MicroPort Orthopedics

ORTHOSET® RADIOPAQUE BONE CEMENT

150812-0

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*** The CE-Marking of Conformity is applied per catalog number and appears on the outer label, if applicable.**

℞ ONLY

October 2013
Printed in U.S.A

EN

Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

ORTHOSET® RADIOPAQUE BONE CEMENT (150812-0)

OUTLINE:

I. GENERAL PRODUCT INFORMATION

A. DESCRIPTION

ORTHOSET® Radiopaque Bone Cement consists of a two component system: a sterile ampule containing bone cement liquid within a blister pack, and a sterile polyethylene bag containing bone cement powder within a peelable pouch. The interiors of the blister pack and peelable pouch are sterile.

Sterilization of the bone cement liquid is achieved by microfiltration; the blister pack by ethylene oxide, and the bone cement powder and peelable pouch by gamma radiation.

Liquid Component

Bone cement liquid is a colorless, flammable liquid with a distinctive odor. Its major component is methyl methacrylate, which has the formula:

$$CH_2 = C\text{-}COOCH_3$$
$$|$$
$$CH_3$$

(Methyl Methacrylate)

Hydroquinone is added as a stabilizer to prevent premature polymerization, which may occur under conditions such as heat or light. N,N-Dimethyl-p-toluidine is added to promote polymerization following the mixing of the liquid and the powder components.

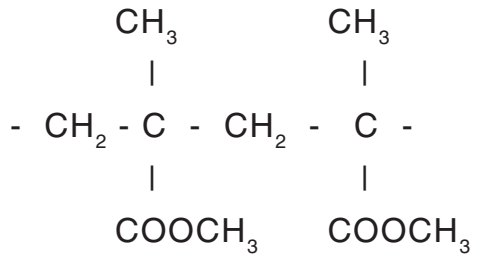
Compositions:

ORTHOSET® 1	ORTHOSET® 2	ORTHOSET® 3
Methyl Methacrylate – 99.18% w/w N,N-Dimethyl-p-toluidine (max) – 0.82% w/w Hydroquinone – 25ppm	Methyl Methacrylate – 98.75% w/w N,N-Dimethyl-toluidine – 1.25 % w/w Hydroquinone – 25 ppm	Methyl Methacrylate – 97.50% w/w N,N-Dimethyl-p-toluidine (max) – 2.50% w/w Hydroquinone – 25ppm

ORTHOSET® UNI CEMENT	ORTHOSET® Premier LV	ORTHOSET® Premier HV
Methyl Methacrylate – 98.75% w/w N,N-Dimethyl-toluidine – 1.25 % w/w Hydroquinone – 25 ppm	Methyl Methacrylate – 99.10% w/w N,N Dimethyl-p-toluidine (max) – 0.90% w/w Hydroquinone – 75 ppm	Methlyl Methacrylate – 99.10% w/w N,N-Dimethyl-p-toludine (max) – 0.90% w/w Hydroquinone – 75 ppm

Powder Component

Bone cement powder is a white, finely divided powder. Its major component is polymethyl methacrylate, which has the general formula:



(Polymethyl Methacrylate)

The polymethyl methacrylate contains benzoyl peroxide that initiates polymerization when the powder and liquid components are mixed. The barium sulfate is present as a radiopaque agent.

Compositions:

ORTHOSET® 1	**ORTHOSET® 2**	**ORTHOSET® 3**
Polymethyl Methacrylate – 88.85% w/w Benzoyl Peroxide – 2.05% w/w Barium Sulfate – 9.10% w/w	Polymethyl Methacrylate – 86.70% w/w Benzoyl Peroxide – 2.00% w/w Barium Sulfate – 11.30% w/w	Polymethyl Methacrylate – 88.00% w/w Benzoyl Peroxide – 2.00% w/w Barium Sulfate – 10.00% w/w

ORTHOSET® UNI CEMENT	ORTHOSET® Premier HV	ORTHOSET® Premier LV
Polymethyl Methacrylate – 86.70 % w/w Benzoyl Peroxide – 2.00% w/w Barium Sulfate – 11.30% w/w	Poly (methyl methacrylate – styrene) co-polymer 84.30% w/w Benzoyl Peroxide – 2.70% w/w Barium Sulfate – 13.00% w/w	Poly (methyl methacrylate-styrene) co-polymer – 88.27% w/w Benzoyl Peroxide – 2.73% w/w Barium Sulfate – 9.00% w/w

B. INDICATIONS

ORTHOSET® Radiopaque Bone Cement is indicated for the fixation of prostheses to living bone in orthopedic musculoskeletal surgical procedures for rheumatoid arthritis, osteoarthritis, traumatic arthritis, sickle cell anemia, osteoporosis, avascular necrosis, collagen disease, severe joint destruction secondary to trauma or other conditions, revision of previous arthroplasty and the fixation of pathological fractures. The ORTHOSET® Radiopaque Bone Cement is an acrylic, cement-like compound that allows seating and securing of a metal or plastic prosthesis into living bone. Upon completion of polymerization, ORTHOSET® Radiopaque Bone Cement is a buffer for even weight distribution and other stresses between prosthesis and bone.

C. CONTRAINDICATIONS

The use of ORTHOSET® Radiopaque Bone Cement in musculoskeletal surgery is contraindicated in the presence of infectious arthritis and in active infection, an incompletely treated infection that could involve the site where the device will be

implanted, or if there is a history of such infection. It is also contraindicated where loss of musculature or neuromuscular disease compromising the affected limb would render the procedure unjustifiable.

D. DOSAGE AND APPLICATION

The ORTHOSET® Radiopaque Bone Cement package consists of an amber colored ampule containing bone cement liquid within a blister pack and a polyethylene bag containing bone cement powder within a peelable pouch.

A dose is prepared by mixing the entire contents of the ampule with the entire contents of the bone cement powder bag.

E. PREPARATION

CAUTION: Personnel wearing contact lenses should not be near or involved in mixing this bone cement.

Bone cements are heat sensitive. Any increase in temperature, either ambient, or of the cement components and mixing equipment above 23°C, will result in shorter doughing, working, and setting times. Conversely, lower temperatures will increase the doughing, working, and setting times.

The peelable pouch and blister pack are opened by a circulating nurse. The sterile powder bag and sterile ampule of the same batch are aseptically transferred into the sterile operative area.

The powder bag is opened with sterile scissors and the entire contents emptied into a suitable clean, dry, sterile mixing bowl made from an inert material.

The ampule of bone cement liquid is opened and the entire content are emptied evenly onto the powder in the mixing bowl (either in a well-ventilated area, or using a suitable exhaust system).

F. WARNINGS

Adverse cardiovascular reactions, including hypotension, hypoxemia, cardiac arrhythmia, bronchospasm, cardiac arrest, myocardial infarction, pulmonary embolism, cerebrovascular accident and possible death: Hypotensive reactions can occur between 10 and 165 seconds after application of the PMMA bone cement and can last for 30 seconds to 5 more minutes. Some hypotensive reactions have progressed to cardiac arrest. The blood pressure of patients should be monitored carefully during and immediately following the application of the PMMA bone cement. In addition, overpressurization of the PMMA bone cement should be avoided during the insertion of the PMMA bone cement and implant in order to minimize the occurrence pulmonary embolism.

Surgeon training and experience: The surgeon should be thoroughly familiar with the properties, handling characteristics and application of the PMMA bone cement. Because the handling and curing characteristics of this cement vary with temperature and mixing technique, they are best determined by the actual surgeon's experience.

Device volatility and flammability and electrocautery devices: As the liquid monomer is highly volatile and flammable, the operating room should be provided with adequate ventilation to eliminate the maximum amount of monomer vapor. Ignition of monomer vapors caused by the use of electrocautery devices in surgical sites near freshly implanted bone cement has been reported.

Irritation of the respiratory tract, eyes, and the liver: Caution should be exercised during the mixing of the liquid and powder components of the PMMA bone cement to prevent

excessive exposure to the concentrated vapors of the liquid monomer, which may produce irritation of the respiratory tract, eyes, and possibly the liver. Personnel wearing contact lenses should not mix PMMA bone cement or be near the mixing of the PMMA bone cement.

Contact Dermatitis: The liquid component is a powerful lipid solvent. It has caused contact dermatitis in susceptible individuals. Wearing of a second pair of surgical gloves and strict adherence to the mixing instructions may diminish the possibility of hypersensitive reactions. The compound should not be allowed to come into direct contact with sensitive tissue or be absorbed by the body. The liquid component should not be allowed to come into contact with rubber including rubber gloves.

Follow-up studies in the literature report satisfactory durability, wearability, and stability of properly cemented prostheses. However, loosening and fracture of either the cement or the prosthesis or both because of disease, trauma, inadequate cementing technique, mechanical failure of the materials, high stresses from excessive physical activity, obesity or latent infection may occur. Therefore, long term follow-up is advised for all patients on a regularly scheduled basis.

Recent animal studies of reproduction in mice, using methyl methacrylate monomer have shown no adverse effect on litter size and resorption when the monomer was used in a concentration 13.3 times higher than the permissible 8-day weighted time average of 110 ppm for humans.

A study in rats found no effect on litter size but some effect on the litter weight and number of fetal malformations which the authors ascribed to the maternal toxicity of the high monomer concentration employed (268 times higher than the permissible 8-day weighted average of 110 ppm for humans). A carcinogenicity study in rats did not show any cancer formation attributable to the device. However, until long-term use data are available, the carcinogenic potential of the device in humans is unknown.

Because of the lack of adequate information, the use of bone cement is not recommended in younger patients or pregnant women.

G. PRECAUTIONS

Evidence from clinical investigation clearly indicates the necessity for strict compliance to good, aseptic surgical technique. It is important to note that deep wound infection will present a serious threat to the ultimate performance of the prosthesis. Such an infection may be latent and not present itself for several years postoperatively. The patient should be monitored carefully for any change in blood pressure during and immediately following the insertion of the cement. Any hypoxia and hypovolemia should be brought up to as near a normal level as possible before surgery.

Contact dermatitis: The liquid monomer has caused contact dermatitis in those handling and mixing PMMA bone cement. Strict adherence to the instructions for mixing the powder and liquid components may reduce the incidence of contact dermatitis.

Hypersensitivity reactions: The liquid component of the PMMA bone cement is a powerful lipid solvent. It should not contact rubber or latex gloves. Double gloving and strict adherence to the mixing instructions may diminish the possibility of hypersensitivity reactions. The mixed PMMA bone cement should not contact the gloved hand until the cement has acquired the consistency of dough, about one or two minutes after mixing.

Inadequate post-operative fixation: Inadequate fixation or unanticipated post-operative events may affect the PMMA cement-bone interface and lead to micro-motion of cement against the bone surface. A fibrous tissue layer may develop between the PMMA bone cement and the bone causing loosening of the prosthesis. Periodic follow-up is advised for all patients.

Exothermic reaction: Polymerization of the PMMA bone cement is an exothermic reaction that occurs while the bone cement is hardening *in situ*. The released heat may damage bone or other tissue adjacent to the implant. Temperature rises reported in the literature are well below the denaturation temperature of body protein and the initial thermal and chemical tissue necrosis is temporary. Retrieval of implanted cement has shown that bone will grow next to firmly fixed cement. However, if inadequate fixation leading to micro-motion of the cement against the bone surface is present, a fibrous tissue layer will tend to develop between the cement and the bone and loosening of the prosthetic component may follow.

Extrusion: Extrusion of the PMMA bone cement beyond the region of its intended application may occur resulting in the following complications: hematuria; dysuria; bladder fistula; delayed sciatic nerve entrapment from extrusion of the bone cement beyond the region of its intended application; local neuropathy; local vascular erosion and occlusion; and intestinal obstruction because of adhesions and stricture of the ileum from the heat released during the exothermic polymerization.

Use in pregnant women and children: The safety and effectiveness of the PMMA bone cement in pregnant women and in children has not been established.

Expiration dating: PMMA bone cement should not be used after the expiration date because the effectiveness of the device may be compromised.

Disposal: Because of the volatility and flammability of the liquid monomer of the PMMA bone cement, the liquid monomer should be evaporated in a well-ventilated hood or absorbed by an inert material and transferred into a suitable container (one that does not react with the PMMA bone cement) for disposal.

Patient counseling: Patient counseling is necessary as the patient may need instructions to avoid excessive physical activity and weight gain to limit the mechanical stresses placed on the bone/cement/implant composite.

Because of possible hematogenous spread of infection to the implant site, patients who subsequently contract infectious diseases should be advised to seek medical advice at once to reduce the risk for potential revision surgery.

Although the results of animal teratology studies with acrylic bone cement were negative, the use of ORTHOSET® Radiopaque Bone Cement in pregnancy or by women of child bearing age requires that the potential benefits be weighed against the possible hazards to the mother or fetus.

H. ADVERSE EVENTS

Listed below are the most serious and frequent adverse reactions, some with fatal outcome, which may occur with the use of bone cement. The surgeon should be aware of these reactions and be prepared to treat such reactions if they are encountered.

The most serious adverse reactions reported with the use of, but not directly related to PMMA bone cement are: (1) myocardial infarction, (2) cerebrovascular accident, (3) cardiac arrest, (4) sudden death, and (5) pulmonary embolism.

The most frequent adverse reactions reported are: (1) transitory fall in blood pressure, (2) thrombophlebitis, (3) hemorrhage and hematoma, (4) loosening or displacement of the prosthesis, (5) superficial or deep wound infection, (6) trochanteric bursitis, (7) short-term cardiac conduction irregularities, (8) heterotopic new bone formation, (9) trochanteric separation, (10) elevated serum gamma-glutamyl-transpeptidase (GGTP) up to 10 days postoperation; and (11) pain and/or loss of function.

Other potential adverse events associated include: (1) allergic pyrexia, (2) hematuria, (3) dysuria, (4) bladder fistula, (5) delayed sciatic nerve entrapment from extrusion of the bone cement beyond the region of its intended application; (6) local neuropathy; (7) local vascular erosion and occlusion, (8) intestinal obstruction because of adhesions, and (9) stricture of the ileum from the heat released during the exothermic polymerization.

Important Physician's Information

Adverse reactions affecting the cardiovascular system have been attributed to leakage of unpolymerized liquid monomer into the circulatory system. More recent data indicate that the monomer undergoes rapid hydrolysis to methacrylic acid, and that a significant fraction of the circulating methacrylate is in the form of the free acid rather than the methyl ester. Correlation between changes in circulating concentrations of methyl methacrylate/ methacrylic acid and changes in blood pressure have not been established. Hypotensive episodes reported appear to occur primarily in patients with elevated or high normal blood pressure, in hypovolemia, and in individuals with pre-existing cardiovascular abnormalities.

If a hypotensive reaction occurs, the onset may appear 10 to 165 seconds following application of the bone cement. Its duration may last from 30 seconds to 5-6 minutes. Although the etiology of cardiac arrest is unclear, it may well be either direct embolic effects or secondary to hypoxia produced by pulmonary embolic phenomena. Clinical experience has shown that fat, bone marrow, and air emboli can be significantly reduced by scrupulous cleaning of the medullary cavity prior to inserting the cement.

II. SPECIFIC PRODUCT INFORMATION

A. ORTHOSET® 1

Mixing Instructions

Mixing with the spatula should be carried out until the semifluid mass acquires the consistency of dough. This occurs about one minute after the addition of the monomer liquid to the powder. The mass can now be manipulated in the gloved hand.

The time will be approximately one and a half minutes after starting the mix, but the actual time is affected by the ambient temperature of the room. If the cement sticks to the surface of the gloves, it has been handled too soon and will require additional kneading time. The mixing is complete and the cement bolus is ready to use after approximately 2-2.5 minutes. The handling and setting characteristics of the ORTHOSET® 1 Radiopaque Bone Cement vary with temperature and mixing technique, and are best determined by actual experience by the surgeon.

Insertion Instructions

Clinical experience has shown that fat, bone marrow, and air emboli can be significantly reduced by scrupulous cleaning of the medullary cavity prior to inserting the cement. After the digital application of the bone cement, the prosthesis is inserted, and held firmly in position until the bone cement is hard. Excess bone cement must be removed before the bone cement is completely hardened. The final hardening is approximately 8 to 9 minutes after adding the fluid to the powder or 5 to 6 minutes after completing the insertion of the bone cement. **Note that during the last 5 minutes the cement, though still not set, is too stiff to insert into a narrow cavity.**

The times provided are average times, since the temperature of the operating room and the heat of the surgeon's hands can make a considerable difference in the handling characteristics of the bone cement. ORTHOSET® 1 Radiopaque Bone Cement is relatively quick setting cement that minimizes the period of waiting for the cement to set during the surgical operation. This cement has no adhesive capabilities and relies on a close mechanical interlocking of the irregular surfaces between the prosthesis and the bone.

How Supplied

Each 40g unit contains:

1. One sterile bag containing 40g of sterile radiopaque bone cement powder.
2. One sterile ampule containing 18.37g of sterile bone cement liquid.

B. ORTHOSET® 2 AND ORTHOSET® UNI CEMENT

Mixing Instructions

Mixing with the spatula could be carried out until the semifluid mass acquires the consistency of dough. This occurs about .75 minute (45 seconds) after addition of the monomer liquid to the powder. The mass can now be manipulated in the gloved hand. The time will be approximately one and a half minutes after starting the mix, but the actual time is affected by the ambient temperature of the room. If the cement sticks to the surface of the gloves it has been handled too soon and will require additional kneading time. The mixing is complete and the cement bolus is ready to use after approximately 1 minute. The handling and setting characteristics of the ORTHOSET® 2 Bone Cement vary with temperature and mixing technique and are best determined by actual experience by the surgeon.

Insertion Instructions

Clinical experience has shown that fat, bone marrow, and air emboli can be significantly reduced by scrupulous cleaning of the medullary cavity prior to inserting the cement. After the digital application of the bone cement, the prosthesis is inserted. Its position must be maintained securely without movement until the bone cement is hard and the prosthesis is firmly in position. Excess bone cement must be removed before the bone cement is completely hardened. The final hardening is approximately 4.5- 5 minutes after adding the fluid to the powder or 2-3 minutes after completing the insertion of the bone cement. **Note that during the last 2 minutes the cement, though still not set, is too stiff to insert into a narrow cavity.**

The times provided are average times since the temperature of the operating room, and the heat of the surgeon's hands, can make a considerable difference in the handling characteristics of the bone cement.

ORTHOSET® 2 Bone Cement is a fast setting cement, which minimizes the period of waiting for the cement to set during the surgical operation. This cement has no adhesive capabilities and relies on a close mechanical interlocking of the irregular surfaces between the prosthesis and the bone.

How Supplied

Each 20g unit contains:

1. One sterile bag containing 20g of sterile radiopaque bone cement powder.
2. One sterile ampule containing 9.19 g of sterile bone cement liquid.

C. ORTHOSET® 3

Mixing Instructions

Mixing with the spatula should be carried out for one minute after the addition of the monomer liquid to the powder. The cement can be inserted by means of a cement gun or a syringe or it can be inserted digitally.

Insertion Instructions

Clinical experience has shown that fat, bone marrow, and air emboli can be significantly reduced by scrupulous cleaning of the medullar cavity prior to inserting the cement.

Cement Gun/Syringe Insertion

After one minute of mixing, the liquid cement can be transferred into a cement gun cartridge or syringe and is ready for extrusion after 2-2.25 minutes from start of mix. The cement should be extruded within a further 1-1.25 minutes (3.5 minutes from start of mix) and the prosthesis is then inserted and held firmly in position until the cement is hard. Excess bone cement must be removed before the bone cement has completely hardened. CAUTION - do not shorten mixing or waiting cycle. Do not inject until at least two minutes from start of mix.

Digital Insertion

After one minute of mixing, the liquid cement is left in the mixing bowl until it is ready to be taken into the gloved hands at approximately 4.5 minutes from start of mix. After digital insertion of the bone cement, the prosthesis is inserted, and held firmly in position until the bone cement is hard. Excess bone cement must be removed before it has completely hardened. The final hardening is approximately 8.5 – 9.5 minutes after adding

the liquid to the powder. **Note that during the last 3.5 minutes the cement, though still not set, is too stiff to insert into a narrow cavity.**

The times provided are average times, since the temperature of the operating room and the heat of the surgeon's hands can make a considerable difference in the handling characteristics of the bone cement. ORTHOSET® 3 Radiopaque Bone Cement is relatively quick setting cement that minimizes the period of waiting for the cement to set during the surgical operation. This cement has no adhesive capabilities and relies on a close mechanical interlocking of the irregular surfaces between the prosthesis and the bone.

How Supplied

Each 40g unit contains:

1. One sterile bag containing 40g of sterile radiopaque bone cement powder.
2. One sterile ampule containing 17.9g of sterile bone cement liquid.

D. ORTHOSET® PREMIER HIGH VISCOSITY

Mixing Instructions

Mixing with a spatula should be carried out until all the powder is uniformly incorporated into the liquid. This occurs about 30-60 seconds after the addition of the monomer liquid to the powder. Allow the mixture to rest for 1-2 minutes before manual use. The actual resting time is affected by the ambient temperature of the room. If the cement sticks to the surface of the gloves it has been handled too soon and will require additional resting time. After the resting period, the cement can be removed from the bowl and manipulated for approximately 1-2 minutes prior to application. During this period, the

cement fully maintains its plasticity, and the dough does not adhere to surgical gloves. Use of dry gloves is recommended for the mixing, kneading, and digital application of the bone cement.

Insertion Instructions

Clinical experience has shown that fat, bone marrow, and air emboli can be significantly reduced by scrupulous cleaning of the medullary cavity prior to inserting the cement. After the digital application of the bone cement, insert the prosthesis. Hold the prosthesis securely in position, without movement, until the bone cement is hard and the prosthesis is firmly in position. Remove any excess bone cement before it has completely hardened. The final hardening is approximately 3-4 minutes after the cement is inserted into the bone cavity. **Note that during the last 3 minutes the cement, though still not set, is too stiff to insert into a narrow cavity.**

The times provided are average times since the temperature of the operating room, the temperature of the mixing materials, and the heat of the surgeon's hands, can make a considerable difference in the handling characteristics of the bone cement.

ORTHOSET® Premier HV Bone Cement is a fast setting cement, which minimizes the period of waiting for the cement to set during the surgical operation. This cement has no adhesive capabilities and relies on a close mechanical interlocking of the irregular surfaces between the prosthesis and the bone.

How Supplied

Each unit contains:

1. One sterile pouch containing 45g sterile radiopaque bone cement powder.
2. One sterile vial containing 15g sterile bone cement liquid.

E. ORTHOSET® PREMIER LOW VISCOSITY

Mixing Instructions

Mixing with a spatula should be carried out until all the powder is uniformly incorporated into the liquid. This occurs about 30-60 seconds after the addition of the monomer liquid to the powder. Once the powder has been uniformly incorporated into the liquid, the mass is handled according to the cement application technique to be used. Use of dry gloves is recommended for the mixing, kneading, and digital application of the bone cement.

Insertion Instructions

Clinical experience has shown that fat, bone marrow, and air emboli can be significantly reduced by scrupulous cleaning of the medullary cavity prior to inserting the cement.

Syringe application without cannula

After 1 minute of mixing, transfer the cement into the syringe using a spatula. Allow the mixture to rest 2-3 minutes then squeeze out the cement.

Syringe application with cannula

After 1 minute of mixing, transfer the cement into the syringe using a spatula. Leave the cement in the syringe for only 1 minute, then squeeze out quickly. The cement should be used no later than 3 minutes from the start of mixing.

Digital Insertion

Following mixing, allow the dough to rest approximately 3-4 minutes, until the viscosity has increased and the cement has a dough consistency. After the resting period, the cement can be removed from the bowl and manipulated approximately 3-4 minutes prior to application.

After application of the bone cement, insert the prosthesis. Hold the prosthesis securely in position, without movement, until the bone cement is hard and the prosthesis is firmly in position. Remove any excess bone cement before it has completely hardened. The final hardening is approximately 3-4 minutes after competing the insertion of the bone cement. **Note that during the last 3 minutes the cement, though still not set, is too stiff to insert into a narrow cavity.**

The times provided are average times since the temperature of the operating room, the temperature of the mixing materials, and the heat of the surgeon's hands, can make a considerable difference in the handling characteristics of the bone cement.

ORTHOSET® Premier LV Bone Cement is a fast setting cement, which minimizes the period of waiting for the cement to set during the surgical operation. This cement has no adhesive capabilities and relies on a close mechanical interlocking of the irregular surfaces between the prosthesis and the bone.

How Supplied

Each unit contains:

1. One sterile pouch containing 45g sterile radiopaque bone cement powder.
2. One sterile vial containing 15g sterile bone cement powder.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.