



CLOTMASTER™
Hula Cup
PS-3111

Platelet rich plasma
clot harvester



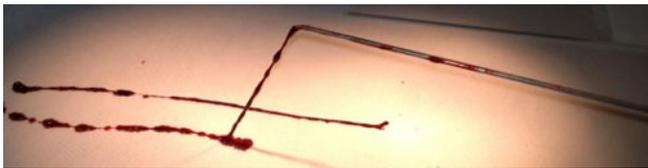
ClotMaster Flowable Biomatrix™

The safe, natural, alternative to PRP and artificial fillers.

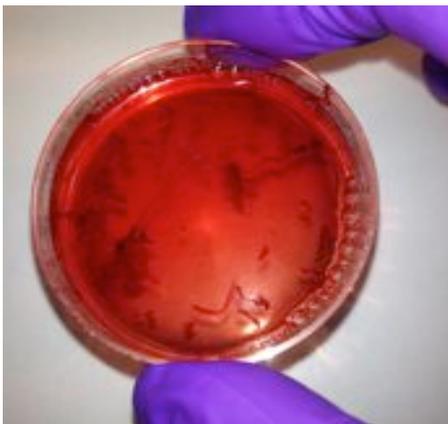
10 minute prep time. No centrifuge or chemicals required. ClotMaster® creates a liquid fibrin matrix with the full compliment of cells and growth factors. Fibrin solids bind to the application site and offer slow release of factors as nature intended. Can be used as a carrier for other agents or materials as deemed appropriate by the physician.

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Viscous high volume fibrin matrix with plasma, passes through 22G needle or larger leaving fibrin solids that offer matrix and bind growth factors for natural delivery over time.



Flowable Biomatrix can formed with whole blood or marrow aspirate (above) or with blood and lipo aspirate (right)



Lab test showing activated whole blood fibril solids after washing in saline

PIERCE SURGICAL
CONSOLIDATED
Regenerative Orthopedic Solutions



Flowable Applications



- Aesthetic filler or topical
- Osteo-Arthritis
- Orthopedic tendinopathies & inflammation
- Soft and Hard Tissue applications Orthopedics
- Urology and Uro-Gynecology
- Topical mask application for Wound Care, Plastic Surgery
- Surgical application in Dentistry & Oral surgery



Concentrated ClotMaster Flowable Biomatrix vs. PRP Platelets, once thought of as being responsible only for clotting, have been scientifically proven to be a reservoir of regenerative growth factors.

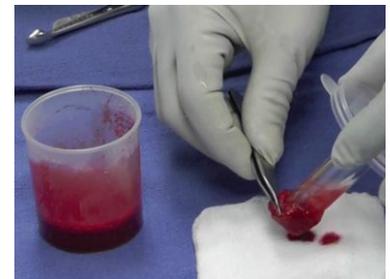
As an alternative method to standard PRP*, Clot Master provides the full compliment of plasma, leukocytes, cytokines and growth factors in an activated fibrin matrix providing structure and sustained release of **Growth Factors** in an exogenous fibrin blood clot scaffold.

Immuno-histochemical staining of these types of fibrin networks has demonstrated “nests” of platelets that become trapped within the fibrin scaffold [1]. Furthermore, cytokines bind to fibrin such that the fibrin scaffold becomes a growth factor reservoir that may allow growth factor release slowly over many days to weeks [2].

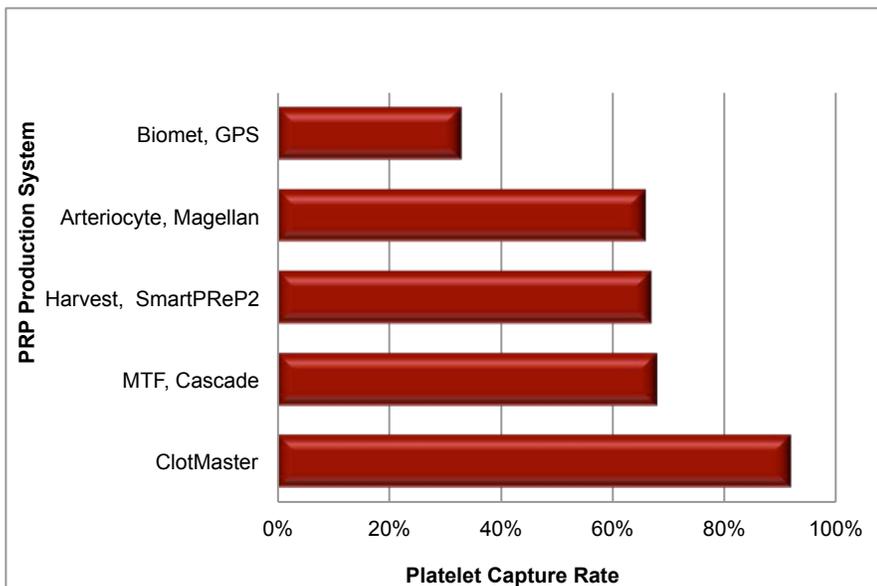
This exogenous fibrin blood clot can act as a stable mechanism for long-term direct delivery of growth factors and as a three dimensional native scaffold for cell adhesion and proliferation.

Figure 11. Summary table of advantages of ClotMaster™ clots¹¹

Biologic Advantages	Technical Advantages	Cost Advantages
<ul style="list-style-type: none"> • Rich in platelets • Structural integrity of fibrin matrix • Rich in growth factors (TGF-B1, PDGF-BB, VEGF, FGF2) • Possible to use as scaffold for TE • Completely autologous (no exogenous activation required) 	<ul style="list-style-type: none"> • Quick • Easy procedure • Consistent results • Requires no extra OR staff • Can suture to repair site • Versatility (different types of clot) 	<ul style="list-style-type: none"> • Inexpensive



Formation of fibrin clot on sintered glass rod. Post-clot serum visible in container.



A study by Proctor, determined that the fibrin clot platelet capture rate to be 92%. [3] This capture rate compares favorably to prior studies that have demonstrated platelet capture rates of traditional PRP ranging from 17-80% [4].

Immunohistochemistry

Results of immunohistochemical staining indicate that TGF- β 1, PDGF- $\beta\beta$, VEGF, and FGF2, are present in human blood clots produced by the Hula Cup. This demonstrates that ClotMaster™ clots deliver the same healing growth factors found in PRP, and therefore have the potential to enhance healing [4]

	Negative Control	Center	Periphery
TGF- β 1			
PDGF- $\beta\beta$			
VEGF			
FGF2			

REFERENCES

1. Visser, L et al., Veterinary Surgery. 2010; 39: 811-817.
2. Macri, L et al., Advanced Drug Delivery Reviews. 2007;59: 1366-1381.
3. Proctor, C Determination of the Platelet Capture Rate of Human Fibrin Blood Clot Alta Orthopaedics, Santa Barbara, CA 2014
4. Doodlesack, A The Characterization and Quantification of Bioactive Components In Human Blood Clots for Tissue Healing and Engineering Spring, 2014, Brown University Biology Master's Thesis, Brown Biomed

Product Description: The ClotMaster PS-3111 “Hula Cup” Autologous Fibrin Clot Harvester is a container with collection rod for harvesting fibrin or platelet rich plasma clot from blood, or bone marrow aspirate. Warning: Federal law (USA) restricts this device to sale by or on the order of a physician.

Intended Use: The ClotMaster Hula Cup™ Autologous Fibrin Clot Harvester is intended to be used for clinical laboratory or intra or peri operative preparation of autologous fibrin or platelet rich plasma clots from a small sample of patient blood. The fibrin, or platelet rich plasma clot may be used as-is or be mixed with, or applied to allograft, autograft, cells, platelet rich plasma, synthetic bone graft, or other materials to prepare a graft or repair substrate. Autologous fibrin or platelet rich plasma clot is to be used as deemed clinically appropriate by a medical practitioner. Contraindications: Not intended for application to the blood stream or lungs.

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