

BRAINTREE SCIENTIFIC, INC.

a breakthrough in Body Temperature control

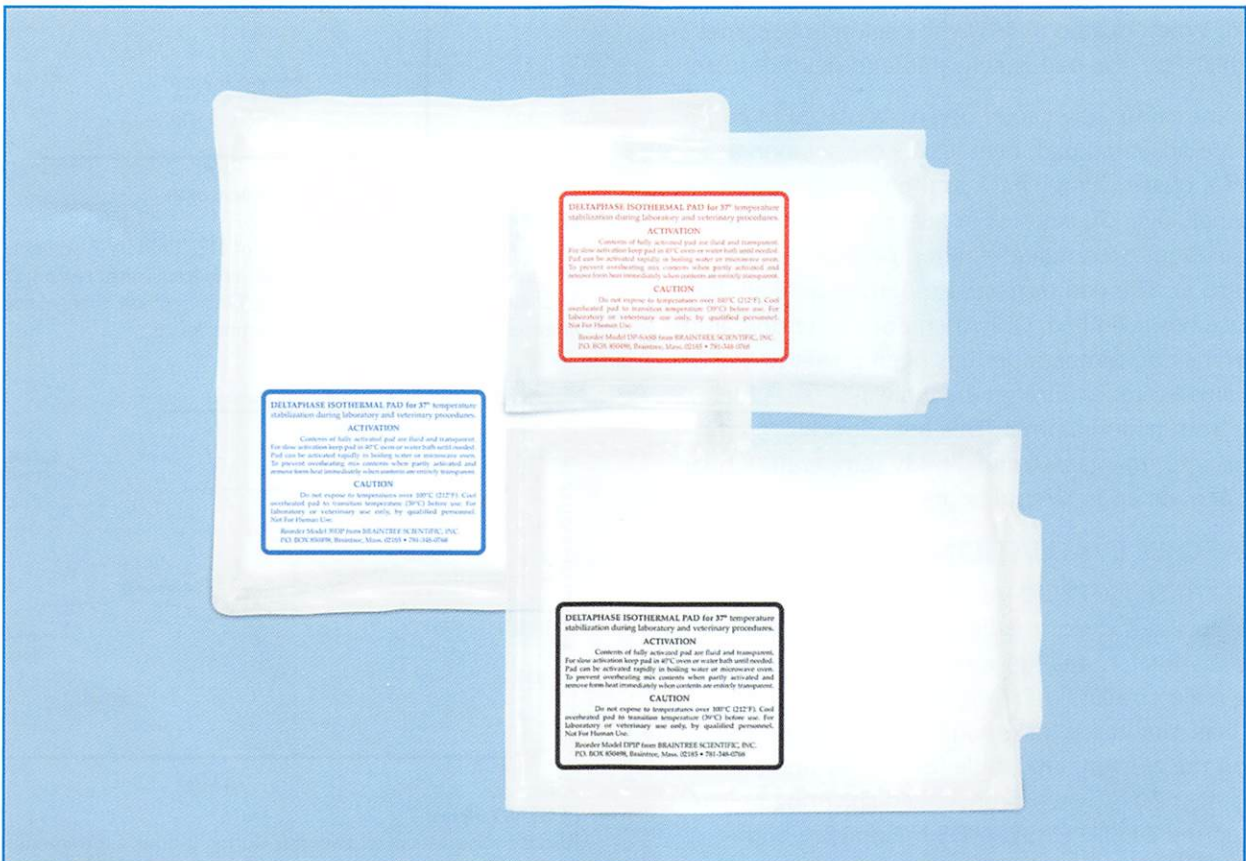
The Deltaphase® Isothermal Pad

- Helps keep body temperature constant during surgical and veterinary procedures in small animals
- Maintains a stable thermal state during experimental studies
 - Speeds post-surgical recovery



The Deltaphase® Isothermal Pad is:

- Based on a fundamental thermodynamic principle
- Completely safe, even with flammable anesthetics
 - Uses no electricity, no wires, no controllers



DEVELOPED BY RESEARCHERS AT A MAJOR MEDICAL CENTER

by: BRAINTREE SCIENTIFIC, INC.

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BACKGROUND

Normal physiological function is based on a body temperature of 37°C (98.6°F). In normal, conscious animals many systems act to generate and retain heat, keeping core temperature in the normal range. Anesthesia blocks those natural mechanisms, so that heat is lost and body temperature falls. Normal function is disturbed. Surgical tolerance is reduced. Recovery is slowed. To help maintain body temperature during surgical or experimental procedures or to assist in recovery, many methods have been tried. Coverings or blankets, for example, slow heat loss significantly. However, such coverings are impractical during surgery, and they cannot replace heat already lost. Electrical heaters are often used. These take the form of heating pads, heated operating tables, or infrared lamps. Such devices can replace lost heat, and with appropriate controlling electronics can maintain body temperature very well. However, such electrical systems are often failure

prone and may be dangerous. They must be carefully monitored to prevent overheating or oscillation. They often interfere with sensitive electronic recording equipment. In the presence of physiological solutions, urine or blood, they present a shock hazard. And the opening spark of a thermostat or switch may ignite a flammable anesthetic (such as ether) and cause an explosion.

The DELTAPHASE ISOTHERMAL PAD is a new approach to body temperature stabilization. It acts as a source of heat. Its constant temperature is based on a thermodynamic principle and needs no electricity or wires, no thermostat or feedback controller. It cannot generate electrical signals or cause interference. It cannot trigger an explosion. It can maintain a small animal at near normal and constant temperature for several hours.

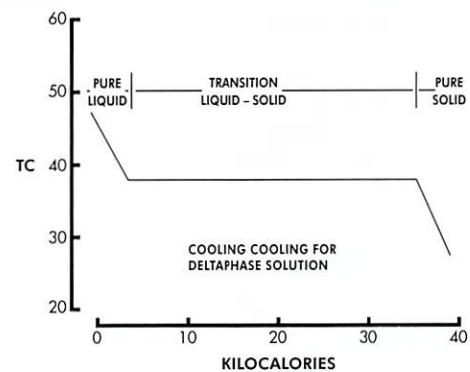
HOW DOES IT WORK?

The DELTAPHASE ISOTHERMAL PAD is based on the thermodynamic principle that a heat releasing phase change is isothermal, that is: that it occurs at constant temperature. A unique chemical solution* is contained within a durable pouch. At room temperature this solution is in solid form. When heated to 39°C, the solution becomes fluid. In this state, the pad is activated and ready for use.

When an animal (or any cooler object) is placed in contact with the activated pad, heat leaves the solution as it undergoes a phase change back to the solid form. In this phase change, over 30 calories of heat are released per gram of solution, even though the temperature is constant (figure 1). The pad remains isothermal until all the liquid phase has solidified. Only then does its temperature fall. The transition temperature has been preset to 39°C, so that a small temperature gradient always exists for heat flow from pad to animal. This heat flow balances heat losses and maintains animal body temperature near 37°C for periods up to several hours.

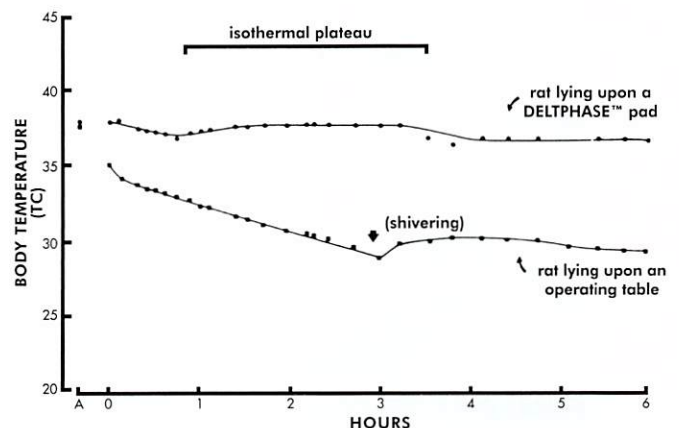
LABORATORY EVALUATION

The DELTAPHASE ISOTHERMAL PAD has been evaluated by researchers at a major medical center. Anesthetized rats (pentobarbital 45 mg/kg) were placed on either an operating table or a DELTAPHASE PAD, and rectal temperature was monitored for 6 hours. The temperature of the rats on the conventional table fell rapidly and stabilized only near 30°C when pronounced shivering began. The rats on the DELTAPHASE PADS maintained body temperature near a constant 37°C for 4 hours. Typical observations are shown in Figure 2.



LEGEND Figure 1

The temperature of one kilogram of DELTAPHASE solution is plotted as a function of kilocalories of heat released. Initial temperature was 9°C above transition temperature. During phase change, solution releases heat without change in temperature.



LEGEND Figure 2

Rectal temperatures of two rats during 6-hour experiment. (Animal weights 350 g, room temperature 24.5°C.) Animal on DELTAPHASE PAD maintained near normal temperature for more than three hours.**

*The chemicals used are non-toxic and have been approved by the U.S. Food & Drug Administration.

**Smaller Pads will hold temperature for approximately 30 minutes.

DELTAPHASE ISOTHERMAL PAD

METHODS OF ACTIVATION

The water bath method of heating the Deltaphase Pads will prolong the life expectancy of the pads. (Approximately 6 + months depending upon frequency of use.)

WATER BATH

Set the water bath temperature control between 43°C and 45°C.

- Place a wooden or plastic rack into the water bath.
- Place the Deltaphase Isothermal Pad onto the rack in the water bath.
- **CAUTION:** Verify that the pad is not touching the bottom or sides of the water bath because the plastic covering of the pad may stick or melt in the water bath. This would damage the pad beyond repair.

- Heat the pad in the water bath for at least 1 hour until the consistency of the pad changes from a solid to a liquid state. The color will also change from white to a clear transparent state. You may notice that the clear liquid will contain small white beads which will indicate that the pad is ready for use. The temperature of the pad will be stable at 37°C.

MICROWAVE OVEN*

- Set the microwave on high.
- Set the microwave timer control to 45 seconds and let it run for that period of time.
- Remove the pad and knead it.
- Return the pad to the Microwave oven and repeat the above steps until the consistency of the pad changes from a solid to a liquid state. The color will also change

from white to a clear transparent state. You may notice that the clear liquid will contain small white beads which will indicate that the pad is ready for use. The temperature of the pad will be stable at 37°C.

- * This method will wear out the life of the pads faster than the water bath method. (Approximately 3 months depending upon frequency of use.)

REGULAR LAB OVEN*

- Set the lab oven temperature control to 42°C or 43°C.
- Place the Deltaphase Isothermal pad on the middle rack in the oven.
- **CAUTION:** Be sure that the rack does not have any sharp burrs or other places where the plastic bag can be punctured or cut; otherwise, the pad can be damaged beyond repair.
- Heat the pad for several hours in the oven until the consistency of the pad changes from a solid to a liquid state. The color will also change from white to a clear transparent state. You may notice that the clear liquid

will contain small white beads which will indicate that the pad is ready for use. The temperature of the pad will be stable at 37°C.

- Some people prefer to place the pad in the oven overnight to activate it before using the following day. This procedure has been successful.

Do not store activated pads at temperatures exceeding 50°C.

- * This method will wear out the life of the pads faster than the water bath method. (Approximately 3 months depending upon frequency of use.)

SPECIAL NOTE

Smaller Pads will take less time to activate. The length of time that the Deltaphase Isothermal Pad can maintain its 37°C temperature may be further maximized by placing the foam insulator (included with shipment) underneath the pad. This insulation will keep any heat from being transferred to the table. A towel covering the exposed pad around the animal will also help extend the time it holds the 37°C temperature.

ACTIVATION AND USE

DELTAPHASE PADS are activated by the addition of heat. At room temperature pads are solid, hard and opaque. Fully activated pads are soft and transparent. Activated pads will slowly solidify, becoming hard and opaque as they release stored energy. Once the solution is fully liquid, additional heat may be stored, but will result in increasing the temperature of the solution. As heat leaves an activated pad during use, the pad will slowly solidify. Once the pad has completely solidified, it will cool slowly to ambient temperature.

Pads may be activated and stored ready for use in convenient constant temperature drying ovens or water baths set to maintain a temperature slightly above 39°C.

Depending upon the efficiency of the oven or water bath, several hours may be necessary to fully activate a cold pad by this method. For this reason, some investigators find it convenient to keep a day's supply of pads ready for use in a small oven.

Rapid activation may be achieved by immersion in boiling water until softened. An electrical fry pan *with at least 1/2" water* makes an ideal container. It is useful to mix the contents by gentle kneading to obtain even activation. The most rapid means of activation is through the use of a microwave oven. (Even the least expensive are suited to this purpose.)

CAUTION:

1. Do not subject pads to intense heat (more than 100°C, hot metal, flame) as this will damage the plastic and cause leaks.
2. When attempting to activate rapidly, do not boil contents within pad, gently mix contents to provide even activation.
3. Beware of sharp edges in ovens and baths which may puncture pads.
4. Activation with burners, hairdryers and other sources capable of heating the surface to more than 100°C are not recommended.
5. An activated pad will increase its temperature for as long as additional heat is added; for example, if stored in boiling water. The contents must then cool to phase change temperature before isothermal energy transfer can occur. If accidental overheating occurs, pads may be cooled in water with gentle kneading until the liquid-solid phase change begins to occur.
6. Old pads will hold a higher temperature as they pass life expectancy. Please check your pad's temperature periodically to assure the safety of your animals.

CARE AND CLEANING

DELTAPHASE PADS are a complete self-contained heat transfer system. Store unused pads at room temperature; do not freeze. Avoid temperature extremes. Protect pads from accidental puncture. Pads may be cleaned with

soap, mild detergents and water. Organic solvents should be avoided. Spot test solvents on outside edge of weld to test compatibility.

APPLICATIONS

DELTAPHASE PADS maintain the temperature of animal or object brought in contact with the pad. To reduce conductive heat loss it is helpful to place the pad on an insulating surface. The foam insulators provided are ideal for this purpose.

Small animals fit nicely on the 8" x 8" surface of a single pad. Anesthetized animals may be taped directly to the pad for surgical procedures. Larger animals may be placed on two or more pads. For long term temperature maintenance, pad temperature should be monitored and exhausted pads replaced as necessary. Surfaces not in contact with animal should be covered to extend isothermal time.

To speed recovery, activated pads may be placed directly under plastic rodent cages. Pads may be used directly in large animal recovery cages, but should be removed when animal is fully conscious.

The DELTAPHASE PAD is also valuable whenever 37°C temperatures are required. For example, during the transfer of tissue cultures from one laboratory to another. Intravenous solutions or blood may be warmed either by placing a DELTAPHASE PAD against the container or by placing a coil of infusion tubing between two pads near the site of infusion.

MATERIAL SAFETY DATA SHEET

Deltaphase Isothermal Pads

Company: Braintree Scientific Inc.
P.O. Box 850498
Braintree, MA 02185

Telephone: 781-917-9526

Composition: Active ingredient: Polyethylene Glycol

Physical Data: A white odorless solution provided in a labeled double bag.

Fire and Explosion Hazard: Not considered to be a fire hazard. The polyethylene glycol component has a flash point of > 500F, (> 260C). Appropriate extinguishing media are water fog, alcohol foam, dry chemical. Polyethylene glycol dust in air can be explosive. Prevent contact of dust and possible ignition sources.

Reactivity: Stable. Product degrades when stored at elevated temperatures in presence of air.

Environmental and Disposal Information:

SPILLS - Should not be left on floor (makes it slippery).

DISPOSAL - Burn in an approved incinerator in accordance with all federal state and local requirements.

Healthy Hazard Data:

EXTERNAL - May cause slight transient (temporary) eye irritation. Prolonged or repeated skin exposure is not likely to cause significant skin absorption. May cause a more severe response if skin is abraded. Prolonged or repeated exposure of damaged skin, as in burn wounds, may result in absorption.

INHALATION: Vapors are unlikely at room temperature due to physical nature.

SYSTEMIC AND OTHER EFFECTS - The Deltaphase Isothermal Pad is designed for warming small animals during surgery. It is for external use only. Based upon available data, repeated exposures to Polyethylene Glycol (outside of the pad) are not anticipated to cause any significant adverse events. Polyethylene glycols have not caused cancer in long term animals studies.

First Aid:

EXTERNAL - Wash off or irrigate affected area with water.

INGESTION - No adverse effects anticipated by this route of exposure incidental to proper handling. If large amounts of solution were ingested get medical attention. Water should be given in copious amounts to prevent dehydration.

NOTE TO PHYSICIAN - No specific antidote. Treatment should be based upon the judgment of the physician in response to reactions of the patient.

Handling Precautions: Good general ventilation should be sufficient for most conditions.

Regulatory Information: STATE RIGHT-TO-KNOW
California Proposition 65

This product contains trace levels of ETHYLENE OXIDE known to the State of California to cause cancer, birth defects or other reproductive harm, and trace levels of ACETALDEHYDE, 1-4 DIOXANE and FORMALDEHYDE known to the State of California to cause cancer.

MASSACHUSETTS Right-To-Know, Substance List (MSL) Hazardous Substances and Extraordinary Hazardous Substances on the MSL must be identified when present in products.

Components present in this product at a level which could require reporting under the statute are:

EXTRAORDINARY HAZARDOUS SUBSTANCES (= > 0.0001 %)

UPPER BOUND

The information presented herein is presented in good faith and believed to be accurate, however, no warranty, express or applied is given. Regulatory requirements are subject to change and may differ from one location to another. Therefore it is the buyer's responsibility to ensure that its activities comply with federal, state and local laws.

HOW TO ORDER

MODEL 39DP	Kit includes: THREE DELTAPHASE® PADS 8" x 8" x 7/8" Three Foam Insulators
MODEL 39OP	Operating Board includes: TWO DELTAPHASE® PADS Two Foam Insulators Operating Board and Steel Plate
	Pads Sold Separately DP-PAD 8" x 8" x 7/8" DP-SASB 6" x 4" x 1/4" DPIP 6" x 7.5" x 1/4"
Be sure to include your tax exempt number where applicable.	
Order From:	BRAINTREE SCIENTIFIC, INC. P.O. Box 850498 Braintree, MA 02185 Telephone: 781-917-9526 Fax: 978-244-8917 www.braintreesci.com email:info@braintreesci.com

Satisfaction Guaranteed!

If for any reason you are not fully satisfied, call or write for return instructions.



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