



Shoulder Recovery with the **GPS III** Platelet Concentrate System

Mini-Open and Arthroscopic
Rotator Cuff Techniques



BIOMET[®]

GPS III Shoulder Recovery

Intended for international use only. Indications for use of products and/or therapies contained herein may not be cleared/approved for use by the U.S. Food and Drug Administration.

Quality Platelet Concentrate

- From a small volume of patient blood, the Gravitational Platelet Separation (GPS III) System may provide the highest quality platelet concentrate in an efficient and user-friendly process.

How Does It Work?

- Patient's own blood (54–108 ml) is spun down in the Biomet® Biologics centrifuge for 15 minutes at 3200 RPMs.
- This consistently provides 6 mls of platelet concentrate that is on average 9x the baseline of the patient's whole blood.*
- The platelet concentrate extracted from the GPS III System is then introduced to the surgical wound to accelerate the body's natural healing process.



Fill disposable tube with blood



Spin for 15 minutes



Extract platelet rich plasma concentrate

GPS III System

- The GPS III System with its automated platelet collection process will produce a consistent 9x baseline count while capturing over 90% of the available platelets within the sample.*

**Data on file at Biomet. Bench test results not necessarily indicative of clinical performance.*

Growth Factors Present in Platelet Concentrate

VEGF	Vascular Endothelial Growth Factor —Increases angiogenesis.
PDGF	Platelet Derived Growth Factor —Induces proliferation of fibroblasts and smooth muscle. May also serve as chemotactic agent for inflammatory cells.
TGF-B	Transforming Growth Factor Beta —Broad effects from cleaning wound to remodeling scar tissue.
FGF	Fibroblast Growth Factor —Initial scar formation and angiogenesis.
EGF	Epidermal Growth Factor —Promote growth of cells and dermal tissue.

Application of the GPS III System

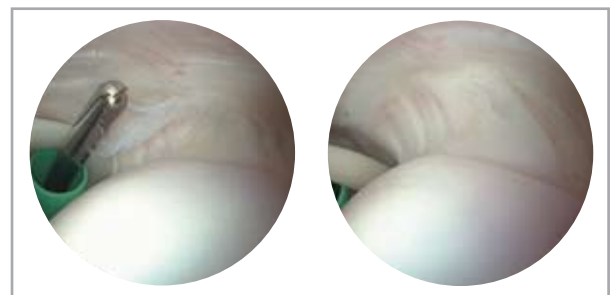
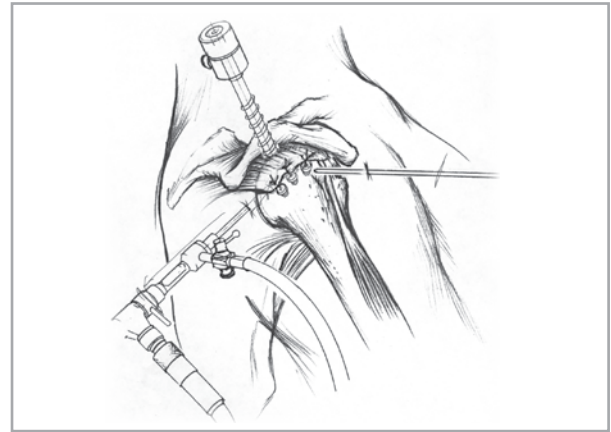
- One advantage of the GPS III System is that surgeons do not have to alter their arthroscopic or open rotator cuff technique.

Arthroscopic Rotator Cuff Repair Using the GPS III System

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Step One

After the Rotator Cuff has been repaired and evaluated, remove the instrument from the portal. This leaves a tract into either the subacromial space or the glenohumeral joint. Next, insert the four inch tip (800-0202) through the tract.



Partial Articular Side
Rotator Cuff Tear

After Debridement

Step Two

Close all portals with horizontal mattress sutures. One of these surrounds the four-inch tip in purse string fashion. Inject the platelet concentrate in the area where the most work was done.

If the work was extensive, inject platelet concentrate in the subacromial space through the lateral portal. Also inject platelet concentrate in the glenohumeral joint through the anterior portal. The anterior portal is closed around the four-inch tip first. The lateral portal is left open to later insert the four-inch tip, but is held closed with a finger over the hole when the glenohumeral joint is injected. After the platelet concentrate is applied to the subacromial space through the lateral portal, remove the four inch tip and close this final portal.



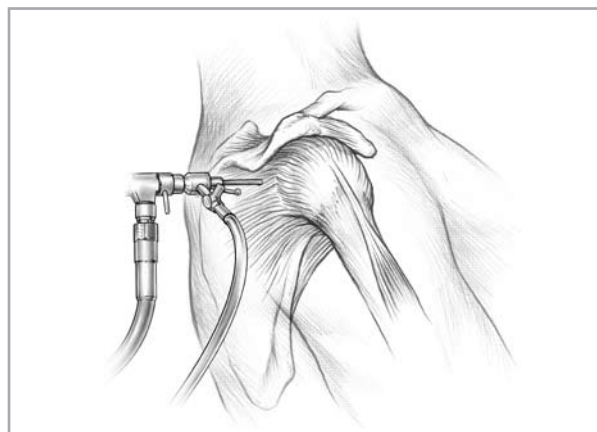
This brochure presented to demonstrate the surgical technique utilized by Frank Bonnarens, M.D., Jewish Hospital, Louisville, Kentucky. Biomet® Biologics, as the manufacturer of this device, does not practice medicine and does not recommend this or any other system for use on a specific patient. The surgeon who performs any procedure is responsible for determining and utilizing the appropriate techniques for such procedure for use on a specific patient. Biomet® Biologics is not responsible for selection of the appropriate product or surgical technique to be utilized for an individual patient.

Mini-Open Rotator Cuff Repair Using the GPS III System

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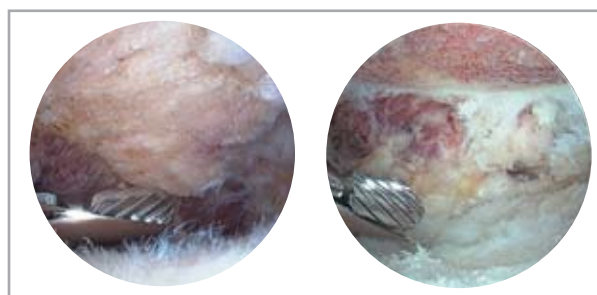
Step One

Routine diagnostic shoulder arthroscopy is performed using a posterior portal. The rotator cuff tear is evaluated with an arthroscope for size and tissue consistency. Labral pathology, articular pathology, and loose bodies are also evaluated through the scope at this time. Following diagnostic shoulder arthroscopy, the subacromial space is identified using the same posterior portal.



Step Two

A superolateral portal is then created and using electrocautery, shavers and burs, the subacromial space is decompressed and the acromion is flattened to create a Type I acromion. The arthroscope is placed in the lateral portal and then the posterior portal to ensure creation of a flatter Type I acromion.



Acromial Spur

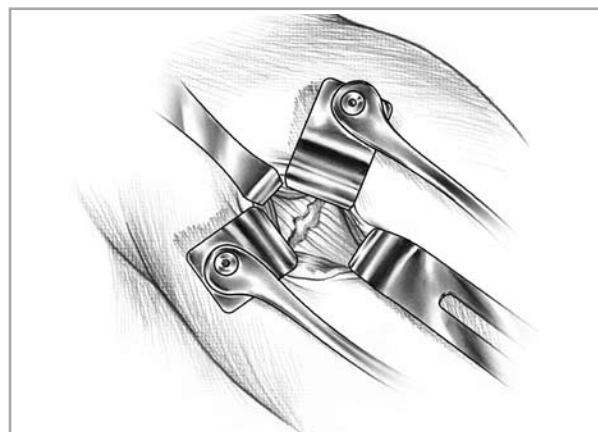
After Acromioplasty

Mini-Open Rotator Cuff Repair Using the GPS III System (continued)

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Step Three

In the majority of instances, the arthroscopic equipment is removed and the lateral portal will be made into a small deltoid splitting incision approximately 2cm in size. The deltoid fibers are bluntly split, a small retractor is placed and the rotator cuff is directly visualized. With internal and external rotation of the shoulder, the entire cuff can be easily accessible. The rotator cuff is then repaired through a variety of techniques, including absorbable suture anchors and occasionally transosseous sutures in the form of a “double row” technique.

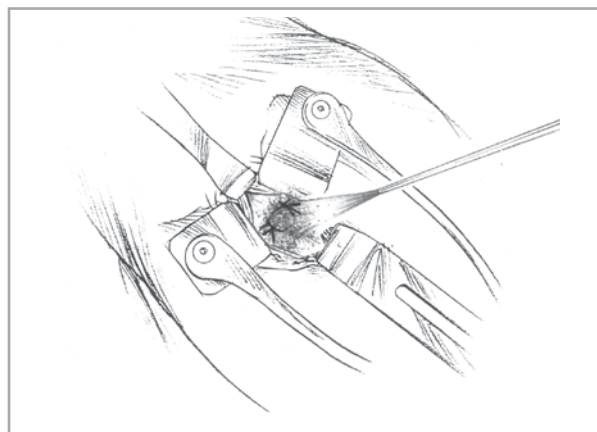


Mini-Open Rotator Cuff Repair Using the GPS III System (continued)

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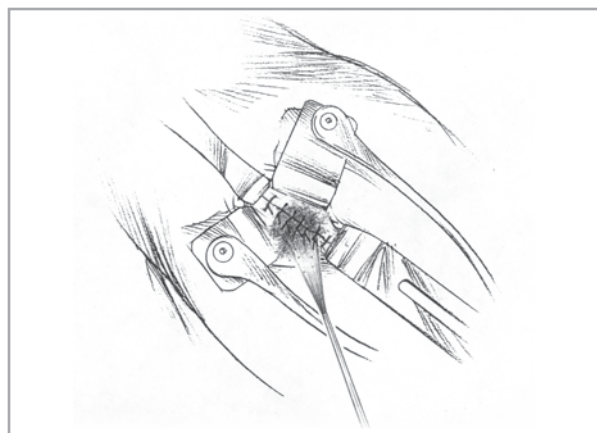
Step Four

After the rotator cuff has been repaired and evaluated, apply the platelet concentrate on and underneath the cuff, acromion, subacromial space, and deltoid split, utilizing the four inch tip.



Step Five

After closing the deltoid, apply the platelet concentrate on the suture line.



Mini-Open Rotator Cuff Repair Using the GPS III System (continued)

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Step Six

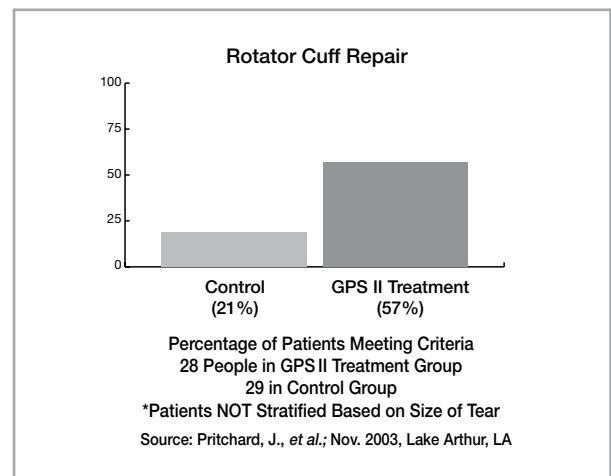
Apply Platelet Poor Plasma (PPP) on the incision to act as a fibrin sealant at closure.



Landmark for Early Stage Healing at Eight Weeks

Criteria

- Pain of two or less on a ten point scale
- End of intensive postoperative management
- Passive motion $\geq 170^\circ$ in flexion and abduction
- Active motion $\geq 150^\circ$ in flexion and abduction



This brochure presented to demonstrate the surgical technique utilized by John Pritchard, M.D., Orthopaedics NorthEast, Fort Wayne, Indiana. Biomet® Biologics, as the manufacturer of this device, does not practice medicine and does not recommend this or any other system for use on a specific patient. The surgeon who performs any procedure is responsible for determining and utilizing the appropriate techniques for such procedure for use on a specific patient. Biomet® Biologics is not responsible for selection of the appropriate product or surgical technique to be utilized for an individual patient.

Biomet Biologics, Inc.
56 E. Bell Drive
P.O. Box 587
Warsaw, Indiana 46581 USA

01-50-1444
Date: 12/07

GPS™ III Platelet Concentrate Separation Kit with ACD-A

ATTENTION OPERATING SURGEON

FOR INTERNATIONAL USE ONLY

NOTE: FOR SINGLE USE ONLY. Discard the entire disposable kit after one use by an acceptable disposal method for devices potentially contaminated with blood products.

DESCRIPTION

The GPS™ III Platelet Concentrate Separation Kit with ACD-A aids separation of the patient's own blood components by density through the use of a Biomet Biologics centrifuge.

The GPS™ III Platelet Concentrate Separation Kit with ACD-A permits platelet concentrate to be rapidly prepared from a small volume of the patient's blood that is drawn at the time of treatment.

MATERIALS

The materials used for syringes, needles, tubing, connectors, and platelet separators consist of medical grade polymers, elastomers and stainless steels suitable for use in medical devices. Blood-draw kit components, when supplied in this kit, are packaged, labeled and sterilized as indicated by their individual labeling. All components in this kit are latex free.

ACD-A is an anticoagulant supplied by Citra Anticoagulants, Inc., Braintree, MA, and manufactured by Cytosol Laboratories, Inc., Braintree, MA. For further information regarding ACD-A Anticoagulant, please contact the supplier at 1-800-299-3411.

The ACD-A included in this kit is only for use with the GPS™ III Platelet Concentrate Separation Kit.

INDICATIONS FOR USE

The GPS™ III Platelet Concentrate Separation Kit with ACD-A is designed to be used for the safe and rapid preparation of autologous platelet-rich-plasma (PRP) from a small sample of blood at the patient's point of care. The PRP can be applied to the surgical site as deemed necessary by clinical use requirements. In addition, it may be used to improve bone graft handling.

WARNINGS AND PRECAUTIONS

1. Use proper safety precautions to guard against needle sticks.
2. Follow manufacturer instructions when using centrifuge. Use only a Biomet Biologics centrifuge (GPS™ – IEC centrifuge or the Drucker Company centrifuge). Outcomes using centrifuges from other manufacturers are unknown.
3. Do not use sterilized components of this kit if package is opened or damaged.
4. Single use device. Do not reuse.
5. The surgeon is to be thoroughly familiar with the equipment and the surgical procedure prior to using this device.
6. The patient is to be made aware of general risks associated with treatment and the possible adverse effects.
7. Use prepared platelet concentrate material within 4 hours after drawing blood from patient.
8. The safety and effectiveness of this device for *in vivo* indications for use has not been established.

POSSIBLE ADVERSE EFFECTS

1. Damage to blood vessels, hematoma, delayed wound healing and/or infection.
2. Temporary or permanent nerve damage that may result in pain or numbness.
3. Early or late postoperative infection.

STERILITY

GPS™ III Platelet Concentrate Separation Kit platelet separator is sterilized by exposure to a minimum dose of 25 kGy gamma irradiation. All other GPS™ III Platelet Concentrate Separation Kit components are sterilized by the respective suppliers using irradiation or ethylene oxide gas (ETO). Do not re-sterilize. Do not use after expiration date.

INSTRUCTIONS FOR USE

NOTE: Use standard aseptic technique throughout the following procedures.

1. **DRAW:** Draw 6ml of ACD-A into 60ml syringe. Attach to 18-gauge apheresis needle and prime with ACD-A. Slowly draw 30 to 54ml of patient's own blood into the 60ml syringe primed with ACD-A. Gently, but thoroughly, mix the whole blood and ACD-A upon collection to prevent coagulation.
2. **LOAD: ENSURE BLOOD FROM ONLY ONE PATIENT IS PROCESSED PER SPIN, and that the platelet separator remains upright.** Unscrew cap on center blood port #1. Remove and discard cap and green packaging post. Slowly load blood-filled 60ml syringe (6ml of ACD-A mixed with 30 to 54ml of patient's whole blood) into center blood port #1. Unscrew and discard clear protective inner piece from white cap tethered to port #1. Screw white cap onto port #1. Place platelet separator filled with anticoagulated blood in Biomet Biologics centrifuge.
3. **BALANCE:**
Processing One Platelet Separator
Fill blue GPS™ counterbalance tube (800-0508) with 36-60ml of sterile saline/water (equal to amount of whole blood plus ACD-A dispensed in the platelet separator). Place filled counterbalance directly opposite from the platelet separator in the centrifuge.
Processing Two Platelet Separators
Fill both platelet separators with equal amounts of whole blood plus ACD-A. Place filled platelet separators directly opposite from each other in the centrifuge.
4. **SPIN:** Close centrifuge lid. Set RPM to 3.2 (x 1,000) and the time to 15 minutes. Press the start button. Once spin is complete, open centrifuge.
5. **EXTRACT PPP:** Unscrew yellow cap on port #2, and save yellow cap. Connect 30ml syringe to port #2, invert platelet separator, and extract platelet-poor-plasma (PPP). Remove 30ml syringe from port #2, cap with a sterile syringe cap, and set aside. Replace yellow cap on port #2.
6. **If PRP is desired, follow steps 7 – 8.**
7. **SUSPEND PRP:** Holding platelet separator in the upright position, unscrew red cap on port #3. Attach 10ml syringe to port #3. Extract 2 ml of PRP into the 10ml syringe. Leave the syringe attached. Shake platelet separator gently for 30 seconds.
8. **EXTRACT PRP:** Immediately after suspending the platelets, extract remaining PRP into the attached 10ml syringe. Remove 10ml syringe from port #3, and cap with a sterile syringe cap.

Comments regarding this device can be directed to Attn: Regulatory Dept, Biomet, Inc. P.O. Box 587, Warsaw, IN 46581 USA. FAX: 574-372-3968.

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Authorized Representative: Biomet U.K., Ltd.
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Bridgend, South Wales
CF31 3XA, U.K.

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2. **LOAD: ENSURE BLOOD FROM ONLY ONE PATIENT IS PROCESSED PER SPIN, and that the platelet separator remains upright.** Unscrew cap on center blood port #1. Remove and discard cap and green packaging post. Slowly load blood-filled 30ml syringe (3ml of ACD-A mixed with 15 to 27ml of patient's whole blood) into center blood port #1. Unscrew and discard clear protective inner piece from white cap tethered to port #1. Screw white cap onto port #1. Place platelet separator filled with anticoagulated blood in Biomet Biologics centrifuge.
3. **BALANCE:**
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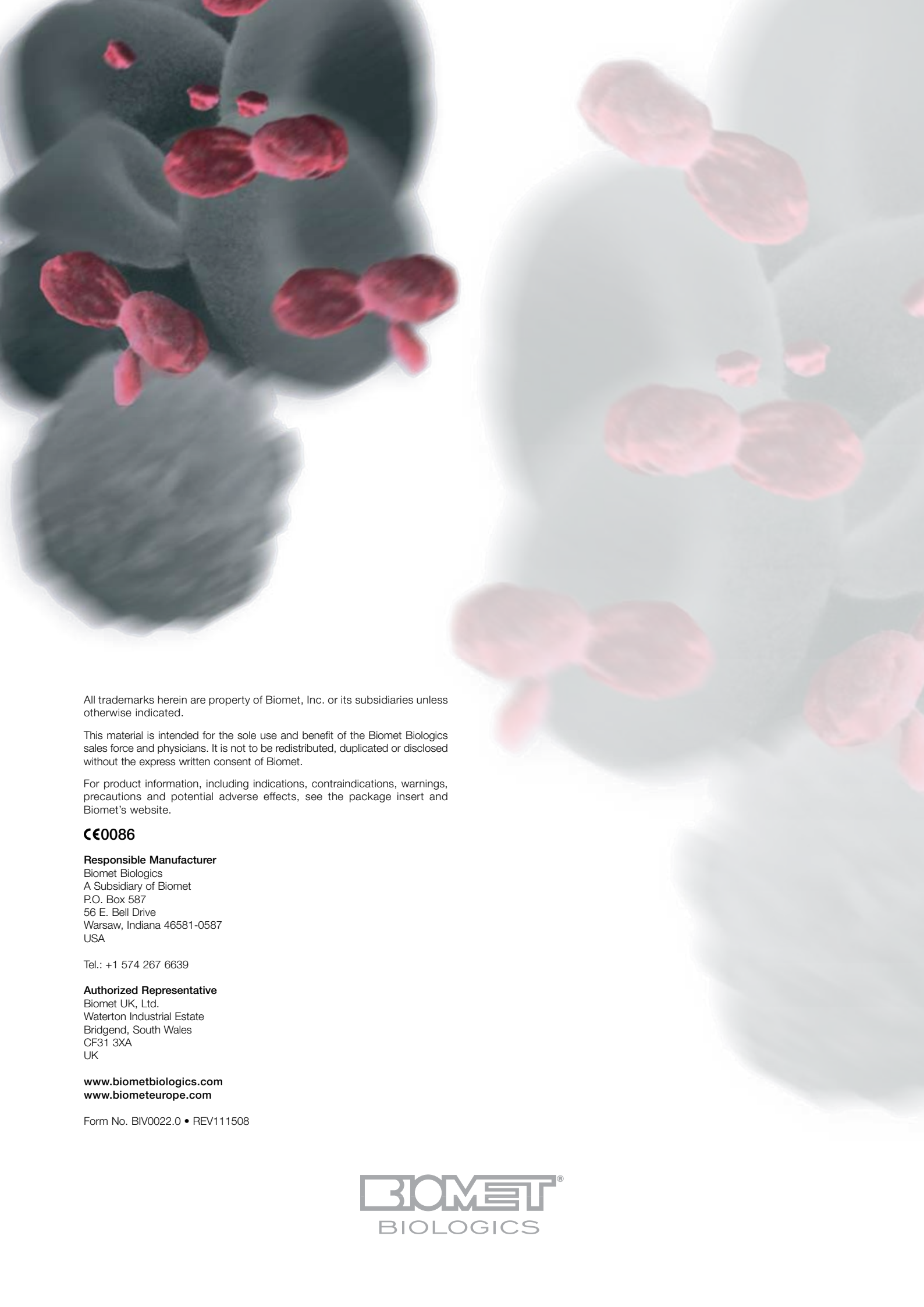
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