



ONCONTROL™ BONE MARROW SYSTEM PROFILE

The OnControl™ Bone Marrow System provides the first advance in bone marrow procedures in over 50 years by combining a lithium battery-powered driver with a specially designed, patented needle set to obtain marrow using Vidacare's patented technology platform. First introduced commercially in late 2009, the OnControl Bone Marrow System offers clinicians a safe, fast and easy way to perform bone marrow aspiration and biopsy procedures and offers patients a less painful experience.

Established in 2001, Vidacare Corporation is the developer of a broad technology platform that is defining the new field of intraosseous (inside the bone) medicine, with the potential to establish new standards of clinical excellence in the safe, rapid performance of medical procedures using the intraosseous space. Current applications include vascular access, emergency and disaster medicine, oncology, spinal surgery applications and regenerative medicine. Vidacare's focus on enhancing clinical efficacy, patient safety and comfort, and reducing complications and their associated costs, has resulted in its devices becoming the recognized technology standard in their respective clinical fields. Privately held, the company is based in San Antonio, Texas, and its products are marketed in over 50 countries worldwide.



FACT SHEET – ONCONTROL™ BONE MARROW SYSTEM

- The OnControl™ Bone Marrow System uses Vidacare’s patented power driver and needle technology to collect bone marrow aspirate and core samples.
- The OnControl Bone Marrow System was made commercially available in late 2009.
- Beta testing on the OnControl Bone Marrow System was completed in October 2009 and showed:
 - Mean user satisfaction score of 4.4 (on a scale of 0-5, with 5 indicating high satisfaction)
 - Needle insertion success rate of 94%
 - Biopsy core acquisition success rate of 90%
 - Mean length of core sample of 1.32 cm
 - Median time to core extraction of 81 seconds
 - Zero complications.
- There are more than 700,000 bone marrow diagnostic procedures done in the US each year, and an estimated 3.9 million bone marrow diagnostic procedures done globally.
- The process for obtaining bone marrow has been largely unchanged for over 50 years.
- Traditional bone marrow procedures use a manual device hand-inserted by the clinician and can take from 2 minutes to more than 30 minutes, with a mean of 7 minutes, to collect a marrow sample.
- The OnControl Bone Marrow System is appropriate for use in the fields of hematology, oncology, interventional radiology and any clinical setting which needs bone marrow for diagnostic and treatment management purposes.
- The OnControl Bone Marrow Aspiration System is also appropriate for use in stem cell collection for use in bone marrow transplant and regenerative medicine procedures.



ONCONTROL™ BONE MARROW SYSTEM TECHNOLOGY

The OnControl™ Bone Marrow System incorporates Vidacare's patented power driver and needle technology to access the intraosseous space inside the bone to collect a bone marrow aspirate or biopsy core.

The speed and torque of the driver are carefully matched to the needles to achieve rapid bone penetration and provide excellent user control and feel to enhance patient safety.

The sealed lithium battery packs provide significant power for hundreds of patient uses, and have a shelf life of 10 years. The driver weighs only 16 ounces and requires no routine maintenance.

The OnControl Biopsy System needle set incorporates a unique approach of welding a metal thread to the inner cannula wall, enabling successful capture of the biopsy core on the first attempt.

The aspiration needle set incorporates a needle and stylet that are ground as a single unit to enable successful capture rates as well.

The OnControl System incorporates an exclusive connector with sterile sleeve that allows for easy and rapid attachment and detachment of the needle set while maintaining a critical sterile barrier.





IO – BONE MARROW PROCEDURES BACKGROUNDER

What is the intraosseous space?

The intraosseous space is the interior of the bone where bone marrow is located and where blood and stem cells develop. Accessing the IO space is critical in diagnosing hematological malignancies and disorders such as leukemia, lymphoma and myelodysplastic syndrome as well as assessing the efficacy of therapy.

Historically, access to the interior of the bones, or the intraosseous (IO) space, was obtained using a manual device consisting of a single needle with a round or T-shaped handle attached to the needle. Depending on the medical need, the needle is manually inserted into the patient through a strenuous and painful procedure.

About bone marrow procedures

There are more than 700,000 bone marrow diagnostic procedures done in the US each year, and an estimated 3.9 million bone marrow diagnostic procedures done globally.

Accessing bone marrow via the intraosseous space is an essential part of diagnostic procedures in hematology and oncology practices. There are three primary procedures in which accessing a patient's bone marrow is necessary: to aspirate a sample of the marrow; to biopsy a core of the marrow; and to harvest bone marrow prior to bone marrow transplantation or regenerative medicine procedures.

Traditionally, bone marrow procedures entail using a manual T-shaped device with a special needle to access the marrow space in the posterior or anterior iliac crest (the pelvis) to obtain marrow samples. The needle is hand-inserted using manual pressure to penetrate the skin and the bone to access the marrow space and obtain samples. The process can take anywhere from 2 to 30 minutes, with a mean time of 7 minutes, to force by hand the device into the bone and obtain samples as needed. Some patients require conscious sedation through this procedure, while most are awake with local anesthetic applied to the entry site.

Generally speaking, the traditional procedure to obtain bone marrow samples is regarded by both patients and physicians as brutal, painful and difficult to master, and yet has not substantially changed in over 50 years.

How does the OnControl™ Bone Marrow System utilize the intraosseous space to improve bone marrow procedures?

The OnControl™ Bone Marrow System is the only powered system on the market in the U.S. or internationally that allows for rapid and safe insertion of aspiration and biopsy needles with minimal pain, and is the first significant technological advance to bone marrow procedures in over 50 years.



Vidacare's patented technology platform incorporating a power driver and needle set allows clinicians to access the bone marrow space and obtain samples quickly, safely and with a quality of sample equal to or greater than the quality of samples derived from traditional procedures.

Historically, the quality of the captured samples is also an issue; in an article published in the *Journal of Clinical Pathology* (FW Bishop, K McNally, M Harris. Audit of bone marrow trephine biopsy. *J Clin Path* 1992; 45: 1105-1108), investigators reported that 58% of the time, the samples collected were "inadequate". This can pose serious challenges to clinicians who analyze the samples and to those whose clinical judgment and treatment decisions rest on this analysis. The OnControl Bone Marrow System offers a 90 percent success rate of quality core captures with a mean length of 1.32 cms or larger.

In addition, the procedure takes under 2 minutes in most cases using the OnControl System, providing a faster and more comfortable experience for the patient.

The speed, efficacy and technological advancement that the OnControl™ Bone Marrow System provides to the process of obtaining bone marrow biopsies and aspirations is the first substantial improvement in the industry in over 50 years.