Advancing Fusion Options with the VIA Bone Matrix Portfolio

Brought to you by VIVEX BIOLOGICS

VIA® Viable Bone Matrices

VIA® Graft and VIA® Form are Viable Bone Matrices containing key elements to support bone formation in a variety of bonegraft clinical applications. The VIA product line provides a uniquely patented combination of optimized osteoconductive scaffold, demineralized osteoinductive potential signaling proteins,[1] and viable spine-derived cells that support an osteogenic healing process. These viable allografts have demonstrated efficacy in complex spinal fusion procedures.[2] VIA Graft/Form is available in different formulations that facilitate handling during surgical procedures.

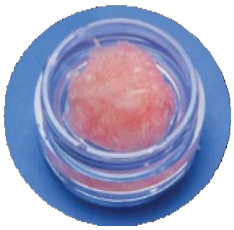

Figure 1: VIA Form

VIA Graft/Form's allograft tissues are engineered to a microparticulate size optimized for bone regeneration that supports ossification with healing rates comparable to autograft.[3] VIA Graft is a proprietary mixture of 100-300 µm demineralized cortical bone and mineralized cortical and cancellous bone. VIA Form is a proprietary mixture of cortical shavings, crushed cancellous chips, and 100-300 µm demineralized cortical bone microparticulate (Figure 1).

VIA Viable Bone Matrices are preserved with VIVEX's patented and proprietary DMSO-free VIACoat™, which uses an extracellular protective coating on the cell to prevent crack propagation and membrane lysis[1] (Figure 2).[1] DMSO cryoprotectants penetrate the cell and prevent ice crystal formation from within (Figure 4). Unlike DMSO-based cryoprotectants,[4,5,6] VIACoat is not cytotoxic at room temperature and does not require multiple rinsing and decanting steps. Allografts treated with VIACoat experience minimal cell loss, retain an average of over 80% cell viability after thaw[1] (Figure 3), and may be used up to 4 hours after thawing. Allografts cryopreserved with VIACoat can be stored for up to 3 years at ≤-65°C.[1]

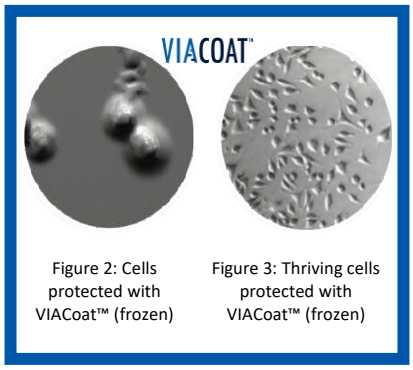

Figure 2: Cells protected with VIACoat™ (frozen)

Figure 3: Thriving cells protected with VIACoat™ (frozen)

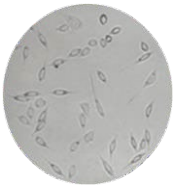

Figure 4: 2.5% DMSO-compromised cells showing reduced viability (thawed)

Clinical studies have demonstrated that VIA Graft/Form provides a sufficient scaffold to support de novo bone formation resulting in clinically successful fusion. In one study, 75 patients were treated with a minimally invasive TLIF using VIA Graft and demonstrated a greater than 96% rate of fusion over 85 treated levels.[2] A second study enrolled 67 patients treated via LLIF and VIA Graft at over 151 levels. Fusion was achieved at 143 levels (94.7%). VIA Graft was effective despite the negative influences on fusion outcomes of an average patient BMI of over 30, 19% tobacco use, and 16% diabetics (Figures 6 and 7).[7] CT scans following LLIF confirmed the presence of trabeculated new bone formation spanning the instrumented disc space. No patient had lucency around the implants or evidence of implant migration or hardware failure throughout the study duration.[7]

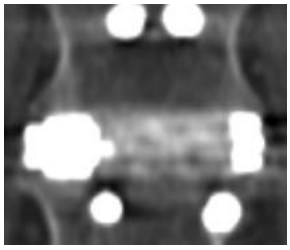

Figure 6: Coronal view L4L5

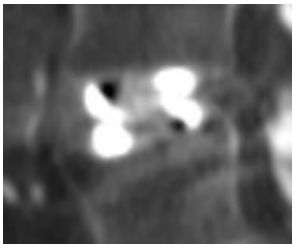

Figure 7: Sagittal view L4L5

VIAFill™ 100% Demineralized Cortical Fibers

Figure 8: VIAFill™ Hydrated and pulled apart

VIAFill™ is a moldable bone void filler comprised of 100% demineralized cortical bone fibers of various lengths with no carrier. VIAFill can be used in a variety of bone graft clinical applications, including spine, cranio-maxillofacial, and orthopedics. Demineralized cortical bone fibers have been shown to offer improved osteoconductivity[8] compared to powder due to the exposed natural bone morphogenic proteins that induce bone formation due to the increased ability for cells to migrate along fibers, creating "cellular highways" for bone formation.[9,10] VIAFill is easily rehydrated with saline and its moldability allows fibers to be shaped as needed. VIAFill is lyophilized and terminally sterilized using e-beam irradiation in a final ready-to-use container, allowing for convenient storage at ambient temperatures and off-the-shelf use.

[1] Data on file at VIVEX Biologics, Inc.
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[3] Malinin TI, et al. Particulate bone allograft incorporation in regeneration of osseous defects; importance of particle sizes. *Open Orthopaed J*. 2007;1:19-24.
[4] Best BP. Cryoprotectant toxicity: facts, issues, and questions. *Rejuvenation Res*. 2015;18(5).
[5] Renzi S, et al. Mesenchymal stromal cell cryopreservation. *Biopreserv Biobank*. 2012;10(3):276-281.
[6] Asghar W, et al. Preserving human cells for regenerative, reproductive, and transfusion medicine. *Biotechnol J*. 2014;9:895-903.
[7] Data submitted for publication.
[8] Urist MR. Bone: formation by autoinduction. *Science*. 1965;150(3698):893-899.
[9] Martin GJ Jr, et al. New formulations of demineralized bone matrix as a more effective graft alternative in experimental posterolateral lumbar spine arthrodesis. *Spine*. 1999;24(7):637-645.
[10] Rajadurai J, et al. The use of demineralised bone fibres (DBF) in conjunction with supercritical carbon dioxide (SCCO2) treated allograft in anterior lumbar interbody fusion (ALIF). *J Spine Surg*. 2019;5(4):589-595.

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