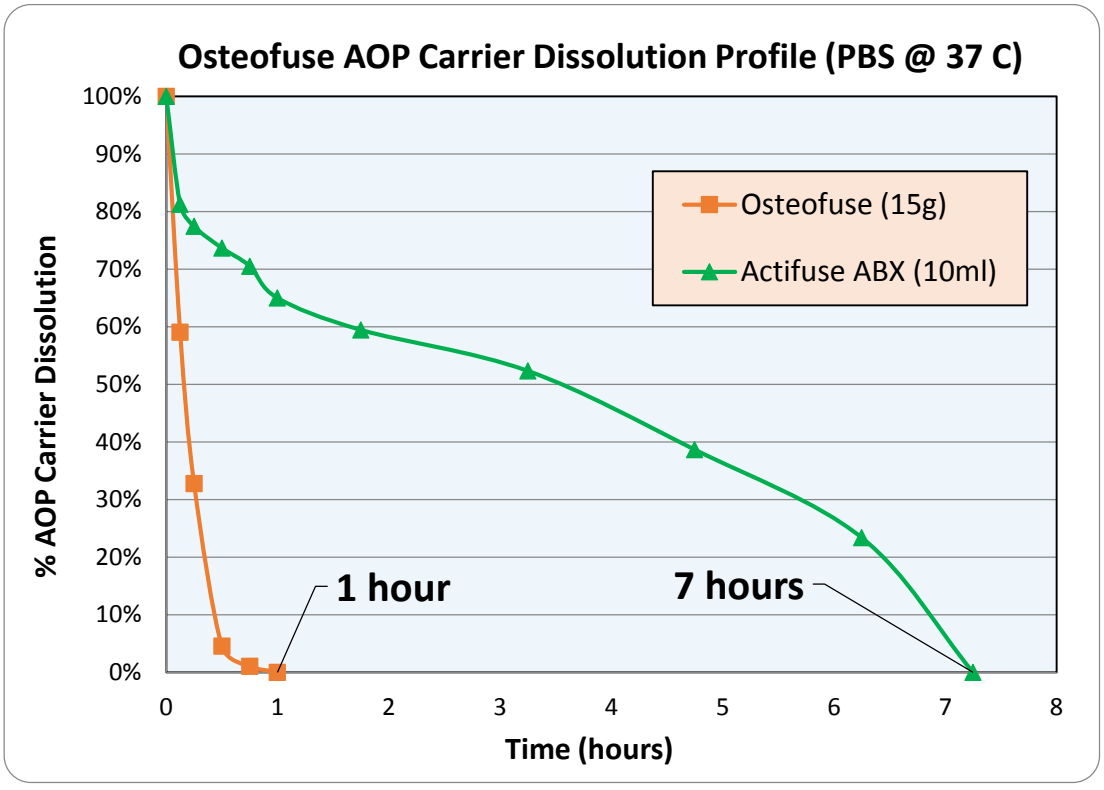
Osteofuse® AOP Carrier Dissolution Profile

The Osteofuse Bioactive Bone Graft Putty comprises 45S5 bioactive glass and biphasic mineral granules suspended in an alkylene oxide polymer (AOP) carrier. The purpose of the carrier is to facilitate intra-operative handling of the graft and to maintain the granulate components in the desired location until closure. Alkylene oxide polymers are highly biocompatible and have been used in a variety of medical applications, including as a carrier in implantable bone void fillers [1]. After implantation, the AOP carrier is readily absorbed into surrounding tissues and eliminated from the body via the urine and feces. Animal studies have shown that AOPs are almost completely excreted from the body within 24 hours [1,2].

Upon exposure to the physiological environment, the 45S5 bioactive glass undergoes an exchange of biologically active ions to produces a bioactive apatite layer to which bone can readily bond to, followed by the proliferation and differentiation of bone related cells as part of the normal healing process. Similarly, dissolution of the biphasic mineral granules produces a direct bonding interface with host bone through the release of calcium and phosphate ions and subsequent formation of a surface apatite layer similar to bone mineral. In addition, the structural microporosity and macroporosity of Osteofuse biphasic granules (1-2 mm) are in the optimal ranges needed to allow penetration of biological fluids (>10 µm) and to support osteoconductivity (>100 µm).

The optimized hydrophilic efficiency and rapid in vivo dissolution of the AOP polymer carrier is critical to allow immediate access to the bone healing effects of these bioactive components, and the rapid dissolution rate provides a distinct advantage over slower dissolving carriers as observed with Actifuse ABX. Figure below compares the in vitro dissolution behavior of Osteofuse and Actifuse ABX demonstrating a greater hydrophilic efficiency with the Osteofuse carrier.



1. Working PK, Newman MS, Johnson J, Cornacoff JB. *Safety of Poly(ethylene glycol) and Poly(ethylene glycol) Derivatives*. Poly(ethylene glycol): Chemistry & Biological Applications, Chapter 4, American Chemical Society, ACS Symposium Series 680. 1997.
2. Henning, T. *Polyethylene glycols (PEGs) & the pharmaceutical industry*. Fine, Specialty & Performance Chemicals. 2002;57-29.