



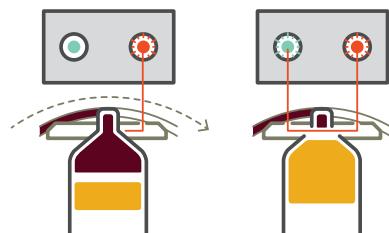
COMPARING SEPARATION SYSTEMS



MANIPULATION AUTOMATION VS. MANUAL

REMOVE THE GUESSWORK

The Magellan® Autologous Platelet Separator is a fully automated separation system capable of accurately selecting the desired cellular fractions to be delivered to the collection syringe via the use of optical sensors.



Other systems on the market rely on the user to “eye-ball” the buffy coat and manually draw the final product into the delivery syringe. Manual manipulation amplifies safety concerns such as contamination and technician exposure to blood products.

SPIN DUAL VS. SINGLE SEPARATE & CONCENTRATE

In order to truly concentrate the platelets, you must use a dual spin centrifugation system.

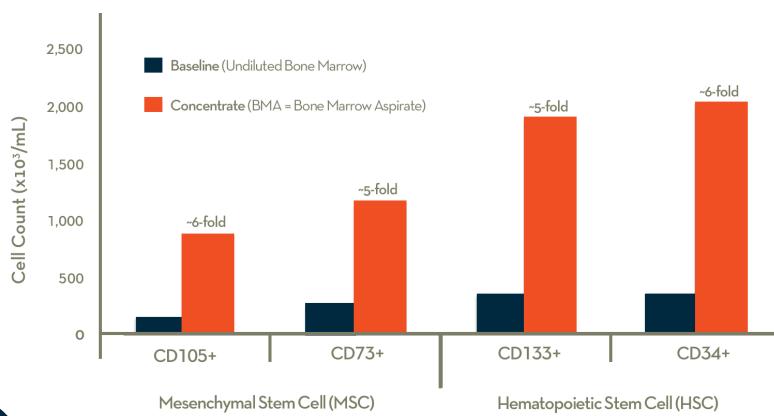
- Initial spin removes the red blood cells from the plasma
- Second spin removes Platelet Poor Plasma (PPP) from the Platelet Rich Plasma (PRP)



SPIN 1 • SEPARATION

SPIN 2 • CONCENTRATION

A dual spin results in a PRP that contains a higher concentration of platelets, and falls within therapeutic levels (4 to 6 times baseline).

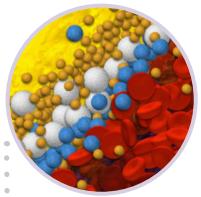


PRP REDDISH VS. YELLOW

COLLECT THE pRBC FRACTION

PRP produced from Magellan® will have a reddish tint due to the collection of a small portion of the packed red blood cell (pRBC) fraction. The reddish color represents a relatively small concentration (6-9%) of red cells suspended within a clear suspension of white cells, platelets, and plasma.

In comparison, PRP from single spin devices is collected from the top of the plasma fraction down, avoiding the pRBC fraction and losing platelets within the red blood cells. Thus, the color of their final product is yellow.



- Platelets
 - White Blood Cells
 - Progenitor Cells
 - Red Blood Cells
-]
- Total Nucleated Cells (TNC)

APPROVAL CBER VS. CDRH

FOCUS ON BIOLOGICS & BLOOD PRODUCTS

The Magellan® system was approved by CBER and contains “Practice of Medicine” language within the indication, which is only possible through CBER approvals.

CDRH approved devices have “K” designators which indicate that although these devices can be used at point of care, their intended use is for diagnostic purposes, not for redelivery to a patient.

CBER | Center for Biologics Evaluation and Research

- Regulates medical devices used for blood collection and processing, as well as CBER regulated cellular therapies

CDRH | Center for Devices and Radiological Health

- Regulates firms who manufacture, repackage, relabel, and/or import medical devices sold in the USA



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Indications

The Magellan® Autologous Platelet Separator system is designed to be used in the clinical laboratory or intraoperatively at point of care for the safe and rapid preparation of platelet poor plasma and platelet concentrate (platelet rich plasma) from a small sample of blood or a small mixture of blood and bone marrow. The plasma and concentrated platelets produced can be used for diagnostic tests. Additionally, the platelet rich plasma can be mixed with autograft and/or allograft bone prior to application to an orthopedic site. The platelet poor plasma can be mixed prior to application to an orthopedic site as deemed necessary by the clinical use requirements.

References

1. David B. Horn, MD; Bradley M. Linzie, MD; Trevor C. Huang, PhD The Healing Effects of Autologous Platelet Gel on Acute Human Skin Wounds
2. Robert E. Marx, DDS Platelet-Rich Plasma (PRP): What Is PRP and What Is Not PRP?