FAQ – ONCONTROL™ BONE MARROW SYSTEM

Q: **How many bone marrow procedures are done on a global scale?**

A: 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.

Q: **In what kind of circumstances might you need a bone marrow procedure?**

A: Bone marrow examination is an important part of the treatment and management of patients with hematological malignancies (leukemia, lymphoma, and myeloma) and non-malignant disorders (thalissemia, myelodysplastic syndrome, aplastic anemia). 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.

Q: **How are traditional bone marrow procedures done?**

A: In most cases, the patient lays face-down or on their side and a T-shaped device with a special needle is manually screwed through the bone of the anterior or posterior iliac crest of the pelvis. A syringe is attached and an aspiration sample is acquired. The needle is then advanced deeper into the bone and a biopsy core is collected. The process can be very painful for the patient and arduous for the clinician, especially in patients with hard or brittle bones.

Q: **Isn't the current bone marrow aspiration or biopsy procedure effective?**

A: With traditional manual aspiration or biopsy needles, the procedure can be very arduous – especially when obtaining an aspiration or biopsy from patients who are younger and athletic, with a tough bone cortex. In addition, manual aspiration or biopsy procedures can be very painful. The OnControl™ System was developed to provide a safe and rapid means to access the bone marrow, resulting in a low level of pain for patients.

In addition, 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" and require multiple attempts to capture a core. This can pose serious challenges to clinicians who analyze the samples and to those whose clinical judgment and treatment decisions rest on this analysis, as well as subjecting the patient to additional trauma. In addition, multiple attempts are often required to obtain a sample of adequate size.

Q: **How does the OnControl™ Bone Marrow System work?**

A: The OnControl Bone Marrow System uses a patented needle set paired with a lithium-powered driver based on Vidacare's award-winning technology platform to access the bone marrow space and obtain marrow samples.

Q: **Why use a power driver for bone marrow diagnostic procedures?**

A: The OnControl System has been developed to address the concerns associated with manual methods of bone marrow aspiration and biopsy. Bone marrow aspiration or biopsy can lead to significant pain for the majority of patients undergoing the procedures. In addition, the process can be very strenuous for clinicians.

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Q: **Why does the OnControl™ Bone Marrow System use a special needle?**
A: The OnControl System's needle is specially designed to acquire core captures successfully and quickly as well as obtain an adequate core sample for examination.

Q: **How long does an aspiration or biopsy take vs. the traditional procedure?**
A: The OnControl System has a median time to core extraction of 81 seconds. Traditional procedures can take anywhere from 2 to 30 minutes and longer, with a mean time of 7 minutes to hand insert the device into the bone and obtain samples as needed. In addition, multiple attempts are often required to obtain a sample of adequate size.

Q: **How difficult is it to use?**
A: The OnControl Bone Marrow System is very easy to use, and Vidacare has developed a training certification program that will enable clinicians to practice using the system in special mannequins that simulate an actual patient.

Q: **How many physicians are using this? Where?**
A: OnControl has been beta-tested by 31 clinicians on over 84 patients in organizations including the Cancer Research and Technology Center of The University of Texas/San Antonio (San Antonio, Texas), M.D. Anderson Cancer Center (Houston, Texas), Wilshire Oncology (Glendora, CA), the National Institute of Health (Bethesda, MD) and Kaiser Permanente Riverside (Riverside, CA).

Q: **What's the difference between a bone marrow biopsy and a bone marrow aspiration?**
A: An aspiration is generally performed to assess how well a patient is responding to their cancer therapy, to gauge the patient's condition between treatment cycles, to identify signs of disease progression, and to evaluate the extent of cell engraftment after bone marrow transplantation. A biopsy is useful in diagnosing and staging a patient's hematological disorder. Prior to performing a biopsy, it is common for clinicians to also obtain an aspiration. The biopsy requires the clinician to actually "core" through the marrow and withdraw a sample that is 1.5-2.5 cm long as opposed to an aspiration in which bone marrow in a more fluid state is simply extracted from the marrow space.

Q: **Can it be used for all bone marrow aspiration or biopsy situations?**
A: Yes, the OnControl System is appropriate for all patient groups, including pediatric patients (aspiration only), those with very soft bones, those with osteoporosis, and those with very difficult to penetrate bones. It is also designed for use in marrow harvesting. The OnControl System has been designed to offer maximum flexibility so that it can be tailored to the specific needs of each patient and each clinician.

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