Rev. 00-130219

PRODUCT DATA SHEET

PRODUCT	G-BEAM™ FUSION BEAMING SYSTEM
MANUFACTURER AND DISTRIBUTOR	Orthofix Srl Via delle Nazioni, 9 37012 - Bussolengo (VR) - ITALY
DESCRIPTION	The G-Beam™ Fusion Beaming System has been designed to address the specific demands of advanced deformity and trauma reconstructions of foot and ankle applications. The system was developed for the treatment of neuropathic deformities, such as Charcot, requiring fusion of the medial and/or lateral columns, with or without corrective osteotomies as well as for joint fusions within the mid- and hindfoot. The G-Beam™ Fusion Beaming System consists of implants available in two different diameter in a range of lengths, designed for optimal implant selection for wide ranging patient anatomies, and an instrumentation including the dedicated G-Beam Sterilization Tray. The G-Beam™ Fusion Beaming System is designed with an instrumentation and technique that have been developed to simplify the surgery.
INDICATIONS FOR USE	The G-Beam™ Fusion Beaming System is intended to be inserted in the bones of the foot and ankle for alignment, stabilization and fixation of various fractures and osteotomies, fusions and reconstructions. It is indicated for fracture and osteotomy fixation, reconstruction procedures, nonunions and fusions of bones of the foot and ankle including metatarsals, cuneiforms, cuboid, navicular, calcaneus and talus.
MATERIAL	The implants are made from stainless steel. The instrumentation is made of stainless steel, aluminum, plastic and silicone.
CLASS	class I, IIa, IIb (conformity to MDD 93/42/ECC as amended by 2007/47/EC)
CE MARKING	CE marking: Class I CE_{0123} marking: Class IIa, IIb (conformity to MDD 93/42/ECC as amended by 2007/47/EC)
PACKAGING	End caps, screws and instrument components supplied in STERILE configuration are packed in a double pouch+cardboard box. Tray, Kits, and the instrument components supplied in NON STERILE configuration are packed in a bag or cardboard box. Orthofix recommended that all products of NON STERILE configuration are properly cleaned and sterilized according to cleaning, maintenance and sterilization instructions (ref. PQ GBM).
STERILIZATION/ SHELF LIFE	Sterile products: Gamma radiation 25 kGy Shelf life: 59 months
NORMATIVE	EN ISO 13485; MDD 93/42/ECC as amended by 2007/47/EC.

Steam sterilizer type	Pre-vacuum	Pre-vacuum (not recommended for use in US)
Minimum exposure Temperature	132°C (270°F)	134°C (273°F)
Minimum exposure Time	4 minutes	3 minutes
Drying Time	30 minutes	30 minutes

➢ Stainless Steel Fusion Beam

Code	Description	Class	Single Use/ Multiple Use	GMDN	GTIN
99-875050	G-BEAM STAINLESS STEEL FUSION BEAM L50MM D5.4MM STERILE	IIb	Single Use	46646	18053504360469
99-875055	G-BEAM STAINLESS STEEL FUSION BEAM L55MM D5.4MM STERILE	IIb	Single Use	46646	18053504360476
99-875060	G-BEAM STAINLESS STEEL FUSION BEAM L60MM D5.4MM STERILE	IIb	Single Use	46646	18053504360483
99-875065	G-BEAM STAINLESS STEEL FUSION BEAM L65MM D5.4MM STERILE	IIb	Single Use	46646	18053504360490
99-875070	G-BEAM STAINLESS STEEL FUSION BEAM L70MM D5.4MM STERILE	IIb	Single Use	46646	18053504360506
99-875075	G-BEAM STAINLESS STEEL FUSION BEAM L75MM D5.4MM STERILE	IIb	Single Use	46646	18053504360513
99-875080	G-BEAM STAINLESS STEEL FUSION BEAM L80MM D5.4MM STERILE	IIb	Single Use	46646	18053504360520
99-875085	G-BEAM STAINLESS STEEL FUSION BEAM L85MM D5.4MM STERILE	IIb	Single Use	46646	18053504360537
99-875090	G-BEAM STAINLESS STEEL FUSION BEAM L90MM D5.4MM STERILE	IIb	Single Use	46646	18053504360544
99-875095	G-BEAM STAINLESS STEEL FUSION BEAM L95MM D5.4MM STERILE	IIb	Single Use	46646	18053504360551
99-875100	G-BEAM STAINLESS STEEL FUSION BEAM L100MM D5.4MM STERILE	IIb	Single Use	46646	18053504360568
99-875105	G-BEAM STAINLESS STEEL FUSION BEAM L105MM D5.4MM STERILE	IIb	Single Use	46646	18053504360575
99-875110	G-BEAM STAINLESS STEEL FUSION BEAM L110MM D5.4MM STERILE	IIb	Single Use	46646	18053504360582
99-875115	G-BEAM STAINLESS STEEL FUSION BEAM L115MM D5.4MM STERILE	IIb	Single Use	46646	18053504360599
99-875120	G-BEAM STAINLESS STEEL FUSION BEAM L120MM D5.4MM STERILE	IIb	Single Use	46646	18053504360605
99-875125	G-BEAM STAINLESS STEEL FUSION BEAM L125MM D5.4MM STERILE	IIb	Single Use	46646	18053504360612
99-875130	G-BEAM STAINLESS STEEL FUSION BEAM L130MM D5.4MM STERILE	IIb	Single Use	46646	18053504360629
99-875135	G-BEAM STAINLESS STEEL FUSION BEAM L135MM D5.4MM STERILE	IIb	Single Use	46646	18053504360636
99-875140	G-BEAM STAINLESS STEEL FUSION BEAM L140MM D5.4MM STERILE	IIb	Single Use	46646	18053504360643
99-875145	G-BEAM STAINLESS STEEL FUSION BEAM L145MM D5.4MM STERILE	IIb	Single Use	46646	18053504360650
99-875150	G-BEAM STAINLESS STEEL FUSION BEAM L150MM D5.4MM STERILE	IIb	Single Use	46646	18053504360667
99-875155	G-BEAM STAINLESS STEEL FUSION BEAM L155MM D5.4MM STERILE	IIb	Single Use	46646	18053504360674
99-875160	G-BEAM STAINLESS STEEL FUSION BEAM L160MM D5.4MM STERILE	IIb	Single Use	46646	18053504360681
99-875165	G-BEAM STAINLESS STEEL FUSION BEAM L165MM D5.4MM STERILE	IIb	Single Use	46646	18053504360698
99-875170	G-BEAM STAINLESS STEEL FUSION BEAM L170MM D5.4MM STERILE	IIb	Single Use	46646	18053504360704
99-877050	G-BEAM STAINLESS STEEL FUSION BEAM L50MM D7.4MM STERILE	IIb	Single Use	46646	18053504360155
99-877055	G-BEAM STAINLESS STEEL FUSION BEAM L55MM D7.4MM STERILE	IIb	Single Use	46646	18053504360162
99-877060	G-BEAM STAINLESS STEEL FUSION BEAM L60MM D7.4MM STERILE	IIb	Single Use	46646	18053504360179
99-877065	G-BEAM STAINLESS STEEL FUSION BEAM L65MM D7.4MM STERILE	IIb	Single Use	46646	18053504360186
99-877070	G-BEAM STAINLESS STEEL FUSION BEAM L70MM D7.4MM STERILE	IIb	Single Use	46646	18053504360193
99-877075	G-BEAM STAINLESS STEEL FUSION BEAM L75MM D7.4MM STERILE	IIb	Single Use	46646	18053504360209
99-877080	G-BEAM STAINLESS STEEL FUSION BEAM L80MM D7.4MM STERILE	IIb	Single Use	46646	18053504360216
99-877085	G-BEAM STAINLESS STEEL FUSION BEAM L85MM D7.4MM STERILE	IIb	Single Use	46646	18053504360223
99-877090	G-BEAM STAINLESS STEEL FUSION BEAM L90MM D7.4MM STERILE	IIb	Single Use	46646	18053504360230
99-877095	G-BEAM STAINLESS STEEL FUSION BEAM L95MM D7.4MM STERILE	IIb	Single Use	46646	18053504360247
99-877100	G-BEAM STAINLESS STEEL FUSION BEAM L100MM D7.4MM STERILE	IIb	Single Use	46646	18053504360254
99-877105	G-BEAM STAINLESS STEEL FUSION BEAM L105MM D7.4MM STERILE	IIb	Single Use	46646	18053504360261
99-877110	G-BEAM STAINLESS STEEL FUSION BEAM L110MM D7.4MM STERILE	IIb	Single Use	46646	18053504360278
99-877115	G-BEAM STAINLESS STEEL FUSION BEAM L115MM D7.4MM STERILE	IIb	Single Use	46646	18053504360285
99-877120	G-BEAM STAINLESS STEEL FUSION BEAM L120MM D7.4MM STERILE	IIb	Single Use	46646	18053504360292
99-877125	G-BEAM STAINLESS STEEL FUSION BEAM L125MM D7.4MM STERILE	IIb	Single Use	46646	18053504360308
99-877130	G-BEAM STAINLESS STEEL FUSION BEAM L130MM D7.4MM STERILE	IIb	Single Use	46646	18053504360315
99-877135	G-BEAM STAINLESS STEEL FUSION BEAM L135MM D7.4MM STERILE	IIb	Single Use	46646	18053504360322
99-877140	G-BEAM STAINLESS STEEL FUSION BEAM L140MM D7.4MM STERILE	IIb	Single Use	46646	18053504360339
99-877145	G-BEAM STAINLESS STEEL FUSION BEAM L145MM D7.4MM STERILE	IIb	Single Use	46646	18053504360346
99-877150	G-BEAM STAINLESS STEEL FUSION BEAM L150MM D7.4MM STERILE	IIb	Single Use	46646	18053504360353
99-877155	G-BEAM STAINLESS STEEL FUSION BEAM L155MM D7.4MM STERILE	IIb	Single Use	46646	18053504360360
99-877160	G-BEAM STAINLESS STEEL FUSION BEAM L160MM D7.4MM STERILE	IIb	Single Use	46646	18053504360377
99-877165	G-BEAM STAINLESS STEEL FUSION BEAM L165MM D7.4MM STERILE	IIb	Single Use	46646	18053504360384
99-877170	G-BEAM STAINLESS STEEL FUSION BEAM L170MM D7.4MM STERILE	IIb	Single Use	46646	18053504360391
99-877175	G-BEAM STAINLESS STEEL FUSION BEAM L175MM D7.4MM STERILE	IIb	Single Use	46646	18053504360407
99-877180	G-BEAM STAINLESS STEEL FUSION BEAM L180MM D7.4MM STERILE	IIb	Single Use	46646	18053504360414
99-877185	G-BEAM STAINLESS STEEL FUSION BEAM L185MM D7.4MM STERILE	IIb	Single Use	46646	18053504360421
99-877190	G-BEAM STAINLESS STEEL FUSION BEAM L190MM D7.4MM STERILE	IIb	Single Use	46646	18053504360438
99-877195	G-BEAM STAINLESS STEEL FUSION BEAM L195MM D7.4MM STERILE	IIb	Single Use	46646	18053504360445
99-877200	G-BEAM STAINLESS STEEL FUSION BEAM L200MM D7.4MM STERILE	IIb	Single Use	46646	18053504360452

➢ End Cap

Code	Description	Class	Single Use/ Multiple Use	GMDN	GTIN
99-870005	G-BEAM STAINLESS STEEL END CAP LOW COMPRESSION STERILE	IIb	Single Use	46646	18053504360711
99-870010	G-BEAM STAINLESS STEEL END CAP HIGH COMPRESSION STERILE	IIb	Single Use	46646	18053504360728

➢ Trays

Code	Description	Class	Single Use/ Multiple Use	GMDN	GTIN
187990	G-BEAM STERILIZATION TRAY	I	Multiple Use	12143	18053504360865
187990C	G-BEAM STERILIZATION TRAY COMPLETE	IIa	Multiple Use	44759	18053504360872

➢ Kits

Code	Description	Class	Single Use/ Multiple Use	GMDN	GTIN
187995C	G-BEAM KIT COMPLETE	IIb	Single Use	44759	18053504360896

➢ Instruments

Code	Description	Class	Single Use/ Multiple Use	GMDN	GTIN
187213	DRILL GUIDE	I	Pluriuso	35095	18053504360780
187223	WIRE GUIDE	I	Pluriuso	35647	18053504360834
187274	SIZING GAUGE	I	Pluriuso	44759	18053504360759
187279	RATCHETING T-HANDLE	I	Pluriuso	47829	18053504360841
187283	LARGE STEPPED DRILL D5.1-7.5MM	I	Pluriuso	32390	18053504360742
187284	SMALL STEPPED DRILL D4-5.5MM	I	Pluriuso	32390	18053504360735
187320	LARGE HEX SCREWDRIVER 5MM	I	Pluriuso	33968	18053504360803
187321	SMALL HEX SCREWDRIVER 4MM	I	Pluriuso	33968	18053504360797
187335	LARGE EXTRACTION TOOL D7.4MM	I	Pluriuso	33968	18053504360810
187336	SMALL EXTRACTION TOOL D5.4MM	I	Pluriuso	33968	18053504360827
187337	CONICAL THREADED EXTRACTOR	I	Pluriuso	12696	18053504360858
99-187287	SMALL GUIDEWIRE D1.9 MM STERILE	IIa	Monouso	46165	18053504360766
99-187288	LARGE GUIDEWIRE D2.8MM STERILE	IIa	Monouso	46165	18053504360773

NOTE: *Orthofix Srl reserves the right to modify this information at any time, in its sole discretion, with or without notice.*

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da Marco Spadoni
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Marco Spadoni
Product Assurance Supervisor