NEW ENGLAND NEWSPAPER OF THE YEAR

WEATHER
Tonight:
Clear,
Low of 52°
Tomorrow:
Some sun,
High of 82°
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The Patriot Ledger

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CANTON
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PLYMOUTH COMPANY

# Feds approve bone marrow device tests

## Would protect ailing limbs from amputation

PLYMOUTH - A Plymouth medical device company has received an approval from federal regulators to start a clinical trial to test the effectiveness of a device that uses bone marrow to protect diseased limbs from amputation.

Harvest Technologies Corp. today reported that it has received the green light from the Food and Drug Administration for a 48-patient trial to assess the company's Bone Marrow Aspirate Concentrate system. Harvest President Gary Tureski said he hopes the company can begin to market the BMAC system in this country by sometime in 2010.

Harvest's device is specifically geared at harnessing the healing power of stem cells contained in a patient's bone marrow to treat a patient with a late-stage form of Peripheral Arterial Disease, which involves clogged arteries, particularly in the legs. In a late stage of the disease known as critical limb ischemia, toes or feet may need to be amputated.

**Harvest's device is geared at harnessing the healing power of stem cells to treat a patient with a late-stage form of a disease that involves clogged arteries.**

The BMAC system takes a patient's bone marrow and concentrates it using a modified centrifuge, focusing on the stem cells contained in the bone marrow that contribute to healing and the creation of new blood vessels.

"We have the ability to separate out those cells that don't aid in healing, and concentrate the cells which do aid in healing," Tureski said.

The stem cell concentrate is then injected into the damaged leg, and the cells do their work by helping to build new vessels.

In a pilot study of the stem cell therapy in Germany involving 22 patients with end-stage critical limb ischemia, 16 patients were able to avoid an amputation.

Other companies make technology that uses stem cells from bone marrow in a similar way, Tureski said. But Harvest's device is unique, he said, because a doctor can use it to withdraw bone marrow, concentrate the useful stem cells and inject them back in the patient all in one sitting. Other companies' systems rely on shipping the bone marrow off-site for the concentration process, requiring a patient to make more than one trip, he said.

"We do it right at the bedside, right at the point of care," Tureski said. "The whole procedure can be done in less than one hour."

The US. study will be led by Dr. Mark Iafrati, the chief of vascular surgery at Tufts-New England Medical Center in Boston. In the next month, five additional research hospitals will be added to the study, Harvest said.

Tureski said doctors started using BMAC systems in Europe about a year ago. The regulatory approval process for medical devices in Europe is typically speedier than the comparable process with the FDA.

Tureski said the first phase of the FDA approval process could take up to a year, and the second part could take an additional 18 months. He said he hopes to start selling the devices in the United States by sometime in 2010.

Tureski said the trial results will help the company find a corporate partner that could effectively market the device.

"A company like Harvest is not a company that will end up marketing the product in the U.S., we're just too small," Tureski said. "This study will carry a lot of weight and help us find a partner when the time comes to market the product."

Harvest, a 10-year-old company that is privately owned by Tureski and other investors, employs about 65 people, primarily at its Plymouth location.

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