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(54) **ULTRASOUND TRANSMISSION GEL PACKET HAVING INTERNAL HEAT SOURCE AND METHOD OF USE**

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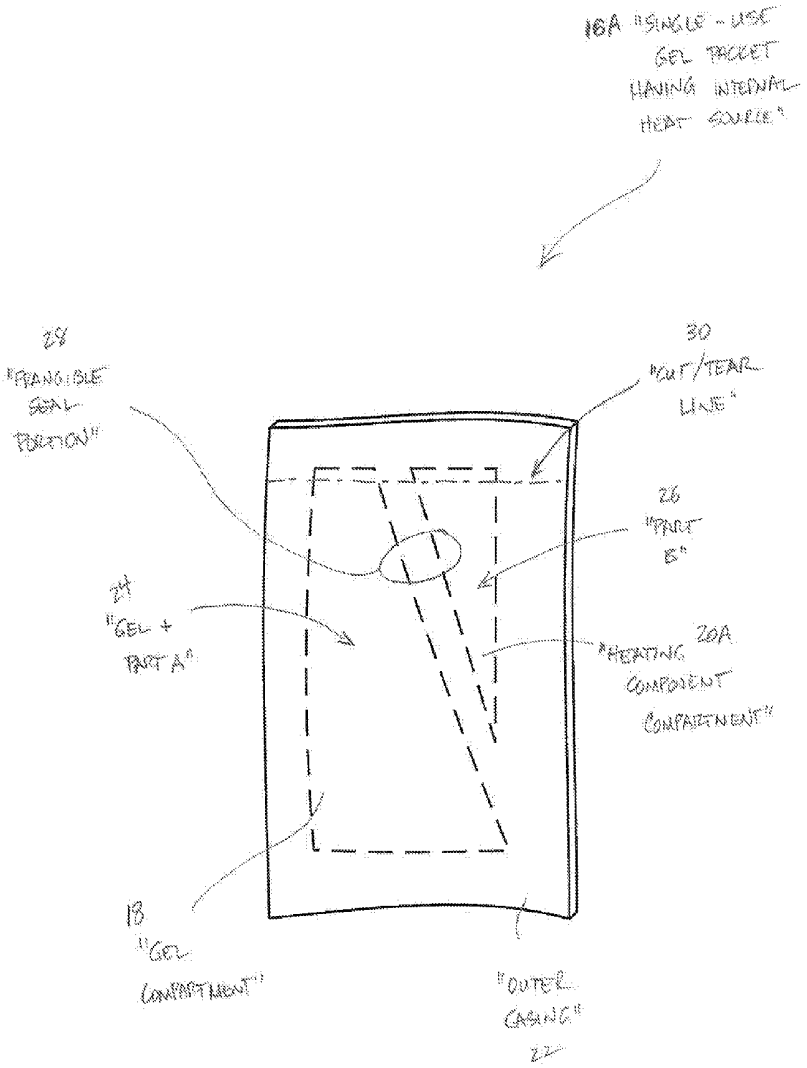
(57) **ABSTRACT**

An Ultrasound Transmission Gel Packet Having Internal Heat Source and Method of Use. The gel packet is sized for a single use, rather than for multiple applications. The gel packets are not pre-heated, but rather are quickly heatable on demand. The gel packets may incorporate a variety of optional internal heating methods, including chemical activation, mechanical agitation and electrical activation, among others. The gel packets are sealed and therefore have extended shelf lives, and further are disposable after use.



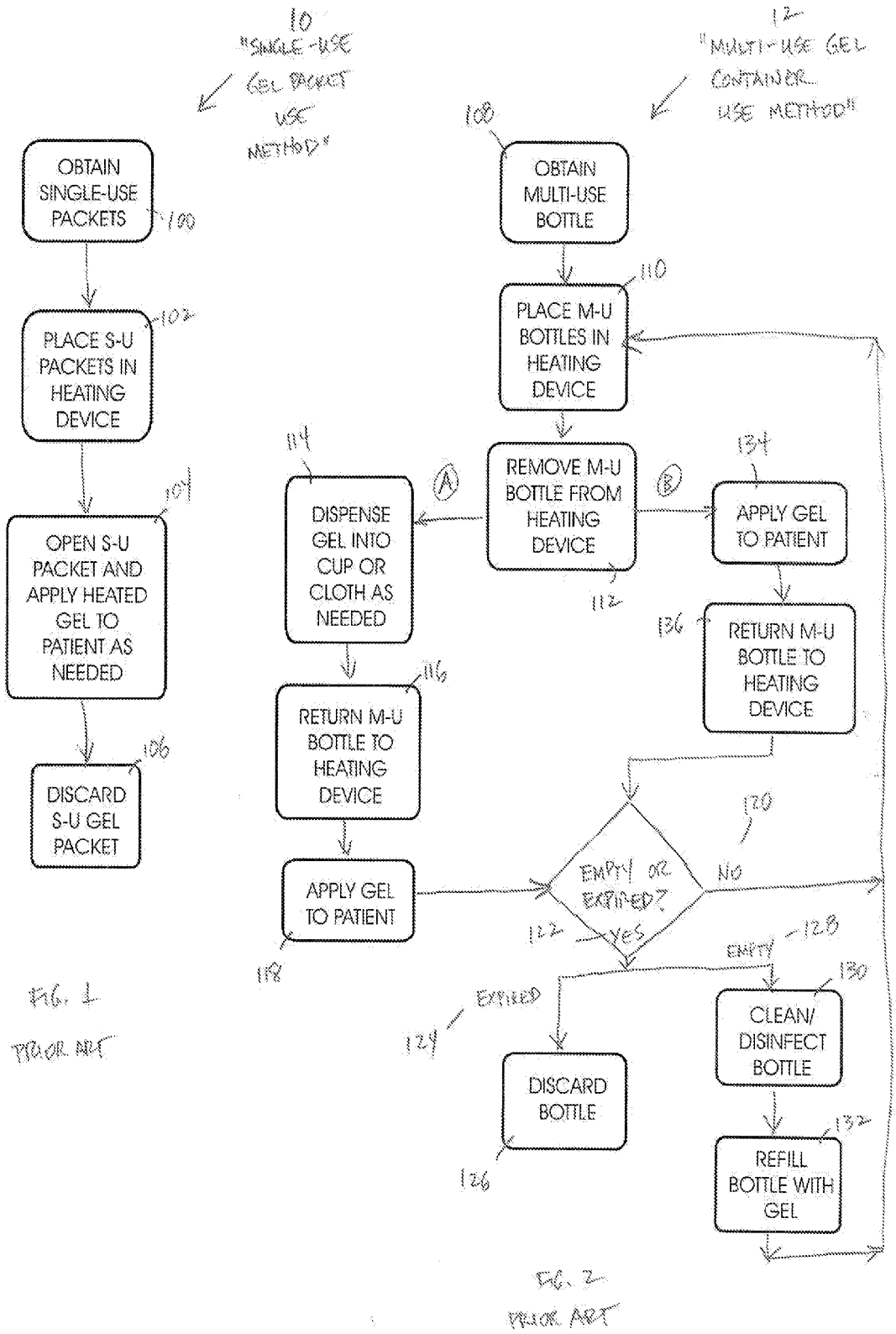
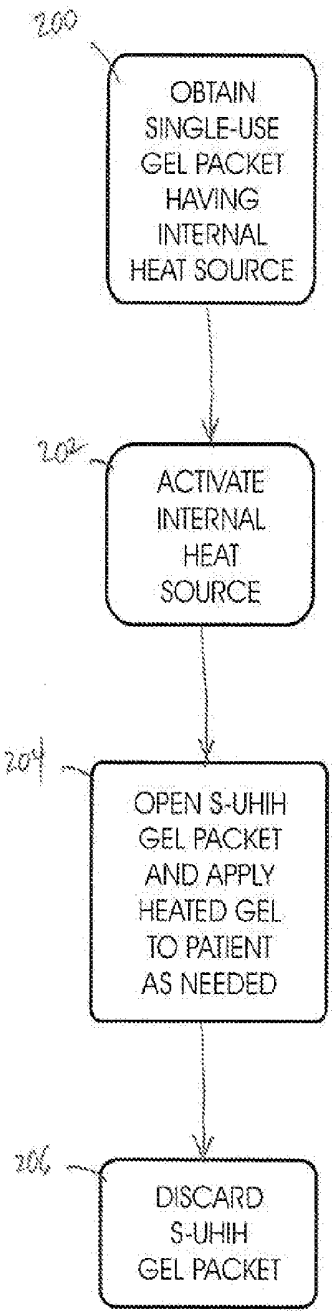


FIG. 1
PRIOR ART

FIG. 2
PRIOR ART



"SINGLE-USE INDIVIDUALLY-HEATABLE GEL PACKET USE METHOD" 14

FIG. 3

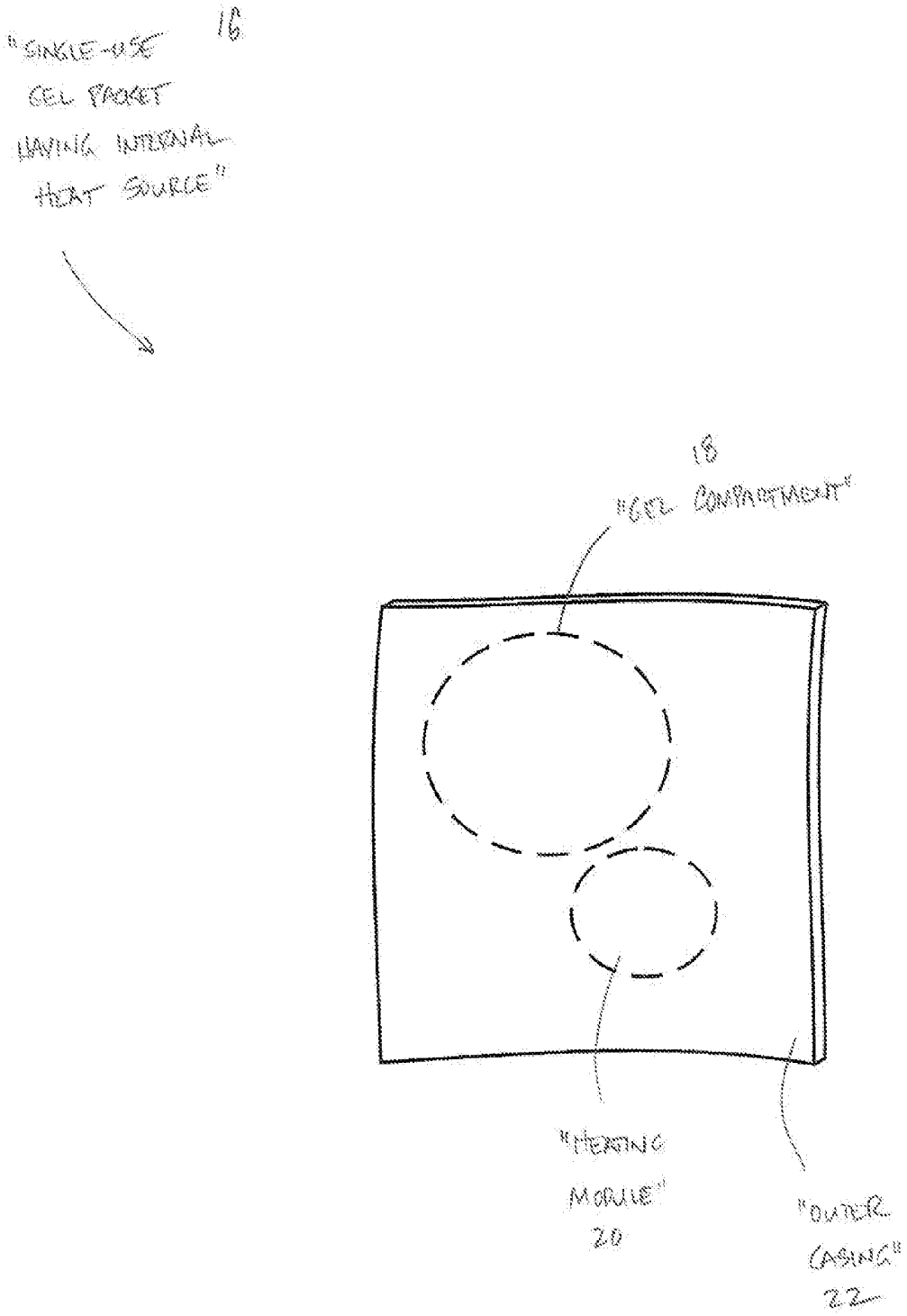

16
"SINGLE-USE GEL PACKET HAVING INTERNAL HEAT SOURCE"
18
"GEL COMPARTMENT"
"HEATING MODULE" 20
"OUTER CASING" 22

FIG. 4

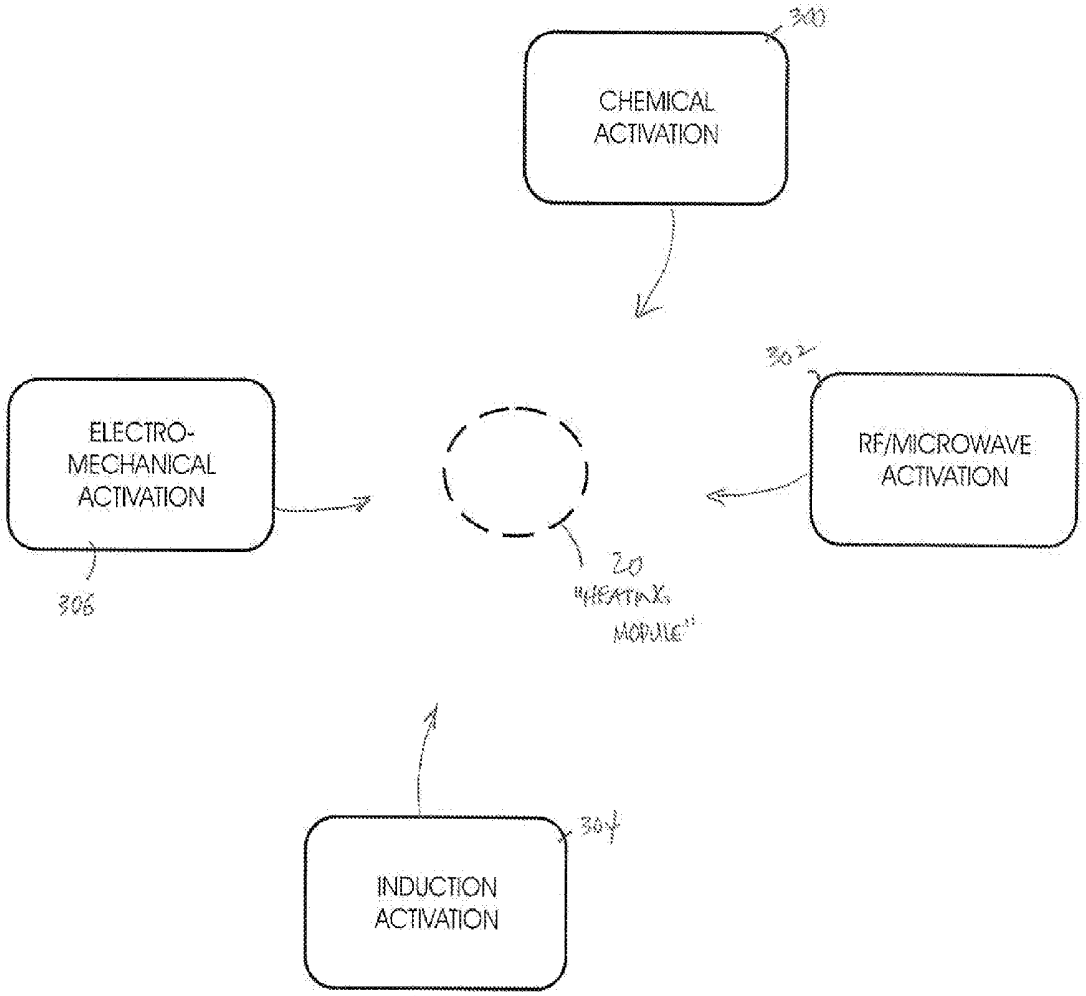

CHEMICAL ACTIVATION
ELECTRO-MECHANICAL ACTIVATION
RF/MICROWAVE ACTIVATION
INDUCTION ACTIVATION

FIG. 5

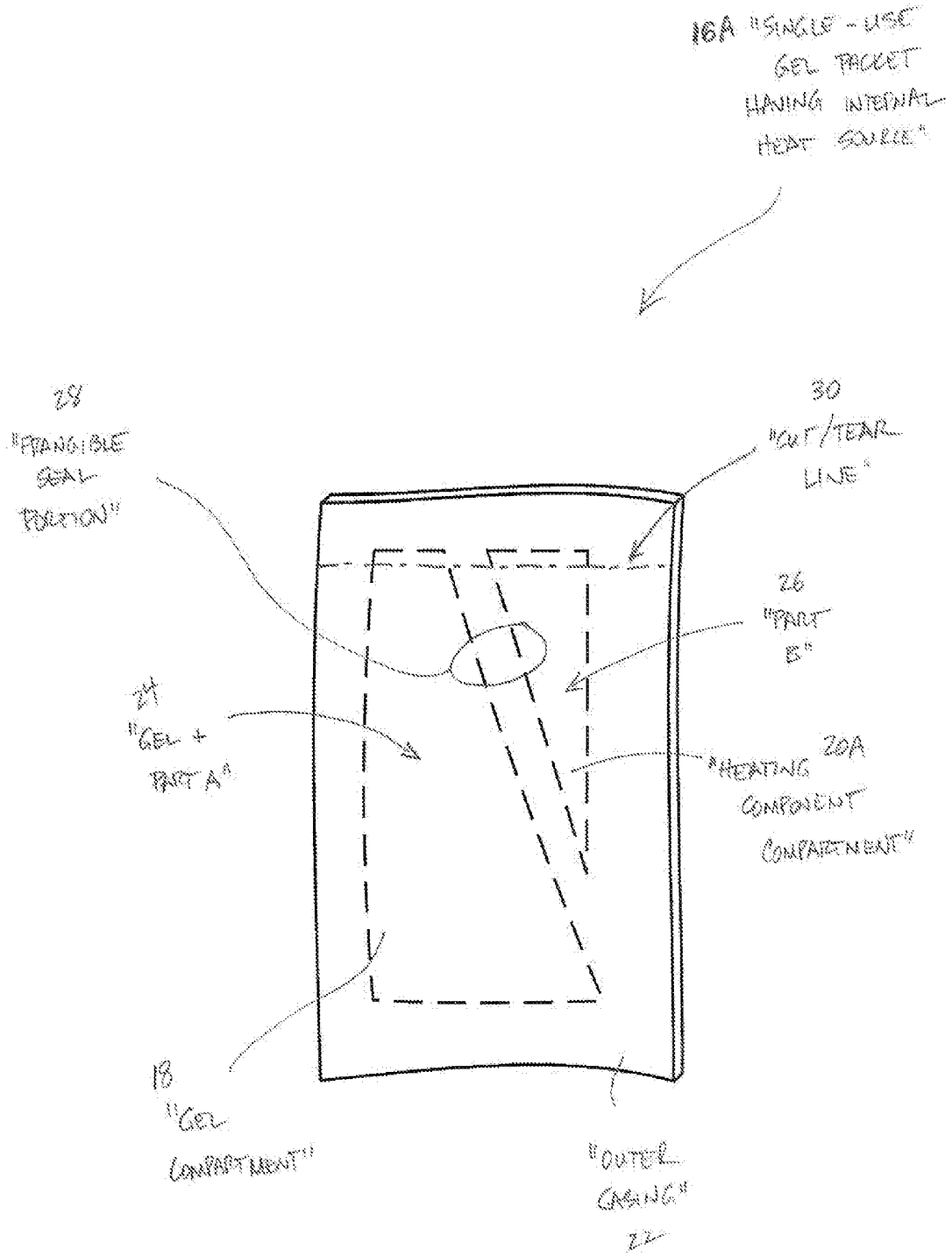

16A "SINGLE-USE GEL PACKET HAVING INTERNAL HEAT SOURCE"
28 "FRANGIBLE SEAL PORTION"
30 "CUT/TEAR LINE"
26 "PART B"
24 "GEL + PART A"
20A "HEATING COMPONENT COMPARTMENT"
18 "GEL COMPARTMENT"
"OUTER CASING" 22

FIG. 6

ULTRASOUND TRANSMISSION GEL PACKET HAVING INTERNAL HEAT SOURCE AND METHOD OF USE

[0001] This application is filed within one year of, and claims priority to Provisional Application Ser. No. 62/356,411, filed Jun. 29, 2016.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0002] This invention relates generally to medical devices and procedures and, more specifically, to an Ultrasound Transmission Gel Packet Having Internal Heat Source and Method of Use.

2. Description of Related Art

[0003] The use of ultrasound technology for the purpose of diagnostic imaging is performed in virtually every hospital and most urgent care facilities in the world. Furthermore, ultrasound scanning is conducted in most of the treatment areas within each health care facility. Because sound does not travel well in air, physicians and technologists performing an ultrasound examination routinely apply a conductive gel to the subject area prior to placing the ultrasound probe against the patient's body. For comfort and other safety reasons (e.g. thermal stress to neonatal infants[1]), it is a common practice for health care facilities to pre-warm the conductive gel prior to patient application. FIGS. **1** and **2** provide the background of how the gel is heated.

[1] "Procedural Hazards of Neonatal Ultrasonography" *J Clin Ultrasound.* 1986 June; 14 (5):361-6.

[0004] Single-use gel packages are often used for dispensing ultrasound gel. FIG. **1** is a flowchart depicting the conventional single-use gel packet use method **10**. Once obtained **100**, the single-use gel packets are typically placed into a dedicated gel-pak warmer **102**. When gel is needed in order to perform an ultrasound scan on a patient, the heated gel packet is retrieved from the warmer, opened, and the heated gel is applied to the patient **104**. The expended gel packet is then discarded **106**.

[0005] In some facilities or environments, multi-use dispensers (e.g. bottles or other containers) of ultrasound gel are employed. FIG. **2** is a flowchart depicting the conventional multi-use gel container use method **12**. The multi-use container is obtained **108** and placed into the warming device **110**, where it/they reside until gel is needed. When desired, the bottle is removed from the heating device **112**, and the heated gel is either applied directly to the patient **134**(and then the bottle returned **136**), or first into a cup or cloth **114**, and then to the patient **118** (usually after returning the bottle to the heating device **116**). This process is repeated until the bottle/container is empty or expired **122**. Expired bottles **124** are discarded **126**. Empty bottles **128** are cleaned and/or disinfected **130**, refilled **132**, and returned to service.

[0006] The problem with these conventional use methods is the prevention of gel contamination. Both methods include a shared or community heating device, typically a water bath or oven, which are known breeding grounds for pathogens. This can easily result in patients contracting a nosocomial infection.[2] While a number of procedures have been developed to curtail this risk, gel bottle warmers continue to be a significant source of nosocomial infection.

[2] See Appendix I

[0007] What is needed is a more sanitary heated gel package and method of use.

SUMMARY OF THE INVENTION

[0008] In light of the aforementioned problems associated with the prior devices and methods, it is an object of the present invention to provide an Ultrasound Transmission Gel Packet Having Internal Heat Source and Method of Use. The gel packet should be sized for a single use, rather than for multiple applications. The gel packets ideally should not be pre-heated, but rather should be quickly heatable on demand. The gel packets should incorporate a variety of optional internal heating methods, including chemical activation, mechanical agitation and electrical activation, among others. The gel packets should be sealed and therefore have extended shelf lives, and further should be disposed of after use.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] The objects and features of the present invention, which are believed to be novel, are set forth with particularity in the appended claims. The present invention, both as to its organization and manner of operation, together with further objects and advantages, may best be understood by reference to the following description, taken in connection with the accompanying drawings, of which:

[0010] FIG. **1** is a flowchart depicting the conventional single-use gel packet use method;

[0011] FIG. **2** is a flowchart depicting the conventional multi-use gel packet use method;

[0012] FIG. **3** is a flowchart depicting a preferred method of use of the single-use individually-heatable gel packets;

[0013] FIG. **4** is a functional perspective view of a single-use gel packet having an internal heat source;

[0014] FIG. **5** is a diagram showing optional heating options for the internal heat source of the gel packet of the present invention; and

[0015] FIG. **6** is a perspective view of a preferred embodiment of a chemically-activated version of the gel packet of FIG. **4**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0016] The following description is provided to enable any person skilled in the art to make and use the invention and sets forth the best modes contemplated by the inventor of carrying out his invention. Various modifications, however, will remain readily apparent to those skilled in the art, since the generic principles of the present invention have been defined herein specifically to provide an Ultrasound Transmission Gel Packet Having Internal Heat Source and Method of Use.

[0017] The present invention can best be understood by initial consideration of FIG. **3**.[3] FIG. **3** is a flowchart depicting a preferred method of use of the single-use individually-heatable gel packets **14**. As discussed previously, the purpose of the instant method and device is to reduce the level of risk of nosocomial infection created by the process steps and the components involved in the heating of ultrasound gel.

[3] As used throughout this disclosure, element numbers enclosed in square brackets [ ] indicates that the referenced element is not shown in the instant drawing figure, but rather is displayed elsewhere in another drawing figure.

[0018] The initial step in this new process involves obtaining a single-use gel packet that has an internal heat source **200**. The design specifics of the individually, internally-heated gel packet will be discussed below in connection with other drawing figures, however, it is sufficient to understand that there is no oven or other water bath involved in the packet-heating process. Each packet is individually heated on an as needed basis in order to minimize the growth and transfer of contaminating microorganisms, as has been shown to be a problem with the prior methods and devices. Consequently, the packages can remain in a hygienic environment until they are removed from the storage container for use.

[0019] The user first obtains a single gel packet of the type described herein below **200**. The internal heat source is then activated within the gel packet **202**. Next, the operator (typically a sonographer or sonologist) opens the gel packet, dispenses the heated gel and applies it to the patient in the area to be scanned **204**. Finally, the operator discards the empty gel package **206**. The steps **200-206** are repeated for each dispensing of heated gel. It should also be noted that if the operator deems that heated gel is not desirable, he or she simply opens the packet and applies the gel without first heating the gel. This additional benefit means that the operator only requires a single source of gel packets, rather than being required to maintain separate inventories of heated and unheated gel packages. FIG. **4** introduces the gel packets used in this process **14**.

[0020] FIG. **4** is a functional perspective view of a single-use gel packet having an internal heat source **16**. The packet **16** is preferably has an outer casing **22** made from sterile, disposable materials. Within the casing, there is a gel compartment **18** and a heating module **20**. As discussed below, the heating module **20** may actually be incorporated into the outer casing **22**, such as to form the gel compartment **18**, in certain versions.

[0021] FIG. **5** is a diagram showing optional heating options for the internal heat source of the gel packet of the present invention. One preferred version of the heating module **20** is by chemical activation—that is to say that the gel in the compartment [**18**] would generally be mixed with a second chemical component (in a second gel compartment [**18**]). When mixed, the two components would generate a desirable amount of heat as a result of the exothermic reaction. This version is more fully described below in connection with FIG. **6**.

[0022] The heating module **20** could also comprise electrical induction activation **304**. This version may have coiled electrical filaments embedded within the casing [**22**] and/or gel compartment [**18**], or even as a series of filaments actually protruding into the gel compartment [**18**] itself. The heating mechanism could be via induction. If a gel package having such a heating module **304** is placed into a magnetic field, the field will cause current to flow through the electrical filaments. The filaments and package will be designed so that they will begin to heat up as current is generated, thereby heating the gel in the compartment [**18**] to the desired temperature. The magnetic field generator could be operated automatically to turn its magnetic field on when a new packet is placed in a predetermined location, and then turn off automatically either after a preset time is reached, or after a preset temperature is reached.

[0023] In another version, the heating module **20** could heat through electro-mechanical means **306**. In this embodiment, a piezoelectric device would be embedded within the casing [**22**] or would protrude into the gel compartment [**18**] itself. When connected to an electrical energy source, the piezoelectric device converts electrical energy into mechanical vibration, thereby generating heat in the gel.[4,5] The energy source could be operated automatically to activate the piezoelectric element or elements when the packet is placed in a predetermined location, and then turn off automatically either after a preset time is reached, or after a preset temperature is reached.

[4] Eduardo Moros, ed., *Physics of thermal therapy: fundamentals and clinical applications*, Imaging in medical diagnosis and therapy (Boca Raton, Fla.: CRC/Taylor & Francis, 2013), 81-82.

[5] Visvanathan, Karthik, and Yogesh B. Gianchandani "Microheaters based on ultrasonic actuation of piezoceramic elements." *Journal of Micromechanics and Microengineering* 21.8 (2011): 085030.

[0024] Finally, the heating module **20** may generate heat via RF or microwave activation. In this version, the gel package would be placed within an RF or microwave-generating device. The casing [**22**] would need to be made from material that is compatible with RF or microwave energy generation. Furthermore, there would need to be safety features, such as overtemp protection and/or room for expansion of the gel as it heats within the compartment [18] in order to prevent the inadvertent explosion of a gel package during the heating process.

[0025] If we now turn to FIG. **6**, we can more closely examine the features of the chemically activated heating module version **300**. FIG. **6** is a perspective view of a preferred embodiment of a chemically activated version **16**A of the gel packet of FIG. **4**. T

[0026] The outer casing **22** will house a two-part gel compartment **18**. As discussed previously, there will be a gel compartment **18** and a heating component compartment **20**A. Part A of the gel **24** will be in the gel compartment **18**. Part B of the gel **26** will be contained within the heating component compartment **20**A. The two compartments **18**, **20**A will be separated by a separation portion **29** of the outer casing **22**.

[0027] In its preferred form, the packet **18**A will have a frangible seal portion **28** that makes up at least a part of the separation portion **29**. This frangible seal portion **28** is designed so that the operator can cause a port to be created between the gel compartment **18** and heating component compartment **20**A without breaking open the outer casing **22**. Once the port between the two compartments **18**, **20**A is created (e.g. by some sort of hand manipulation of the package **18**A by the operator), the two parts of the gel **24**, **26** will come into contact with one another so that they will mix. The parts **24**, **26** are designed to generate heat when they mix with each other.

[0028] There are several possible chemical compositions for warming gel. One possible composition utilizes an acid-base neutralization reaction. These reactions are typically highly exothermic when between a weak acid and strong base, or between a strong acid and weak base. Depending on the specific acids and bases used, the composition could be engineered to leave a neutral pH reaction-this ideally would stay in solution and be non-toxic (e.g. the resulting products of the reaction would be saltwater). This would require a gel, an acidic solution, and a basic solution to be stored in separate compartments prior to activation (each compartment would be separated from the others by inter-compartmental seals/walls). To activate heat generation, the seal between the acid and base would be broken,

allowing the neutralization reaction to take place, producing a salt solution hotter than 40° C., which would then be mixed with a very thick gel by breaking a second frangible seal in the package containing the gel.

[0029] Another possible form of heating the gel utilizes an exothermic reaction via introduction of catalyst(s) whereby heat is produced through polymerizations. In a preferred form, the dissolution of an anhydrous salt into the gel is an effective method of warming. The two salts that have the highest enthalpy of solution are calcium chloride and magnesium chloride. On the assumption that the mass of the gel is 30 g and that it's heat capacity is 4.18 J/(K·g), the required enthalpy to heat the gel from 21° C. to 40° C. is calculated using Equation 1 below:

$$\Delta H = c_p \cdot m \cdot \Delta T = 4.18 \frac{\mathrm{J}}{\mathrm{K \cdot g}} \cdot 30\ \mathrm{g} \cdot 19\ \mathrm{K} = 2383\ \mathrm{J}$$

Based upon the standard enthalpies of formation, the standard enthalpies of the solution for anhydrous calcium chloride and anhydrous magnesium chloride are −82.0 kJ/mol and −155.0 kJ/mol, respectively. Thus, using the molar masses of the two salts, the amount of salt needed to achieve a 19° C. temperature increase is 3.23 g of calcium chloride or 1.46 g of magnesium chloride. The difference in masses between salt types shows that the use of magnesium chloride would decrease the mass of salts required and, as discussed below, would likely decrease both the activation time and the introduction of air into the gel. The theoretical numbers for each salt are detailed in Table I below.

TABLE I

Theoretical Salt Requirements

Compound	Standard enthalpy of solution (kJ/mol)	Molar Mass (g)	Required Mass (g)
Calcium Chloride (anhydrous)	−82.0	111.0	3.23
Magnesium Chloride (anhydrous)	−155.0	95.2	1.46

[0030] Several additional viable formulations have been developed, with all containing similar ingredients. All of the formulations contain a cellulosic thickener, glycerin, deionized water, sodium benzoate, and an anhydrous salt. Two different thickeners were used including Natrosol 250 HHR (a hydroxyethylcellulose), and KELTROL CG-T (a xanthan gum). Both of the thickeners are used in a wide range of products, and are very pH stable. Because these thickener products are nonionic, their combination with salts will not affect their ability to thicken into a gel. Glycerin, which acts as a stabilizer and emulsifier, is also a common additive in many cosmetic formulations. It aids in keeping the hydroxyethylcellulose or xanthan gum stable in the gel. Sodium benzoate, which is a common preservative and is compatible with both Natrosol 250 HHR and xanthan gum.

[0031] Continuing with preferred form options, a two-part system for heating of clear gel by the addition of an anhydrous salt is described. This is a two-part formulation which consists of a base gel, which, when mixed with an anhydrous salt, heats up to about 40° C. (depending on ambient storage temperature). After activation, these gel formulations have viscosities at 37° C. that are similar to current products on the market, such as Aquasonic 100, Aquasonic Clear, and Clear Image Singles, which all range from 35000-41000 cP. Two variations of this formulation were prepared and tested. The first was a two-part formulation which consisted of a gel made with hydroxyethylcellulose (HEC, Natrosol 250 HHR), glycerin, and sodium benzoate. Hydroxyethylcellulose is a cellulosic thickener used in a wide range of industries and used in levels ranging from 0.1-3.0%. It is stable in the pH range of 2-12, and its ability to thicken into a gel is nonionic, therefore salts do not affect its viscosity. Glycerin is a common additive to many cosmetic formulations as a stabilizer and emulsifier that stabilizes the hydroxyethylcellulose within the gel. Sodium benzoate is a common preservative and is compatible with Natrosol 250 HHR. For a 30 g transmission gel, a base gel containing 96.10% deionized water, 2.62% hydroxyethylcellulose, 1.16% glycerin, and 0.12% sodium benzoate was made. Next, 4.05 g of anhydrous calcium chloride was added, raising the temperature to from 23.4° C. to 41.6° C. It took approximately 45 seconds to activate, and the final viscosity after activation at 37° C. was 40800 cP.

[0032] A second iteration of this two-part formulation utilized anhydrous magnesium chloride instead of anhydrous calcium chloride. The base gel for this formulation kept the ratio of the hydroxyethylcellulose to water in the base gel the same while keeping the percent of glycerin and sodium benzoate the same in the overall formula. For a 30 g transmission gel, a base gel containing 96.21% deionized water, 2.62% hydroxyethylcellulose, 1.16% glycerin, and 0.12% sodium benzoate was made according to the section below. Next, 1.8 g of anhydrous magnesium chloride was added, raising the temperature to from 22.9° C. to 41.6° C. It took approximately 15 seconds to activate, and the final viscosity after activation at 37° C. was 42800 cP. Because anhydrous magnesium chloride has a much higher standard enthalpy of solution, much less material was needed to achieve the same temperature increase as when anhydrous calcium chloride was substituted. Both the anhydrous calcium chloride and the anhydrous magnesium chloride required about 1.4-1.6 times the theoretical amount of salt (based off thermodynamic data found using Equation 1 and data in Table I), most likely due to heat loss through the package during the activation period, but also possibly due to unavoidable water uptake from exposure to atmosphere during testing. Handling the salts under inert gas during the manufacturing/packaging process might reduce the amount of salt required.

[0033] Another option is the formation of a gel by mixing a powder with a second component that is in liquid phase. This requires the use of a thickener that has a lower required temperature for activation KELTROL CG-T is a xanthan gum specifically designed to produce a more transparent gel than most other xanthan gums. Both KELTROL CG-T and the anhydrous salts tested were in the form of a fine powder, so these were mixed to form a homogeneous powder. The water, glycerin, and sodium benzoate were mixed together and then added to the powdered components and then mixed continuously. The temperature immediately rose to 44.1° C. (this slightly higher temperature was chosen in order to help decrease hydration time of the thickener as well as compensate for heat loss through the packaging during the longer activation time). This option would decrease manufacturing costs considerably, but at the cost of a longer activation time

(1.5-2 min). Additionally, the gel is not as transparent and is therefore visually distinct as compared to current gel products on the market.

[0034] A three phase system for gel warming is described. This option used the same ingredient percentages as Formulations 1 and 2, but separates it into 3 phases in order to decrease the activation time. An amount of water (roughly 40% for each formulation) equal to that from Phase A would be kept as a separate phase (Phase C). Activation of this formula consists of mixing Part B and Part C together, and then be adding this mixture to Part A, and then mixing thoroughly. This decreased the activation time significantly because the dissolution of the salt into water was much faster than dissolution of the salt into a gel. However, the drawback was the final gel formed was not homogenous due to Phase A being too thick. Natrosol 250 HHR has a maximum usage of 3.0%, but when the water is not included in Phase A, Natrosol 250 HHR content increases to about 4.5%. At this concentration the hydroxyethylcellulose is not fully hydrated and the resulting gel is too thick and very clumpy. In order for the further addition of water to be effective, the Natrosol 250 HHR would still need to be fully hydrated, which requires time and a temperature of at least 55° C., thus when Phase CB were mixed in with this thicker form of Phase A, they remained separate and a homogeneous gel was not obtained.

[0035] Once the now-mixed gel has reached the desired temperature, the operator opens the casing **22**, such as by cutting or tearing off the end of the packet **18**A along a line **30** that denotes an end of the two compartments **18**, **20**A, as depicted here. The heated gel is applied directly to the patient's body, and then the used package **18**A is discarded.

[0036] Those skilled in the art will appreciate that various adaptations and modifications of the just-described preferred embodiment can be configured without departing from the scope and spirit of the invention. Therefore, it is to be understood that, within the scope of the appended claims, the invention may be practiced other than as specifically described herein.

APPENDIX I

"Fomites and Infection transmission" Infection Control Today magazine 11/07/2006 ***In a systematic review of the literature, German researchers explored the ability of infectious organisms to survive on inanimate surfaces. They found that most gram-positive bacteria, including VRE, MRSA and streptococcus pyogenes can survive for months on dry surfaces." "In the hospital environment, surfaces with which hands come in contact are often contaminated with Nosocomial pathogens, and may serve as vectors for cross-contamination." (*****A fomite is any object that may be contaminated with infectious organisms and serve in their transmission.)**

"Sustained Endemicity of Burkholderia Cepacia Complex in a Pediatric Institution, Associated with Contaminated Ultrasound Gel."" Infection Control Hospital Epidemiology 2006, April 27; 362-6 Conclusions: Contaminated ultrasound gel contributed to nosocomial infection due to B. cepacia complex in this institution over the course of 10 years.

"Sonographers and the Fight Against Nosocomial Infections: How Are We Doing?" JDMS 21: 7 –11, January/February 2005: **One in six (16.7%) gel bottle tips contaminated with bacteria/fungi.**

Health Products and Food Branch of Canada Safety Alert October 2004: ***Risk of Serious Infection from Ultrasound and Medical Gels – Notice to Hospitals.*** *In order to minimize the health risks associated with the use of ultrasound gels, Health Canada is making the following recommendations: Single Use Containers are recommended for non-sterile gel.*

"An Outbreak of Pyodermas Among Neonates caused by Ultrasound Gel Contaminated with Methicillin-Susceptible Staphylococcus Aureus." December 2000 *Infection Control and Hospital Epidemiology* Volume 21, No. 12. *Conclusion: Inappropriate hygienic measures in connection with lubricants (gels) during routine ultrasound scanning may lead to nosocomial S aureus infections of the skin.*

"An Investigation of the microbiological contamination of ultrasound equipment" Sykes A', Appleby M, Perry J, Gould K. British Journal of Infection Control August 2006 Vol 7 NO. 4. This study was undertaken to determine the extent of contamination of ultrasound equipment including probe, probe holder, keyboard and gel. *The results revealed that 64.5% of the samples were contaminated with environmental organisms, 7.7% with potential pathogens* and 27.8% were no growth.

"Iatrogenic urinary tract infection with Pseudomonas cepacia after transrectal ultrasound guided needle biopsy of the prostate" Journal of Urology 1993, March;

149(3) "Environmental investigations revealed the ultrasound transmission gel as the source of the contamination."

"Nosocomial Outbreak of Klebsiella pneumoniae Producing SHV-5 Extended-Spectrum - Lactimase, Originating from a Contaminated Ultrasonography Coupling Gel."" *Journal of Clinical Microbiology*, May 1998 p 1357 -1360 *"To summarize, this outbreak showed unique features., i.e., very early cross-contamination, lack of recognized risk factors of patients, transmission of the multiresistant strain by a soiled ultrasonography coupling gel, and intrapartum contamination of two neonates.* ***It highlights the necessity of evaluation of nosocomial risks associated with procedures with good safety records such as ultrasonography."***

"Ultrasound Instruments as Possible Vectors of Staphylococcal Infection."" *Journal of Hospital Infection Control*, September 1998, 40 (1) 73 -7 *"S. Aureus was more resistant to the ultrasonic medium than Pseudomonas aeruginosa, also a significant cause of hospital-acquired infections."*

"Risk of Staphylococcus Aureus Transmission during Ultrasound Investigation," *Journal of Ultrasound in Medicine*, November 1989 8 (11): 619 20. *"An investigation of staphylococcal transmission between patients undergoing routine abdominal ultrasound procedures was carried out to assess the potential risks of cross-infection. Two of 19 patients were shown to have become colonized as a result of the procedure and some evidence is presented of possible interpatient cross-colonization. It is suggested that this is an underestimation of the potential of cross-infection and simple inexpensive infection control procedures are suggested."*

"Burkholderia cepacia infections associated with intrinsically contaminated ultrasound gel: the role of microbial degradation of parabens." Infection Control and Hospital Epidemiology. 2004 Apr;25(4):291-6. CONCLUSIONS: Ultrasound gel is a potential source of infection.

"Physical methods of reducing the transmission of nosocomial infections via ultrasound and probe." Clinical Radiology 1998 Mar; 53(3):212-4 "Nosocomial infections are posing an increasingly serious problem in the hospital setting. With the increasing use of ultrasound in medical diagnosis, there is the potential for transmission of nosocomial infections via the ultrasound transducer and coupling gel."

APIC Archives established mechanisms of Gel Contamination including:

- *Contamination during dispensing practices* – i.e., use of large containers purchased as a bulk supply and refilling smaller containers as needed for daily use.
- *Environmental contamination* via nipple style tip.
- *Contamination at point of use* – a patient or ultrasound probe could harbor pathogenic organisms. The application of gel involves squeezing the bottle to dispense

gel. If the bottle is not withdrawn before pressure is released, the vacuum formed within the bottle could aspirate both gel and flora from the surface of the patient or the probe into the bottle.

"**Ultrasound Gel: a breeding ground for germs?**" *ADVANCE for Imaging and Radiation Therapy Professionals*, June 3, 2002

An Epidemic, Toxin Gene–Variant Strain of *Clostridium difficile*, L. Clifford McDonald, M.D., George E. Killgore, Dr.P.H., Angela Thompson, M.M.Sc., Robert C. Owens, Jr., Pharm.D., Sophia V. Kazakova, M.D., M.P.H., Ph.D., Susan P. Sambol, M.T., Stuart Johnson, M.D., and Dale N. Gerding, M.D.

- A previously uncommon strain of *C. difficile* with variations in toxin genes has become more resistant to fluoroquinolones and has emerged as a cause of geographically dispersed outbreaks of *C. difficile* –associated disease. Strict infection-control measures, including contact precautions, should be instituted for all patients with *C. difficile*–associated disease.
- This article highlights the risks of using multiple use gel bottles where they are used on successive patients and Ultrasound Technicians touch the patient and the outside of the gel bottle with their gloved hands. The outside of the gel bottle becomes contaminated with microorganisms, such as c. difficile, and a vector for spreading infection.

(*Source Sonotech, Inc. "Journal Citation - Infection Control Risk with Bottles of Ultrasound Scanning Gel:"*

What is claimed is:

1. A method for applying heated gelatinous material to the skin of a patient, comprising the steps of:

obtaining a container containing gelatinous material and a heating device;

activating said heating device whereby said heating device produces heat;

waiting for a sufficient amount of time until said gelatinous material is heated;

opening said container and applying said heated gelatinous material to the skin of the patient.

2. The method of claim **1**, wherein said heating device of said container obtaining step comprises a module that generates heat as a result of a chemical reaction between two or more chemicals contained within said heating device.

3. The method of claim **1**, wherein said heating device of said container obtaining step comprises a material that generates heat responsive to the application of microwaves thereto.

4. The method of claim **1**, wherein said heating device of said container obtaining step comprises a material that generates heat responsive to the application of Radio Frequency energy thereto.

5. The method of claim **1**, wherein said heating device of said container obtaining step comprises a material that generates heat responsive to application of a magnetic field thereto.

6. The method of claim **1**, wherein said heating device of said container obtaining step generates heat in response to physical manipulation.

7. The method of claim **6**, wherein said heating device of said container obtaining step comprises a piezoelectric transducer that vibrates responsive to the application of electrical current.

8. A self-heating packet containing gelatinous material, comprising:

an outer casing;

a compartment within said casing containing gelatinous material; and

a heating module contained within said casing in spaced relation to said gelatinous material compartment.

9. The self-heating packet of claim **8**, wherein said heating module comprises a module that generates heat as a result of a chemical reaction between two or more chemicals contained within said heating module.

10. The self-heating packet of claim **8**, wherein said heating module comprises a material that generates heat responsive to the application of microwaves thereto.

11. The self-heating packet of claim **8**, wherein said heating module comprises a material that generates heat responsive to the application of Radio Frequency energy thereto.

12. The self-heating packet of claim **8**, wherein said heating module comprises a material that generates heat responsive to application of a magnetic field thereto.

13. The self-heating packet of claim **12**, wherein said application of a magnetic field thereto generates electrical current that results in said heating module generating heat.

14. The self-heating packet of claim **8**, wherein said heating module generates heat in response to physical manipulation.

15. The self-heating packet of claim **14**, wherein said module comprises an element that generates physical movement responsive to the application of electrical current thereto.

16. The self-heating packet of claim **15**, wherein said physical movement generation element comprises a piezoelectric transducer.

17. An ultrasonic gel packet, comprising:

an outer casing;

non-solid material contained within a first compartment;

a heating component material contained within a second compartment; and

a frangible seal portion separating said first compartment from said second compartment.

18. The packet of claim **17**, wherein said non-solid material and said heating component material cooperate to generate heat and a gelatinous material when mixed together.

19. The packet of claim **18**, wherein said frangible seal portion is configured to allow a user to rupture said seal while not rupturing said outer casing.

20. The packet of claim **19**, wherein said non-solid material and said heating component material are allowed to mix when said frangible seal portion is ruptured.

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专利名称(译)	具有内部热源的超声透射凝胶包及使用方法		
公开(公告)号	US20180002096A1	公开(公告)日	2018-01-04
申请号	US15/638199	申请日	2017-06-29
[标]申请(专利权)人(译)	STEINS ROBERT		
申请(专利权)人(译)	STEINS，ROBERT		
当前申请(专利权)人(译)	STEINS，ROBERT		
[标]发明人	STEINS ROBERT		
发明人	STEINS, ROBERT		
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优先权	62/356411 2016-06-29 US		
其他公开文献	US10556734		
外部链接	Espacenet USPTO		

摘要(译)

具有内部热源的超声透射凝胶包及使用方法。凝胶包的尺寸适合单次使用，而不是用于多种应用。凝胶包不是预热的，而是可以根据需要快速加热。凝胶包可以包含多种可选的内部加热方法，包括化学活化，机械搅拌和电激活等。凝胶包是密封的，因此具有延长的保质期，并且在使用后还可以是一次性的。