

INDICATIONS FOR USE

The BSD-500 Hyperthermia System has been approved by the FDA for use alone or in conjunction with radiation therapy in the palliative management of certain solid surface and subsurface malignant tumors (i.e., melanoma, squamous- or basal-cell carcinoma, adenocarcinoma, or sarcoma) that are progressive or recurrent despite conventional therapy.

CONTRAINDICATIONS

Because the patient's ability to detect pain is an essential safety mechanism, hyperthermia is contraindicated in patients whose pain response has been significantly decreased by any means (previous surgery or ionizing radiation therapy, regional or general anesthetic, or other condition).

Since excessive heating of normal tissue is prevented by normal blood perfusion, it is imperative that adequate circulation be present and maintained in all tissues within the heating field. Treatment with the BSD-500 Hyperthermia System is contraindicated in patients having known decrease in circulation in the heated area produced by any means (i.e., vasoconstrictive drugs, DIC, ischemia or other cause).

Because electromagnetic radiation from the applicators of the BSD-500 Hyperthermia System may interfere with the operation of an electronic device, hyperthermia treatments are contraindicated in patients with cardiac pacemakers.

RESTRICTIONS

The sale, distribution, and use of the BSD-500 Hyperthermia System are restricted to prescription use.

The BSD-500 Hyperthermia System is to be used only by qualified operators upon the prescription and under the supervision of a physician who is experienced in clinical hyperthermia.

WARNINGS

Hyperthermia treatment can be safely and effectively administered only after careful placement of temperature probes as described in the Reference Manual and with alert monitoring of tissue temperatures during treatment.

Hyperthermia treatment presents a potential safety hazard in patients whose pain response has been decreased because of disease, previous surgery, ionizing radiation therapy, chemotherapy, or general or regional anesthesia.

The electromagnetic energy from microwave applicators may interfere with the operation of the cardiac pacemakers or other implanted electronic devices.

Large thermal doses (a continued elevation of moderately high temperature or a short extreme elevation of temperature) in normal tissues situated in the vicinity of the treated tumor or between the tumor and the body surface may result in regions of thermal aseptic necrosis that require medical intervention and that may not be apparent on inspection of the skin.

Treatment of tumors located in the neck and head may cause inadvertent heating of thermoregulatory centers located in the brain stem and induce general thermoregulatory response exceeding the patient's compensatory capabilities.

PRECAUTIONS

Adhere to recommended procedures for temperature probe placement and selection of control probe to minimize the probability of excessive temperature in normal tissue or of inadequate temperature in the tumor. Observe strict adherence to aseptic techniques during the invasive placement of catheters to avoid localized infections, and instruct patients in the daily care of indwelling catheters and probe sites to prevent sepsis.

To ensure accurate temperature monitoring during treatments, verify calibration of temperature probes daily or as used.

Adhere to recommended applicator placement and bolusing practices to reduce the likelihood of surface burns and blistering from the subsequent delivery of therapeutic heat.

In patients with severely compromised pain response, monitor closely other physiological indicators of excessive heat delivery.

Monitor closely patients with metallic implants (joint prostheses, dental braces, etc.) during treatment because such metal objects may be excessively (and preferentially) heated.

ADVERSE REACTIONS

SIDE EFFECTS Although hyperthermia has the potential for producing a variety of adverse effects, those actually observed have been limited to direct effects of heating upon tissue and indirect effects related to tumor necrosis. Statistical analysis of clinical data obtained in BSD Medical's studies has provided the following approximate figures for hyperthermia in general:

Burns. Patients have experienced in 9.7% of tumor sites studied, surface burns and blistering in the area of the delivery of therapeutic heat by local microwave applicators of the BSD-500 Hyperthermia System. Adherence to recommended applicator placement techniques and bolusing practices greatly reduces the number of incidents.

Pain. Patients have experienced, in 8.4% of tumor sites studied, localized and temporary pain in the area of, and during delivery of, therapeutic heat by local microwave applicators of the BSD-500 Hyperthermia System. The use of surface cooling techniques can diminish this pain.

Ulceration. Patients have experienced, in 3.6% of tumor sites studied, ulceration from rapid tumor necrosis following successful hyperthermia treatment with the BSD-500 Hyperthermia System. Such ulceration may produce both fever through toxemia and patient discomfort through drainage and bleeding.

Infection. Patients have experienced, in 1.8% of tumor sites studied, local and systematic infections resulting from the placement of the temperature probes of the BSD-500 Hyperthermia System and from the ulceration related to rapid tumor necrosis. These infections have generally been local.

POTENTIAL ADVERSE HEALTH EFFECTS OF THE DEVICE

Hyperthermia has the potential for producing the conditions listed below, as a result of the delivery of therapeutic heat or of exposure to electromagnetic radiation. However, none of these adverse reactions was observed during the clinical investigation of local hyperthermia.

Cataracts. Inadvertent heating of the eye may occur during treatment of tumors in the head or neck. A single high dose of microwave radiation or repeated exposure over a long period of time may result in cataract formation which may not be observable for several weeks.

Male Sterility. A single high dose of microwave radiation to the testes, or testicular heating for a prolonged period of time, may result in temporary or permanent sterility.

Exacerbation of pre-existing disease. Patients having borderline cardiopulmonary function secondary to coronary atherosclerosis, emphysema, or other conditions, may not be able to tolerate the additional systematic stress of extensive or prolonged hyperthermia.

Enhanced drug activity. Elevated temperatures may be expected to affect the pharmacologic activity of some drugs, with unpredictable results. Altered vascular perfusion may dramatically affect the local tissue effects of systemic or infused drugs.

Thermal Stress. Significantly increasing the core temperature of the body or overheating the thermo-regulatory center in the brain may result in thermal stress exceeding the patient's compensatory mechanisms. Reliable prediction of the consequences of thermal stress in patients with cardiovascular impairment is not possible. Signs of consequences of thermal shock or of local brain overheating may appear after several (up to 24) hours.

ABOUT BSD MEDICAL

BSD Medical develops, manufactures, markets and services systems to treat cancer and benign diseases using heat therapy via focused radio frequencies and microwave energy.



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Hyperthermia Therapy

Information For Cancer Patients

Is Hyperthermia Therapy Right for You?

What is Hyperthermia?

Hyperthermia is a therapy used to heat tumors. Research has shown that heat can damage cancer cells while also increasing the effect of radiation therapy in treating some tumors that are recurrent or progressive despite conventional therapy.

While it has been known for hundreds of years that fevers can kill cancer cells, only recently has technology been developed that can control and focus heat specifically on tumors. Hyperthermia treatments are typically given in Radiation Oncology departments several times a week either before or after radiation therapy. Each treatment session lasts for approximately one hour.

Recurrent Cancer Management Using Hyperthermia

The BSD-500 Hyperthermia System has been approved by the FDA for use alone or in conjunction with radiation therapy in the palliative management of certain solid surface and subsurface malignant tumors (i.e., melanoma, squamous- or basal-cell carcinoma, adenocarcinoma, or sarcoma) that are progressive or recurrent despite conventional therapy.



Clinical studies using BSD's hyperthermia systems in conjunction with radiation therapy have shown that 83.7% of patients had some tumor regression (reduction), 37.4% of patients had a complete tumor regression and 24.5% had a greater than 50% tumor regression. The

primary types of tumors included in this study were recurrent chest wall cancer, recurrent head and neck cancer, recurrent melanoma, and recurrent sarcoma.

Although hyperthermia has the potential for producing a variety of adverse effects, those regularly observed during clinical studies have been limited to the direct effects of heating upon tissue and indirect effects related to the tumor including burns (9.9%), pain (8.4%), ulceration (3.6%) and infection (1.8%). A complete description of all adverse effects is included on the back page of this brochure.

Please talk with your physician regarding hyperthermia therapy.

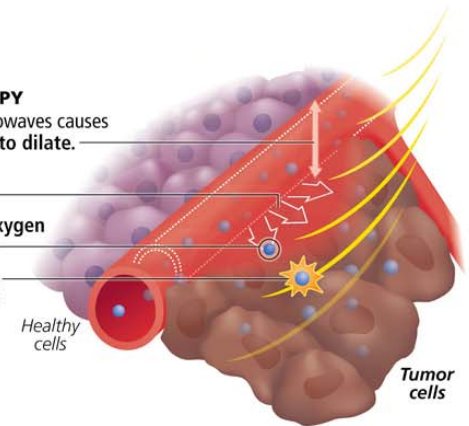
How Does Hyperthermia Therapy Work?

Using focused microwave energy, the tumor is heated to approximately 108°F. Performed superficially or via interstitial probes, heat can damage cancer cells at levels that are usually safe for normal cells, and can be used to attack cancer in four major ways:

First, heat damages or weakens the cells of the tumor. Second, heat increases blood flow through the weakened tumor, which can allow radiation therapies to permeate the tumor, not just attack it from the outside. Third, increased blood flow raises oxygen levels in tumors so that the cancer can be more effectively treated by radiation therapy. Fourth, when the body senses fever it can stimulate the natural immune system. For these reasons, hyperthermia is usually used in combination with radiation therapy.

RADIOTHERAPY

Heat from microwaves causes blood vessels to dilate.
Blood spreads into the tumor.
Blood carries oxygen into the tumor.
Oxygen reacts with radiation to attack the tumor cells.



Is Hyperthermia Covered By Medicare and Private Insurance?

Although many insurance carriers pay for hyperthermia treatment for some tumors, you should always check with your physician to make sure that your therapy will be covered.