

*Are your patients interested in an alternative  
to surgical treatment of their tendinosis or  
acute soft tissue injuries?*

# Recover<sup>®</sup>

platelet separation kit

Accelerating the Body's  
Natural Healing Process



This brochure is for International use only.  
It is not for distribution in the United States.

**BIOMET**  
BIOLOGICS, INC.

# Tennis Elbow (Lateral Epicondylitis)

## 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.

### 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.

### Lateral Epicondylitis Facts:

- Condition typically occurs in patients in their 40s and 50s.<sup>1,2</sup>
- An estimated 4 in 1000 individuals are affected at some time.<sup>3</sup>
- Manual workers and racquet sports athletes are at high risk.<sup>2,4-8</sup>
- Tennis Elbow is a frequent cause of missed work.<sup>9,10</sup>

### Common Treatments:

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



## Recover® Treatment

The Recover® platelet separation kit provides autologous growth factor therapy for accelerated healing of tendinosis/tendinitis.

This brochure is for international use only, and is not for distribution in the USA.

This brochure describes the surgical techniques, stretching/strengthening programs and postoperative protocol used by 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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For product information, including indications, contraindications, warnings, precautions and potential adverse effects, see the package insert herein and Biomet's Biologics website at [www.bmetbiologics.com](http://www.bmetbiologics.com).

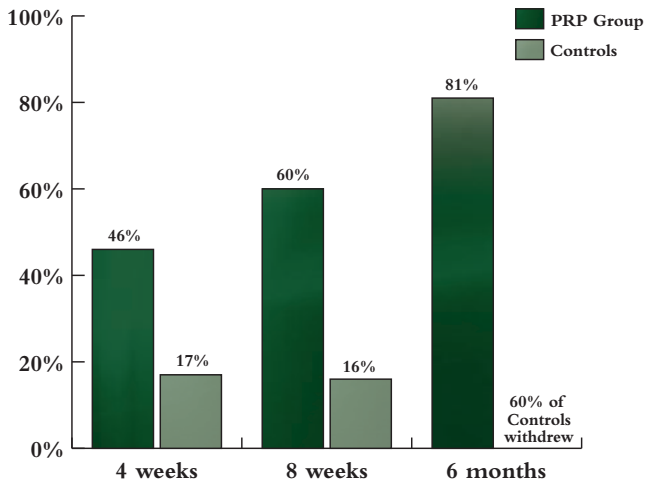
# Treatment of Chronic Severe Elbow Tendinosis with Platelet Rich Plasma: Clinical Results<sup>11</sup>

**20 Patients** – Severe, Chronic Lateral Epicondylitis

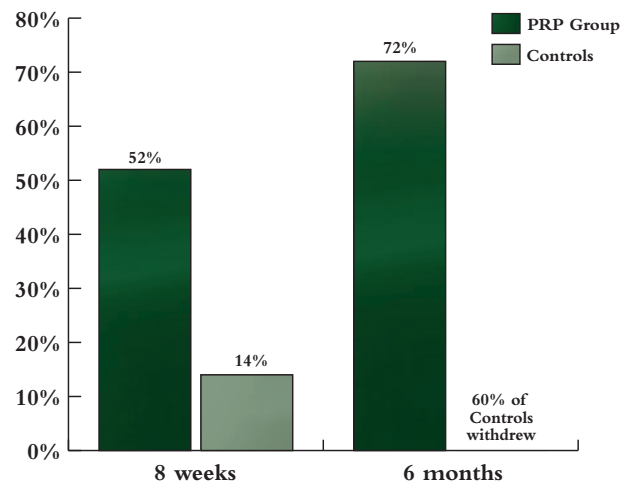
**PRP Application (N=15)** – Single Percutaneous Injection

**Controls (N=5)** – Single Bupivacaine Injection

## Visual Analog Pain Score Improvement



## Mayo Elbow Score Improvement

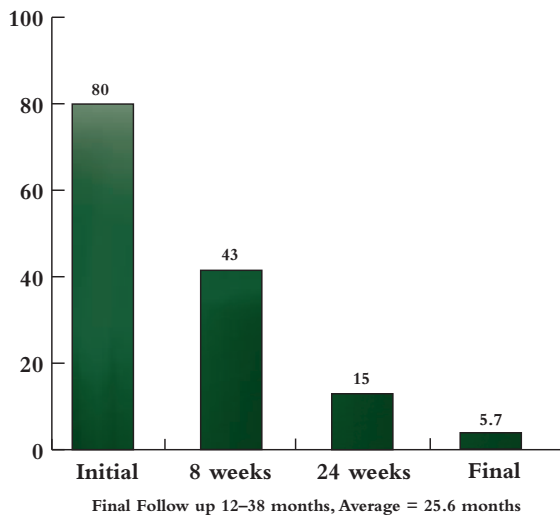


## Final Follow Up<sup>11</sup>

Average Time: 25.6 months (Range 12-38 months)

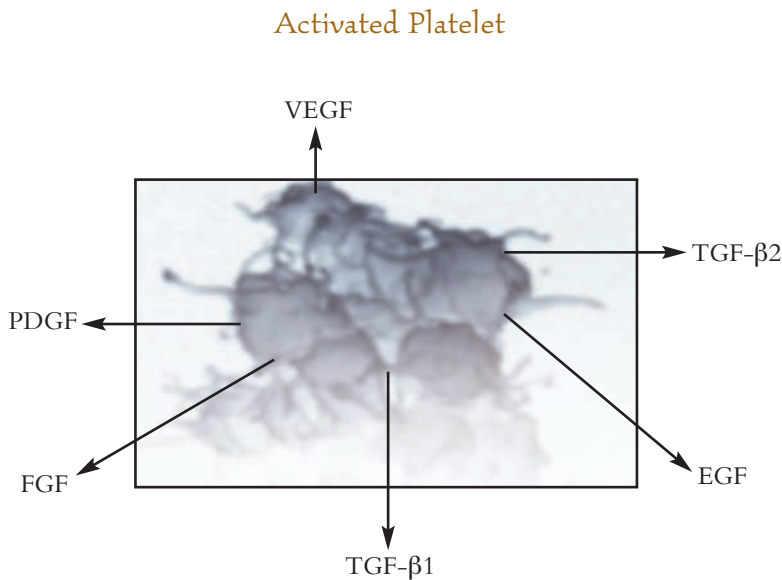
93% Completely Satisfied with treatment – (7% partially satisfied)

## Visual Analog Pain Scores



# Why Platelets?

Utilizing the GPS® II System the patient's own platelets, that travel through the blood stream, can be collected into a highly concentrated formula. When platelets become activated, growth factors are released and initiate the body's natural healing response.



## Platelet Derived Growth Factor (PDGF-aa, PDGF-ab, PDGF-bb)<sup>12</sup>

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

## Transforming Growth Factor (TGF-β1, TGF-β2)<sup>12</sup>

- Promotes formation of extracellular matrix
- Regulates bone cell metabolism

## Vascular Endothelial Growth Factor (VEGF)<sup>12</sup>

- Promotes angiogenesis

## Epidermal Growth Factor (EGF)<sup>12</sup>

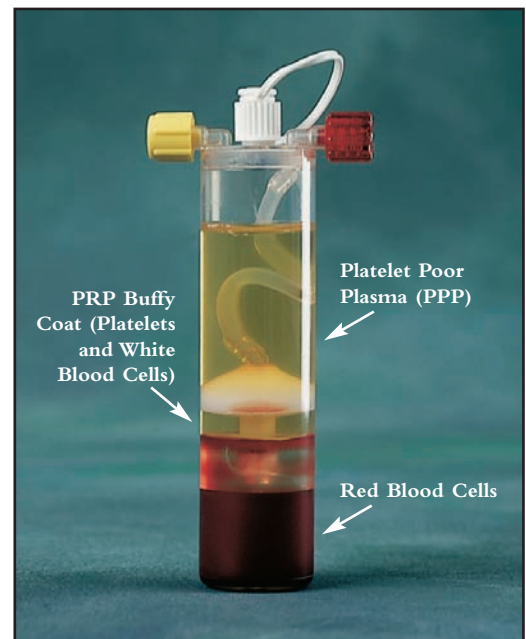
- Promotes cell differentiation
- Stimulates re-epithelialisation, angiogenesis and collagenase activity

## Fibroblast Growth Factor (FGF)<sup>12</sup>

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

# Automated Platelet Collection

In one short, simple spin, the GPS® II System can efficiently capture a majority of the patient's platelets. The patent-pending GPS® II System 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 haematocrit of the patient, the GPS® II System can automatically collect a consistent, high platelet count for each patient.<sup>13</sup>



# Preparation of Platelet Rich Plasma (PRP) with GPS® II and Mini GPS® II System

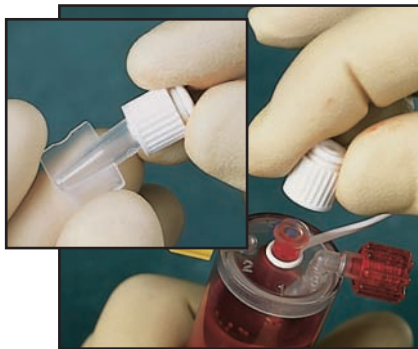
## Step One: Load and Balance



**Mini GPS® II:** Withdraw 3 ml of ACD-A (Citrate Anticoagulant) into 30 ml syringe. Withdraw 27 ml of blood from the uninvolved 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® II:** Slowly load blood-filled 60 ml syringe (6 ml of ACD-A and 54 ml of whole blood) into centre port (Achilles/Plantar Fascia Procedures).



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



**Mini GPS® II:** Place Mini GPS® II canister into centrifuge. Fill the purple Mini GPS® II counterbalance with 30 ml of sterile saline and place into the opposite side of the centrifuge.

**Single GPS® II:** If using the single GPS® II canister, the appropriate buckets and counterbalance must be utilised. Fill the blue GPS® II system counterbalance with 60 ml of sterile saline and place into opposite side of centrifuge (Achilles/Plantar Fascia Procedures).

## Step Two: Spin



Close the lid and set speed for 3.2 (x1000RPM) and timer to 15 minutes. Press green button to start spin. Once complete, press red button to open lid.

## Step Three: PPP Extraction



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

## Step Four: PRP Extraction



**Mini GPS® II:** Shake the Mini GPS® II canister vigorously for 30 seconds to re-suspend platelets. Unscrew red cap and withdraw 3 ml of PRP with a 10 ml syringe from port No. 3.

**Single GPS® II:** Shake canister vigorously for 30 seconds to re-suspend platelets. Unscrew red cap and withdraw 6 ml of PRP with a 10 ml syringe from port No. 3 (Achilles/Plantar Fascia Procedures).

**Note:** If the Thermo IEC centrifuge is being utilised, the red or yellow cap of the canister should be pointed towards the center rotor.

# Recover® Buffering Technique for PRP: Patent No. 6,811,777 B2



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

# Recover® Tennis Elbow Protocol: PRP Application

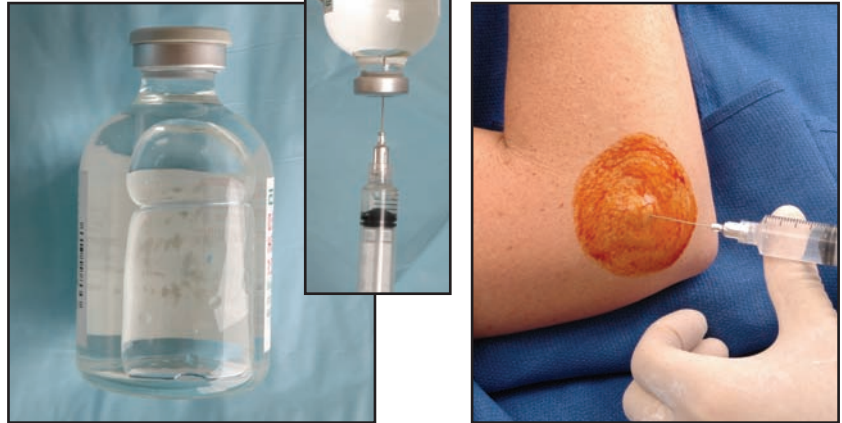
**Note:** 3 ml of platelet concentrate (Mini GPS® II) is the maximum amount that should be utilised for this technique.

## Step One



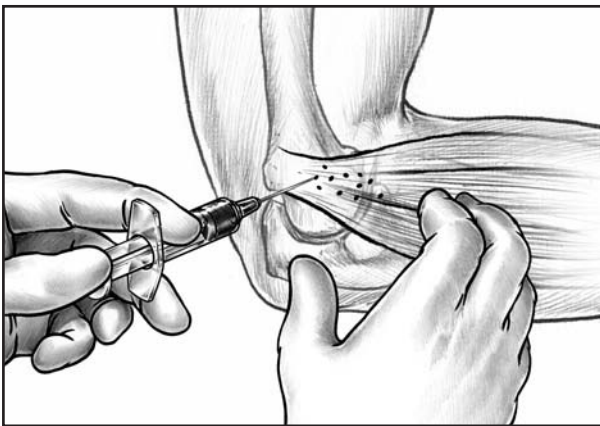
Confirm the limb to be treated. The patient is placed in the supine position in preparation for the tendon injection. The area is palpated for the spot of maximal tenderness. This is noted and the skin is sterilely prepped.

## Step Two



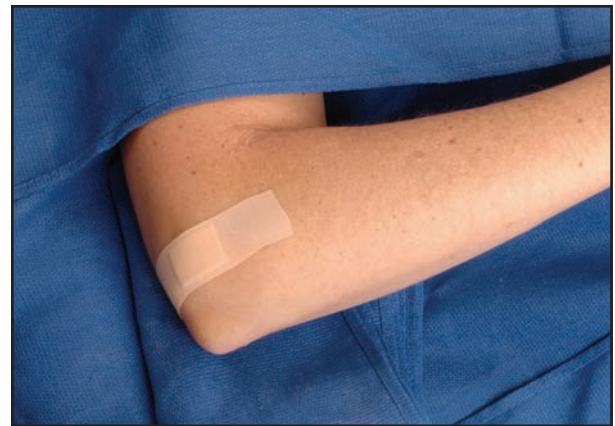
Utilising the supplied 25-gauge needle and 5 ml syringe, a numbing injection consisting of 2–3 ml of 0.5% Bupivacaine HCL and Epinephrine (or an equivalent anaesthetic) is placed in the area of maximal tenderness. The injections are placed superficially in the skin and dermis over the common extensor tendon origin. Approximately 0.5 ml of Bupivacaine HCL and Epinephrine (or an equivalent anaesthetic) should also be injected into the tendon. Wait 2 minutes to allow anaesthetic to take effect.

## Step Three



**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.

## Step Four



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

## Postoperative

The patient is sent home with a prescription for a narcotic pain medication for pain control overnight. Non-steroidal anti-inflammatory medication should not be used post-operatively. Cold therapy/icing of the affected area may be used at the treating physician's discretion.

## Activity After the Procedure

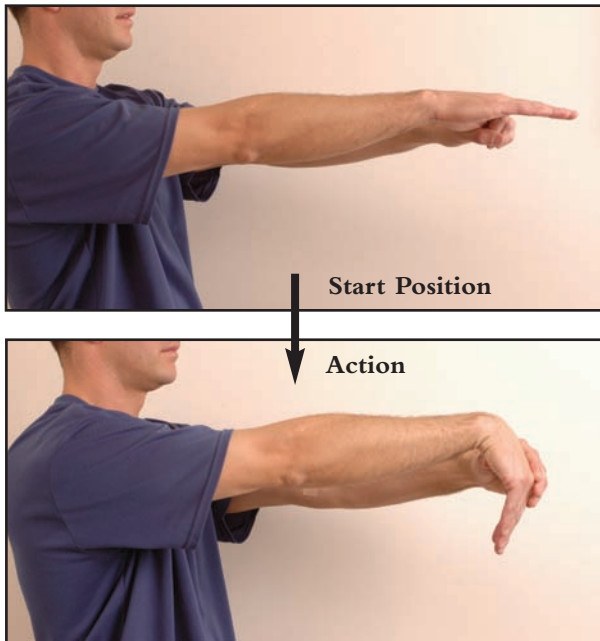
No vigorous activities, strong gripping or lifting of loads greater than 4.5 kilograms for four weeks post procedure. See the following pages for stretching/strengthening protocol.

# Tennis Elbow Stretching and Strengthening Program

The patient begins a stretching program (Level One) 48 hours after the injection and progresses to a strengthening program two weeks later (Level Two).

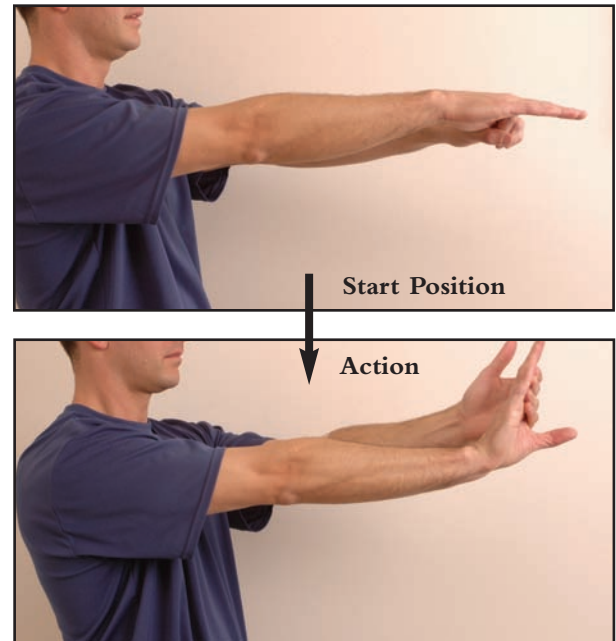
## Level One: Stretching

The stretches in this section should be done daily for two weeks. When the elbow pain improves, proceed to Level Two.



### Wrist Extensor Stretch

Purpose	To stretch the forearm muscles and wrist.
Start Position	Hold your arm straight out in front of you with your palm facing down. Keep your elbow perfectly straight.
Action	Grasp the hand to be stretched with the other hand and slowly bend it toward the floor until the stretch is felt along the top of the forearm and elbow.
Parameters	Hold the stretch for 20 seconds, Repeat 10 times.
Tips	Keep shoulder relaxed and do the stretch slowly as tolerated.



### Wrist Flexor Stretch

Purpose	To stretch the forearm muscles and wrist.
Start Position	Hold your arm straight out in front of you with your palm facing down. Keep your elbow perfectly straight.
Action	Grasp the fingers with the other hand and slowly bend them toward the ceiling until the stretch is felt along the underside of the forearm and elbow.
Parameters	Hold the stretch for 20 seconds, Repeat 10 times.
Tips	Keep shoulder relaxed and do the stretch slowly as tolerated.

## Level Two: Strengthening

The exercises in this section should be done every other day for 2–4 weeks after completion of Level One Stretching. The band (shown below in the photos) is included in the Recover™ Kit.



### Wrist Extensor Strengthening Exercise

Purpose	To strengthen the forearm muscles and wrist.
Start Position	In a seated position, rest your forearm on your thigh and let your wrist fall palm downward toward the floor. Hook the band around your foot.
Action	Grasp the band and then slowly move your wrist and hand toward the ceiling while keeping your forearm on your thigh. Hold for one second then slowly move wrist and hand toward the floor again.
Parameters	Perform 3 sets of 20 repetitions, every other day.
Tips	Squeeze shoulder blades together as you do this exercise. Also, keep the movements slow and controlled.

### Wrist Flexor Strengthening Exercise

Purpose	To strengthen the forearm muscles and wrist.
Start Position	In a seated position, rest your forearm on your thigh and let your wrist fall palm upward toward the floor. Hook the band around your foot.
Action	Grasp the band and then slowly move your wrist and hand toward the ceiling while keeping your forearm on your thigh. Hold for one second then slowly move wrist and hand toward the floor again.
Parameters	Perform 3 sets of 20 repetitions, every other day.
Tips	Squeeze shoulder blades together as you do this exercise. Also, keep the movements slow and controlled.

# Plantar Fasciitis

## 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.

### Causes:

- A change or increase in activities
- No arch support
- Lack of flexibility in the calf muscles
- Being overweight
- A sudden 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:

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

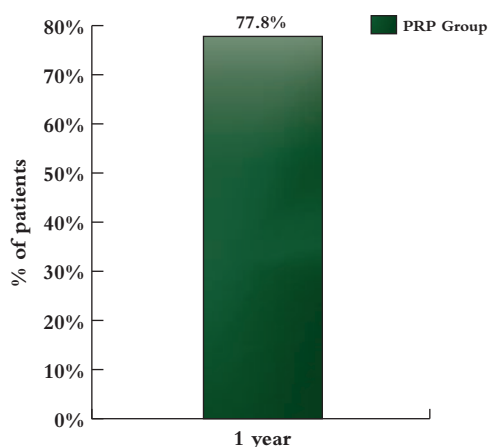


## Growth Factors for Chronic Plantar Fasciitis?: Clinical Results<sup>14</sup>

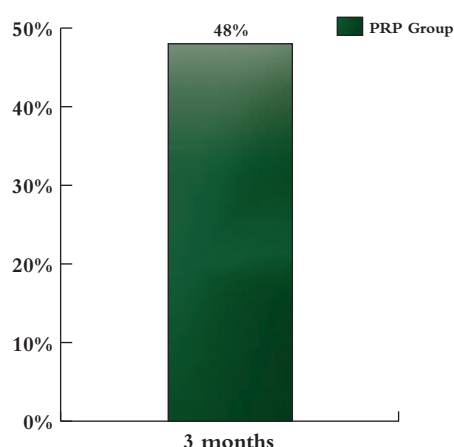
**9 Patients** – Chronic Plantar Fasciitis

**PRP Application** – Single Percutaneous Injection

Complete Resolution of Pain



Average Decrease in Medial Band Thickness



# Recover® Plantar Fasciitis Protocol: PRP Application

**Note:** 3 to 5 ml of platelet concentrate (Single GPS® II) is the maximum amount that should be utilised for this technique.

## Step One



Place the patient in the supine position with the foot in an optimal position for injection. Palpate for maximal area of tenderness.

## Step Two



Prep and drape the patient in a sterile manner.

## Step Three



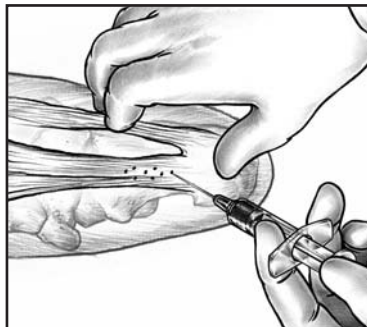
Utilising the supplied 25 gauge needle and 5 ml syringe, infiltrate the skin, subcutaneous tissue, and tendon with 2–3 ml of local anaesthetic in the area of maximal tenderness. Wait 2 minutes for the anaesthetic to take effect.

## Step Four



**Note: Buffer PRP first using the technique on page 4.** Utilising the supplied 22g needle and 10 ml syringe, introduce 3–5 ml of buffered platelet rich plasma into the area of maximal tenderness or pathology.

## Step Five



A single skin poke with multiple penetrations (5–7) into the fascia is sufficient.

## Step Six



The injection area is then sterilely dressed. Keep the patient in the supine position for 15 minutes to allow PRP to stay in the local area. Give the patient a prescription for narcotic pain medication to use over the first 24–48 hours after the injection.

## Step Seven



Place the patient in a boot-type immobiliser. Keep the patient non-weight bearing for 48 hours. The boot immobiliser should be worn for 2–3 weeks after the injection.

## Activity After the Procedure

See pages 12–13 for Plantar Fasciitis Stretching/Strengthening Program.

# Achilles Tendinosis

## Introduction

**Achilles tendinitis** 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.

### Causes:

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

### Common Treatments:

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



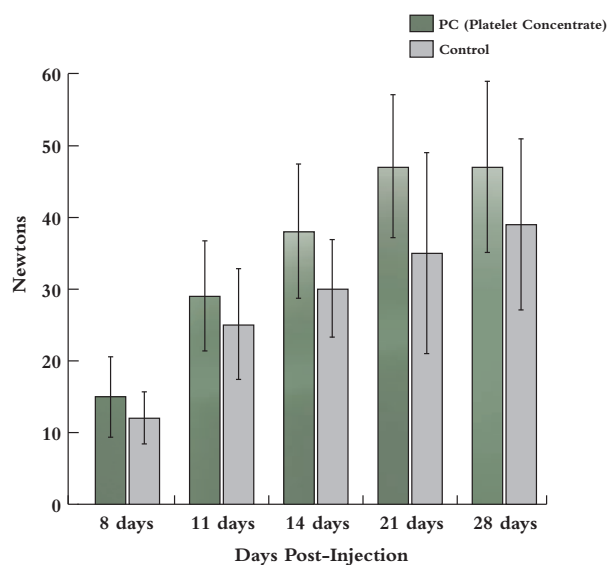
## Platelet Concentrate Injection Improves Achilles Tendon Repair in Rats<sup>15</sup>

### 20 Rats

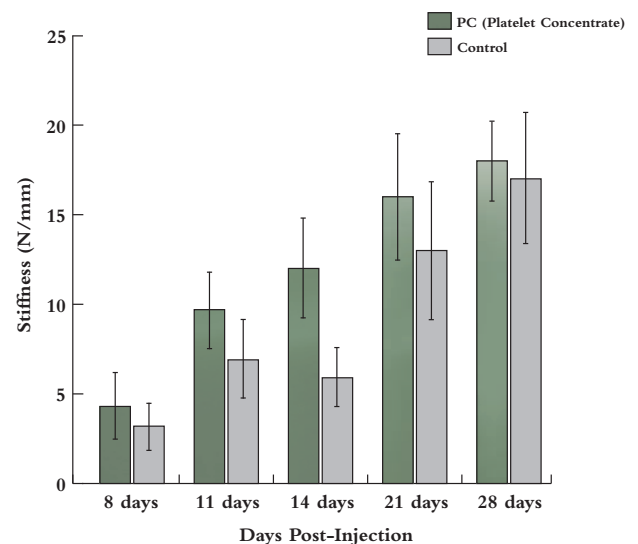
**Platelet Concentrate Injection (N=10)** – Single Percutaneous Injection

**Controls (N=10)** – Single Bupivacaine Injection

Force to Tendon Failure (N)



Tendon Stiffness (N/mm)



# Recover<sup>®</sup> Achilles Tendinosis Protocol: PRP Application

**Note:** 3 to 5 ml of platelet concentrate (Single GPS<sup>®</sup> II) is the maximum amount that should be utilised for this technique.

## Step One



Place the patient in the prone position. Palpate for area of maximal tenderness.

## Step Two



Prep and drape the patient in a sterile manner.

## Step Three



Utilising the supplied 25 gauge needle and 5 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 Four



**Note: Buffer the PRP first using the technique on page 4.** Utilising the supplied 22g needle and 10 ml syringe, introduce 3–5 ml of buffered platelet rich plasma into the area of maximal tenderness or pathology.

## Step Five



A single skin poke with multiple penetrations (5–7) into the maximal area of tenderness is sufficient.

## Step Six



The injection area is then sterilely dressed. Keep the patient in the prone position after the injection for 15 minutes to allow PRP to stay in the local area. Give the patient a prescription for narcotic pain medication to use over the first 24–48 hours after the injection.

## Step Seven



Place the patient in a boot-type immobiliser. Keep the patient non-weight bearing for 48 hours. The boot immobiliser should be worn for 2–3 weeks after the injection.

## Activity After the Procedure

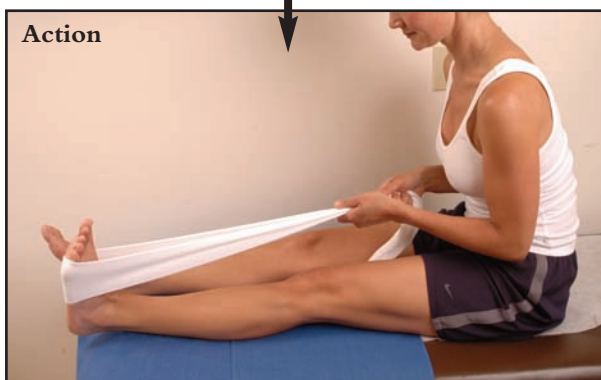
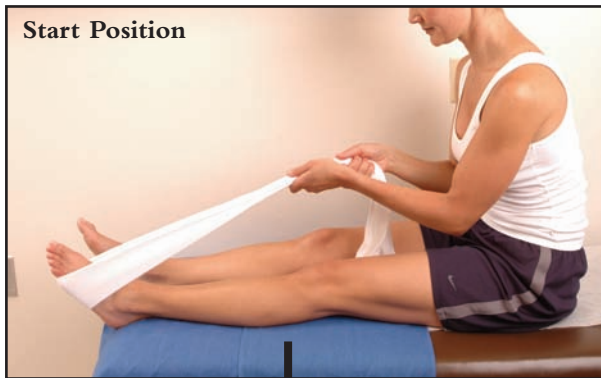
See pages 12–13 for Achilles Stretching/Strengthening Program.

# Achilles/Plantar Fascia Stretching and Strengthening Program

The patient begins a stretching program (Level One) 72 hours after the injection and progresses to a strengthening program two weeks later (Level Two).

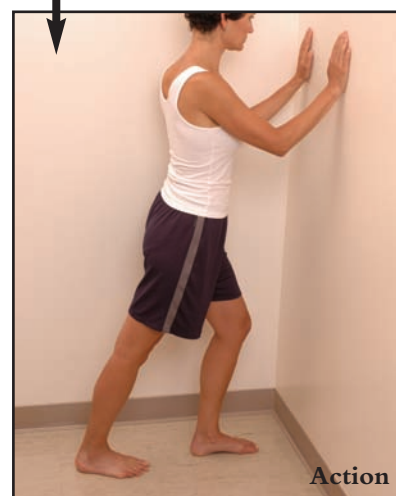
## Level One: Stretching

The stretches in this section should be done daily for two weeks. When the pain improves, proceed to Level Two. The band included in the Recover® Kit may also be utilised for stretching.



### Passive Seated Achilles/Plantar Fascia Stretching Exercise

- Purpose** To passively stretch the Achilles and Plantar Fascia.
- Start Position** Seated with leg fully extended. Loop a towel/band around your foot.
- Action** Slowly and gently pull the towel/band toward your chest. This will stretch your Achilles and Plantar Fascia.
- Parameters** Hold the stretch for 20 seconds and repeat 10 times.
- Tips** Keep your knee fully extended and make sure to do the stretch slowly. Do not stretch into any significant pain.

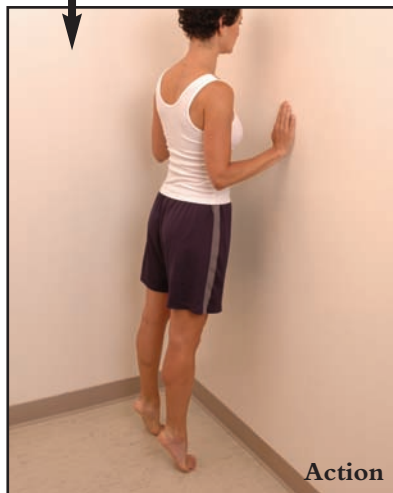


### Calf/Achilles Standing Stretching Exercise

- Purpose** To gain flexibility in the muscles that run along the back of your lower leg.
- Start Position** Lean against the wall with the leg to be stretched behind the other. Disperse weight of back leg on the ball of the foot.
- Action** Shift your body weight toward the wall and gently press back heel to the floor. Perform exercise with back knee completely straight.
- Parameters** Hold stretch for 20 seconds, Repeat 10 times.
- Tips** Keep back heel on the ground during the 20 second stretch; the movement for this stretch is subtle.

## Level Two: Strengthening

The exercise in this section should be done every other day for 2–4 weeks after completion of Level One Stretching.



### Heel Raises Strengthening Exercise

Purpose	To strengthen the muscles along the back of the lower leg/ankle.
Start Position	Stand with feet flat on the floor and hands on a wall.
Action	While keeping the balls of the feet on the ground, lift both heels off the floor.
Parameters	Repeat for 3 sets of 25–30 repetitions.
Tips	Lower the weight back to the floor very slowly in comparison to the rate in which you raise it (1 second up, 3 seconds down); distribute the weight evenly between the first and fifth toe throughout the exercise.

### Heel Raises Strengthening Exercise

Purpose	To strengthen the muscles along the back of the lower leg/ankle.
Start Position	Stand on the leg to be exercised next to the wall.
Action	While keeping the ball of the foot on the ground, lift your heel off the floor.
Parameters	Repeat for 3 sets of 25–30 repetitions.
Tips	Lower the weight back to the floor very slowly in comparison to the rate in which you raise it (1 second up, 3 seconds down); distribute the weight evenly between the first and fifth toe throughout the exercise.

# Ordering Information

Description	Catalog Number
<b>Recover® Platelet Separation Kit (Tennis Elbow)</b>	<b>800-0650</b>
<p><b>Contents:</b></p> <ul style="list-style-type: none"> <li>One Disposable Mini GPS® II Separation Tube</li> <li>One 1 ml Syringe with Attached Needle</li> <li>Two 5 ml Syringes</li> <li>One 10 ml Syringe</li> <li>Two 30 ml Syringes</li> <li>*One 18 Gauge Needle Set with Clamp</li> <li>*Four Gauze Sponges</li> <li>*One Roll of Adhesive Tape</li> <li>*One 18" Tourniquet</li> <li>One 18 Gauge Needle (1½")</li> <li>One 30 ml Bottle of ACD-A</li> <li>One 25 Gauge Needle (1¼")</li> <li>One 22 Gauge Needle (1½")</li> <li>One Band-aid</li> <li>One Orange 4' Exercise Band</li> </ul>	
<b>Recover® Platelet Separation Kit (Achilles/Plantar Fascia)</b>	<b>800-0655</b>
<p><b>Contents:</b></p> <ul style="list-style-type: none"> <li>One Disposable GPS® II Separation Tube</li> <li>One 1 ml Syringe with Attached Needle</li> <li>Two 5 ml Syringes</li> <li>One 10 ml Syringe</li> <li>One 30 ml Syringe</li> <li>One 60 ml Syringe</li> <li>*One 18 Gauge Needle Set with Clamp</li> <li>*Four Gauze Sponges</li> <li>*One Roll of Adhesive Tape</li> <li>*One 18" Tourniquet</li> <li>One 18 Gauge Needle (1½")</li> <li>One 30 ml Bottle of ACD-A</li> <li>One 25 Gauge Needle (1¼")</li> <li>One 22 Gauge Needle (1½")</li> <li>One Band-aid</li> <li>One Orange 4' Exercise Band</li> </ul>	

\*Denotes blood draw kit items

# Ordering Information

Recover® Mini GPS® II Platelet Separation Kit/Recover® GPS® II System	
Description	Catalog Number
Drucker 230 Volt 50–60 Hz Centrifuge (Table Top) (Replacing Thermo IEC Centrifuge [7427])	755VES-230V
GPS® Spare Bucket Kit (2 Blue Centrifuge Buckets for Drucker Centrifuge) (Achilles/Plantar Fascia Procedures)	7431
GPS® Mini Spare Bucket Kit (2 Purple Centrifuge Buckets for Drucker Centrifuge) (Tennis Elbow Procedures)	7433
Biomet Biologics Cart	7440
GPS® Non-Sterile Counterbalance (Purple; Tennis Elbow Procedures)	800-0505
GPS® Non-Sterile Counterbalance (Blue; Achilles/Plantar Fascia Procedures)	800-0508



Biomet Biologics  
Cart



Drucker 230 Volt  
50–60 Hz Centrifuge



GPS® Spare  
Bucket Kit (Blue)



GPS® Mini Spare  
Bucket Kit (Purple)



GPS® and GPS®  
Mini Non-Sterile  
Counterbalance

Note: If the Thermo IEC centrifuge (7427) is being utilised, the GPS® spare bucket kit (7430) and the GPS® mini spare bucket kit (7432) are needed.

Biomet Biologics, Inc.  
P.O. Box 587  
Date: 05/06  
56 E. Bell Drive  
Warsaw, Indiana 46581 USA

01-50-1419

6. RE-SUSPEND: Shake tube vigorously for 30 seconds to re-suspend the platelets.
7. PRP EXTRACTION: Unscrew red cap on port #3. Connect 10ml syringe and extract platelet-rich-plasma (PRP).

These devices are approved for international distribution only.

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.

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

CC' 0086

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

01-50-1420  
Date: 05/06

## Recover® GPS® II Platelet Concentrate Separation Kit With 30ml ACD-A Anticoagulant

### FOR INTERNATIONAL USE ONLY

#### ATTENTION OPERATING SURGEON

#### DESCRIPTION

Recover® GPS® II Platelet Concentrate Separation KitThe Recover® GPS® II Platelet Concentrate Separation Kit aids separation of the patient's own blood components by density through the use of the GPS® - Thermo International Equipment Company (IEC) centrifuge or The Drucker Company centrifuge. Recover® GPS® II Platelet Concentrate Separation Kit 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® GPS® II Platelet Concentrate Separation Kits, are packaged, labeled and sterilized as indicated by their individual labeling. Recover® GPS® II Platelet Concentrate Separation Kit and blood draw kit components do not contain latex.

ACD-A Anticoagulant is supplied by Citra Anticoagulants, Inc. Braintree, MA manufactured by Cytosol Laboratories, Inc. Braintree, MA.

#### INDICATIONS FOR USE

Recover® GPS®II Platelet Concentrate Separation Kit Recover® GPS® II Platelet Concentrate Separation Kit 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). This kit, with ACD-A Anticoagulant in the 30 ml container, is not cleared or approved for marketing in the United States.

#### INTENDED USE

Recover® GPS® II Platelet Concentrate Separation Kit Blood is drawn from the patient. The blood is then spun in a Thermo IEC centrifuge or Drucker Company centrifuge in accordance with centrifuge operating directions. The platelet concentrate is then collected with a syringe. ACD-A Anticoagulant is for use only with the Recover® GPS® II Platelet Concentrate Separation Kit.

#### WARNINGS AND PRECAUTIONS

1. Use proper safety precautions to guard against needle sticks.
2. Follow manufacturer instructions when using centrifuge. Use only GPS® – IEC centrifuge or Drucker Company centrifuge. Outcomes using centrifuges from other manufacturers are unknown.
3. Follow manufacturer package insert for ACD-A Anticoagulant.
4. Do not use sterile component of this kit if package is opened or damaged.
5. Single use device, do not reuse.
6. The surgeon is to be thoroughly familiar with the equipment and the surgical procedure prior to using this device.
7. The patient is to be made aware of general risks associated with treatment and the possible adverse effects.
8. Use prepared platelet concentrate material within 6 hours after drawing blood from patient.
9. 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® GPS® II Platelet Concentrate Separation Kit unit is sterilized by exposure to a minimum dose of 25 kGy gamma irradiation. All other Recover® GPS® II Platelet Concentrate Separation Kit components are sterilized by the respective suppliers using irradiation or ethylene oxide gas. Do not re-sterilize. Do not use after expiration date.

#### INSTRUCTIONS FOR USE

1. DRAW 6ml of anticoagulant into 60ml syringe, attach to apheresis needle and prime with anticoagulant. Draw blood using standard aseptic practice. Draw 30 to 54ml of blood from patient. Gently, but thoroughly mix the whole blood and anticoagulant upon collection to prevent coagulation.
2. LOAD: Unscrew cap on center blood port #1 and remove cap with green packaging post. Discard cap and green packaging post. Slowly load blood-filled 60ml syringe (6 ml of citrate anticoagulant and 30 to 54ml of whole blood) into center blood port #1. Unscrew clear protective inner piece from white tethered cap and screw back onto center blood port #1. Place separator in centrifuge.
3. BALANCE: Fill Recover® GPS® II blue counterbalance tube (800-0508) with 30-54ml of sterile saline (equal to amount of whole blood +ACD-A dispensed in the Recover® GPS® II disposable). Place into opposite side of centrifuge.
4. SPIN: Close lid and set speed for 3.2 (x 1,000) and time to 15 minutes. Press green button to start spin. Once spin is complete, press red button to open lid.
5. PPP EXTRACTION: Unscrew yellow cap on port #2. Connect 30ml syringe and extract platelet poor plasma (PPP).

## Recover® GPS® Mini Platelet Concentrate Separation Kit With 30ml ACD-A Anticoagulant

### FOR INTERNATIONAL USE ONLY

#### ATTENTION OPERATING SURGEON

#### DESCRIPTION

Recover® GPS® Mini Platelet Concentrate Separation Kit The Recover® GPS® Mini Platelet Concentrate Separation Kit aids separation of the patient's own blood components by density through the use of the GPS® - Thermo International Equipment Company (IEC) centrifuge or The Drucker Company centrifuge. Recover® GPS® Mini Platelet Concentrate Separation Kit 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® GPS® Mini Platelet Concentrate Separation Kits, are packaged, labeled and sterilized as indicated by their individual labeling. Recover® GPS® Mini Platelet Concentrate Separation Kit and blood draw kit components do not contain latex.

ACD-A Anticoagulant is supplied by Citra Anticoagulants, Inc. Braintree, MA manufactured by Cytosol Laboratories, Inc. Braintree, MA.

#### INDICATIONS FOR USE

Recover® GPS® Mini Platelet Concentrate Separation Kit Recover® GPS® Mini Platelet Concentrate Separation Kit 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). This kit, with ACD-A Anticoagulant in the 30 ml container, is not cleared or approved for marketing in the United States.

#### INTENDED USE

Recover® GPS® Mini Platelet Concentrate Separation Kit Blood is drawn from the patient. The blood is then spun in a Thermo IEC centrifuge or Drucker Company centrifuge in accordance with centrifuge operating directions. The platelet concentrate is then collected with a syringe. ACD-A Anticoagulant is for use only with the Recover® GPS® Mini Platelet Concentrate Separation Kit.

#### WARNINGS AND PRECAUTIONS

1. Use proper safety precautions to guard against needle sticks.
2. Follow manufacturer instructions when using centrifuge. Use only GPS® – IEC centrifuge or Drucker Company centrifuge. Outcomes using centrifuges from other manufacturers are unknown.
3. Follow manufacturer package insert for ACD-A Anticoagulant.
4. Do not use sterile component of this kit if package is opened or damaged.
5. Single use device, do not reuse.
6. The surgeon is to be thoroughly familiar with the equipment and the surgical procedure prior to using this device.
7. The patient is to be made aware of general risks associated with treatment and the possible adverse effects.
8. Use prepared platelet concentrate material within 4 hours after drawing blood from patient.
9. 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® GPS® Mini Platelet Concentrate Separation Kit unit is sterilized by exposure to a minimum dose of 25 kGy gamma irradiation. All other Recover® GPS® Mini Platelet Concentrate Separation Kit components are sterilized by the respective suppliers using irradiation or ethylene oxide gas. Do not re-sterilize. Do not use after expiration date.

#### INSTRUCTIONS FOR USE

1. DRAW 3ml of anticoagulant into 30ml syringe, attach to apheresis needle

- and prime with anticoagulant. Draw blood using standard aseptic practice. Draw 15 to 27ml of blood from patient. Gently, but thoroughly mix the whole blood and anticoagulant upon collection to prevent coagulation.
2. LOAD: Unscrew cap on center blood port #1, and remove cap and green packaging post. Discard both. Slowly load blood-filled 30ml syringe (3ml of citrate anticoagulant and 15 to 27ml of whole blood) into center blood port #1. Unscrew clear protective inner piece from white tethered cap and screw back onto center blood port #1. Place separator in centrifuge.
  3. BALANCE: If processing one disposable, fill Recover® GPS® Mini purple counterbalance tube (800-0505) with 15-30ml of sterile saline (equal to amount of whole blood +ACD-A dispensed in the Recover® GPS® Mini disposable). Place into opposite sides of centrifuge. If processing two GPS® disposables, fill both tubes with equal amounts of whole blood +ACD-A. Place into opposite sides of centrifuge.
  4. SPIN: Close lid and set speed for 3.2 (x 1,000) and time to 15 minutes. Press green button to start spin. Once spin is complete, press red button to open lid.
  5. PPP EXTRACTION: If platelet-poor-plasma (PPP) is desired, unscrew yellow cap on port #2. Connect 30ml syringe and extract PPP.
  6. SUSPEND: Shake tube vigorously for 30 seconds to suspend the platelets.
  7. PRP EXTRACTION: Unscrew red cap on port #3. Connect 5ml syringe and extract platelet-rich-plasma (PRP).

These devices are approved for international distribution only.

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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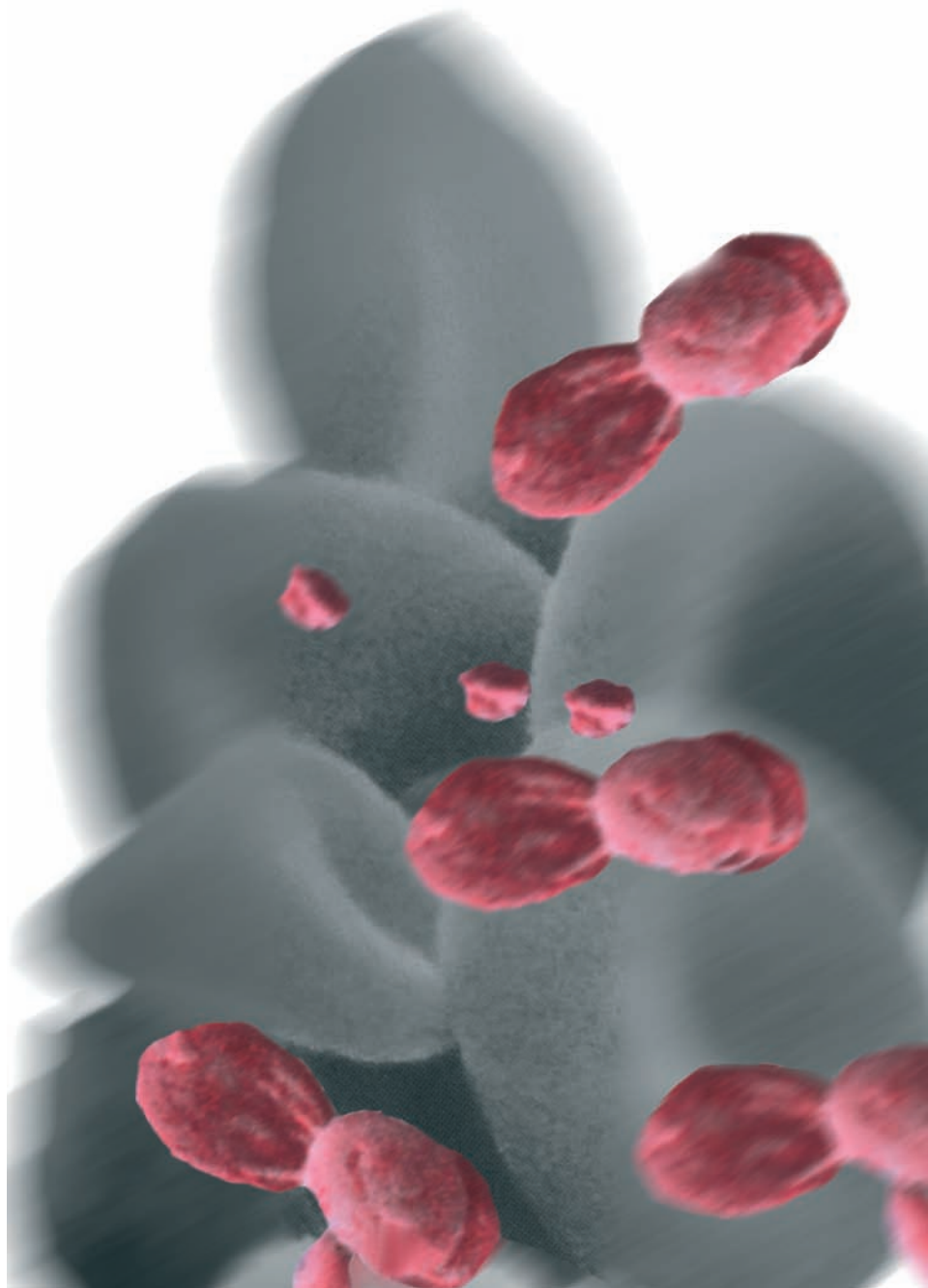
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