



MEDCO FORUM[®]

PRESENTING INNOVATIVE PRODUCTS AND SERVICES TO HEALTHCARE PROFESSIONALS

VOLUME 15 NUMBER 37

SEPTEMBER 2008

REPRINT

OFF TO SEE THE WIZARDS: OSTEOCLEANSE[™]

Dorothy, in the MGM classic, *The Wizard of Oz*, exclaims, “There’s no place like home!” In the context of bone flaps this might be paraphrased, “There’s no bone like your bone!”

Every year 30,000 Americans require the removal of a cranial bone flap. Following the removal of this piece of bone, performed to access an aneurysm, remove a tumor or reduce intracranial pressure, surgeons face a difficult decision. They can either store the patient’s own bone and re-implant it at a later date or they can discard the patient’s bone and choose between several synthetic options.

Saving and re-implanting the patient’s own bone is the optimal solution. Unfortunately, the infections rate can be as high as 20%. The increased risks associated with saving the patient’s bone, spurred the development of several treatment options to lower the risk of infection. These options include ethylene oxide and/or steam sterilization, in situ antibiotic irrigation, and freezing and storage of tissue until needed for re-implantation. Even though these treatment options offer an improvement these options are not optimal.

Infections and the lack of ideal ways for addressing them, has forced surgeons to use synthetic or metal implants. Synthetic options include cement-like materials composed of variable commercially available substances, titanium meshes, or custom-made implants. Unfortunately, just like autograft, these synthetic and metal solutions are not optimal. They do not always match the patient’s anatomy, they are technique-dependent, there is

always the potential of an immunological reaction, are often very expensive, and are incapable of osteo-integration.

Looking for alternative treatments to help his patients, Scott Graham, MD (Associate Professor, Department of Neurosurgery, Virginia Commonwealth University), having experienced the benefits of **LifeNet Health Allowash XG** allograft tissue cleaning and disinfecting technology, approached LifeNet Health and asked “would it be possible to take an infected bone flap and put it through your process [Allowash XG] to give it a second chance?” Realizing the potential of this technology to improve patient outcomes, LNH rose to the occasion and created the **OsteoCleanse Autograft Cleaning Service**.

According to Rony Thomas, CEO of LifeNet Health, “OsteoCleanse[™] is a unique service that is offered only by LifeNet Health. We developed this service in response to a need voiced to us by neurosurgeons that were unhappy with the cranial bone flap salvage solutions that were

“Would it be possible to take an infected bone flap and put it through your process [Allowash XG] to give it a second chance?”

Scott Graham, MD

available to them and we are proud to do our part toward improving the clinical outcome for patients with traumatic brain injuries.”

The OsteoCleanse Autograft Cleaning Service is based on Allowash XG, LifeNet Health’s proven technology for cleaning and disinfecting allograft tissue. Since 1995 this technology has been used by LifeNet Health to process and distribute over 1.8 million allografts without one reported case of disease transmission. Allowash XG is a patented and validated process. Along with chemical treatments and other sterilization steps, Allowash XG has been shown to render a Sterility Assurance Level (SAL) of 10^{-6} without compromising the biomechanical or biochemical properties of the tissue.

The patient’s own tissue has long been established as the most clinically effective solution for bone grafting. OsteoCleanse is a four-step process that offers surgeons the ability to re-implant the patient’s own tissue, while addressing the limitations experienced by currently and previously available treatment options.

Because OsteoCleanse allows for the re-implantation of the patient’s own bone, there is no risk of an immunological response. Furthermore, because the bone

OSTEOCLEANSE PROCESS

Step 1: Controlled Processing

Step 2: Rigorous Cleaning

Step 3: Disinfection and Rinsing


Step 4: Terminal irradiation

flap matches the patient’s skull defect, surgeons can better retain the natural contour of the patient’s skull, providing an esthetic effect superior to many synthetic options, and saving valuable OR time. Also, OsteoCleanse is cost-effective. There is reduced hospitalization when compared to the time required for an *in situ* antibiotic regimen. There are reduced hospital visits when compared to performing a fitting for custom implants. And no medical imaging is required as compared to designing and developing a custom implant.

The procedure to use OsteoCleanse is straightforward. LifeNet Health will provide the hospital a transport kit. This kit will be used for the delivery of the bone flap to LifeNet Health. When the need arises, the hospital fills out a Service Request Form and faxes it to the toll-free number, 1-800-617-1389. LifeNet Health confirms the request and schedules a private courier to pick up the shipment from the facility. The kit and flap are tracked by the patient’s own medical record

number provided by the hospital. A private courier is used to allow for the continuous tracking of the tissue and minimize the chances of the tissue being lost. Once the bone flap is processed, the hospital is contacted to arrange the final date and time the cleaned bone flap will be delivered back to the hospital.

Dr. Graham finds that the OsteoCleanse service is easy to use. The expected turn-around time for the bone is a couple of weeks; so, it isn’t the “rate limiting step” for the bone-replacement surgery. Dr. Graham observes, “This service is a good option for my patients.” Dr. Graham has particularly noted the value a service such as OsteoCleanse could provide the military. The day may come when a soldier may be able to have his own bone flap re-implanted after a traumatic event in battle.

While the key to returning Dorothy to home was a pair of magic shoes, the key to returning resected cranial bone flaps to their home is adequate cleaning using OsteoCleanse Autograft Cleaning Service. 

To Learn More

For further information, please call **LifeNet Health** toll-free at 1-888-847-7831.