

The Optivac® System has enjoyed over 20 years of clinical success since its introduction in 1986.



**Optivac®
Total Hip
Kit**
417000
418000
(Max. capacity)*



**Optivac®
40g Kit
Single Mix**
417100
418100
(Max. capacity)*



**Optivac®
80g Kit
Double Mix**
417200
418200
(Max. capacity)*



**Optivac®
120g Kit
Triple Mix**
417300
418300
(Max. capacity)*

* For use with Simplex® cement.

OPTIVAC® VACUUM MIXING SYSTEM
REF 417000, 417100, 417200, 417300
REF 418000, 418100, 418200, 418300

Read through this insert before using your OPTIVAC® Vacuum Mixing System.

INTENDED USE

OPTIVAC® is a vacuum mixing and application system for bone cement.

DESCRIPTION

Mixing takes place in a partial vacuum, 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.

All components are packed in an inner blister pack, where the bottom of the tray serves as a tool tray. Ampoule breakers are included to facilitate the opening of the monomer bottle. The blister pack is placed in a polyethylene-Tyvec pouch.

OPTIVAC® is available in four versions:

- OPTIVAC® Total Hip Kit
- OPTIVAC® 40 gram, Single Mix Kit
- OPTIVAC® 80 gram, Double Mix Kit
- OPTIVAC® 120 gram, Triple Mix Kit

OPTIVAC® Total Hip Kit (for two mixings, for example for hip arthroplasty).

Consists of: Short and long cartridges, two breakaway nozzles, funnel, line with sterile and charcoal filters.

OPTIVAC® 40 gram, Single Mix Kit (for mixing 40 grams of cement).

Consists of: Short cartridge, breakaway nozzle, funnel, line with sterile and charcoal filters.

OPTIVAC® 80 gram, Double Mix Kit (for mixing 80 grams of cement).

Consists of: Long cartridge, breakaway nozzle, funnel, line with sterile and charcoal filters.

OPTIVAC® 120 gram, Triple Mix Kit (for mixing 120 grams of cement).

Consists of: Extra long cartridge, breakaway nozzle, funnel, line with sterile and charcoal filters.

ADDITIONAL COMPONENTS

- OPTIVAC® nozzles, Slim, Revision and Right Angled Nozzle
- OPTIGUN
- VACUUM PUMP

USER INFORMATION

See operating instructions.

STERILITY

OPTIVAC® Vacuum Mixing Systems are delivered sterilized by beta irradiation, min 25 kGy. Check the package prior to use for possible breaks.

SAFETY PRECAUTIONS

Temperature: Max temperature 25° Celsius.

Humidity: No special storage requirements.

OPTIVAC® components must be disposed of after use and never reused. Never re-sterilize used components. Before removal of the blue plug the vacuum pump shall always be disconnected.

If in doubt as to the use of OPTIVAC® or related products, please contact your local distributor or the manufacturer.

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

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Web site: www.biomet.com, email: biomet@biomet.com

Optivac is a Reg TM of Biomet Cementing Technologies AB.

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

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CO 15-0208

The information contained in this package insert was current on the date this brochure was printed. However, the package insert may have been revised after that date. To obtain a current package insert, please contact Biomet at the contact information provided herein.

References

1. Wang, J.S.; et al.: Is There Any Difference Between Vacuum Mixing Systems in Reducing Bone Cement Porosity? *Journal of Biomedical Materials Research*, Vol. 33, 115-119 (1996).
2. Data on file at DJO Surgical. Bench test results not necessarily indicative of clinical performance.

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Cobalt™ is a trademark of Biomet Manufacturing Corp.

Simplex® is a registered trademark of Stryker Howmedica Osteonics Corp.

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For product information, including indications, contraindications, warnings, precautions and potential adverse effects, see the package insert and DJO Surgical's website.

OPTIVAC®
vacuum mixing system

MIXING INSTRUCTIONS



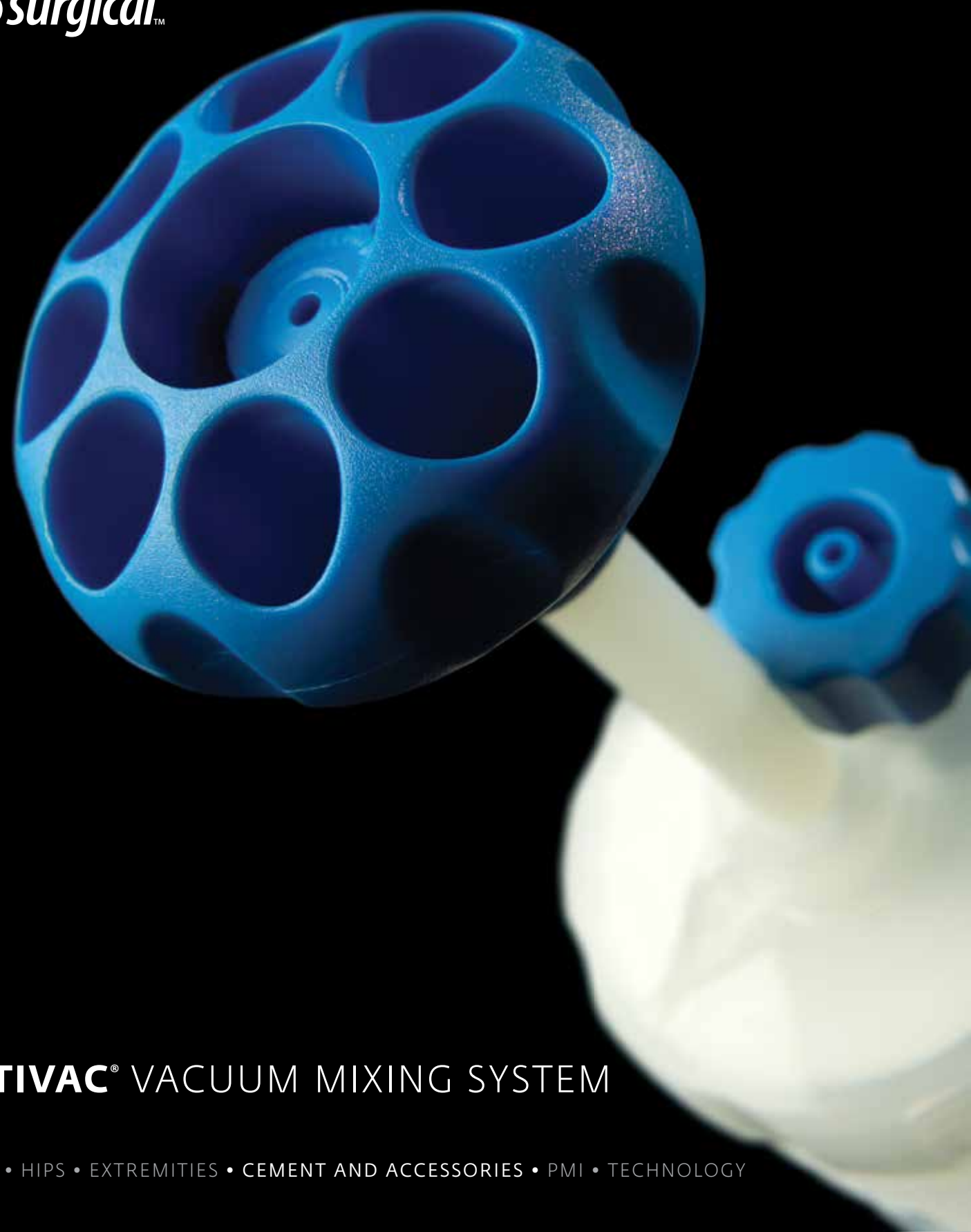
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djosurgical™



OPTIVAC® VACUUM MIXING SYSTEM

KNEES • HIPS • EXTREMITIES • CEMENT AND ACCESSORIES • PMI • TECHNOLOGY



OPTIVAC® VACUUM MIXING SYSTEM

The Optivac® Vacuum Mixing System is the only cartridge system to mix and collect cement under vacuum, providing a consistently high-quality, homogenous cement, and leading the industry in porosity reduction.¹



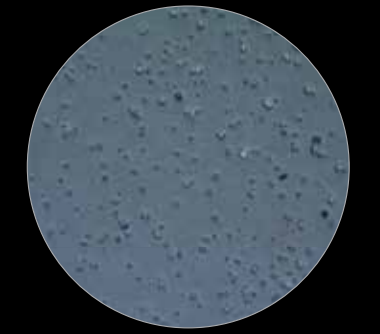
PATENTED PADDLE

designed to mix all types of bone cement, regardless of viscosity.

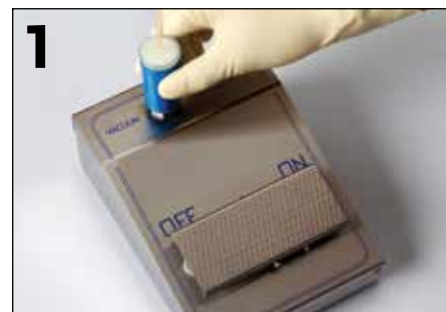
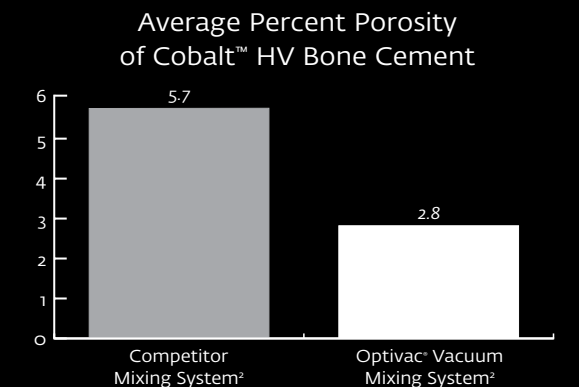
Patented design enables both mixing and collection of cement under vacuum, minimizing the possibility of air entrapment.¹



Competitor Mixing System²



Optivac® Vacuum Mixing System²



1 Open Optivac® mixing station and attach vacuum line to foot pump and small blue cap on lid of cartridge. Fasten line to table with tape or forceps.



2 Place cartridge in tray's round socket and carefully add bone cement components. If using Cobalt™ cement, liquid monomer is added first followed by polymer powder.



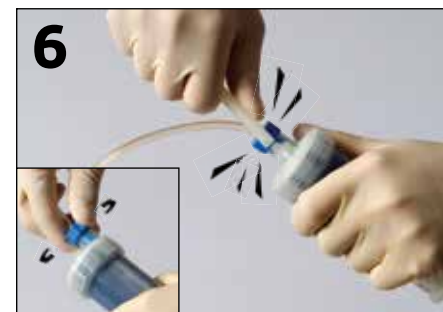
3 Screw on cartridge top and tighten firmly. Start vacuum pump using foot switch.



4 Once top is firmly tightened, tilt cartridge and begin mixing by moving paddle up and down smoothly with rotation. Mix 30–45 seconds. Finish by rotating mixing rod with paddle fully extracted.



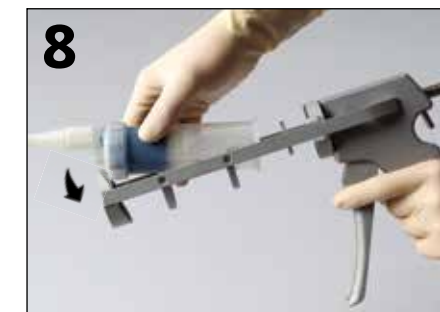
5 Place cartridge firmly onto tray's releasing knobs. Twist cartridge a quarter turn. Plunger will now move upward under vacuum, collecting cement and removing entrapped air.



6 Once floor of cartridge has stopped moving, snap off mixing rod with a firm, quick movement near the cylinder top. Stop vacuum pump and unscrew blue plug from top of cartridge.



7 Apply desired nozzle.



8 Position cartridge in cement gun. Release cement gun piston and push it forward. Press out cement with gun in an upward position. Start cementing when cement has reached desired viscosity for application.