



Recover™ Platelet Separation Kit

The Natural Option
for Tendon Treatment

BIOMET®
BIOLOGICS

Recover™ Platelet Separation Kit

This brochure is intended solely for use outside of the United States.

Tendinosis

Introduction

Tendinosis, a chronic degeneration of the tendon, can occur due to an accumulation over time of microscopic injuries to the tendon. This damage can result in pain and disability.

The Recover™ Platelet Separation Kit was developed to address these difficult cases. Utilising the GPS™ III Separation Tube, the patient's own platelets are collected into a highly concentrated formula. When platelets become activated, growth factors are released and initiate the body's natural healing response.

Automated Platelet Collection

In one short, simple spin, the GPS™ III tube can efficiently capture a majority of the patient's platelets. The patent-pending GPS™ III tube dual buoy is tuned to the density between platelets and red blood cells. Under centrifugal force, the dual buoy will "float" within the tube to the interface point, collecting and trapping the platelet rich layer between the bottom and top buoys. Regardless of the hematocrit of the patient, the GPS™ III tube can automatically collect a consistent, high platelet count for each patient.¹³



This brochure describes the surgical techniques and postoperative recommendations based on the published data of Allan Mishra, M.D.

Biomet Biologics does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and using the appropriate techniques for each individual patient. Biomet Biologics is not responsible for selection of the appropriate products and or surgical technique(s) to be used on any individual patient.

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Activated Platelets Release Growth Factors

Platelet Derived Growth Factor (PDGF-aa, PDGF-ab, PDGF-bb)¹²

- Stimulates cell replication
- Promotes angiogenesis
- Promotes epithelialisation
- Promotes granulation tissue formation

Transforming Growth Factor (TGF-β1, TGF-β2)¹²

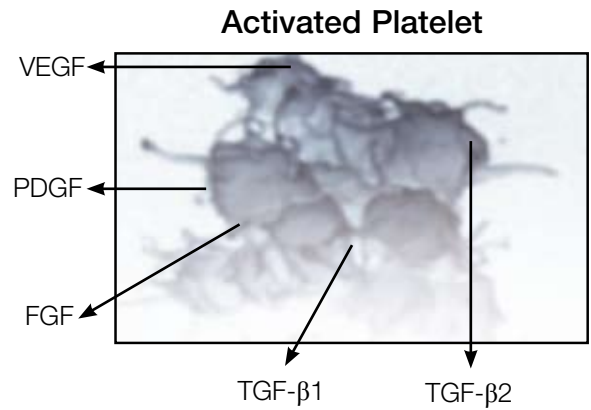
- Promotes formation of extracellular matrix
- Regulates bone cell metabolism

Vascular Endothelial Growth Factor (VEGF)¹²

- Promotes angiogenesis

Fibroblast Growth Factor (FGF)¹²

- Promotes proliferation of endothelial cells and fibroblasts
- Stimulation of angiogenesis



Tendinopathy: Rationale for PRP Use

1. Fibroblast influx/proliferation

- PDGF, bFGF
- Create receptive tissue bed for vascularisation¹⁶

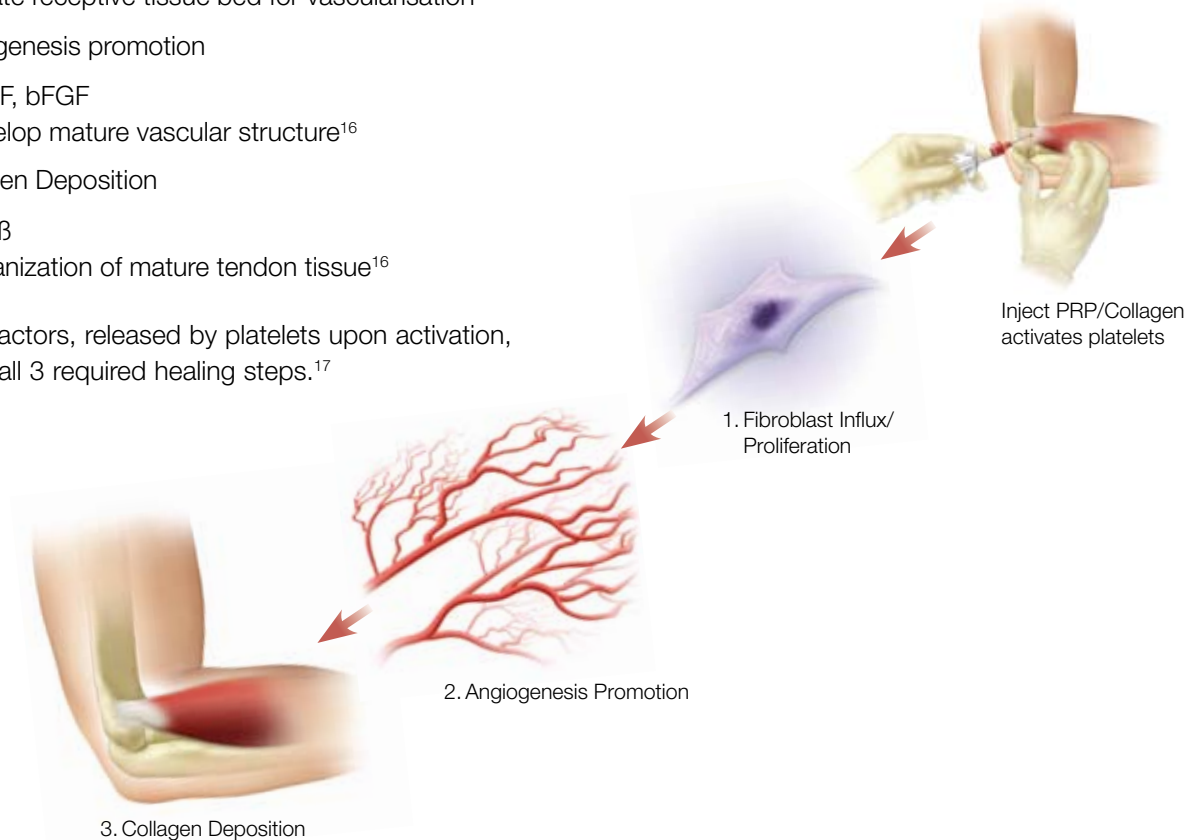
2. Angiogenesis promotion

- VEGF, bFGF
- Develop mature vascular structure¹⁶

3. Collagen Deposition

- TGFβ
- Organization of mature tendon tissue¹⁶

Growth factors, released by platelets upon activation, address all 3 required healing steps.¹⁷



Preparation of Platelet Rich Plasma (PRP) with GPS™ III and Mini GPS™ III Tubes

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Step 1: Load and Balance



Mini GPS™ III: Withdraw 3 ml of ACD-A (Citrate Anticoagulant) into 30 ml syringe. Withdraw 27 ml of blood from the uninvolvement arm into the same 30 ml syringe.

Unscrew cap on centre port No. 1, which will remove packaging post and discard. Slowly load blood filled 30 ml syringe into centre port.

Single GPS™ III: Load blood filled 60 ml syringe (6 ml of ACD-A and 54 ml of whole blood) into centre port.



Remove protective cover on white cap and discard. Screw white cap onto centre port.



Mini GPS™ III: Place Mini GPS™ III tube into centrifuge. Adjust depth gauge of universal counterbalance to appropriate volume (30 ml). Place into opposite side of the centrifuge.

Single GPS™ III: If using the single GPS™ III tube, adjust depth gauge of universal counterbalance to appropriate volume (60 ml). Place into opposite side of centrifuge.

Step 2: Spin



Close the lid and turn the latch clockwise to lock. "Latched" indicator will illuminate. Set speed for 3200 RPM and timer to 15 minutes. Press green button to start spin. Once spin is complete, press red button to illuminate the "unlocked" indicator. Twist latch counterclockwise to open lid.

Step 3: PPP Extraction



Remove GPS™ III tube and unscrew yellow cap. Invert the tube and withdraw PPP (port No. 2) with a 30 ml syringe. Replace yellow cap.

Step 4: PRP Suspension and Extraction



Remove Red Cap (port No. 3) and connect 10 ml syringe.

Mini GPS™ III: Withdraw 1 ml of PRP. With 10 ml syringe attached, suspend the platelets by gently shaking the tube for 30 seconds. Extract remaining PRP contents.

Single GPS™ III: Withdraw 2 ml of PRP. With 10 ml syringe attached, suspend the platelets by gently shaking the tube for 30 seconds. Extract remaining PRP contents.

Note: If buffy coat does not dissolve completely, shake tube vigorously.

Recover™ Kit Buffering Technique for PRP: Patent No. 6,811,777 B2

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Utilising the 1 ml syringe with attached needle, the platelet concentrate is buffered by adding 0.05 ml of 8.4% sodium bicarbonate to each ml of platelet concentrate. For example, if 3 ml of PRP is obtained, add 0.15 ml of sodium bicarbonate. Refer to table below for proper PRP/Sodium Bicarbonate mixing ratio. In a 10 ml syringe, gently agitate the PRP and sodium bicarbonate to ensure adequate mixing. This will raise the pH to approximately 7.4, matching the pH of the tissue in which the PRP is injected.



PRP Buffering Table

ml of PRP	ml of 8.4% Sodium Bicarbonate Buffer
1	0.05
2	0.10
3	0.15
4	0.20
5	0.25
6	0.30



Tennis Elbow (Lateral Epicondylitis)

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Introduction

Tennis elbow, medically known as lateral epicondylitis, is characterized by tissue degeneration of the wrist and forearm extensor tendons at the elbow. It is not typically associated with acute inflammation. Chronic and severe cases may lead to partial or full thickness tearing of the tendons.¹⁸

Causes:

The injuries are usually caused by overuse of the forearm muscles in repeated actions associated with racquet sports, manual work with twisting hand movements, weight training, or any other traumatic movement of the elbow or wrist.¹⁸

Lateral Epicondylitis Facts:

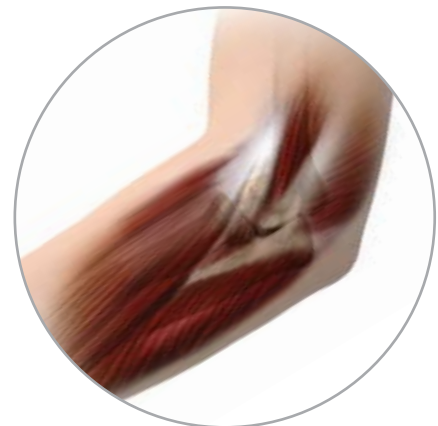
- Typically occurs in patients in their 40's and 50's.^{1,2}
- Epidemiological studies show an incidence of tennis elbow between 1 and 2%.³
- Manual workers and racquet sports athletes are at highest risk.^{2,4-8}
- Is a frequent cause of missed work.^{9,10}

Common Treatments:¹⁸

- Rest
- Activity restriction
- Compressive forearm band
- Physical therapy
- Shockwave therapy
- Anti-inflammatory medications/creams
- Acupuncture
- Steroid injections (cortisone)

Recover™ Kit Treatment

The Recover™ Platelet Separation Kit provides autologous growth factor therapy for accelerated healing of tendinosis.



Tennis Elbow (Lateral Epicondylitis)

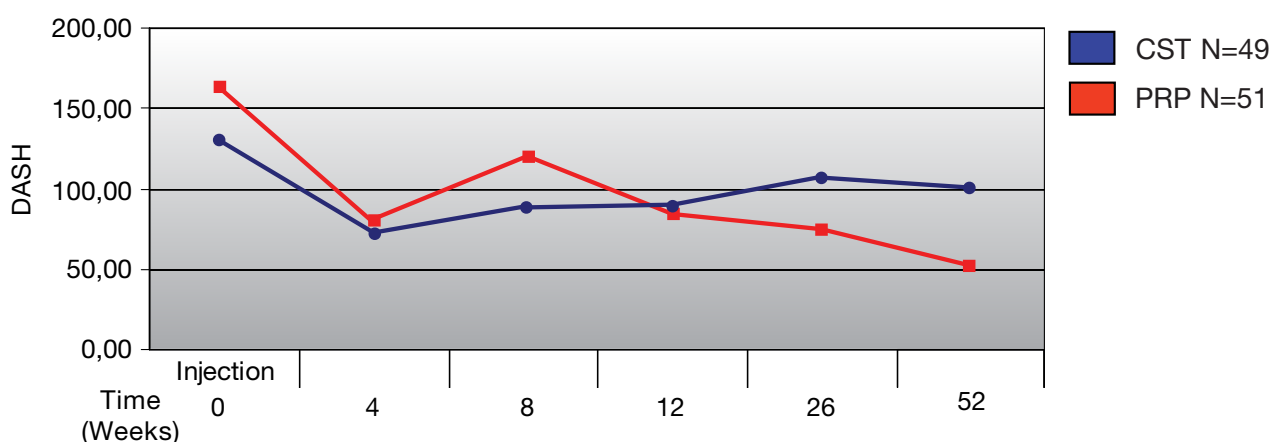
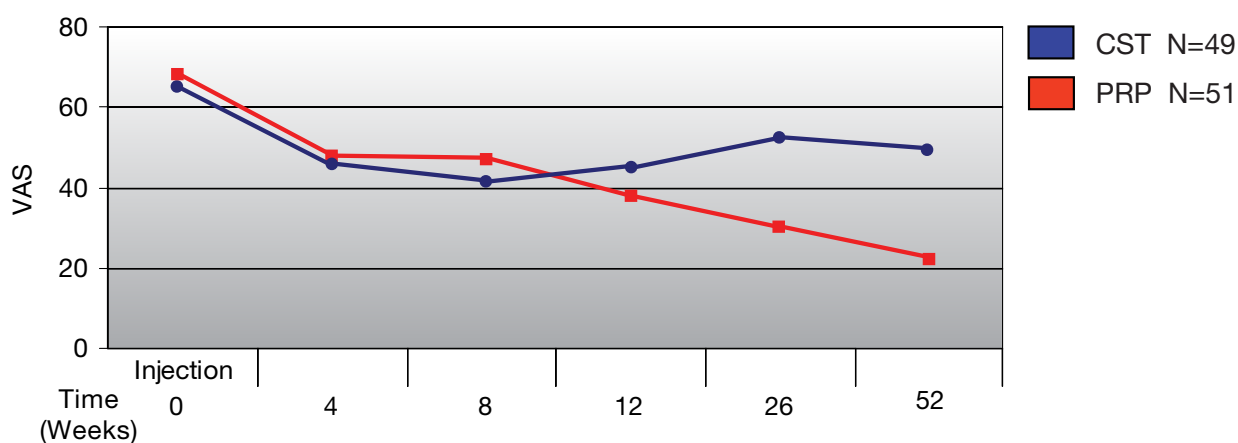
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Prospective randomised study on the effect of autologous platelets injection in lateral epicondylitis compared with corticosteroid injection.¹¹

- The study was designed as a Prospective Double-Blind Randomized Control Trial with a one year follow up.
- 100 patients enrolled with severe, chronic lateral epicondylitis.
- PRP application (N=51) — Single percutaneous injection.
- Controls (N=49) — Single corticosteroid injection.
- Criteria for success was defined as more than a 25% reduction in VAS or DASH score without reintervention after 1 year.

Results

- 24 of the 49 patients (49%) in the corticosteroid group and 37 of the 51 (73%) in the PRP group were defined as successful with the VAS score, which was statistically significant.
- 25 of the 49 patients (51%) in the corticosteroid group and 37 of the 51 (73%) patients in the PRP group were defined as successful with the DASH, which was also statistically significant.
- The corticosteroid group was better initially and then declined, while the PRP group progressively improved.



Conclusion

Treatment of patients with chronic lateral epicondylitis with PRP reduces pain and increases function significantly, exceeding the effects of corticosteroid injection.

Recover™ Kit Tennis Elbow Protocol: PRP Application

This brochure is intended solely for use outside of the United States. Biomet, as the manufacturer of medical devices, does not practice medicine. This procedure is presented to demonstrate the surgical technique and post-operative protocol utilised by Allan Mishra, M.D.

Note: 2–3 ml of platelet concentrate (Mini GPS™ III) is the maximum amount that should be utilised for this technique.

Step 1



Confirm diagnosis with preference of MRI, ultrasound, and/or clinical examination. Confirm the limb to be treated. The patient is placed in the supine position in preparation for the tendon injection. The area is palpated for the spot of maximal tenderness. This is noted and the skin is sterilely prepped.

Step 2



Utilising the supplied 25 gauge needle and 10 ml syringe, a numbing injection consisting of 2–3 ml of 0.5% Bupivacaine HCL with Epinephrine (or an equivalent anaesthetic) is inserted in the area of maximal tenderness. The injections are placed superficially in the skin and dermis over the common extensor



tendon origin. Approximately 0.5 ml of Bupivacaine HCL with Epinephrine (or an equivalent anaesthetic) should also be injected into the tendon. Wait 2 minutes to allow anaesthetic to take effect.

Step 3



Note: Buffer PRP first using technique on page four. Utilising the supplied 22 gauge needle and 10 ml syringe, inject 2–3 ml of the buffered platelet concentrate into the area of maximal tenderness. A single skin poke with multiple penetrations into the tendon is used.

Two penetrations into the lateral epicondyle and five penetrations into the extensor carpi radialis brevis (ECRB) tendon are performed. Ultrasound may be used for most accurate placement of PRP.

Step 4



Post Procedure

The injection area is then sterilely dressed. Following the injection, the patient is kept in the supine position for approximately 15 minutes without moving the involved arm, wrist or hand.

Note: The patient is provided with a prescription for pain medication to use over the first 24–48 hours post procedure. **NSAIDS should not be used for one week before the treatment and four weeks post procedure.** Cold therapy/icing of the affected area may be used at the treating physician's discretion. No vigorous activities, strong gripping or lifting of loads greater than 4.5 kilograms for four weeks post procedure.

Plantar Fasciitis

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Introduction

Plantar fasciitis is a common cause of heel pain that may result in pathologic degenerative tissue changes similar to tennis elbow. Severe or prolonged cases of plantar fasciitis may result in partial or full thickness tearing of this important connective tissue. The plantar fascia encapsulates the muscles in the sole of the foot. It is responsible for supporting the arch of the foot and endures tension that is approximately two times body weight. Poor calf flexibility can contribute to the development of plantar fasciitis.¹⁸

Causes:¹⁸

- A change or increase in activities
- No arch support
- Lack of flexibility in the calf muscles
- Being overweight
- An acute injury
- Using shoes with little cushion on hard surfaces
- Using shoes that do not easily bend under the ball of the foot
- Excessive standing

Common Treatments:¹⁸

- Rest
- Ice
- Stretching
- Shockwave therapy
- In severe cases, surgery may be needed



Recover™ Kit Plantar Fasciitis Protocol: PRP Application

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Note: 3–5 ml of platelet concentrate (Single GPS™ III) is the maximum amount that should be utilised for this technique.

Step 1



Confirm diagnosis with preference of MRI, ultrasound, and/or clinical examination. Confirm the limb to be treated. Place the patient in the supine position with the foot in an optimal position for injection. Palpate for maximal area of tenderness.

Step 2



Prep and drape the patient in a sterile manner.

Step 3



Utilising the supplied 25 gauge needle and 10 ml syringe, infiltrate the skin, subcutaneous tissue, and tendon with 2–3 ml of local anaesthetic in the area of maximal tenderness. Wait 2 minutes for the anaesthetic to take effect.

Step 4



Note: Buffer PRP first using the technique on page 6. Utilising the supplied 22 gauge needle and 10 ml syringe, introduce 3–5 ml of buffered platelet rich plasma into the area of maximal tenderness or pathology.

Step 5



A single skin poke with multiple penetrations (5–7) into the fascia is sufficient. Ultrasound may be used for most accurate placement of PRP.

Step 6



Post Procedure

The injection area is then sterily dressed. Keep the patient in the supine position for 15 minutes to allow PRP to stay in the local area.

Step 7



Post Procedure Continued

Place the patient in a boot-type immobilizer. Keep the patient non-weight bearing for 48 hours. The boot immobiliser

should be worn when walking or standing for 2–3 weeks after the injection.

Note: The patient is provided with a prescription for pain medication to use over the first 24–48 hours post procedure. **NSAIDs should not be used for one week before the treatment and four weeks post procedure.** Cold therapy/icing of the affected area may be used at the treating physician's discretion.

Achilles Tendinosis

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Introduction

Achilles tendinopathies can be acute or chronic. In acute tendinitis there is inflammation present and in chronic cases there is degeneration of the tendon fibers that may progress to a partial or complete tear. The Achilles tendon is located in the back of the leg and attaches to the heel bone (calcaneus). It is the largest and strongest tendon in the body and gives us the ability to rise up on our toes and jump.¹⁸

Causes:¹⁸

- Participating in activities that involve sudden stops and starts
- Activities that involve repetitive jumping
- Training on poor surface
- Wearing inappropriate footwear

Common Treatments:¹⁸

- Pain medication
- Anti-inflammatory medication (Aspirin, Ibuprofen)
- Physical therapy
- In severe cases, surgery may be needed



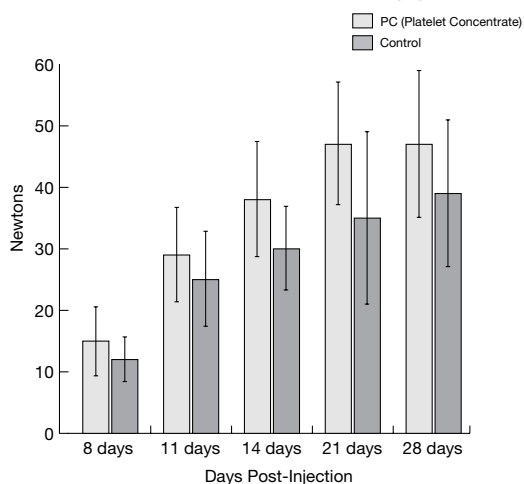
Platelet Concentrate Injection Improves Achilles Tendon Repair in Rats¹⁵

20 Rats

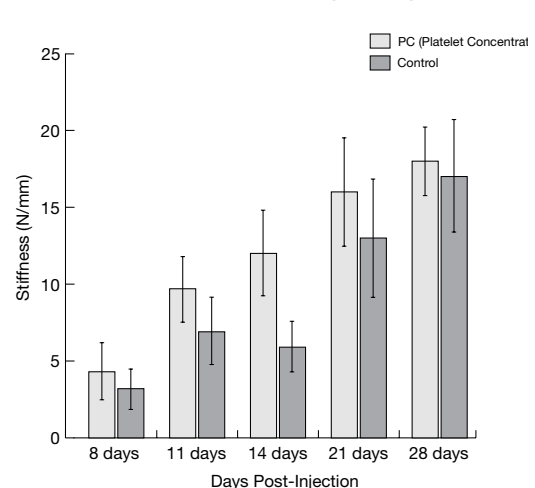
Platelet Concentrate Injection (N=10) – Single Percutaneous Injection

Controls (N=10) – Single Bupivacaine Injection

Force to Tendon Failure (N)



Tendon Stiffness (N/mm)



Recover™ Kit Achilles Tendinosis Protocol: PRP Application

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Note: 3–5 ml of platelet concentrate (Single GPS™ III) is the maximum amount that should be utilised for this technique.

Step 1



Confirm diagnosis with preference of MRI, ultrasound, and/or clinical examination. Confirm the limb to be treated. Place the patient in the prone position. Palpate for area of maximal tenderness.

Step 2



Prep and drape the patient in a sterile manner.

Step 3



Utilising the supplied 25 gauge needle and 10 ml syringe, infiltrate the skin, subcutaneous tissue, and tendon with 2–3 ml of local anaesthetic in area of maximal tenderness. Wait 2 minutes for the anaesthetic to take effect.

Step 4



Note: Buffer the PRP first using the technique on page 6. Utilising the supplied 22 gauge needle and 10 ml syringe, introduce 3–5 ml of buffered platelet rich plasma into the area of maximal tenderness or pathology.

Step 5



A single skin poke with multiple penetrations (5–7) into the maximal area of tenderness is sufficient. Ultrasound may be used for most accurate placement of PRP.

Step 6



Post Procedure

The injection area is then sterily dressed. Keep the patient in the prone position after the injection for 15 minutes to allow PRP to stay in the local area.

Step 7



should be worn for 2–3 weeks after the injection.

Note: The patient is provided with a prescription for pain medication to use over the first 24–48 hours post procedure. **NSAIDS should not be used for one week before the treatment and four weeks post procedure.** Cold therapy/icing of the affected area may be used at the treating physician's discretion.

Post Procedure Continued

Place the patient in a boot-type immobiliser. Keep the patient non-weight bearing for 48 hours. The boot immobiliser

Patellar Tendinosis (Jumper's Knee)

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Introduction

Patellar tendinosis is the degeneration of the tendon that connects the knee cap (Patella) to the shin bone (Tibia). This disorder is seen in patients and athletes that engage in running and jumping type sports such as basketball, volleyball, and soccer. It is characterized by pain in the front of the knee that ranges from a dull ache to severe and sharp pain. As the inflammation progresses, pain will occur during sports and may occur at rest. This is almost always an overuse syndrome.¹⁸

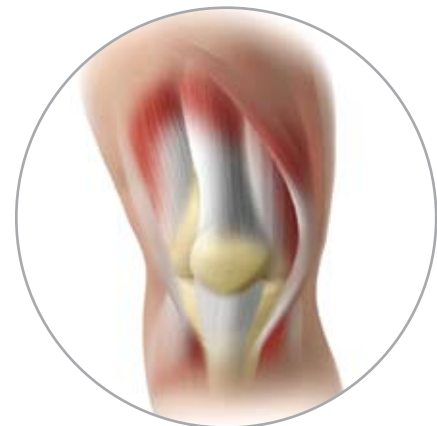
Patellar tendinosis is diagnosed when an athlete or patient complains of pain in the front of the knee coupled with tenderness over the area between the knee cap (Patella) and the shin bone (Tibia). X-rays may show a knee cap riding high (Patella Alta). An MRI scan or ultrasound is employed to confirm the extent of the patellar tendon involvement in chronic cases.¹⁸

Causes

Repetitive or power jumping contributes to swelling and inflammation in the patellar tendon. If untreated, small tears and degeneration of the tendon may occur. Poor muscle flexibility may also be responsible for causing patellar tendinosis.¹⁸

Common Treatments:¹⁸

- Rest
- Ice
- Activity modification
- Patellar tendon strap
- Anti-inflammatory medications
- Eccentric quadriceps strengthening exercises
- Stretching your muscles and tendons
- Electrical stimulation
- In severe cases, surgery may be needed



Recover™ Kit Patellar Tendinosis Protocol: PRP Application

This brochure is intended solely for use outside of the United States. Biomet, as the manufacturer of medical devices, does not practice medicine. This procedure is presented to demonstrate the surgical technique and post-operative protocol utilised by Allan Mishra, M.D.

Note: 3–5 ml of platelet concentrate (Single GPS™ III) is the maximum amount that should be utilised for this technique.

Step 1



Confirm diagnosis with preference of MRI, ultrasound and/or clinical examination. Confirm the limb to be treated.

Step 2



Prep and drape the patient in a sterile manner with the leg hanging over an exam table at 90 degrees.

Step 3



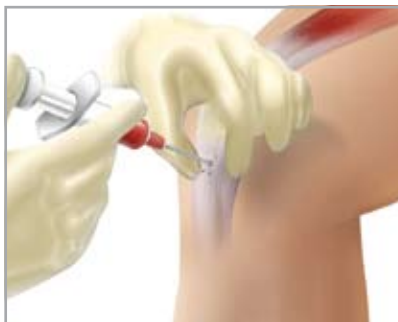
Utilising the supplied 25 gauge needle and 10 ml syringe, infiltrate the skin, subcutaneous tissue, and tendon with 2–3 ml of local anaesthetic in the area of maximal tenderness. Wait 2 minutes for the anaesthetic to take effect.

Step 4



Note: Buffer PRP first using the technique on page 6. Utilising the supplied 22 gauge needle and 10 ml syringe, introduce 3–5 ml of buffered PRP into the area of maximal tenderness or pathology.

Step 5



A single skin poke with multiple penetrations (5–7) into the tendon should be performed. Ultrasound may be used for most accurate placement of PRP.

Step 6



Post Procedure

The procedure area is then sterilely dressed. Keep the patient in the supine position for 15 minutes to allow PRP to soak into patellar tendon. After a patellar tendon Recover™ procedure, a customized rehabilitation protocol should be followed. Initially, the patient can be partial weight bearing with crutches. Progressive exercises should be started about 5–7 days after the procedure.

Note: The patient is provided with a prescription for pain medication to use over the first 24–48 hours post procedure. **NSAIDS should not be used for one week before the treatment and four weeks post procedure.** Cold therapy/icing of affected area may be used at treating physician's discretion.

Recover™ Kit Ordering Information

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Description	Catalog Number
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Recover™ Platelet Separation Kit (Mini GPS™ III)

800-0660

Contents:

- One Disposable Mini GPS™ III Separation Tube
- One 1 ml Syringe with Attached Needle
- Three 10 ml Syringes
- Two 30 ml Syringes
- *One 18 Gauge Needle Set with Clamp
- *Four Gauze Sponges
- *One Roll of Adhesive Tape
- *One 18" Non-latex Tourniquet
- One 18 Gauge Needle (1½")
- One 30 ml Bottle of ACD-A
- One 25 Gauge Needle (1¼")
- One 22 Gauge Needle (1½")
- One Adhesive Bandage
- Six Syringe Tips-Sterile



Recover™ Platelet Separation Kit (Single GPS™ III)

800-0665

Contents:




- One Disposable GPS™ III Separation Tube
- One 1 ml Syringe with Attached Needle
- Three 10 ml Syringes
- One 30 ml Syringe
- One 60 ml Syringe
- *One 18 Gauge Needle Set with Clamp
- *Four Gauze Sponges
- *One Roll of Adhesive Tape
- *One 18" Non-latex Tourniquet
- One 18 Gauge Needle (1½")
- One 30 ml Bottle of ACD-A
- One 25 Gauge Needle (1¼")
- One 22 Gauge Needle (1½")
- One Adhesive Bandage
- Six Syringe Tips-Sterile



*Denotes blood draw kit items

Recover™ Kit Ordering Information

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	Description	Catalog Number
	GPS™ Spare Bucket Kit (Drucker Centrifuge; 2 Green Buckets)	7436
	GPS™ Mini Spare Bucket Kit (Drucker Centrifuge; 2 Purple Buckets)	7433
	Drucker 230 Volt 50-60 Hz Centrifuge	755VES-230V
	GPS™ Mini Non-Sterile Counterbalance (Purple)	800-0505
	GPS™ Standard Non-Sterile Counterbalance (Blue)	800-0508
	Universal Adjustable Counterbalance	800-0507

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

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Date: 03/07

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Authorized Representative: Biomet U.K., Ltd.
Waterton Industrial Estates
Bridgend, South Wales
CF31 3XA UK

Recover® Platelet 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, using acceptable disposal method for potentially contaminated blood products.



DESCRIPTION

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

Recover® Platelet 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 Recover® Platelet Separation Kits with ACD-A, 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 Recover® Platelet Separation Kit with ACD-A.

INDICATIONS FOR USE

Recover® Platelet 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 used for the treatment of tendonosis (recalcitrant tendonitis).

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 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

Recover® Platelet Separation Kit platelet separator is sterilized by exposure to a minimum dose of 25 kGy gamma irradiation. All other Recover® Platelet 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 anticoagulant. Slowly draw 30 to 54ml of patient's own blood. 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:** 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.
4. **SPIN:** Close centrifuge lid. Set RPM to 3.2 (x 1,000) and the time to 15 minutes. Press the start spin. 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 2ml 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: 574-372-1683.

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

01-50-1450
Date: 03/07

This device is approved for international distribution only.

Recover and GPS are registered trademarks in the United States.

Authorized Representative: Biomet U.K., Ltd.
Waterton Industrial Estates
Bridgend, South Wales
CF31 3XA UK

Recover® Mini Platelet Separation Kit with ACD-A

FOR INTERNATIONAL USE ONLY

ATTENTION OPERATING SURGEON

NOTE: FOR SINGLE USE ONLY. Discard the entire disposable kit after one use, using acceptable disposal method for potentially contaminated blood products.



DESCRIPTION

The Recover® Mini Platelet Separation Kit with ACD-A aids separation of the patient's own blood components by density through the use of a Biomet Biologics centrifuge.

Recover® Mini Platelet 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 Recover® Mini Platelet Separation Kits with ACD-A, 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 Recover® Mini Platelet Separation Kit.

INDICATIONS FOR USE

Recover® Mini Platelet 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 used for the treatment of tendonosis (recalcitrant tendonitis).

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 Drucker Company centrifuge). Outcomes using centrifuges from other manufacturers are unknown.
3. Do not use sterilized component 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

Recover® Mini Platelet Separation Kit platelet separator is sterilized by exposure to a minimum dose of 25 kGy gamma irradiation. All other Recover® Mini Platelet 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.

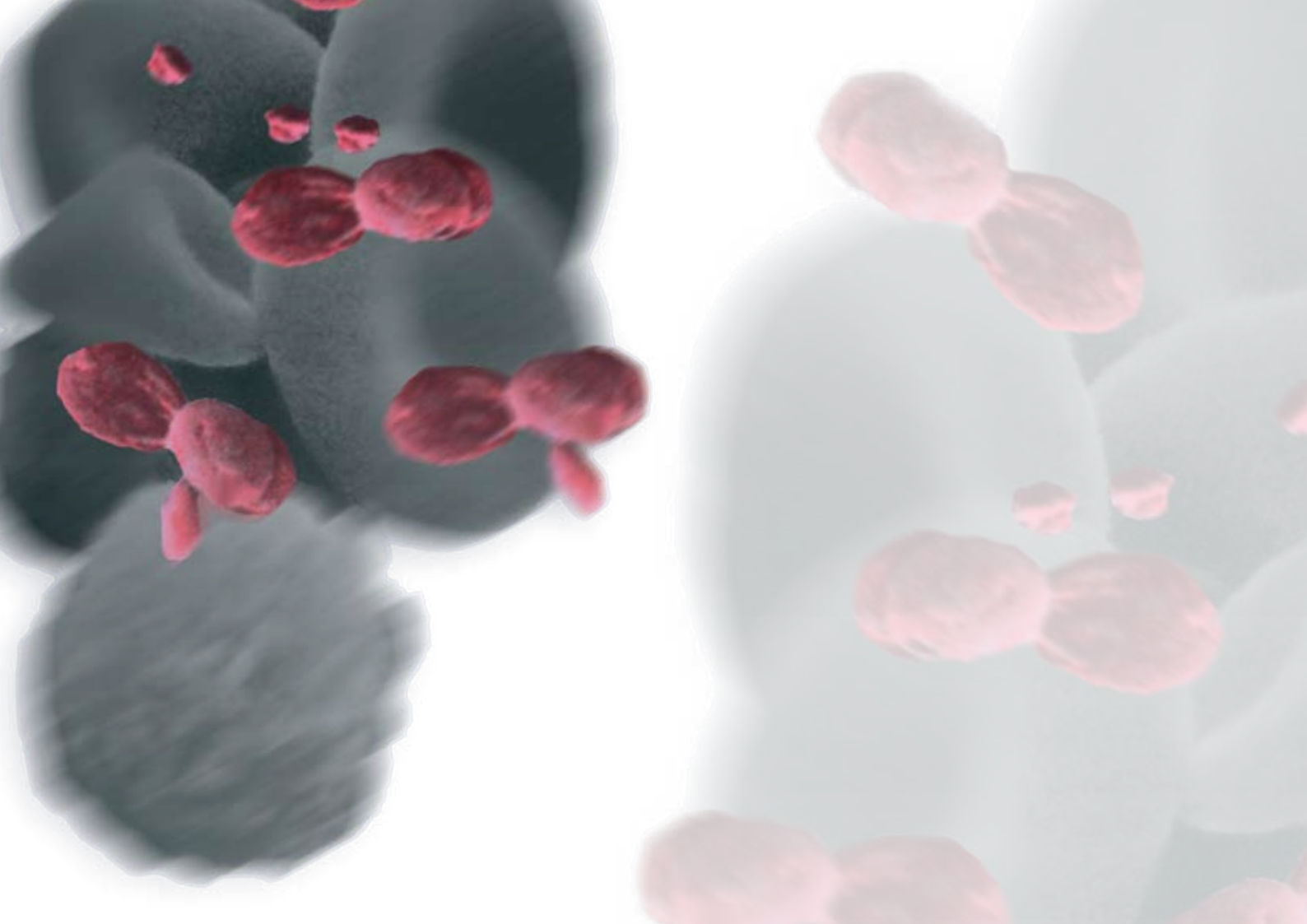
INSTRUCTIONS FOR USE

NOTE: Use standard aseptic technique throughout the following procedures.

1. **DRAW:** Draw 3ml of ACD-A into 30ml syringe. Attach to 18-gauge apheresis needle and prime with ACD-A. Slowly draw 15 to 27ml of patient's own blood into the 30ml 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, 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:** Processing One Platelet Separator Fill purple GPS® Mini counterbalance tube (800-0505) with 18-30ml 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 spin. 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 1ml 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: 574-372-1683.

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

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Responsible Manufacturer

Biomet Biologics LLC
A Subsidiary of Biomet
P.O. Box 587
56 E. Bell Drive
Warsaw, Indiana 46581-0587
USA

Tel.: +1 574 267 6639

Authorized Representative

Biomet UK, Ltd.
Waterton Industrial Estate
Bridgend, South Wales
CF31 3XA
UK

www.biometbiologics.com
www.biometeurope.com

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