

Overview of the Autologous Platelet Grafting™ The Need and the Market Approach

SAFEBLOOD**® Technologies**

SAFE**BLOOD**® Technologies was founded in 1998 on the belief that autologous point of care therapies is the preferred standard of care for both the patient and the physician in many situations. We are committed to developing, delivering and supporting the highest quality equipment, procedures, protocols and educational training available in auto-transfusion and wound care.

SAFE**BLOOD**® Technologies currently supports physician/clinician directed care in numerous treatment venues, including hospital operating rooms and outpatient treatment facilities. By providing state of the art, on-site blood processing equipment with our proprietary treatment and procedure protocol, we offer both auto-transfusion services and platelet sequestration for constructing an Autologous Platelet Graft™. These platelet grafts have found efficacy in both the chronic and acute settings. We believe the continued development and use of these autologous programs will be pivotal in improving the standards and outcomes in the long-term, chronic, and acute care arenas in the coming years.

We are also developing educational and training programs for those populations most susceptible to chronic wounds. These programs will address current standards of care for treating diabetic, venous stasis and decubitus ulcers in both long-term care facilities and outpatient situations. We believe this holistic or global approach to wound management provides the highest quality care to patients and the greatest value to our customers.

SAFE**BLOOD**® is committed to being the product and service provider of choice to those delivering the highest standard of care to wound patients.

History of Platelet Grafting in Chronic Wounds

SAFE**BLOOD**® Technologies' primary goal is to provide physicians and facilities with the ability to construct an Autologous Platelet Graft™ that has a wide range of biological applications. The company embraces the concept of using a person's own natural healing capacity to treat and heal wounds. The idea of using various components of blood for use as a biological glue or peri-operative adjunct has been utilized in the past for tissue repair. This is not a new procedure, but one that has been written about in the literature for many years. We are taking the procedure to a new level by demonstrating the ease, simplicity and consistency possible in replicating the body's own natural wound healing by nourishing the wound with the very first step of the healing process: the platelet.

The platelet is the first cellular element working in the wound at the time of injury to mediate blood loss and stability. Additionally, the platelets lay down the basic scaffolding for wound closure by interconnecting themselves with fibrin bridges and using specialized proteins to initiate the healing process and stimulate tissue repair.

Background:

Traditionally, wound care involves the treatment of four principal categories of non-healing cutaneous wounds. In descending order, these categories are: venous stasis ulcers; diabetic foot and ankle ulcers; pressure ulcers; and ulcers resulting from ischemia, vasculitis, insect bites, and old trauma. The first two categories constitute a clear majority of the wounds treated, accounting for more than 75% of the cases in some facilities or locales.

Most of the wound cases addressed by the Autologous Platelet Graft™ procedure (“APGP”) are classified as chronic, non-healing cutaneous wounds. Our definition, in laymen’s terms, is a wound or skin injury that has failed to heal in a reasonable period of time.

According to the Center for Disease Control’s (“CDC”)1998 National Diabetes Fact Sheet, 15.7 million people or 5.9% of the population of the United States have diabetes. Currently it is estimated that this percentage has grown to a little over 6% of the overall population. Of that population, numerous studies indicate a conservative estimate of that population who will have diabetic foot or ankle ulcers at any given point is 7%. (7% of 6% = .0042% of the population)

A starting point for local market development and a more detailed overview of the diabetic population, as presented by the American Diabetic Association, breaks down the population by ethnic and gender categories as follows:

Population:

Diabetic Characteristics

African American

10.8 % have diabetes
1/3 have not yet been identified
1.7 times more likely than non-Latino whites
25% between ages of 65 – 74 have diabetes
1 in 4 women over 55 have diabetes
1.5 to 2.5 times more likely for amputations than whites

Latinos:

10.6% of all Mexican Americans have diabetes
2 times more likely to have diabetes than whites
24% of Mexican Americans between 45 & 74 have diabetes

Native Americans:

12.2% over age 19 have diabetes
50% of adults between 30 & 64 have diabetes

Adult Male Population:

8.2% of all men in U.S. have diabetes (1/3 undetected)

Amputation rates are 1.4 to 2.7 times higher in men than in women with diabetes

Adult Female Population: 8.2% of all women in US have diabetes (1/3 undetected)

General risk factors:

Diabetics are 15 to 40 times more at risk to having an amputation due to diabetes

This is 3 to 4 times higher than average population.

One half of all diabetes cases occur in people over 55

18.4% of US population over 65 has diabetes

18% of all nursing home residents have diabetes

The average cost to treat a diabetic ulcer is \$25,000. If amputation is required, a patient will accrue about \$64,000 in costs. These patients have a 50% chance of incurring an ulcer on the remaining limb within 2 years, and the 3-year survival rate, post amputation, is 50%. Diabetes is the 3rd leading cause of death in the U.S. Diabetics account for over 85,000 amputations per year.

The second category we normally address encompasses venous stasis ulcers.

Conservative prevalence estimate for these wounds is .6% of the population, although it is also believed that the actual population of wounds may be much higher, but simply not reported or treated.

Until recently pressure ulcers or “bed sores” were estimated at a much higher ratio than other wound types. This is attributed in part to other categories of wound patients being ambulatory, which is not the case with many pressure sore patients. Recent studies now indicate that wound population or prevalence in community-based adults receiving home care is conservatively the in 6% range, as opposed to 8 to 29% who are hospitalized or in long term care facilities. Therefore, for our market estimates, we use a .9% factor in our analysis. Also, in projecting potential patient or wound prevalence, we normally take a 25% factor of this number because many of these potential patients are unavailable to the conventional wound treatment facility.

Finally, in reviewing the market potential for APGP, one must also consider the acute component of the market. In treating chronic wounds, the process begins by converting a chronic (long term) wound to an acute wound (open and treatment receptive). Most surgical procedures fall into this latter category, and many may qualify for the APGP, either during the procedure, or as a follow-up, post-surgical wound treatment. We do not propose percentages for pro-forma use, but have found varying degrees of acceptance and efficacy across the country and patient groups. We believe active communication to the Plastics, Cardio-vascular, Orthopedic, OB-GYN, Internal Medicine, Family practice and surgeon groups should become a significant marketing component, both from a facility and a physician perspective.