Instruction for Use

OPTIVAC VACUUM MIXING SYSTEM

REF 417000, 417100, 417200, 417300
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Before using the OPTIVAC Vacuum Mixing System, this insert should be read through.

DESCRIPTION

OPTIVAC is a vacuum mixing and application system for PMMA "polymethylmethacrylate" bone cement. This system is for single use only and supplied sterile.

OPTIVAC consists of:
- Cartridge(s); available in 3 sizes
- Breakaway nozzle(s) and/or breakaway knee nozzle(s)
- Funnel, sterile line set with charcoal filters

These components are plastic parts in accordance with NF EN ISO 16061 and NF EN ISO 10993-1.
OPTIVAC is available in 8 versions (4 for normal capacity and 4 for maximum capacity):

OPTIVAC	OPTIVAC Normal capacity		OPTIVAC Maximum capacity		Specific nozzles
	Reference	Specific Cartridge(s)	Reference	Specific Cartridge(s)	
Total Hip Kit 40 g single mix 80 g double mix	417000	Long + Short	418000	Long + Short + Extender	2 breakaway nozzles
40 g, Single mix kit	417100	Short	418100	Long	1 breakaway nozzle 1 knee nozzle breakaway
80 g, Double Mix Kit	417200	Long	418200	Short + Extender	1 breakaway nozzle 1 knee nozzle breakaway
120 g, Triple Mix Kit	417300	Short + Extender	418300	Long + Extender	1 breakaway nozzle

The breakaway knee nozzle is intended to be used during knee surgery.

The breakaway knee nozzle enables the user to apply an even layer of cement. The flat portion of the nozzle can be manually removed (no need to use the nozzle cutter). By breaking it off, the remaining round nozzle can be used to fill the cavities.

All components are packed in an inner blister pack, where the bottom of the tray serves as a tool tray. The blister pack is placed in a polyethylene-Tyvek pouch.

ASSOCIATED MEDICAL DEVICES

Name		Reference
OPTIVAC Nozzles	Slim	4154
	Revision	4155
	Right Angled	414900
	Knee	4312
	Small Diameter Cement	414991
OPTIGUN		419300
OPTIGUN RATCHET		419500
VACUUM PUMP		422800

CE 0459

Patents U.S. 5 328 262 , U.S. 5 501 520

BIOMET®

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INTENDED USE

- Mixing and collecting PMMA “polymethylmethacrylate” bone cement under vacuum
- Deliver the PMMA “polymethylmethacrylate” bone cement

Mixing takes place in a partial vacuum (0.15 bar), resulting in an almost non-porous cement with improved fatigue strength. The closed system minimizes the amount of free monomer in the operating theatre; the application method eliminates direct contact with the cement.

WARNINGS:

Do not use with any instruments other than those defined in the chapter ASSOCIATED MEDICAL DEVICES.
Do not use knee nozzle breakaway for hip femoral surgery.
The application of an excessive force on the nozzles may lead to unexpected breaking of the removable part.

USER INFORMATION

See operating instructions on the lid of the blister.

SHELF LIFE AND STERILITY

OPTIVAC Vacuum Mixing Systems are delivered sterilized by beta irradiation, min 25 kGy.
The expiration date is printed on the label.

SAFETY PRECAUTIONS

Do not use products after the expiration date.
This product is for single use only and has not been designed or tested for re-use.
Do not attempt to clean or re-sterilize the product due to the risk of cross infection and/ or possible alterations in the product performance.

Packaging must not show signs that could indicate a defect in the sterility and/or integrity of the medical device.
Never use a damaged product.
When handling products in the operating room, all necessary precautions must be taken to avoid damaging them.
This system must be used by a trained orthopaedic surgeon or trained nurse taking into account the step by step IFU on the lid.
The non-used products without initial packaging must be thrown out.

Optivac and its components must not be used in conjunction with other companies mixing systems.

Before using Optivac, the user must be thoroughly familiar with its properties, handling and use and should have read the instructions for use as well as the instructions for use for the chosen bone cement.
Temperature and humidity: No special storage requirements.
Before removal of the blue plug, the vacuum pump shall always be disconnected.
If in doubt as to the use of OPTIVAC Vacuum Mixing Systems or related products, please contact Biomet.

DISPOSAL

OPTIVAC components must be disposed of after use and never reused.
Once used, the system must be handled by the proper disposal channel for infectious health care wastes
CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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⚠	**Warning, see instruction leaflet**
⊘	**Do not reuse**
LOT	**Batch code**
REF	**Catalogue reference**
	Use by
STERILE R	**Sterilized by irradiation**

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