

# REVIVE

ADVANCED TRAINING CONSULTANTS

Introducing

**REVIVE**

ADVANCED TRAINING CONSULTANTS

Shilpi Khetarpal, MD, FAAD



# A Clinician's Guide to Regenerative Medicine

Shilpi Khetarpal, MD, FAAD

<https://revivetrainings.com>

Call us at (833) 573-8483

# The FDA and Physicians

Important to understand that the FDA DOES NOT regulate the practice of medicine. They regulate companies that are commercializing medical devices and drugs.

However...

- There are risks, including **legal, safety** and **ethical issues** that must be understood by medical providers that knowingly or unknowingly choose to purchases unapproved drugs and devices to treat patients.
- This is a much different from using FDA-Approved drugs and FDA-Cleared Devices in an off-label application



# Definitions

- Allogeneic Products and Regulatory Status
- 351 vs. 361 designations (Drugs vs. Homologous use)
- Minimal Manipulation definition
- Autologous Products and Regulatory Status
- Legal/Approved/Cleared Autologous Cellular Therapies

# Allogeneic vs. Autologous

**Allogeneic** describes a human cell or tissue procedure that is harvested from a donor patient, typically cultured in a lab and reapplied to a different patient of the same species.

- Classic examples of allogeneic products:
  - *Amniotic Fluid or Tissues (intact dehydrated tissue matrix – no live cells)*
  - *Cord blood derived Mesenchymal Stem Cells (MSC)*
  - *Placental derived (MSC)*
  - *Exosomes*

# Allogeneic vs. Autologous

**Autologous** describes a human cell or tissue procedure that is harvested from the patient and reapplied to the same patient at the point of care.

- Classic examples of Autologous procedures in Aesthetics and Orthobiologics
  - *PRP*
  - *Fat Transfer*
  - *BAMC (Bone Marrow Transplant)*

# Definition: 351 Drug Pathway

Cellular or Tissue products that do not meet the description of **Minimal Manipulation** are typically being cultured in a lab, mixed with enzymes or processed in a way that is dramatically altering its original form.

Companies with these products are required by the FDA to apply for an IND (Investigational New Drug) in the case of allogeneic cellular or tissue products.

The IND pathway is legal but takes 5-10 years. All physicians using the product pre-FDA approval must be part of the IND and patients must apply to participate in the experimental drug clinical trial. All of which is governed by an IRB (Institutional Review Board).

No practical way to legally or commercially introduce these products into your practice without great expense and subsidization of the procedure with funding by the company. In summary, no commercial opportunity exists and ethical questions arise when charging patients for experimental procedures.

# Common Autologous Regenerative Medicine Procedures

- Platelet-Rich Plasma (PRP)
  - *Pure PRP (Leukocyte Poor)*
  - *L-PRP (Leukocyte Rich)*
  - *PRFM (PRP with added 10% calcium chloride for activation)*
- Platelet Rich Fibrin (PRF)
  - *Platelet clot activated during centrifugation*
- Adipose Derived Regenerative Cells (ADRCs) and Fat Transfer
  - *SVF = Manipulated*
  - *Nanofat = non-manipulated*
- Bone Marrow Aspirate Stem Cell Concentrate (**BMAC**)

# PRP Kits: Are they all the same?

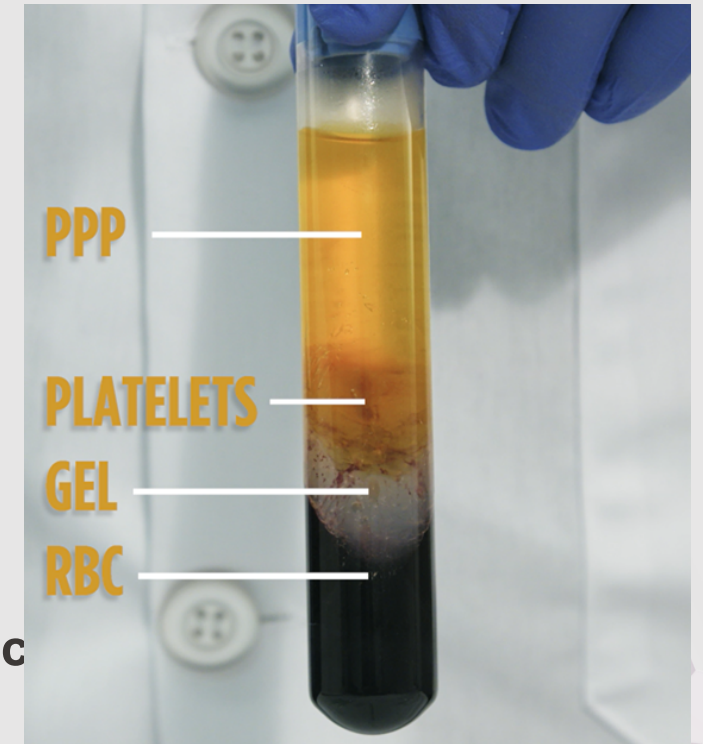
- Umbrella term does not allow for distinction between available products
- Does not take into account platelet concentration, presence of RBC & leukocytes
- **Not all concentrates are equal**
- **>20 PRP separation systems** available
- **No standardization** in PRP dosing
- Lack of standardized method for preparation → difficult to correlate clinical results between studies



# Device Selection Criteria

## Primary Considerations

- **FDA-Clearance** (Is it being sold/used legally?)
  - *What does FDA-clearance say about safety?*
- **Manufacturer** (Who makes it? Where is it made?)
- **Device Type**
  - *Single Spin vs. Double Spin vs. Computer Aided*
  - *DEPA classification*
- **Validated Cellular Characteristics (Not White Papers or Broc**
  - *Published Peer Reviewed Literature*
  - *Videos from PRP Truth Project*
- **Safety track record/** History of the device (How long on the market?) – How many cases performed, any safety recalls or maude reports?
- **Peer Reviewed Published Studies validating off-label use?**
- **Social Proofing** – Has it been working well in the hands of doctors you know and Trust?
- **Patient Experience** (Comfort and Results)



# Device Selection Criteria

## Secondary Considerations

- Cost of device
- Quality of Training Provided (CME?)
- Ease-of-Use
- Ongoing Rep Support
- Marketing Resources



# Types of FDA-Cleared PRP Systems

## Small Volume/Single Spin/ Simple

No Red Cells - Less inflammatory  
Ideal for Dermatologic Applications

### Large Tube Separator Gel Systems

22ml @ 2.5 - 3.4x PLT

30ml @ 1.1x PLT

**ECLIPSE PRP HC**  
HIGH CONCENTRATION

**HEALEON**  
MEDICAL

### Small tube Separator Gel Systems

1.5X

1.1x PLT

1x PLT

0.6x PLT

**ECLIPSE**  
PRP

**HEALEON**  
MEDICAL

**SELPHYL**  
Because Nothing is More Natural than You

**regenlab**

**SUNEVA**  
MEDICAL HD PRP

**BELLUS**  
MEDICAL  
Division of Cronos Laboratories, Inc.

20ml Buffy Coat (no separator gel)

2X PLT

**Arthrex** ACP



## VS. Large Volume/Double Spin/Complex Systems

Designed for Orthopedics – High in Red Cells and granulocytes

27-60ml Floating Buoy Systems Buffy Coat (no separator gel)

### CellMedix 3-4x



Emcyte 4-7x



Harvest 6-7x



Celling/Thermi



### 30-150ml Computer-Aided Systems

Arteriocyte 5-7x

DePuy Synthes (3ml of 6x)

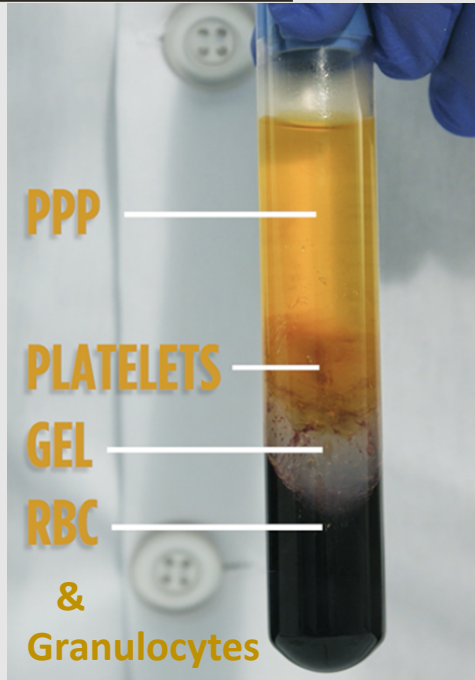
Arthrex 4-9x



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# SEPARATOR GEL SYSTEMS



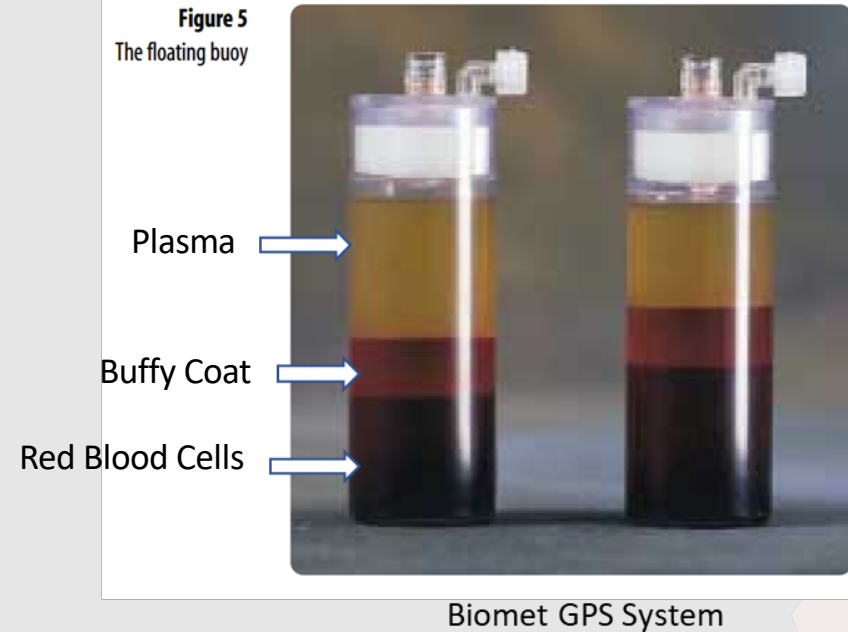
**No Buffy Coat – Platelets are physically resting on top of the gel**

Eliminates the RBC and Granulocytes.

Limited to smaller blood draws but easier to use.

# Floating Buoy/Buffy Coat Systems

**Figure 5**  
The floating buoy



**Buffy Coat** – The fraction of the anticoagulated blood sample that contains most of the white blood cells and platelets following density gradient centrifugation of the blood.

**Arthrex ACP, Harvest and Emcyte** all use a floating buoy or buffy coat suspension.

Due to the lack of separator gel, the buffy coat (where highest concentration of platelets reside) tends to have high RBC counts.

# Direct To Consumer Marketing In Office

<https://revivetrainings.com>

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# Steps to Launch PRP in Your Practice

- Patient Brochures
- Brochure Display with Powerful Before & After Photos
- Video Loop for Waiting Room



Brochures



Brochure Stand

<https://revivetrainings.com>

Call us at (833) 573-8483



# Steps to Launch PRP in Your Practice

- Update website with graphics and Before & After photos.
- Schedule in-service date, Staff Training day & Schedule Launch Party.

16 BEFORE & AFTERS

High Quality for Display & Printing

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## Template for Open House – Launch Party

- Stand Alone Prices
- 3 Month Supply Vitamin/Topical= \$270 Retail Price
- 1 Month Vitamin = \$72
- 1 Month Vitamin/Foam Combo \$99
- 1 PRP Tx = \$1000 per Tx to Patient

### Sign up today and get this Deal:

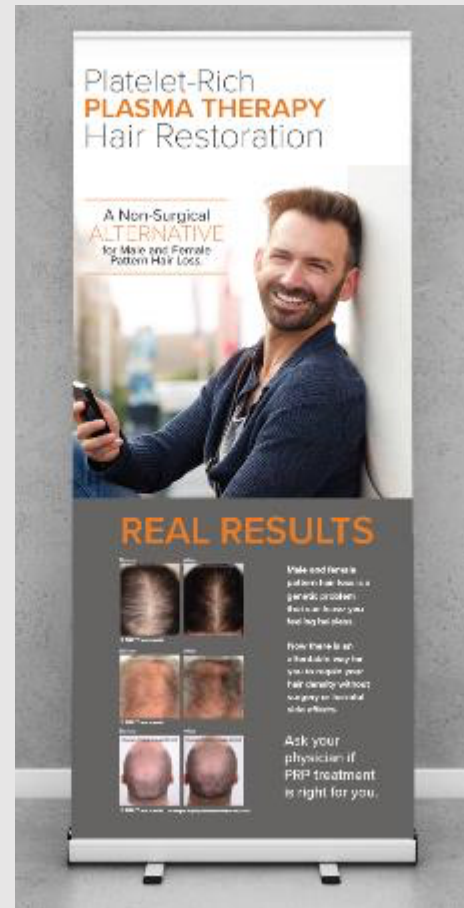
\$3200 Special  
\$800 off 4 PRP Tx (3 monthly + 1 Maintenance)  
+ 3 months supply of Topical + Oral Vitamin Free! (\$270 value)



**Patient Saves \$1070 by buying package up front.**

Continues to purchase supplements in between maintenance PRP Tx.

# Marketing Materials



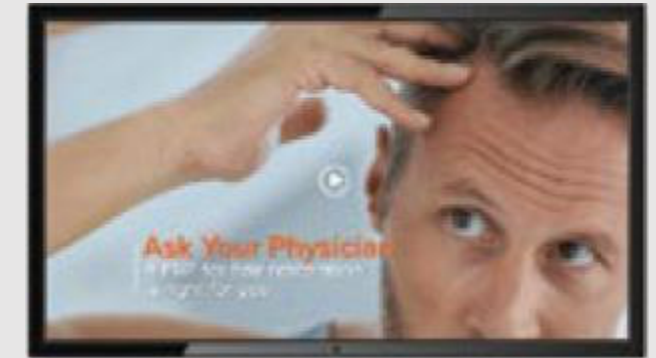
Lobby Banners <https://revivetrainings.com>



Before & After Photos



Brochures



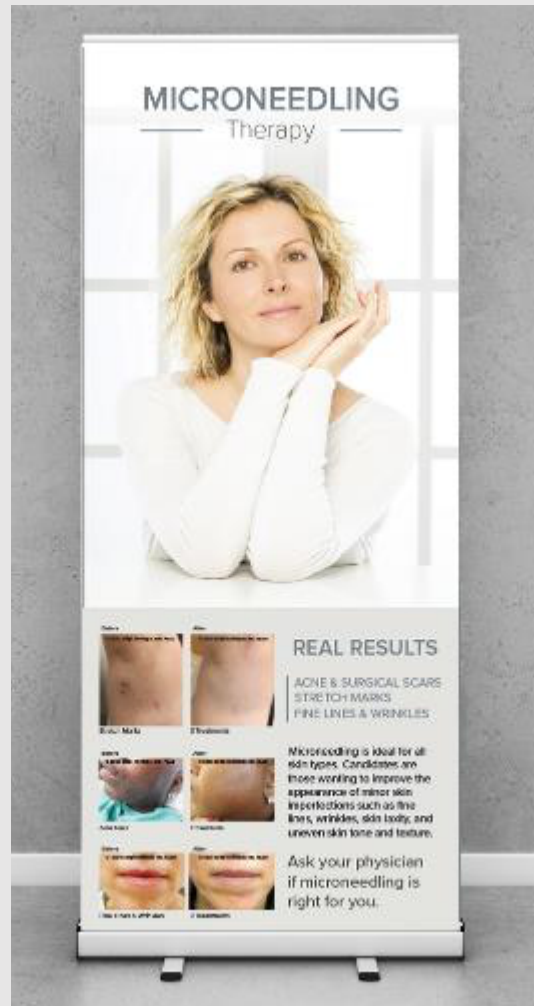
Lobby Looper



Brochure Stand



# Microneedling Marketing Materials



Lobby Banner



Before & After Photos



Brochures



Lobby Looper



Brochure Stand

# Launching PRP in your Practice

As a thank you to our attendees please  
use coupon code:

**PRP15%OFF**

Enjoy free shipping. Offer good through April

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## PRP Hair Restoration Launch Checklist

- ☐ Add this verbiage to your patient intake form:  
"Concerned about Thinning Hair? Check Yes to receive info on our Non-surgical Hair Restoration program."
- ☐ Patient brochures set up on display unit in waiting room and clinic treatment room.
- ☐ Add PRP Hair Restoration Lopper to waiting room video.
- ☐ Update website with graphics and Before & After photos.
- ☐ Schedule in-service date/Staff Training day – pick staff person to be testimonial patient/training patient.
- ☐ Schedule Launch event (use bundle promo template).
- ☐ Contact Revivetrainings.com for PRP training on Skin Rejuvenation and Sexual Wellness.
- ☐ Schedule 30 day follow up meeting with your PRP rep for a refresher and assess launch success (Goal = min. 5 PRP Patients Per month)
- ☐ Keep PRP Reorder form on hand, know volume discounts, and register online reorder account with PRP vendor.
- ☐ Watch Practice Marketing/Business Consultation Webinar through REVIVE™
- ☐ Note other potential applications/procedures PRP will enhance
  - Facial rejuvenation
  - Male and female sexual rejuvenation
  - Stretch mark and scar revision

REVIVE™ provides training in all these applications with board-certified experts. For Course Descriptions and Training Details please call 833.573.8483

<https://revivetrainings.com>

Call us at (833) 573-8483



# Upcoming Courses

## Select Individual Online Training Below

Select a 15 Day Pass to an Online Training below. Once purchased, you can log in and have unlimited access to your online training during your 15 days of access.

SPECIAL: If you purchase the 3.0 CME Credit "Dream Team" Training, you will be given an opportunity to get 25% OFF the Marketing Bundle!

**Platelet Rich Plasma (PRP)  
Hair Restoration & Facial Rejuvenation**

Wima Bergfeld, MD, FACP  
Shilpi Khetarpal, MD  
Jeffrey A. Rapaport, MD, FAAD  
Reena Jogi MD, FAAD






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Platelet-Rich  
PLASMA THERAPY  
ONLINE TRAINING

PRP Hair Restoration & Facial Rejuvenation Online  
Training 15 Day Access  
**\$395.00**

**Platelet Rich Plasma (PRP)  
Hair Restoration**

Jeffrey A. Rapaport MD  
BOARD CERTIFIED  
DERMATOLOGIST



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ADVANCED TRAINING CONSULTANTS

Platelet-Rich  
PLASMA THERAPY  
ONLINE TRAINING

Online Training w/ Jeffrey Rapaport - Platelet  
Rich Plasma (PRP) Hair Restoration  
**\$295.00**

**Platelet Rich Plasma (PRP)  
Hair Restoration &  
Facial Rejuvenation**

Dr. Shilpi Khetarpal  
BOARD CERTIFIED  
DERMATOLOGIST



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Platelet-Rich  
PLASMA THERAPY  
ONLINE TRAINING

Online Training w/ Shilpi Khetarpal - Platelet Rich  
Plasma (PRP) Hair Restoration & Facial  
Rejuvenation  
**\$295.00**

## Select Individual Online Training Below


Select a 15 Day Pass to an Online Training below. Once purchased, you can log in and have unlimited access to your online training during your 15 day membership.



**PRP and  
Extracorporeal  
Shockwave  
Therapy (ESWT)  
for Male Sexual  
Wellness**

Robert Bowen, MD  
BOARD CERTIFIED

- P Shot® Provider Certification
- ESWT Active Device
- Pyrexia's Disease Demo



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Platelet-Rich  
PLASMA THERAPY  
ONLINE TRAINING

Platelet Rich Plasma (PRP) & Extracorporeal  
Shockwave Therapy (ESWT) for Male Sexual  
Wellness with Revive  
**\$1,295.00**

**PRP and  
Extracorporeal  
Shockwave  
Therapy (ESWT)  
for Male Sexual  
Wellness**

Dr. Robert Bowen  
BOARD CERTIFIED

- P Shot® Provider Certification
- ESWT Active Device
- ESWT Z Wave Device



**REVIVE**  
ADVANCED TRAINING CONSULTANTS

Platelet-Rich  
PLASMA THERAPY  
ONLINE TRAINING

Platelet Rich Plasma (PRP) & Extracorporeal  
Shockwave Therapy (ESWT) for Male Sexual  
Wellness with Z Wave  
**\$1,295.00**

**Extracorporeal  
Shockwave  
Therapy (ESWT)  
+ PRP Injections  
for Male Sexual  
Wellness**

Dr. Russ Bartels  
BOARD CERTIFIED



**REVIVE**  
ADVANCED TRAINING CONSULTANTS

Platelet-Rich  
PLASMA THERAPY  
ONLINE TRAINING

Extracorporeal Shockwave Therapy (ESWT) + PRP  
Injections for Male Sexual Wellness  
**\$995.00**

Select Online Training Available  
Hair Restoration/Facial  
Rejuvenation/Sexual Wellness  
O-Shot® P-Shot®

Coupon Code:

**PRP25%OFF**

## Purchase a 15 Day Membership Pass

Enjoy a 15 day pass to view the content of recent courses that you may have missed. Once purchased, you can log in and have unlimited access to your recording during your 15 days. Your 15 days begins when you purchase the recording. Take the required CME quiz to receive CME credits for this training.

**PRP Injections +  
O-Shot™ + RF  
Technology  
for Female  
Sexual Wellness**

Burt Webb, MD, FACOG  
BOARD CERTIFIED GYNECOLOGIST



**REVIVE**  
ADVANCED TRAINING CONSULTANTS

Platelet-Rich  
PLASMA THERAPY  
ONLINE TRAINING

Online Training w/ Burt Webb - PRP O-Shot® |  
Energy Based Therapy | Vaginal Wellness

**\$997.00**

# THANK YOU!

Q&A will be available with all handouts.

Clinical Studies can be found here: <https://revivetrainings.com/news-articles/>



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