



Developing
technologies
to accelerate
healing,
naturally[™]

Company Fact Sheet
2006

Harvest[®] Technologies' breakthrough BMAC[™] (Bone Marrow Aspirate Concentrate) System is currently being used in Europe to treat vascular, orthopedic and cardiovascular diseases. Internationally, it is the first and only product that makes possible the use of a clinically effective quantity of cellular compositions from a small aspirate of autologous bone marrow, which includes a large quantity of adult stem cells, derived from a patient at the point-of-care, in just 15 minutes.

It is well-established in the scientific literature that a concentrate of autologous adult stem cells from bone marrow is extensively used in achieving tissue regeneration in cardiovascular and vascular diseases. A concentrate of these cells contains "not only stem cells and precursor cells as a source of regeneration tissue, but also accessory cells that support angiogenesis and vasculogenesis by producing several growth factors and cytokines." (Saigawa et al; *Circulation Journal*; Vol. 68, December 2004; 68:1189-1193). Until now, it has been difficult to process and concentrate a clinically significant dose of adult stem cells from a patient's bone marrow at the point-of-care.

Harvest's BMAC System is a breakthrough because it can process *and concentrate* the cellular components from autologous bone marrow, including adult stem cells, (a) at the point-of-care (b) in just 15 minutes. The concentrate produced by the BMAC System has been documented to generate more mononuclear cells with enhanced viability that affect a desired outcome in animal models compared to concentrations obtained by using the most common laboratory methods described in successful clinical studies—while being significantly easier to implement and requiring one-third-less aspirate of bone marrow from the patient.

"There are 20 published clinical studies involving 1,483 patients at 36 sites worldwide offering compelling evidence that this approach (concentrating adult stem cells derived from autologous bone marrow) is enabling international clinicians to offer new therapies for a variety of serious diseases," says Thomas F. O'Donnell, M.D., Senior Surgeon, Vascular Surgery Division, Tufts-New England Medical Center, Boston. "With further clinical validation, the Harvest technology may offer us the possibility, for example, of harvesting a quick, simple and clinically effective stem cell concentration from a patient at the point of care to treat his vascular disease," adds Dr. O'Donnell, who is a scientific advisor to Harvest Technologies.

An IDE/PMA multicenter clinical study using Harvest's BMAC System is planned in the U.S. targeting patients with *Critical Limb Ischemia (CLI)*, which is the later stage of *Peripheral Arterial Disease (PAD)*—clogged arteries, particularly in the lower legs. Patients with *CLI* are at extreme risk for amputation. Reportedly, approximately 500,000 people worldwide suffer from *CLI*, and about 160,000 amputations are performed each year in the U.S. as a result of this condition (source: The Sage Group). A recent pilot study conducted in Berlin using the BMAC System to produce adult stem cell therapy showed a 60 percent reduction in amputation for patients with severe *Critical Limb Ischemia*. An additional randomized prospective clinical study is planned for Europe in the near term.

Examples of compelling clinical evidence from the scientific literature that adult stem cells derived from bone marrow are being used successfully to fight difficult-to-treat diseases....

Vascular
Critical Limb Ischemia

Therapeutic angiogenesis for patients with limb ischemia by autologous transplantation of bone-marrow cell (LANCET)

Cardiovascular
Coronary Artery Disease

Ex vivo pretreatment of bone marrow mononuclear cells ... enhances their functional activity for cell therapy (PNAS)

Orthopedic
Broken Bones

Percutaneous autologous bone marrow grafting for nonunions (THE JOURNAL OF BONE AND JOINT SURGERY)

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