact with the treatment site.
STARTING A TREATMENT SESSION

- Press the START/STOP button on the Control Panel.
- A short beep will sound, letting you know that treatment has begun.
- Three lights will illuminate on the Control Panel during treatment: a green “CPI RUNNING” light; a stack of green lines that scroll from left to right; and a green 30-minute count-down timer.
- The count-down timer tells you how much time remains in the treatment session and counts down in one-minute increments.

FINISHING TREATMENT

- At the end of 30 minutes, treatment automatically ends. All indicator lights will turn off and a long beep will sound to let you know the treatment session is finished.
- Turn Provant “Off” by pressing the Power Switch on the side of the Control Panel. The green light on the Power Switch will turn off.
- Remove the Treatment Applicator Pad from the treatment site. Remove the Disposable Applicator Cover from the Treatment Applicator Pad and discard it as normal waste. The Disposable Applicator Covers are not recyclable.
- You may stop Provant prior to the end of the treatment session by pressing the START/STOP button on the Control Panel, or pressing the Power Switch.
**Cleaning PROVANT**

**IMPORTANT:** Do not submerge any part of Provant in any liquid.  
**IMPORTANT:** Do not use organic cleaners other than isopropyl alcohol / water solution as this may damage Provant and void the warranty.  
**IMPORTANT:** If desired, the Treatment Applicator Pad can be cleaned following the directions below.

- Before cleaning, first unplug Provant from the electrical outlet.
- Prepare a dilute solution of rubbing alcohol (70% isopropyl alcohol) and water by mixing equal parts of rubbing alcohol and tap water.
- Moisten a clean cloth with the rubbing alcohol/water solution and gently wipe the surface of the Treatment Applicator Pad.
- For further instructions, contact Regenesis Customer Service at 1-877-970-4970.

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**Servicing PROVANT**

- All service is provided and conducted by Regenesis. Please call 1-877-970-4970.
- Do not attempt to disassemble or repair Provant.
- There are no user-serviceable parts in Provant.
- Any unauthorized attempts to service or repair Provant will void the warranty and may result in additional charges.
**IMPORTANT:** To avoid damage, properly pack the A/C Power Cable, Yellow Cable and Treatment Applicator Pad.

- Unplug the A/C Power Cable from the wall, bundle and place in the space next to the Control Panel.

- Place the Treatment Applicator Pad on top of the Control Panel. Do NOT wrap cables around the Treatment Applicator Pad.

- Bundle the Yellow Cable and place in the space next to the Control Panel, on top of the A/C Power Cable.

- Close and latch the lid, making sure no cables are caught when closing the lid.

- The Provant Therapy System should not be exposed to environmental conditions outside the following ranges for extended periods of time:
  
  - Operating Temperature: 54º–90ºF (12º–32ºC)
  - Storage Temperature: -40º–158ºF (-40º–70ºC)
  - Operating/Storage Humidity: 10%–95%, non-condensing
  - Operating Altitude: 500–1060mbar (-1,000–18,000ft/-304–5486m)

- Handle the Provant Therapy System using the convenient carrying handle.

- Do not use or leave Provant in direct sunlight, high humidity, or severe heat or cold as this could adversely affect performance.
Returning PROVANT to Regenesis

When your treatment is complete and your prescribing physician has instructed you to discontinue the use of Provant, please call Regenesis Customer Service within 24 hours to arrange the easy return of Provant. Call 1-877-970-4970.

- Locate the original Provant shipping box.
- Remove the pre-addressed, pre-paid Overnight Shipping return label provided with the device. Apply the shipping label to the Provant shipping box over the original shipping label.
- Place Provant, handle-side up, into the box by slipping it between the foam packing strips. Close the shipping box and secure the box lid with packing tape.
- Discard all used Disposable Applicator Covers. Do not return the used Disposable Applicator Covers with Provant.
- Call Regenesis toll-free at 1-877-970-4970 to arrange for door-to-door Overnight Shipping pick-up.
- If you do not have the original Provant shipping box or return label, call Regenesis for assistance toll-free at 1-877-970-4970.
During use, problems may arise. This section will help you troubleshoot common problems. Call Regenesis Customer Service for additional assistance by calling toll-free 1-877-970-4970.

If your problem involves a health issue and you need emergency assistance, please call 911 and/or contact your health care professional.

Please report serious side effects to Regenesis Customer Service by calling 1-877-790-4790.

**PROVANT DOES NOT START AND/OR THERE ARE NO INDICATOR LIGHTS:**

- Make sure the A/C Power Cable is firmly plugged into the electrical wall outlet.
- Make sure that the opposite end of the A/C Power Cable is firmly plugged into the side of the Control Panel.
- Make sure the Power Switch is “On.” The Power Switch lights up green when it is “On.”
- If problem persists, call Customer Service at 1-877-970-4970.

**WHEN THE START/STOP BUTTON IS PUSHED, PROVANT BEEPS THREE TIMES:**

- Replace the Disposable Applicator Cover with a new, unused cover. Make sure “This side toward patient” is easily visible through the clear window.
- Turn the Power Switch “Off” and then “On.”
- Press the Start/Stop button.
- If the problem persists, repeat with another new cover.
- If problem persists, call Customer Service at 1-877-970-4970.
SERVICE REQUIRED LIGHT IS LIT:

- Make sure only light pressure from the patient’s limb or body is on the Treatment Applicator Pad, and turn Provant “Off”, then “On”.
- If problem persists, call Customer Service at 1-877-970-4970.

PROVANT APPEARS TO INTERFERE WITH OPERATION OF OTHER ELECTRONIC DEVICES:

- Make sure the Treatment Applicator Pad is not near other electronic devices or their cables.
- Make sure the Provant A/C Power Cable and Yellow Cable are not near other electronic device or their cables.
- Plug Provant into a different electrical wall receptacle.
- Increase the distance between the Treatment Applicator Pad and the other electronic devices.
- Move other electronic devices to a place where there is no interference.

For further troubleshooting assistance, call Regenesis customer service at the toll-free number below.

Regenesis Customer Service
Toll-Free
1-877-970-4970

IMPORTANT:
Please have the Serial Number located on the label on the back of Provant ready for Customer Service.
Electromagnetic Compatibility (EMC) User Information

WARNING:

Provant Therapy System needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

Portable and mobile RF communications equipment can affect the Provant Therapy System.

The use of accessories, transducers and cables other than those specified by Regenesis Biomedical may result in increased emissions or decreased immunity of the equipment.

This equipment should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.

NOTE: The EMC tables and other guidelines that are included in the Instruction Manual provide information to the customer or user that is essential in determining the suitability of the equipment or system for the electromagnetic environment of use, and in managing the electromagnetic environment of use to permit the equipment or system to perform its intended use without disturbing other equipment and systems or non-medical electrical equipment.

Guidance and manufacturer's declaration – electromagnetic emissions

The PROVANT THERAPY SYSTEM is intended for use in the electromagnetic environment specified below. The customer or the user of the PROVANT THERAPY SYSTEM should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>The PROVANT THERAPY SYSTEM must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 2</td>
<td></td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Voltage Fluctuations/ Flicker emissions</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>

The PROVANT THERAPY SYSTEM is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
### Guidance and manufacturer’s declaration – electromagnetic immunity

The PROVANT THERAPY SYSTEM is intended for use in the electromagnetic environment specified below. The customer or the user of the PROVANT THERAPY SYSTEM should assure that it is used in such an environment.

#### Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment – guidance
---|---|---|---
Electrostatic discharge (ESD) IEC 61000-4-2 | ±6 kV contact ±8 kV air | ±15 kV contact ±30 kV air | The relative humidity should be at least 5%.

Electrical fast transient/burst IEC 61000-4-4 | ±2 kV for power supply lines | ±2 kV for power supply lines | Mains power quality should be that of a typical commercial or hospital environment.

Surge IEC 61000-4-5 | ±1 kV differential mode ±2 kV common mode | ±1 kV differential mode ±2 kV common mode | Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | <5 % $U_T$ (>95 % dip in $U_T$) for 0,5 cycle 40 % $U_T$ (60 % dip in $U_T$) for 5 cycles 70 % $U_T$ (30 % dip in $U_T$) for 25 cycles <5 % $U_T$ (>95 % dip in $U_T$) for 5 sec | <5 % $U_T$ (>95 % dip in $U_T$) for 0,5 cycle 40 % $U_T$ (60 % dip in $U_T$) for 5 cycles 70 % $U_T$ (30 % dip in $U_T$) for 25 cycles <5 % $U_T$ (>95 % dip in $U_T$) for 5 sec | Mains power quality should be that of a typical commercial or hospital environment. If the user of the PROVANT THERAPY SYSTEM requires continued operation during power mains interruptions; it is recommended that the PROVANT THERAPY SYSTEM be powered from an uninterruptible power supply or a battery.

(50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

**NOTE** $U_T$ is the a.c. mains voltage prior to application of the test level.

**ESSENTIAL PERFORMANCE:** The Provant Therapy System shall indicate proper operation or shutdown, alarm or stand-by.
The PROVANT THERAPY SYSTEM is intended for use in the electromagnetic environment specified below. The customer or the user of the PROVANT THERAPY SYSTEM should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>IEC 61000-4-6</td>
<td></td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the PROVANT THERAPY SYSTEM, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>IEC 61000-4-3</td>
<td></td>
<td>Recommended separation distance ( d = 0.35\sqrt{P} ) ( 80 \text{ MHz to } 800 \text{ MHz} ) ( d = 0.7\sqrt{P} ) ( 800 \text{ MHz to } 2.5 \text{ GHz} ) where ( P ) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and ( d ) is the recommended separation distance in meters (m).</td>
</tr>
</tbody>
</table>

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol:

**NOTE 1** At 80 MHz and 800 MHz, the higher frequency range applies.

**NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

**a** Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PROVANT THERAPY SYSTEM is used exceeds the applicable RF compliance level above, the PROVANT THERAPY SYSTEM should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PROVANT THERAPY SYSTEM.

**b** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.
Recommended separation distances between portable and mobile RF communications equipment and the PROVANT THERAPY SYSTEM

The PROVANT THERAPY SYSTEM is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PROVANT THERAPY SYSTEM can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PROVANT THERAPY SYSTEM as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter W</th>
<th>Separation distance according to frequency of transmitter m</th>
<th>150 kHz to 80 MHz</th>
<th>80 MHz to 800 MHz</th>
<th>800 MHz to 2.5 GHz</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>d = 0.35√P</td>
<td>d = 0.35√P</td>
<td>d = 0.7√P</td>
</tr>
<tr>
<td>0.01</td>
<td></td>
<td>0.04</td>
<td>0.04</td>
<td>0.07</td>
</tr>
<tr>
<td>0.1</td>
<td></td>
<td>0.11</td>
<td>0.11</td>
<td>0.22</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>0.35</td>
<td>0.35</td>
<td>0.77</td>
</tr>
<tr>
<td>10</td>
<td></td>
<td>1.1</td>
<td>1.1</td>
<td>2.2</td>
</tr>
<tr>
<td>100</td>
<td></td>
<td>3.5</td>
<td>3.5</td>
<td>7.0</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
DetaiLeder SpEcifiCatiOns

**INDICATIONS FOR USE**
Provant is indicated for adjunctive use in the palliative treatment of postoperative pain and edema of soft tissue.

**CONTRAINdications**
Provant SHOULD NOT BE USED:
- By patients with cardiac pacemaker or defibrillator
- By patients during pregnancy
- Over bony growth areas in children
- Over active or previously treated cancer, either solid or blood-related in origin.

**WARNINGS AND PRECAUTIONS**
- Provant SHOULD NOT BE USED over ANY implanted metal lead wires. Closely follow any directions published by the manufacturer's information for use (IFU).
- The long-term health effects of Provant Therapy are not known.
- The long-term biologic effects of exposure to Provant Therapy beyond the manufacturer's recommended dosing are not known.
- The effect of Provant Therapy on topical medicated dermal applications has not been evaluated. Consult your physician prior to use of Provant Therapy over topical medicated dermal applications.
- DO NOT USE Provant Therapy if you are using another electronic medical device without first contacting your physician.
- The effect of Provant Therapy on cancer, either solid or blood-related, and precancerous lesions is not known.
- In some patients, pain (hyperalgesia) with use of Provant Therapy has been reported.

**CAUTION**
- Federal law restricts this device to sale by, or on the order of, a licensed healthcare practitioner.

**OVERVIEW**
The Provant Therapy System is a solid-state, fixed-power output pulsed electromagnetic field (PEMF) generator and transmitter designed to operate at the Federal Communications Commission authorized medical device frequency of 27.12 MHz. During therapy, the Provant transmits a fixed dose of non-ionizing, non-thermal shortwave therapy (SWT) energy via an applicator pad that is placed adjacent to the area to be treated. The SWT energy produced by Provant is similar to that of cell phones and AM/FM radio transmissions. The Provant device also contains an RFID function which transmits at the 13.56 MHz frequency. Provant has been designed with the patient in mind -- it is lightweight, easy to transport and requires little patient or care-provider interface. There are only two switches, a Power On/Off switch and a Treatment START/STOP switch; no adjustments are necessary. Provant automatically delivers and monitors a preset therapeutic energy dose during each 30-minute treatment cycle. The Provant Therapy System complies with the following standards: UL 60601-1 and IEC 60601-2-3.

**DETAILED SPECIFICATIONS**

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size (closed)</td>
<td>13.8” x 10.3” x 6.0”</td>
</tr>
<tr>
<td>Weight</td>
<td>10 pounds</td>
</tr>
<tr>
<td>Applicator size</td>
<td>7.5” x 8.5” x 1.0”</td>
</tr>
<tr>
<td>A/C Power Cable</td>
<td>10’ Hospital Grade, 10 AMP, 18 AWG</td>
</tr>
<tr>
<td>Treatment Applicator</td>
<td>8’ RG-316 Coaxial cable, Silver plated copper clad steel</td>
</tr>
<tr>
<td>Power Requirements</td>
<td>AC 100-240V, 47-63 Hz</td>
</tr>
<tr>
<td>Circuit Protection</td>
<td>AC 0.5 Amp Slow Blow</td>
</tr>
<tr>
<td>Power Consumption</td>
<td>35 Watts</td>
</tr>
<tr>
<td>Operating Frequency</td>
<td>27.12 MHz</td>
</tr>
<tr>
<td>Transmission Profile</td>
<td>Pulsed Sine Wave</td>
</tr>
<tr>
<td>Pulse Duration</td>
<td>42 µsec</td>
</tr>
<tr>
<td>Pulse Frequency</td>
<td>1 KHz</td>
</tr>
<tr>
<td>Duty Cycle</td>
<td>4.2%</td>
</tr>
<tr>
<td>Signal Strength</td>
<td>591 V/m</td>
</tr>
<tr>
<td>Effective Radiated Power</td>
<td>&lt;3W @5.0cm</td>
</tr>
<tr>
<td></td>
<td>27.55 dBuV/m @3.0 m</td>
</tr>
</tbody>
</table>

Federal law restricts this device to sale by, or on the order of, a licensed healthcare practitioner.