Bravo HV
Bravo MV

EN(US)

Bravo HV Sterile radiopaque bone cement
High viscosity

EN(US)

Bravo MV Sterile radiopaque bone cement
Medium viscosity

Caution: Federal Law (USA) restrict this device to sale by or on the order of a physician

BRAVO HV Radiopaque bone cement

Device Description

BRAVO HV bone cement is a self-curing, radiopaque, polymethylacrylate (PMMA) based cement which is used for securing a metal or polymeric prosthesis to living bone in arthroplasty procedures. The hardened bone cement secures the fixation of the grafted artificial joint improving the transfer of forces at the interface of the implant-bone.

The bone cement is supplied as a two-component system, consisting of separate, sterile liquid and powder components, which are mixed together at the point of use to produce the cement.
The liquid component is sterilized by membrane filtration and aseptically filled into a sterile glass ampoule. The ampoule is contained within a sealed blister pack, which is sterilized using ethylene oxide. The powder component is contained in a Tyveck/PE pouch, within a peelable pouch and is sterilized by ethylene oxide. The sterile powder component is supplied within an outer, protective, non-sterile, laminated foil pouch.
BRAVO HV bone cement is a high viscosity cement, primarily intended for manual application.

Pack size	
Powder weight (g)	40,00
Liquid volume (ml)	18,30

Composition

The qualitative and quantitative composition of the bone cement is specified in the tables below:

Composition of the powder component (% w/w)	
Polymethyl Methacrylate	88,8
Benzoyl Peroxide	1,2
Barium Sulfate	10,0

Composition of the liquid component (% w/w)	
Methyl Metacrylate	97,50
N,N dimethyl-p-toluidine	2,5
Methy Ether of Hydroquinone	50 ppm

Intended use

BRAVO HV radiopaque bone cements is intended for use in arthroplasty procedures of the hip, knee, ankle, shoulder and other joints for the fixation of polymer or metallic prosthetic implants to living bone.

Contraindications

The use of **BRAVO HV** is contraindicated:

- when a patient is known to be hypersensitive to the constituents of bone cement or to the contrast medium (barium sulfate);
- when the local or systemic infections not completely resolved;
- where there is no possibility of bone regeneration;
- during pregnancy or breast-feeding: The safety and effectiveness of the radiopaque bone cements in pregnant women or in children has not yet been established.

Precautions/Warnings

Bone cement preparation:

- **BRAVO HV** bone cement is supplied sterile for single use only. Do not re-use. Re-sterilization of any components of the cement must not be attempted.
- Ensure the inner packages and components are undamaged. Powder should be consistent (no agglomerations) and not yellow or brown in color. The contents within the vial should appear as a medium viscosity liquid. Do not use the liquid monomer if it shows any sign of thickening or premature polymerization. Always check the condition of the liquid monomer before performing the procedure. If the powder has a yellowish or brownish color or if the liquid is syrupy, do not use product. This indicates the product has not been stored properly.
- A dose is prepared by mixing the entire contents of the bag of cement powder with all the monomer liquid of an ampoule. The quantity of cement dough required depends on the specific surgical intervention and on the technique being used. At least one additional dose of **BRAVO HV** should be available before commencing the operation.
- The protective outer foil pouch and the outer peelable pouch are non-sterile and must not be transferred into the sterile field
- The surgeon should, by specific training and experience, be thoroughly familiar with the properties, handling characteristics and application of bone cements. The user is advised to practice the entire procedure of mixing, handling and introducing **BRAVO HV** before using it for the first time. Detailed knowledge is necessary even if mixing systems and syringes are being used for application of the cement. Because the handling and curing characteristics of these cements vary with temperature and mixing technique, they are best determined by the surgeon's actual experience.
- Handling characteristics and setting time of bone cements are affected by:
  - temperature
  - humidity
  - vacuum mixing
- Refer to clinical timing and usage charts at the end of this leaflet for effect of temperature on handling and setting times.
- Manual handling of the cement and body temperature will reduce the final setting time.
- Variations in humidity will affect the cement handling characteristics and setting time.

- Variations in setting time over the cement's shelf life can be minimized by storing the cement under the recommended conditions
- The surgeon should be familiar with the effects of a particular mixing system on handling characteristics and setting time of the cement before use. Vacuum mixing can noticeably accelerate the setting time of the product.

Handling of the liquid monomer:

- As the liquid monomer is highly volatile and flammable, the operating room should be adequately ventilated to eliminate as much monomer vapor as possible. Ignition of monomer fumes caused by use of electrocautery devices in surgical sites near freshly implanted bone cements has been reported.
- Caution should be exercised during the mixing of the two components to prevent excessive exposure to the concentrated vapors of the monomer, which may produce: irritation of the respiratory tract, eyes, and possibly the liver; contact dermatitis. If the liquid component comes into contact with the eyes, wash with copious amounts of water.
- Concentrated vapors of the liquid component may have an adverse reaction with contact lenses. Since soft contact lenses are permeable to liquids and gases, they should be worn in the operating theather if methyl metacrylate is being used.
- Methyl methacrylate has been demonstrated to cause hypersensitivity in susceptible persons, which may result in an anaphylactic response.
- The liquid component of bone cement is a powerful lipid solvent. This liquid component should not be allowed to come into contact with rubber or latex surgical gloves. Wearing of a second pair of gloves and strict adherence to the mixing instructions may diminish the possibility of hypersensitivity reactions. Gloves made of PVP (polyethylene, ethylene vinylalcohol copolymer, polyethylene) and Viton ®/butyl gloves have proved to provide good protection over a lengthy period. For safety's sake it is recommended that two pairs of gloves be worn over one another, e.g. one polyethylene surgical glove over an inner pair of standard latex surgical gloves. The use of latex or polystyrene-butadiene gloves on their own is inadequate. Please make enquiries with your supplier to establish which gloves are suitable for such an application.

Bone cement application:

- Clinical studies show the need to maintain strictly aseptic surgical procedures. Any deep infection of a surgical wound is a serious risk and will affect the successful outcome of the technique. Deep wound infection is a serious post-operative complication and may require total removal of the embedded cement. Deep wound infection may be latent and not manifest itself even for several years post-operatively.
- Patients should be carefully monitored for any change in blood pressure during and immediately following the application of bone cement. Adverse patient reactions affecting the cardiovascular system have been associated with the use of bone cements, these include: hypotension, hypoxemia, cardiac arrhythmia, bronchospasm, cardiac arrest, myocardial infarction, pulmonary embolism, cerebrovascular accident and possible death. Hypotensive reactions have occurred between 10 and 165 seconds following application of bone cement; they have lasted from 30 seconds to 5 or more minutes. Some have progressed to cardiac arrest. In addition, the over-pressurization of the bone cement should be avoided during the insertion of the bone cement and the implant in order to minimize the occurrence of pulmonary embolism.
- The preparation of the bone marrow cavity results in marrow contents entering the blood stream. Prior to the application of bone cement to the bone, the cavity should be thoroughly cleaned by brushing and washing (lavage) to remove fat, marrow and other debris. The cavity should be kept as dry as possible to prevent blood and debris becoming mixed with the cement. Thorough cleaning of the bone reduces the risk of marrow content being forced into the vascular system during the insertion of bone cement and subsequent pressurization. The expulsion of bone marrow has been associated with the occurrence of pulmonary embolisms, and this risk has been found to be increased in patients with highly osteoporotic bone and patients diagnosed with femoral neck fracture. Reaming of the marrow cavity can have similar effects on mean arterial pressure as the introduction of the bone cement. Marrow cavities should be vented when the cement is introduced digitally.
- Consideration should be given to the use of acrylic bone cement in patients diagnosed with femoral neck fracture, as some published literature has indicated there is a potential for increased mortality compared with uncemented techniques.
- Inadequate fixation or unanticipated post-operative events may affect the cement-bone interface and lead o micromotion of the cement against bone surfaces with which the cement is in contact. A fibrous tissue layer may develop between the cement and the bone. Long term follow-up is advised for all patients on a regular scheduled basis.
- Prosthesis to be implanted must be compatible with the use of bone cement.
- The completion of cement polymerization occurs in the patient and is an exothermic reaction with considerable liberation of heat. The long term effects of the heat produced in situ have not yet been established.

Incompatibilities

- Aqueous solutions (e.g. ones containing antibiotics) must not be added to the bone cement because they have a considerable detrimental effect on the physical and mechanical properties of the cement.

Precautions during pregnancy, breast-feeding and in children.

- The safety and effectiveness of **BRAVO HV** bone cements in pregnant women or in children has not yet been established.

Adverse events

Serious adverse events, some with fatal outcome, associated with the use of acrylic bone cements include:

- Myocardial infarction.
- Cardiac arrest.
- Cerebrovascular accident.
- Pulmonary embolism.
- Anaphylaxis.

The most frequent adverse reactions reported with acrylic bone cements are:

- Transitory fall in blood pressure.
- Elevated serum gamma-glutamyl-transpeptidase (GGTP) up to 10 days post-operation.
- Thrombophlebitis.
- Hemorrhage and hematoma.
- Pain and/or loss of function.
- Loosening or displacement of the prosthesis.
- Superficial or deep wound infection.
- Trochanteric bursitis.
- Short-term cardiac conduction irregularities.
- Heterotopic new bone formation.
- Trochanteric separation.

Other potential adverse events reported for bone cements include:

- Hypoxemia.
- Cardiac arrhythmia.
- Bronchospasm.
- Adverse tissue reaction.
- Pyrexia due to allergy to the bone cement.
- Hematuria.
- Dysuria.
- Bladder fi stula.
- Local neuropathy.
- Local vascular erosion and occlusion.
- Transitory worsening of pain due to heat released during polymerization.
- Delayed sciatic nerve entrapment due to extrusion of the bone cement beyond the region of its intended application.
- Intestinal obstruction because of adhesions and stricture of the ileum due to the heat released during cement polymerization.

Dose

Choose the dose considering the intervention to be performed. As a preventive measure, it is advisable to keep at hand at least a second package of **BRAVO HV** bone cement to be able to prepare an extra quantity of bone cement, if required during the procedure.
The maximum recommended dose of **BRAVO HV** bone cement is of 3 packs.

Directions for use

Cement Preparation

- The protective outer foil pouch, the outer peelable pouch of the powder component and the blister pack enclosing the ampoule of liquid component, should be opened by a circulating nurse. The inner bag (or pouch) containing the powder component and the sterile ampoule containing the liquid component are aseptically transferred into the sterile operative area.
- The sterile bag (or pouch) containing the powder component is opened with sterile scissors and the entire contents are emptied into a suitable clean, dry, sterile mixing vessel made from an inert material (such as glass, ceramic, stainless steel, or non-reactive plastics). The sterile ampoule containing the liquid component is opened and the entire contents are emptied evenly onto the powder in the mixing vessel.
- A standard dose of bone cement is prepared by mixing the entire liquid contents of the ampoule with the entire contents of the powder bag. The amount of mixed cement required for clinical use is determined by the surgeon in each individual case.

Mixing and Digital Application

- **BRAVO HV** can be applied digitally. The surgeon must use their clinical judgement to decide when the cement is
- of a suitable viscosity to allow the surgical procedure to continue.
- Prior to cement application, it is recommended that a cement restrictor is always used during cementation of the femur and that this is introduced at the required depth.
- The cement is mixed thoroughly but carefully to minimize the entrapment of air. Once a dough is formed the surgeon should wait until the cement no longer adheres to the glove. The cement can then be taken into gloved hands and kneaded thoroughly. It is vital that premature insertion of cement is avoided as this may lead to a drop in the patient's blood pressure. To avoid this, the appearance of the cement should be observed to ensure the surface has become dull as opposed to shiny. Also cement should not adhere excessively to the surgeon's gloves. The time of cement application and prosthesis insertion is at the discretion of the surgeon and will depend upon the surgical procedure used.
- Implant insertion should be carried out at a time appropriate for the bone/joint and prosthesis design concerned. In general, implant insertion should be delayed until the cement has developed a sufficient degree of viscosity to resist excessive displacement by the implant. However, implant insertion should not be delayed such that there is a risk that the procedure cannot be completed due to cement hardening.
- Following introduction the implant must be firmly held in position to avoid movement and pressurization must be maintained until the cement finally hardens. Excess bone cement must be removed before the cement has completely hardened.

The handling characteristics and setting times are affected by ambient temperature. Please refer to the end of the instruction leaflet for guidance charts (Note: the usage charts were generated under controlled laboratory conditions).

Storage

- Store the sealed outer pack between 5°C (41°F) and 25°C (77°F) and protect it from light to prevent premature polymerization of the liquid monomer component.
- Store at the intended operating room temperature for a minimum 24 hrs before use.
- Do not use the product after the expiration date.

Disposal

Dispose the remaining of **BRAVO HV** bone cement and the content of partially utilized, expired, not usable or damaged packages in an authorized waste facility; any leftover liquid component should be evaporated under a well-ventilated hood or absorbed by an inert material and transferred to a suitable container for disposal.

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BRAVO MV Radiopaque bone cement

Device Description

BRAVO MV bone cement is a self-curing, radiopaque, polymethylacrylate (PMMA) based cement which is used for securing a metal or polymeric prosthesis to living bone in arthroplasty procedures. The hardened bone cement secures the fixation of the grafted artificial joint improving the transfer of forces at the interface of the implant-bone.

The bone cement is supplied as a two-component system, consisting of separate, sterile liquid and powder components, which are mixed together at the point of use to produce the cement.
The liquid component is sterilized by membrane filtration and aseptically filled into a sterile glass ampoule. The ampoule is contained within a sealed blister pack, which is sterilized using ethylene oxide. The powder component is contained in a Tyveck/PE pouch, within a peelable pouch and is sterilized by ethylene oxide. The sterile powder component is supplied within an outer, protective, non-sterile, laminated foil pouch.
BRAVO MV bone cement is a medium viscosity cement, primarily intended for syringe application.

Pack size	
Powder weight (g)	34,40
Liquid volume (ml)	20,00

Composition

The qualitative and quantitative composition of the antibiotic bone cement is specified in the tables below:

Composition of the powder component (% w/w)	
Polymethyl Methacrylate	88,8
Benzoyl Peroxide	10,0
Barium Sulfate	1,2

Composition of the liquid component (% w/w)	
Methyl Metacrylate	97,50
N,N dimethyl-p-toluidine	2,5
Methy Ether of Hydroquinone	50 ppm

Intended use

BRAVO MV radiopaque bone cements is intended for use in arthroplasty procedures of the hip, knee, ankle, shoulder and other joints for the fixation of polymer or metallic prosthetic implants to living bone.

Contraindications

The use of **BRAVO MV** is contraindicated:

- when a patient is known to be hypersensitive to the constituents of bone cement or to the contrast medium (barium sulfate);
- when the local or systemic infections not completely resolved;
- where there is no possibility of bone regeneration;
- during pregnancy or breast-feeding: The safety and effectiveness of the radiopaque bone cements in pregnant women or in children has not yet been established.

Precautions/Warnings

Bone cement preparation:

- **BRAVO MV** bone cement is supplied sterile for single use only. Do not re-use. Re-sterilization of any components of the cement must not be attempted.
- Ensure the inner packages and components are undamaged. Powder should be consistent (no agglomerations) and not yellow or brown in color. The contents within the vial should appear as a medium viscosity liquid. Do not use the liquid monomer if it shows any sign of thickening or premature polymerization. Always check the condition of the liquid monomer before performing the procedure. If the powder has a yellowish or brownish color or if the liquid is syrupy, do not use product. This indicates the product has not been stored properly.
- A dose is prepared by mixing the entire contents of the bag of cement powder with all the monomer liquid of an ampoule. The quantity of cement dough required depends on the specific surgical intervention and on the technique being used. At least one additional dose of **BRAVO MV** should be available before commencing the operation.
- The protective outer foil pouch and the outer peelable pouch are non-sterile and must not be transferred into the sterile field
- The surgeon should, by specific training and experience, be thoroughly familiar with the properties, handling characteristics and application of bone cements. The user is advised to practice the entire procedure of mixing, handling and introducing **BRAVO MV** before using it for the first time. Detailed knowledge is necessary even if mixing systems and syringes are being used for application of the cement. Because the handling and curing characteristics of these cements vary with temperature and mixing technique, they are best determined by the surgeon's actual experience.
- Handling characteristics and setting time of bone cements are affected by:
  - temperature
  - humidity
  - vacuum mixing
- Refer to clinical timing and usage charts at the end of this leaflet for effect of temperature on handling and setting times.
- Manual handling of the cement and body temperature will reduce the final setting time.

- Variations in humidity will affect the cement handling characteristics and setting time.
- Variations in setting time over the cement's shelf life can be minimized by storing the cement under the recommended conditions
- The surgeon should be familiar with the effects of a particular mixing system on handling characteristics and setting time of the cement before use. Vacuum mixing can noticeably accelerate the setting time of the product.

Handling of the liquid monomer:

- As the liquid monomer is highly volatile and flammable, the operating room should be adequately ventilated to eliminate as much monomer vapor as possible. Ignition of monomer fumes caused by use of electrocautery devices in surgical sites near freshly implanted bone cements has been reported.
- Caution should be exercised during the mixing of the two components to prevent excessive exposure to the concentrated vapors of the monomer, which may produce: irritation of the respiratory tract, eyes, and possibly the liver; contact dermatitis. If the liquid component comes into contact with the eyes, wash with copious amounts of water.
- Concentrated vapors of the liquid component may have an adverse reaction with contact lenses. Since soft contact lenses are permeable to liquids and gases, they should be worn in the operating theather if methyl metacrylate is being used.
- Methyl methacrylate has been demonstrated to cause hypersensitivity in susceptible persons, which may result in an anaphylactic response.
- The liquid component of bone cement is a powerful lipid solvent. This liquid component should not be allowed to come into contact with rubber or latex surgical gloves. Wearing of a second pair of gloves and strict adherence to the mixing instructions may diminish the possibility of hypersensitivity reactions. Gloves made of PVP (polyethylene, ethylene vinylalcohol copolymer, polyethylene) and Viton ®/butyl gloves have proved to provide good protection over a lengthy period. For safety's sake it is recommended that two pairs of gloves be worn over one another, e.g. one polyethylene surgical glove over an inner pair of standard latex surgical gloves. The use of latex or polystyrene-butadiene gloves on their own is inadequate. Please make enquiries with your supplier to establish which gloves are suitable for such an application.

Bone cement application:

- Clinical studies show the need to maintain strictly aseptic surgical procedures. Any deep infection of a surgical wound is a serious risk and will affect the successful outcome of the technique. Deep wound infection is a serious post-operative complication and may require total removal of the embedded cement. Deep wound infection may be latent and not manifest itself even for several years post-operatively.
- Patients should be carefully monitored for any change in blood pressure during and immediately following the application of bone cement. Adverse patient reactions affecting the cardiovascular system have been associated with the use of bone cements, these include: hypotension, hypoxemia, cardiac arrhythmia, bronchospasm, cardiac arrest, myocardial infarction, pulmonary embolism, cerebrovascular accident and possible death. Hypotensive reactions have occurred between 10 and 165 seconds following application of bone cement; they have lasted from 30 seconds to 5 or more minutes. Some have progressed to cardiac arrest. In addition, the over-pressurization of the bone cement should be avoided during the insertion of the bone cement and the implant in order to minimize the occurrence of pulmonary embolism.
- The preparation of the bone marrow cavity results in marrow contents entering the blood stream. Prior to the application of bone cement to the bone, the cavity should be thoroughly cleaned by brushing and washing (lavage) to remove fat, marrow and other debris. The cavity should be kept as dry as possible to prevent blood and debris becoming mixed with the cement. Thorough cleaning of the bone reduces the risk of marrow content being forced into the vascular system during the insertion of bone cement and subsequent pressurization. The expulsion of bone marrow has been associated with the occurrence of pulmonary embolisms, and this risk has been found to be increased in patients with highly osteoporotic bone and patients diagnosed with femoral neck fracture. Reaming of the marrow cavity can have similar effects on mean arterial pressure as the introduction of the bone cement. Marrow cavities should be vented when the cement is introduced digitally.
- Consideration should be given to the use of acrylic bone cement in patients diagnosed with femoral neck fracture, as some published literature has indicated there is a potential for increased mortality compared with uncemented techniques.
- Inadequate fixation or unanticipated post-operative events may affect the cement-bone interface and lead o micromotion of the cement against bone surfaces with which the cement is in contact. A fibrous tissue layer may develop between the cement and the bone. Long term follow-up is advised for all patients on a regular scheduled basis.
- Prosthesis to be implanted must be compatible with the use of bone cement.
- The completion of cement polymerization occurs in the patient and is an exothermic reaction with considerable liberation of heat. The long term effects of the heat produced in situ have not yet been established.

Incompatibilities

- Aqueous solutions (e.g. ones containing antibiotics) must not be added to the bone cement because they have a considerable detrimental effect on the physical and mechanical properties of the cement.

Precautions during pregnancy, breast-feeding and in children.

- The safety and effectiveness of **BRAVO MV** bone cements in pregnant women or in children has not yet been established.

Adverse events

Serious adverse events, some with fatal outcome, associated with the use of acrylic bone cements include:

- Myocardial infarction.
- Cardiac arrest.
- Cerebrovascular accident.
- Pulmonary embolism.
- Anaphylaxis.

The most frequent adverse reactions reported with acrylic bone cements are:

- Transitory fall in blood pressure.
- Elevated serum gamma-glutamyl-transpeptidase (GGTP) up to 10 days post-operation.
- Thrombophlebitis.
- Hemorrhage and hematoma.
- Pain and/or loss of function.
- Loosening or displacement of the prosthesis.
- Superficial or deep wound infection.
- Trochanteric bursitis.
- Short-term cardiac conduction irregularities.
- Heterotopic new bone formation.
- Trochanteric separation.

Other potential adverse events reported for bone cements include:

- Hypoxemia.
- Cardiac arrhythmia.
- Bronchospasm.
- Adverse tissue reaction.
- Pyrexia due to allergy to the bone cement.
- Hematuria.
- Dysuria.
- Bladder fi stula.
- Local neuropathy.
- Local vascular erosion and occlusion.
- Transitory worsening of pain due to heat released during polymerization.
- Delayed sciatic nerve entrapment due to extrusion of the bone cement beyond the region of its intended application.
- Intestinal obstruction because of adhesions and stricture of the ileum due to the heat released during cement polymerization.

Dose

Choose the dose considering the intervention to be performed. As a preventive measure, it is advisable to keep at hand at least a second package of **BRAVO MV** bone cement to be able to prepare an extra quantity of bone cement, if required during the procedure.
The maximum recommended dose of **BRAVO MV** bone cement cement is n° 3 packs

Directions for use

Cement Preparation

- The protective outer foil pouch, the outer peelable pouch of the powder component and the blister pack enclosing the ampoule of liquid component, should be opened by a circulating nurse. The inner bag (or pouch) containing the powder component and the sterile ampoule containing the liquid component are aseptically transferred into the sterile operative area.
- The sterile bag (or pouch) containing the powder component is opened with sterile scissors and the entire contents are emptied into a suitable clean, dry, sterile mixing vessel made from an inert material (such as glass, ceramic, stainless steel, or non-reactive plastics). The sterile ampoule containing the liquid component is opened and the entire contents are emptied evenly onto the powder in the mixing vessel.
- A standard dose of bone cement is prepared by mixing the entire liquid contents of the ampoule with the entire contents of the powder bag. The amount of mixed cement required for clinical use is determined by the surgeon in each individual case.

Mixing and Syringe application

- **BRAVO MV** bone cements may be applied using a suitable cement gun and syringe.
- The bone cement is prepared and mixed as described previously by adding all of the liquid component to all the powder component. The cement is then transferred into a suitable cement gun cartridge. The surgeon should use their experience to judge when the cement has reached an appropriate viscosity to be extruded. This will not occur until after the cement has formed a dough. A small amount of cement should be extruded from the syringe and visually assessed to ensure that the surface of the cement appears dull and excessive flow under gravity has ceased.
- Prior to extrusion, it is recommended that a cement restrictor be inserted, at the required depth into, the prepared bone cavity. Introduction of bone cement into the prepared cavity should be carried out in a retrograde fashion. Once the cavity is filled it is strongly advised that adequate pressurization is applied and maintained up to the point of hardening. Implant insertion should be carried out at a time appropriate for the bone/joint and prosthesis design concerned. In general, implant insertion should be delayed until the cement has developed a sufficient degree of viscosity to resist excessive displacement by the implant. However, implant insertion should not be delayed such that there is a risk that the procedure cannot be completed due to
- cement hardening.
  Following introduction the implant must be firmly held in position to avoid movement and pressurization must be maintained until the cement finally hardens. Excess bone cement must be removed before the cement has completely hardened

The handling characteristics and setting times are affected by ambient temperature. Please refer to the end of the instruction leaflet for guidance charts (Note: the usage charts were generated under controlled laboratory conditions).

Storage

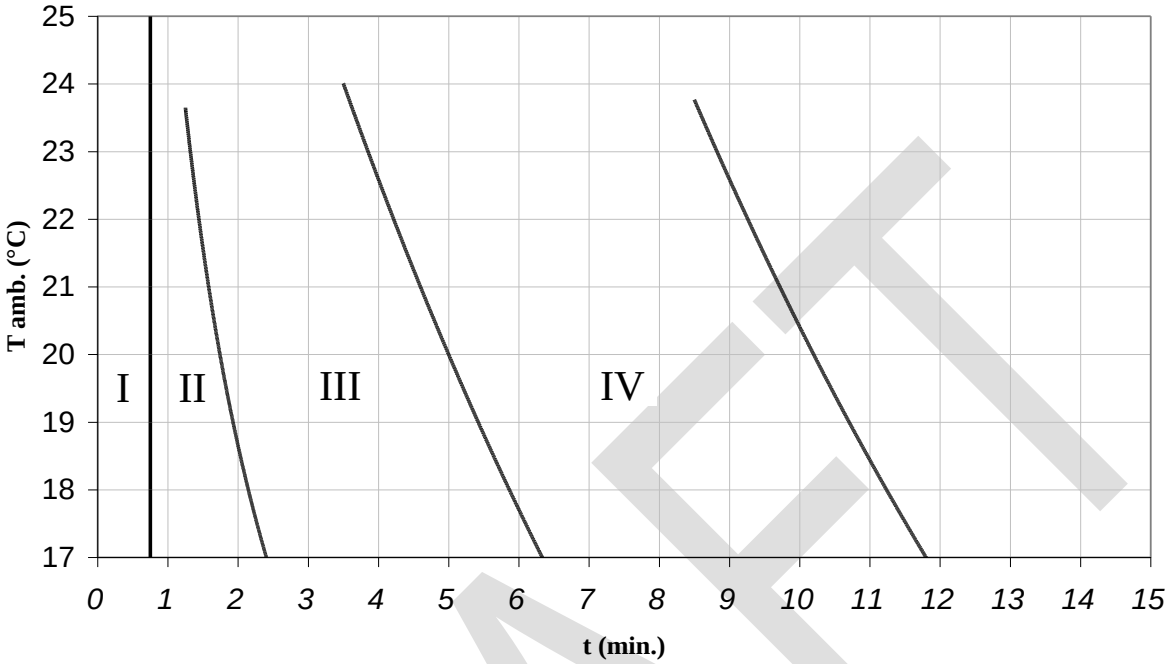
- Store the sealed outer pack between 5°C (41°F) and 25°C (77°F) and protect it from light to prevent premature polymerization of the liquid monomer component.
- Store at the intended operating room temperature for a minimum 24 hrs before use.

- Do not use the product after the expiration date.

Disposal

Dispose the remaining of **BRAVO MV** bone cement and the content of partially utilized, expired, not usable or damaged packages in an authorized waste facility; any leftover liquid component should be evaporated under a well-ventilated hood or absorbed by an inert material and transferred to a suitable container for disposal.

BRAVO HV



BRAVO MV

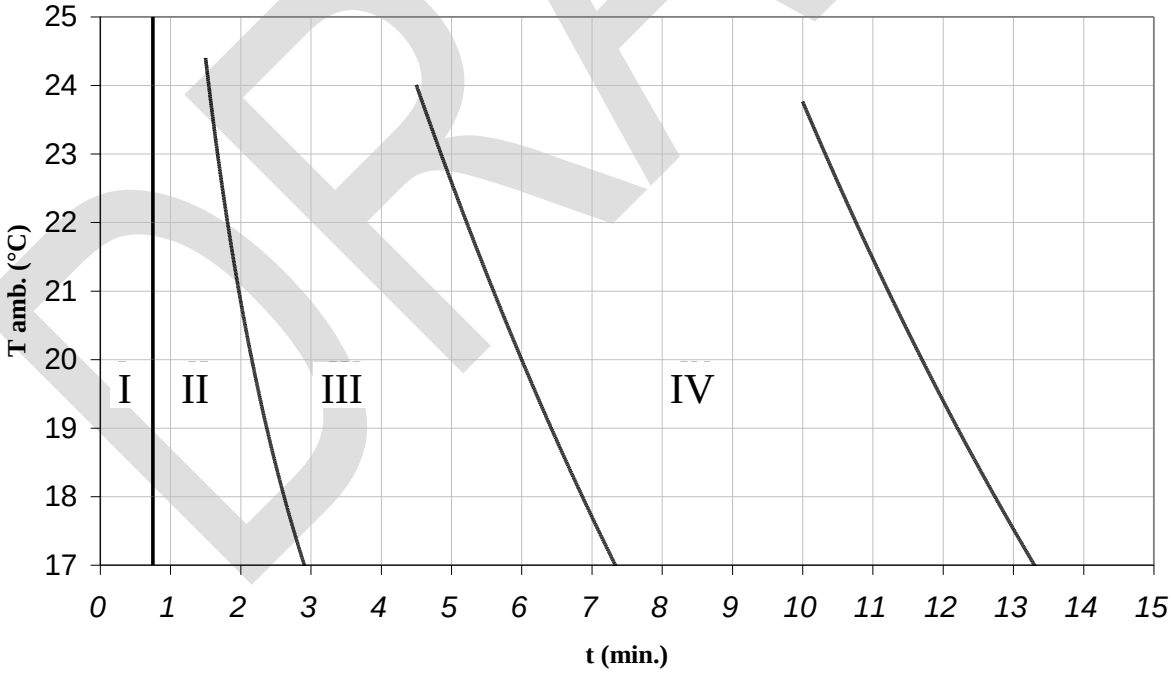
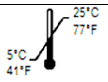
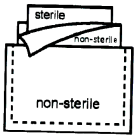


Fig. 1

Mixing, waiting, application, setting phases timing depend on the ambient temperature	
T amb.	Ambient temperature in °C
I	Mixing time
II	Waiting time
III	Application phase
IV	Setting phase

Symbols

Symbols	Description
 ISO 15223-1 5.4.2	Do not re-use
 ISO 15223-1 5.2.6	Do not resterilize
 ISO 15223-1 5.1.4	Use-by date
 ISO 15223-1 5.1.6	Catalogue number
 ISO 15223-1 5.1.5	Batch code
 ISO 15223-1 5.3.2	Keep away from sunlight
 ISO 15223-1 5.4.4	Caution
 ISO 15223-1 5.4.3	Consult instructions for use or consult electronic instruction for use
 ISO 15223-1 5.2.3	Sterilized using ethylene oxide
 ISO 15223-1 5.2.2	Sterilized using aseptic processing techniques
 ISO 15223-1 5.2.13	Single sterile barrier system with protective packaging inside
 ISO 15223-1 5.3.7	Temperature limit : Store between 5°C (41°F) and 25°C (77°F)

 ISO 15223-1 5.2.8	Do not use if the package is damaged and consult instruction for use
 ISO 15223-1 5.1.1	Manufacturer
 ISO 15223-1 5.1.9	Distributor
 *	The inner pouch (first pouch) is sterile. The pouch in the middle (second pouch) and the external pouch (third pouch) are not sterile
 *	The liquid in the vial is sterilized using aseptic processing techniques, the vial is sterilized using ethylene oxide
 *	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Symbols indicated in this table are derived from ISO 15223-1, with the exception of those indicated with *

Manufactured by:

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