



HARVEST® PLATELET CONCENTRATE SYSTEM

THE HIGHEST PLATELET CONCENTRATION
WHEN COMPARED TO 12 OTHER SYSTEMS*



HARVESTING
PLATELET-RICH PLASMA

Platelet-rich plasma (PRP) is a blood product with a concentration of platelets greater than the baseline level.¹ Autologous PRP also contains growth factors that may help optimize the conditions needed for the healing of bone and soft tissue.^{2,3}

The Harvest platelet concentrate system is designed for the safe and rapid preparation of highly concentrated autologous PRP. The PRP can be mixed with autograft and allograft bone before application to an orthopedic surgical site.

While platelets are the primary component of PRP, preparations also contain other cellular components such as white blood cells (WBCs) and peripheral stem cells. These key components play a biological role in the healing process. Platelets are rich in growth factors which support several key processes, including stem cell recruitment, angiogenesis, cell proliferation and differentiation.⁴ When more platelets are isolated in a PRP preparation, more growth factors can be delivered to the application site.

Growth factor concentration is directly proportional to platelet concentration.⁵ PRP produced using the Harvest SmartPrep® Multicellular Processing System delivers the highest concentration and yield of platelets when compared to 12 other systems.*

*Compare the numbers. Find the mean nucleated cell count and yield for the 12 other systems at HARVESTTECH.COM/clinician.^{6,7,8,9}

QUALITY: NEVER COMPROMISE

The Harvest SmartPrep system has the ability to generate up to 1.5 million platelets/μL of PRP. Some other systems do not produce high enough platelet concentrations to facilitate angiogenesis—a biological process critical to healing.¹

The Harvest platelet concentrate system contains essential components to generate PRP, including:^{4,10,11,12}

- Platelet concentration at 5 to 6 times baseline levels^{4,10,12}
- Significantly elevated levels of all key growth factors critical to the healing process^{4,10,12}
- Retention of the stem-cell-rich mononuclear WBC fraction (as evidenced by CD34+ counts)
- Reduced levels of the inflammatory granulocyte WBC fraction¹⁴

FLEXIBILITY: EXPANDED
TREATMENT OPTIONS

The SmartPrep system has 510(k) clearance to process all three major biologics, including PRP, concentrated bone marrow aspirate (BMA) and concentrated adipose tissue.^{10,14} The SmartPrep System is a single platform that enables you to offer multiple treatment options to patients.

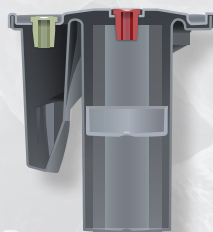
Processes All Three Autologous Biologics



Harvest® Platelet Concentrate System

Harvest® Bone Marrow Aspirate Concentrate (BMAC®) System

Harvest® AdiPrep® Adipose Concentration System



The Harvest PC process disposable includes a proprietary, self-calibrating floating shelf that is optimized for concentrating platelets. The floating shelf is engineered to concentrate 60 mL of starting product from a healthy patient with a normal baseline platelet count into as many as 1.5 million platelets/μL in 10 mL.^{4,12,13,16}

Selective Capture of the Stem-Cell-Rich Mononuclear White Blood Cell (WBC) Fraction

The floating shelf used in the Harvest PC process disposable is designed to selectively capture the mononuclear cell fraction of the WBC population, unlike many other PRP systems that remove this important component. This mononuclear cell fraction contains the majority of peripheral stem cells, identified by the CD34+ marker. CD34+ cells aid in angiogenesis and tissue regeneration at the application site.^{2,3} The concentration of stem cells found in PRP prepared on the SmartPrep system is indicated by the predominance of CD34+ cells.⁸

Selective Reduction of the Inflammatory Granulocyte Fraction

Similarly, the floating shelf of the Harvest PC process disposable also preferentially reduces the granulocyte population in the final PRP product, delivering lower-than-baseline levels to limit inflammation. This chart shows the composition and concentration of a typical PRP preparation from the Harvest platelet concentrate system:

Composition of PRP When Prepared on the SmartPrep System

	Whole Blood	PRP on SmartPrep System
WBCs	5.83 × 10 ³ /μL	21.09 × 10 ³ /μL
Mononuclear cells	34.78%	75.54%
Granulocytes	65.22%	24.46%
CD34+ (total cells delivered)		171,571

Kevy S., et al. Defining the composition and healing effect of platelet-rich plasma for regenerative medicine. Poster: TERMIS-Americas; December 5-8, 2010; Orlando, Florida.

RELIABILITY: PROVEN RESULTS

In addition to generating concentrated autologous biologics in as little as 15 minutes' processing time,¹⁶ the Harvest technology also provides clinicians and physicians with the following advantages:

- Generates biologic treatments with no manual adjustment from patient to patient
- Produces concentrated, high-quality, injection-ready biologics with simple operation
- Delivers low run-to-run variability^{10,11,16}

Automated Processing


Combined with SmartPrep system procedure packs, the SmartPrep system automates the point-of-care processing of biologics.

- Reduces the number of steps versus a manual method
- Simplifies training among multiple users


Designed to Reduce Risk of Contamination

The resealable injection ports on the Harvest PC process disposable can be aseptically disinfected prior to entry. This significantly reduces the risk for contamination of the final product.¹⁷

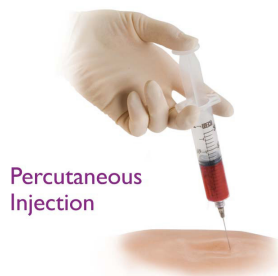
Delivery Options




Enriched Bone Grafts



Topical Spray (SK/S Shown)



Percutaneous Injection



Liquid Application (LK/2 Shown)

To arrange an evaluation or for more information, call
1.877.8.HARVEST (toll-free) or visit HARVESTTECH.COM.

Harvest Technologies, a Terumo BCT company, has long been a leader in point-of-care cell therapy products.

Harvest Terumo BCT is a global leader in blood component, therapeutic apheresis and cellular technologies, offering more than 30 years of cell processing expertise and a comprehensive range of solutions that cover the continuum of cell therapy—from point-of-care to cell therapy manufacturing.

As a leader in innovation with established global reach, we are shaping the future of cell therapy.

INDICATIONS FOR USE

The Harvest platelet concentrate system is designed to be used for the safe and rapid preparation of autologous PRP from a small sample of blood at the patient's point of care. The PRP can be mixed with autograft and allograft bone before being applied to an orthopedic surgical site as deemed necessary by the clinical use requirements.

RISK INFORMATION

This information does not take the place of discussing your medical condition with your doctor. These procedures require needle access, possibly resulting in apprehension, discomfort, tenderness, bruising, swelling, bleeding or pain at the access site, at which there is a small risk of infection. Lightheadedness, fainting, nausea or vomiting may occur. Before any medical procedure, tell your doctor about prescription and nonprescription medicines and any natural or herbal remedies you are taking or plan to take; and consult your insurance company to verify coverage.

Scientific References

1. Marx RE. Platelet-rich plasma (PRP): What is PRP and what is not PRP? *Implant Dent*. 2001;10(4):225-228.
2. Matsumoto T, et al., Therapeutic potential of vasculogenesis and osteogenesis promoted by peripheral blood CD34-positive cells for functional bone healing. *Am J Pathol*. 2006; 169(4): 1440-1457.
3. Middleton KK, et al., Evaluation of the effects of platelet-rich plasma (PRP) therapy involved in the healing of sports-related soft tissue injuries. *The Iowa Orthopaedic Journal*. 2012; 32: 150-163.
4. Giusti I, Rugghetti A, D'Ascenzo S, et al. Identification of an optimal concentration of platelet gel for promoting angiogenesis in human endothelial cells. *Transfusion*. 2009;49(4):771-778.
5. Eppley BL, Woodell JE, Higgins J. Platelet quantification and growth factor analysis from platelet-rich plasma: implications for wound healing. *Plast Reconstr Surg*. 2004;114(6):1502-1508.
6. El-Sharkawy H, Kantarci A, Deady J, et al. Platelet-rich plasma: Growth factors and pro- and anti-inflammatory properties. *J Periodontol*. 2007;78(4):661-669.
7. Fiore S, Serhan CN. Lipoxin A4 receptor activation is distinct from that of the formyl peptide receptor in myeloid cells: Inhibition of CD11/18 expression by lipoxin a4-lipoxin a4 receptor interaction. *Biochemistry*. 1995;34(51):16678-16686.
8. Matsumoto T, Mifune Y, Kawamoto A, et al. Fracture induced mobilization and incorporation of bone marrow-derived endothelial progenitor cells for bone healing. *J Cell Physiol*. 2008;215(1):234-242.
9. Mifune Y, Matsumoto T, Kawamoto A, et al. Local delivery of granulocyte colony stimulating factor-mobilized CD34-positive progenitor cells using bioscaffold for modality of unhealing bone fracture. *Stem Cells*. 2008;26(6):1395-1405.
10. Nurden A, Nurden P, Sanchez M, Andia I, Anitua E. Platelets and wound healing. *Front Biosci*. 2008;13(9):3532-3548.
11. Kevy SV, Jacobson MS. Platelet concentrate preparation: A comparison of the Harvest SmartPrep® 2 with the Biomet GPS® III. Immune Disease Institute. 2008.
12. Kevy SV, Jacobson MS. Comparison of methods for point of care preparation of autologous platelet gel. *J Extra Corpor Technol*. 2004;36(1):28-35.
13. Marx RE. Platelet-rich plasma: Evidence to support its use. *J Oral Maxillofac Surg*. 2004;62(4):489-496.
14. Data on file.
15. Muschler G. Comparison of bone marrow aspiration and bone core biopsy as methods for harvest and assay of human connective tissue progenitor. Paper 41 presented at: 58th Association of Bone and Joint Surgeons Annual Meeting; April 3-7, 2006; Buenos Aires, Argentina.
16. Kevy SV, Jacobson MS. Immune Disease Institute. Platelet-rich plasma preparation: A comparison of the Harvest SmartPrep® 2 APC+® with the Arthrex ACP. 2009. Unpublished data.
17. Center for Blood Research Laboratories. Sterility of platelet concentrates collected with the SmartPrep System and disposables. 2001;TR-063. Unpublished data.

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