Codman

CRANIOPLASTIC®
TYPE 1 – SLOW SET

DePuy International Ltd.
T/A DePuy CMW
Blackpool FY4 4QQ England

DIST
Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02767-0350 USA
☎ 800 225 0460
☎ +1 508 828 3000

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Made in UK

CE
0086

LCN 205599-001/A

♻ Printed 08/07

ENGLISH

IMPORTANT INFORMATION
Please Read Before Use

CRANIOPLASTIC®
TYPE 1 – SLOW SET

℞ Only

DESCRIPTION
The CRANIOPLASTIC Kit, catalog no. 43-1280 is a self-curing methyl methacrylate resin consisting of two complete sets of the powder polymer component, the liquid monomer component, and the plastic sleeve. The powder component is contained within a foil pouch and the liquid component in a sterile ampoule within a blister pack. The blister pack, foil pouch and plastic sleeve are affixed and held securely on a card insert that is sealed into a peelable pouch.

Sterilization of the liquid component is achieved by filtration and the powder component by gamma irradiation. The contents of the peelable pouch, which include the blister pack, the foil pouch and the plastic sleeve, are sterilized by ethylene oxide.

The powder is composed of:
- Methyl methacrylate polymer 79.36%w/w
- Methyl methacrylate – styrene copolymer 19.84%w/w
- Benzoyl peroxide 0.8%w/w

The liquid is composed of:
- Methyl methacrylate monomer 95.05%v/v
- Ethylene dimethacrylate monomer 4.28%v/v
- Dimethyl-p-toluidine 0.67%v/v
- Hydroquinone 75 ppm
- 4-methoxyphenol 12 ppm

Indication
CRANIOPLASTIC is a resinous material for repairing cranial defects.

Contraindications
CRANIOPLASTIC resin is contraindicated in cases of active infection.

CRANIOPLASTIC resin should not be used in patients previously sensitized to methyl methacrylate.

WARNINGS
Follow carefully the supplied instructions for mixing and handling CRANIOPLASTIC resin.

For safe and effective use of CRANIOPLASTIC resin, the surgeon must have specific training, experience, and thorough familiarity with the properties, handling characteristics, and application of the CRANIOPLASTIC resin. Strict adherence to good surgical principles and techniques is essential.

Deep wound infection is a serious post-operative complication and can require total removal of the embedded resin. Deep wound infection can be latent and not manifest itself even for several years post-operatively.

Adverse patient reactions affecting the cardiovascular system have been associated with the use of acrylic PMMA cements in surgery. Hypotensive reactions have occurred and some have progressed to cardiac arrest. For this reason, patients must be monitored for any change in blood pressure during and immediately following the application of the CRANIOPLASTIC resin. Acute hypotensive effects can be associated with absorption of methyl methacrylate into the vascular system.

Methyl methacrylate has been demonstrated to cause hypersensitivity in susceptible persons, which can result in an anaphylactic response.

The completion of resin 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.

The safety and effectiveness of CRANIOPLASTIC resin in pregnant women or in children has not yet been established. CRANIOPLASTIC resin must not be used during the first third of pregnancy, and during the rest of pregnancy period must only be used in life-threatening illnesses.

Precautions
Inspect the sterile package carefully. Do not use if:
- the package or seal appears damaged,
- contents appear damaged, or
- the expiry date has passed.

Ensure that the powder and liquid components to be mixed together are from the same batch, since the composition of each batch of the powder component is specifically formulated to the corresponding batch of liquid component.

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The liquid monomer is highly volatile and flammable. The operating room must be well ventilated so as to minimize the concentration of monomer vapor. Ignition of monomer fumes caused by the use of electrocautery devices in surgical sites near freshly implanted acrylic cements in surgery has been reported. Exercise care to prevent exposure to the monomer vapors, which may produce irritation of the respiratory tract and eyes and possibly liver.

Concentrated vapors of the liquid component can have an adverse reaction with soft contact lenses. Personnel wearing contact lenses should not be near or involved with the mixing of this product.

Liquid methyl methacrylate is a powerful lipid solvent; it must not be allowed to come in direct contact with sensitive tissue or be absorbed by the body. The liquid component must not be allowed to come into contact with surgical gloves. Wearing of a second pair of gloves and strict adherence to the mixing instructions can diminish the possibility of hypersensitivity reactions.

Use care when opening glass vials. Do not allow the liquid component to come into contact with rubber.

As the monomer is volatile and flammable, any waste liquid component must be evaporated under a well-ventilated hood or absorbed by an inert material and transferred to a suitable container (which does not react with the monomer) for disposal. Prior to disposal the surplus resin must be allowed to set. The polymer component and waste powder can be disposed in a landfill.

Adverse Events

The most frequently reported adverse complications with acrylic PMMA resin in cranioplasty are:

- Infection (bacterial affinity for the material necessitates isolation from the frontal sinuses, ethmoid sinuses and nose)
- Extrusion, extravasation and tissue erosion
- Hematoma
- Seroma
- Cerebrovascular fluid leakage
- Transitory pain associated and local tissue necrosis with exothermic curing of the resin.

Sterility

CRANIOPLASTIC resin is intended for SINGLE USE ONLY; DO NOT RESTERILIZE. Use aseptic technique in all phases of handling. Codman & Shurtleff will not be responsible for any product that is resterilized, nor accept for credit or exchange any product that has been opened but not used.

As long as the individual package is not opened or damaged, the product is sterile. To preserve this sterility upon presentation, the sterile powder bag, sterile plastic sleeve, and sterile ampoule must be aseptically transferred into the sterile operative area.

Storage

Store this package below 77°F (25°C) and protect it from light to prevent premature polymerisation of the liquid monomer component. Always check the condition of the liquid monomer before performing the procedure. Do not use the liquid monomer if it shows any sign of thickening or premature polymerisation. Do not use the product after the expiration date.

Instructions for Use

1. Acrylic resins are heat sensitive. Any increase or decrease in temperature (either ambient, and/or of the resin components), from the recommended temperature of 73°F (23°C) will affect the handling characteristics and setting time of the resin. **Note:** Manual handling and body temperature will reduce the final setting time.
2. Variations in humidity will affect the resins characteristics and setting time.
3. The handling characteristics and setting time can vary if the product has not been fully equilibrated to 73°F (23°C) before use. Store the unopened product at 73°F (23°C) for a minimum of 24 hours before use.
4. As with all acrylic resins, variations to the expected setting time over the shelf life can occur. This variation in setting time can be reduced to a minimum providing the resin is stored under the recommended conditions throughout its shelf life.

Dosage and Administration

To prepare a dose of CRANIOPLASTIC resin, mix the entire contents of one pouch of powder with the entire contents of the ampoule. Depending upon the extent of the surgical procedure and the technique employed, one to two doses may be required. Each required dose must be mixed separately.

Preparation of the Mix

Mix only in a well ventilated area. Noxious fumes are emitted during mixing and doughing. Ventilate

the area by working under a fume hood or other partial enclosure with local ventilation.

Open the peelable pouch enclosing the foil pouch, the ampoule blister pack and plastic sleeve. Aseptically transfer the foil pouch containing the powder component, the ampoule blister containing the ampoule of liquid and plastic sleeve into the sterile operative area.

Open the sterile foil pouch and empty the entire contents into a suitable clean, dry, sterile mixing vessel made from an inert material (such as glass, ceramic, stainless steel, or non-reactive plastic). Remove the sterile ampoule containing the liquid component from the sterile blister, open it and empty the entire contents evenly onto the powder in the mixing vessel.

Stir with a spatula made from an inert material until the powder is completely wetted with the liquid (approximately 30 seconds). Cover the mixing vessel with a glass plate to prevent evaporation of the monomer. Test intermittently with a spatula for approximately 5 minutes. The CRANIOPLASTIC resin will lose its sheen and a dough-like mass will be formed that can be separated cleanly from the walls of the container. When the dough-like mass will not adhere to the surgical gloves of the operator, the CRANIOPLASTIC resin is ready for manipulation. DO NOT ATTEMPT TO MIX BEYOND THE INITIAL 30 SECONDS.

TEMPERATURE	DOUGH TIME
73°F (23°C)	6 MINUTES MAXIMUM

Manipulation and Placement

Place the mix into the plastic sleeve that is provided with the kit. Knead the mix only enough to shape for application. (**Note:** Shaping outside the plastic sleeve causes evaporation of the monomer and causes a crust-like set. The working time at 73°F (23°C) is 5–12 minutes from the start of mix).

TEMPERATURE	HANDLING (WORKING) TIME	SETTING TIME
73°F (23°C)	5–12 MINUTES	14–20 MINUTES

Apply the CRANIOPLASTIC resin to the bone and remove excess resin. After application, the position of the implant must be maintained securely without movement until the resin is hard and firmly fixed in position. The setting time at 73°F (23°C) is 14–20 minutes from the start of the mix.

The setting time is also dependent on the quantity of resin used. When the implant is large and thick, it may be desirable (when it becomes warm to the gloved finger) to cool by irrigating with a spray of sterile water or sterile saline normally used during the procedure. (**Note:** This technique can affect the setting time of the resin).

Further information on the use of CRANIOPLASTIC resin can be obtained from the manufacturer.

Warranty

Codman & Shurtleff, Inc. warrants that this medical device is free from defects in both materials and workmanship. **Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed. Suitability for use of this medical device for any particular surgical procedure should be determined by the user in conformance with the manufacturer's instructions for use. There are no warranties that extend beyond the description on the face hereof.**

FRANÇAIS

INFORMATIONS IMPORTANTES

À lire avant utilisation

CRANIOPLASTIC®
TYPE 1 – PRISE LENTE

℞ Only

DESCRIPTION

Le kit CRANIOPLASTIC, numéro de catalogue 43-1280, est une résine autopolymérisable de méthacrylate de méthyle contenant deux jeux complets du composant polymère en poudre, du composant monomère liquide et du manchon plastique. Le composant en poudre est contenu dans un sachet en aluminium et le composant liquide dans une ampoule stérile à l'intérieur d'un emballage blister. L'emballage blister, le sachet en aluminium et le manchon plastique sont collés et fixés sur une carte qui est scellée dans une poche pelable.

La stérilisation du composant liquide est obtenue par filtrage tandis que le composant en poudre est stérilisé par irradiation gamma. Le contenu de la poche pelable, laquelle contient l'emballage blister, le sachet en aluminium et le manchon plastique, est stérilisé à l'oxyde d'éthylène.

La poudre est composée de :
polymère méthacrylate de méthyle 79,36 % m/m
copolymère méthacrylate de méthyle-styrène 19,84 % m/m
peroxyde de benzoyle 0,8 % m/m

Le liquide est composé de :
monomère méthacrylate de méthyle 95,05 % v/v
monomère de diméthacrylate d'éthylène 4,28 % v/v
diméthyl-p-toluidine 0,67 % v/v
hydroquinone 75 ppm
4-méthoxyphénol 12 ppm

Indication
CRANIOPLASTIC est un matériau résineux pour la réfection des anomalies crâniennes.

Contre-indications
La résine CRANIOPLASTIC est contre-indiquée en cas d'infection active.

La résine CRANIOPLASTIC ne doit pas être utilisée chez des patients précédemment sensibilisés au méthacrylate de méthyle.

MISES EN GARDE
Suivre scrupuleusement les instructions fournies pour le malaxage et la manipulation de la résine CRANIOPLASTIC.

Pour une utilisation sûre et efficace de la résine CRANIOPLASTIC, le chirurgien doit avoir reçu une formation spécifique, posséder une expérience et une connaissance approfondie des propriétés, des caractéristiques de manipulation et de l'application de la résine CRANIOPLASTIC. Il importe de respecter strictement les principes et techniques chirurgicaux adéquats.

Une infection profonde de la plaie est une complication post-opératoire grave susceptible de nécessiter le retrait total de la résine implantée. Cette infection peut être latente et ne se manifester que plusieurs années après l'intervention chirurgicale.

Des effets indésirables touchant le système cardiovasculaire ont été associés à l'utilisation de ciments acryliques (PMMA) en chirurgie. On a observé des réactions hypotensives qui, dans certains cas, ont provoqué un arrêt cardiaque. Pour cette raison, il est nécessaire de surveiller les patients afin de pouvoir détecter toute modification de la tension artérielle pendant et tout de suite après l'application de la résine CRANIOPLASTIC. Des effets hypotenseurs aigus peuvent être liés à l'absorption de méthacrylate de méthyle dans le système vasculaire.

Le méthacrylate de méthyle est connu pour provoquer une hypersensibilité chez les personnes à risque, ce qui peut entraîner une réaction anaphylactique.

L'achèvement de la polymérisation de la résine survient chez le patient et constitue une réaction exothermique associée à une libération de chaleur importante. Les effets à long terme de la chaleur produite in situ n'ont pas encore été établis.

La sécurité et l'efficacité de la résine CRANIOPLASTIC chez les femmes enceintes ou chez les enfants n'ont pas encore été établies. La résine CRANIOPLASTIC ne doit pas être utilisée pendant le premier trimestre de la grossesse et, au cours des deuxième et troisième trimestres, elle ne doit être utilisée que pour des maladies mettant la vie en danger.

Précautions d'emploi
Inspecter avec soin l'emballage stérile. Ne pas l'utiliser si :
- l'emballage ou le système de fermeture semble endommagé,
- son contenu semble endommagé, ou
- la date de péremption est dépassée.

S'assurer que les composants sous forme de poudre et de liquide devant être mélangés proviennent du même lot, car la composition de chaque lot du composant en poudre est formulée spécifiquement en fonction du lot de composant liquide correspondant.

Le monomère liquide est hautement volatile et inflammable. La salle d'opération doit être bien aérée afin de minimiser la concentration des vapeurs dégagées par le monomère. On a constaté des cas d'inflammation des fumées de monomère provenant de l'utilisation de dispositifs d'électrocautérisation dans des sites chirurgicaux à proximité de ciments acryliques récemment implantés. Prendre garde à éviter l'exposition aux vapeurs de monomère qui peuvent provoquer une irritation des voies respiratoires, des yeux et éventuellement du foie.