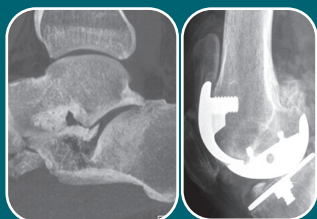




Challenge of bone regeneration in Ortho/Trauma surgery



The ongoing challenge of Trauma surgery is to obtain sufficient stability and anatomical reduction such that the natural bone healing process can successfully repair the bone injury. Despite rapid advances in design of osteosynthesis hardware (eg anatomical locking screws/plates, IM nails), there is still a need for improved treatment of bone voids

(such as in compression fractures), stabilization of comminuted fractures, and osteotomy repairs. Lack of stability and adequate contact between fragments can lead to non-union, pain, implant failure, and revision.

Bone voids in revision or primary orthopedic surgery may compromise implant stability, their functionality, and strength over the long term. Moreover, these bone losses create further risk to future revision procedures. Several trends are underway which increase the need to optimize bone stock and ensure that bone voids are addressed fully: longer life expectancy, increased volumes of joint replacement and early age joint replacement. Compromised bone stock over the long term increases the risks inherent in revision surgery.

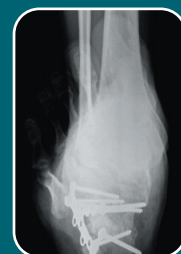
Why use Graftys® HBS or Graftys® Quickset in Ortho/Trauma surgery?

GRAFTYS® HBS and **GRAFTYS® QUICKSET** are intended for bony voids or defects that are not intrinsic to the stability of the bony structure. **GRAFTYS® HBS** and **GRAFTYS® QUICKSET** are intended to be placed or injected into bony voids or gaps of the skeletal system (the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides bone void filler that resorbs and is replaced with bone during the healing process.

Characteristics	Features	Benefits
Composition	Biphasic 60% HA 40% β -TCP for natural speed	Facilitates formation of healthy mineralized bone following the natural remodeling process
Global Porosity : 70%	Microporosity (pores<10 μ m) 45% Mesoporosity (10-100 μ m) 20% Macroporosity (pores>100 μ m) 35%	Resorption throughout the implant by osteogenic cell
Mechanical strength	>10 MPa	Easy to manipulate intraoperatively
Configurations	Numerous shapes and volumes including granules	Shape adapted to clinical needs. Can be used as graft extender

The solution by Graftys® Quickset

GRAFTYS® QUICKSET is a fast setting high Viscosity material. Its high viscosity confers an excellent cohesiveness and ensures excellent performance in open cavities which minimize leak risks. The short initial setting time (8 min) permits a notable time gain and reinforce the cohesiveness properties of the material. Finally, all these properties give the possibility to position the material comfortably even when the gravity (gravitation) plays against the operator (e.g. Acetabulum filling) and limit anatomical reduction loosening.



The solution by Graftys® HBS








GRAFTYS® HBS is a patented phosphocalcic, macroporous, injectable, hardening, resorbable cement. Its physicochemical structure provides osteoconductive properties adapted to trauma & recon surgery. Low viscosity ensures excellent injectability along with a means to bond bone fragments by stabilization of the osteosynthesis primarily through void filling and secondarily by resorption/substitution of the material by mineralized healthy bone. This ease of injection minimizes risks of anatomical reduction loosening and provides the option to inject after the implants are in place (eg. use of screw holes in plates, cephalic screw hole for inter trochanteric nails, use of screw holes of tibial plateau implant). This capability ensures excellent interface between both bone/material and implant/material. The slow setting time (15 min) allows multiple injections with the same syringe. Finally, **Graftys® HBS** facilitates injection throughout the trabecular structure, without damaging it.




Graftys®

www.graftys.com



Indications	References UE	References US	Designation	Clearance UE/US	Shape
MIS procedures, Multi Injection procedures Small/closed, deep and difficult access cavities, Reasonable blood flow, Intrabone Injection Gravity 	GYHBSV1Q5	na	GRAFTYS HBS 5cc DOSE	CE marked	
	GYHBSV1Q8	na	GRAFTYS HBS 8cc DOSE	CE marked	
	GYHBSV1Q16	na	GRAFTYS HBS 16cc DOSE	CE marked	
	na	HBSKITUSV1Q5	GRAFTYS HBS KIT US 5cc	510(k) cleared	
	na	HBSKITUSV1Q8	GRAFTYS HBS KIT US 8cc	510(k) cleared	
	na	HBSKITUSV1Q16	GRAFTYS HBS KIT US 16cc	510(k) cleared	
Mono injection procedures, Open and easy access cavities Large blood flow, Procedures under arthroscopy Gravity 	GYQSMV1Q5	na	GRAFTYS QUICKSET 5cc DOSE	CE marked	
	GYQSMV1Q8	na	GRAFTYS QUICKSET 8cc DOSE	CE marked	
	GYQSMV1Q16	na	GRAFTYS QUICKSET 16cc DOSE	CE marked	
	na	QSKITUSV1Q5	GRAFTYS QUICKSET KIT US 5cc	510(k) cleared	
	na	QSKITUSV1Q8	GRAFTYS QUICKSET KIT US 8cc	510(k) cleared	
	na	QSKITUSV1Q16	GRAFTYS QUICKSET KIT US 16cc	510(k) cleared	
Use with GRAFTYS syringe	GYINJECTHBSS	na	GRAFTYS DELIVERING GUN CE	CE marked	

Preparation



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