

Healeon Announces FDA 510(k) Clearance for Duet Office-Based Blood Separation and Concentration System

Healeon Duet enables customized concentrations of PRP at the point-of-care

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Healeon, a wholly owned subsidiary of Bimini Health Tech, announced today it received FDA 510(k) clearance for its novel blood separation system for Platelet Rich Plasma (PRP) preparation, the Healeon Duet (BK200449). Healeon's new Duet technology is exclusively distributed by Suneva Medical, under the tradename Amplifine, in the Aesthetic Marketplace. "We, at Suneva Medical, are thrilled that Amplifine PRP has obtained 510K clearance and believe that this further strengthens our portfolio and our leadership position as the essential source for facial regenerative aesthetic treatments. We look forward to providing a game-changing technology to our provider partners looking to offer customizable PRP to their patients" said Pat Altavilla, Chief Executive Officer of Suneva Medical.

The Healeon Duet enables safe, quick, and easy separation of blood components into customizable platelet concentrations. Designed for use within the practitioner's office, the launch of the Healeon Duet system creates a new product category focused on delivering a tailored concentration approach for patient treatment applications, and allows:

- Small blood draw (25ml) into a closed system.
- Provides operators full control of all desired parameters to fine-tune the approach depending on the application, offering 5 platelet derived solutions in a single technology:
 - Low Density PRP (LD PRP)
 - High Density PRP (HD PRP)
 - Leukocyte Rich PRP (LR-PRP)
 - Leukocyte Poor PRP (LP-PRP)
 - Platelet Rich Fibrin (PRF)

"The Healeon Duet overcomes one of the most challenging parts of platelet preparation -- customizing concentration levels in controlled dosages for specific procedure types in a single platform," said Jeff Greiner, CEO of Healeon and CCO of Bimini Health Tech. "The Duet provides the operator total control over the concentration process, post platelet isolation."

"The Duet was developed with ease of use in mind while still providing the operator flexibility in the preparation process, with the ability to produce several desired platelet preparations in a single technology. With FDA clearance of the Duet, we have expanded our blood separation and PRP product portfolio to broaden the use across medical specialties." Added Mr. Greiner, "PRP preparation is not a one-size-fits-all for all applications. It's important that the clinician has the appropriate technology to support the proper treatment applications. It's now easier for clinicians to

feel confident they are providing their patients the highest quality PRP for each desired treatment application”.

ABOUT BIMINI HEALTH TECH and HEALEON®

Bimini Health Tech is a global leader in the medical aesthetics and regenerative market. The Bimini Health Tech portfolio includes Healeon®, Puregraft®, Dermapose®, and Kerastem®. The company develops and commercializes products that are elegant in their simplicity, yet impactful and proven in their aesthetic and therapeutic benefit. Since 2013, they have been developing innovative products to provide premium aesthetic care options to consumers and physicians alike.

Healeon® is dedicated to paving the way for regenerative solutions by providing innovative medical devices for autologous, point-of-care treatments. Healeon has rapidly emerged as a major player in the regenerative medicine market. Specifically, Healeon's technologies offer easier and safer solutions that provide unparalleled cell and protein concentrates designed to meet individual practice and patients' needs.

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