VADIN implants

OptiFuse

OptiFuse Genta

more to life™

▸ OptiFuse
▸ OptiFuse Genta

Synthetic Bone Substitute

The innate issues of high variability and chance of viral transmission in naturally derived bone grafts have led to the development of synthetic alternatives. Synthetically derived bone grafts are rigorously tested for safety and efficacy, are produced in a consistent manner within small tolerance limits and have no viral or bacterial transmission issues.
OptiFuse is a biphasic calcium phosphate composed of 70% of Hydroxyapatite and 30% of β-TCP, offered in two versions: with and without antibiotic. OptiFuse is comprised of:

Hydroxyapatite (HA)

Is one of the most biologically compatible substances used as a bone graft substitute material. Synthetic hydroxyapatite (HA) share similarities with the mineral density of the bone and is used to restore the physical structure of a bone defect due to its osteoconductive properties.

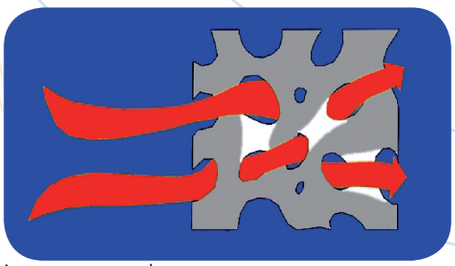
β-TCP

Beta Tricalcium Phosphate (β-TCP) is more soluble than HA. It is biocompatible, with osteoconductive properties and is degradable by osteoclast activity.

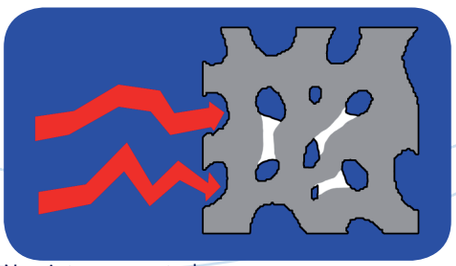
OptiFuse characteristics:

- It acts as a scaffold for cell migration and new bone formation.
- Due to the addition of β-TCP, OptiFuse is more rapidly degradable than hydroxyapatite alone.
- OptiFuse Genta releases the antibiotic gradually over a period of 48 hours postoperatively.

One of the essential elements of bone regeneration is osteoconduction, the ability to support new bone formation via ingrowth of new host bone into/onto a scaffolding material. The pore size and porosity are important characteristics for the ability of osteoprogenitor cells to migrate throughout the implant and ultimately form new bone. OptiFuse has interconnected pores with sizes 300-500 microns which is thought to be ideal since vascular ingrowth can occur. The interconnectivity of the internal structure plays considerable role to the neo-angulation, osteoblast migration and new bone formation.



Interconnected pores



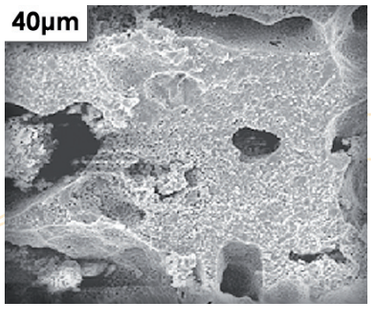
Non interconnected pores

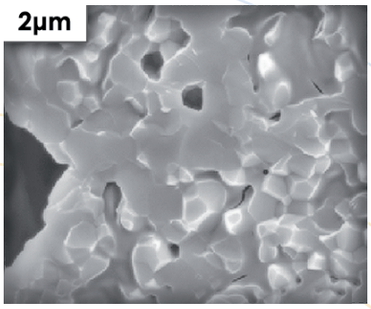
Combining bone filling and local *ANTIBIOPROPHYLAXIS*

OptiFuse Genta is particularly indicated when germs sensitive to gentamicin constitute a possible risk.

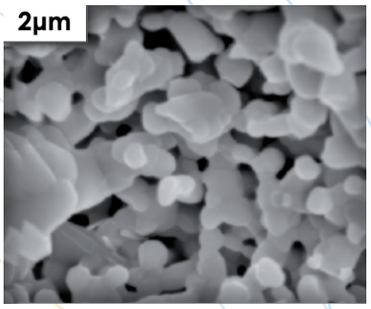
In OptiFuse Genta, the Gentamicin is uniformly distributed over the structure of the substitute without affecting its porous characteristics.

Microscopic structure from electronic microscope





OptiFuse Genta



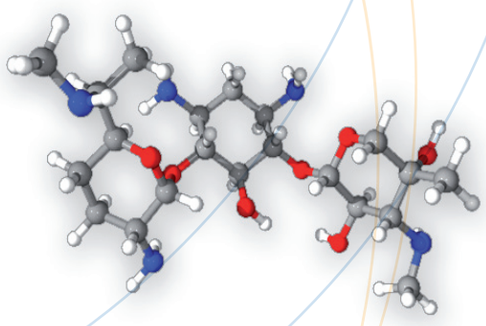
OptiFuse Genta
In magnification with Gentamicin

- The Gentamicin is homogeneously distributed in the pores of the structure.
- The interconnected pores remain open for the generation of newly formed bone.

The diameter of the porous is the critical factor for the formation of new bone. The optimal pore size will allow for greater cell infiltration and faster resorption of the synthetic substitute. β-TCP is resorbed by osteoclastic activity and functions similarly to autologous bone. The combination of β-TCP and HA provides a biocompatible and osteoconductive substitute with the "bone-friendliness" of the hydroxyapatite and the soluble properties of β-TCP.

Gentamicin

Gentamicin is an aminoglycoside antibiotic, used to treat many types of bacterial infections, particularly those caused by Gram-negative organisms. Like all aminoglycosides, when gentamicin is given orally, it is not systemically active. This is because it is not absorbed to any appreciable extent from the small intestine.
It is administered intravenously, intramuscularly or topically to treat infections.



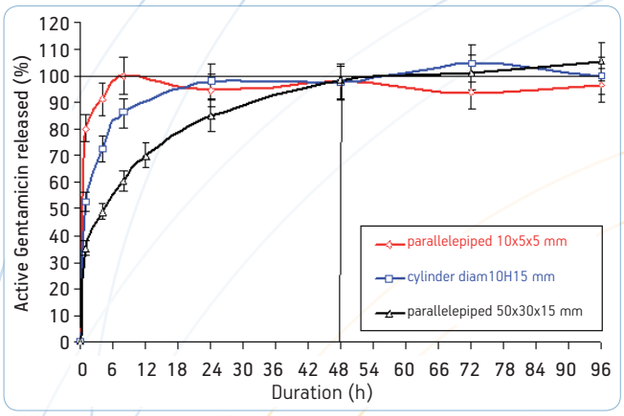
OptiFuse Genta contains 150 mg of gentamicin basis, intended to be diffused in the zone operated in the hours which follow the implantation:

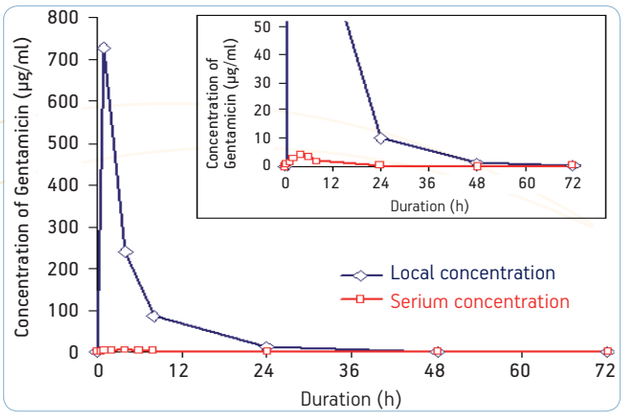
- The diffusion lasts less than 48 hours thus avoiding any risk of bacterial resistance.
- The gentamicin dose corresponds to the usual therapeutic dose (3 mg/kg) for a patient of 50 kg
- Effective local concentrations (largely higher than the BMC of the germs sensitive to gentamicin) can be reached thanks to the dose and the speed of diffusion.

Pharmacological Characteristics

Gentamicin Release over time: in vitro analysis

The antibiotic is released one hour after the implantation until 48 h postoperatively. The local release of the substance makes its concentration higher in the surgical area than if the antibiotic was inserted in the body through an injection. Thus, resulting in maximum prophylaxis.





Different volumes have different release period of the gentamicin, according to the graph above.

Product ordering information

	Reference Numbers	Shape	Size	Volume
OptiFuse Standard	F – G02	Granules	0,5mm	20cm³
	F – G12		1mm	20cm³
	F – G22		2mm	20cm³
	F – G42		4mm	20cm³
	F – G01		0,5mm	10cm³
	F – G01		1mm	10cm³
	F – G21		2mm	10cm³
	F – G41		4mm	10cm³
	F – G004		0,5mm	4x1cm³
	F – G104		1mm	4x1cm³
	B – I01	Bar	50 x 30 x 15mm	22,5cm³
	B – I05		20 x 10 x 10mm	4cm³
	B – I07		20 x 5 x 5mm	2cm³
	C – I11	Cylinder	D=30mm H=15mm	10,6cm³
	C – I122		D=15mm H=15mm	5,4cm³
	C – I14		D=10mm H=15mm	2,4cm³
	W – I22	Wedge	H=35mm L=30mm B1=12mm B2=4,6mm a=12°	8,7cm³
	W – I24		H=35mm L=30mm B1=10mm B2=3,8mm a=10°	7,2cm³
	W – I26		H=35mm L=30mm B1=8mm B2=3,1mm a=8°	5,8cm³

	Reference Numbers	Shape	Size	Volume
OptiFuse Genta	F – G02 - G	Granules	0,5mm	20cm³
	F – G12 - G		1mm	20cm³
	F – G22 - G		2mm	20cm³
	F – G42 - G		4mm	20cm³
	F – G01 - G		0,5mm	10cm³
	F – G01 - G		1mm	10cm³
	F – G21 - G		2mm	10cm³
	F – G41 - G		4mm	10cm³
OptiFuse Genta	B – I01 - G	Bar	50 x 30 x 15mm	22,5cm³
	B – I05 - G		20 x 10 x 10mm	4cm³
	B – I07 - G		20 x 5 x 5mm	2cm³
	C – I11 - G	Cylinder	D=30mm H=15mm	10,6cm³
	C – I122 - G		D=15mm H=15mm	5,4cm³
	C – I14 - G		D=10mm H=15mm	2,4cm³
	W – I22 - G	Wedge	H=35mm L=30mm B1=12mm B2=4,6mm a=12°	8,7cm³
	W – I24 - G		H=35mm L=30mm B1=10mm B2=3,8mm a=10°	7,2cm³
	W – I26 - G		H=35mm L=30mm B1=8mm B2=3,1mm a=8°	5,8cm³
BTCP	F – G02 - T	Granules	0,5mm	20cm³
	F – G12 - T		1mm	20cm³
	F – G22 - T		2mm	20cm³
	F – G42 - T		4mm	20cm³
	F – G01 - T		0,5mm	10cm³
	F – G01 - T		1mm	10cm³
	F – G21 - T		2mm	10cm³
	F – G41 - T		4mm	10cm³
	F – G004 - T		0,5mm	4x1cm³
	F – G104 - T		1mm	4x1cm³
	F – G002 - T		0,5mm	4x0,5cm³
	F – G102 - T		1mm	4x0,5cm³

References

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