



Procedural kit for Kyphoplasty

G21 was set up in 2009 by expert entrepreneurs originating from the medical and pharmaceutical sector.

G21 is situated in proximity of the main cities and infrastructures in northern Italy, approximately 40 km from Modena and Bologna, in the Italian "Medical Valley" famous all over the world for its tradition, know-how and innovative spirit in the field of Medical Devices.

The company is strategically managed by a team of young people that stand out for their integrity, expertise and professionalism and who continuously bring the energy, enthusiasm and dynamism necessary to satisfy the requirements of an ever more demanding and developing market.

G21 has its own product portfolio (among which long-term implantable devices and Class III medical devices) of which it fully possesses the know-how as well as the design and production technology, the result of Research and Development programs conducted in-house and in

collaboration with major international research institutes and Universities.

High-quality raw materials, absolute process control, compliance with the most stringent international standards, continuous personnel training and painstaking care to details: this is the profile of G21's in-house production unit, which includes clean rooms certified up to Class ISO 5 to guarantee a production process under sterile conditions.

Manufacture the products complying with the most stringent quality standards and distribute them internationally in collaboration with trade partners with whom establish and maintain long-term relationships based on trust, cooperation and responsibility.

Since 2010 G21 has been operating according to a quality system in compliance with EN ISO 13485 "Quality Management Systems - Requirements for regulatory purposes applicable to Medical Devices".

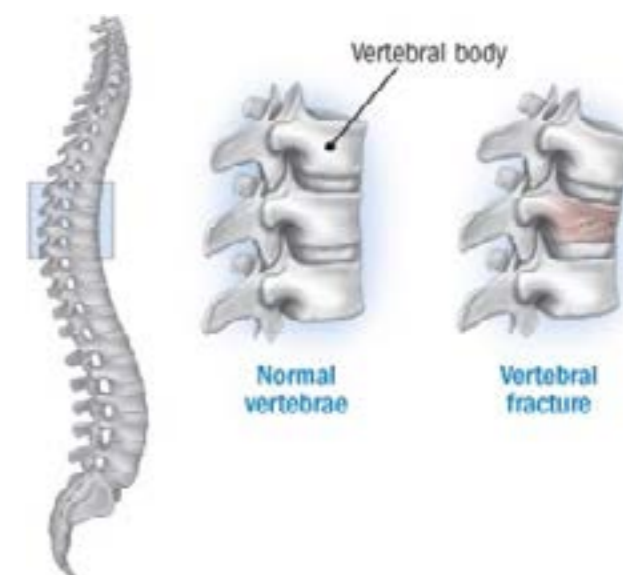
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Osteoporotic vertebral fractures are usually compression fractures that result in a loss of vertebral body height. These fractures sometimes need to be stabilized, and in many cases they can be treated without open surgery, using interventional radiology procedures [1].

Spine reinforcement with vertebroplasty or kyphoplasty is part of the recommended treatments for symptomatic vertebral fractures. The main goal of these procedures is the treatment of pain and secondary deformities [1].

Balloon kyphoplasty is intended alleviate pain, stabilize the fracture and restore the loss of height of the vertebral body, correcting and preventing the progression of the kyphotic deformity. The procedure involves the insertion of one or two inflatable bone buffers (balls) in the vertebrae. Once inflated, the ball creates a cavity, filled with bone cement. It is believed that the creation of this cavity decreases the risk of loss of cement. The effect of the balloon is to create a cavity compressing the trabeculae that provides a solid front capable of moving the vertebral plate. [1-4].

Fluoroscopy permits direct control of the injection, thanks to the G21 bone cements for vertebral consolidation containing a contrast agent (Barium sulphate for V-FIX and Zirconium oxide for V-FAST and V-STEADY) that makes them visible.

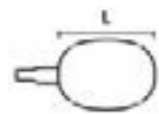
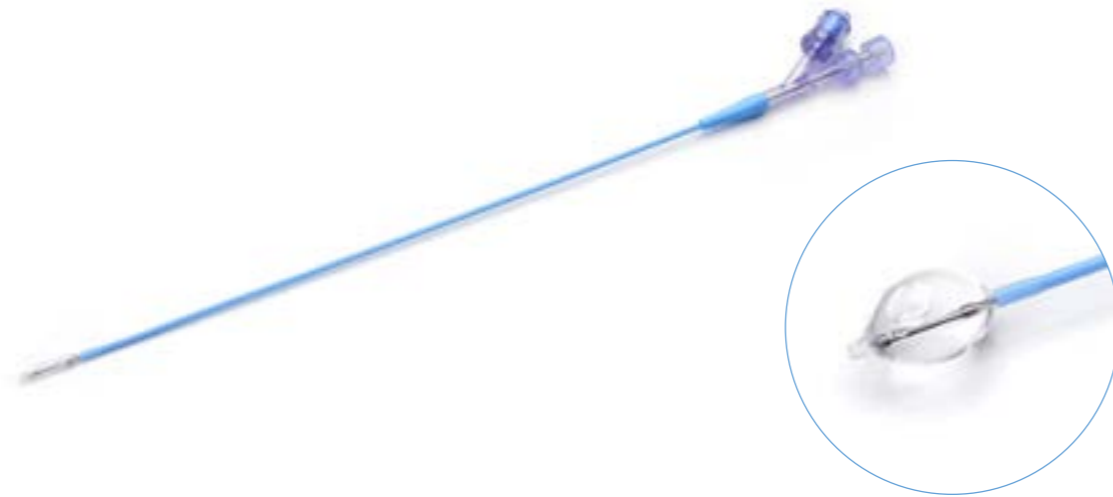


The kit includes all the needed instruments for a minimally invasive (10 gauges) direct access kyphoplasty procedure. Integrated, one-step design for quick and efficient percutaneous access to the bone and creation of the working channel. No change of cannulated needle and smaller diameter allow to reduce trauma effectively.

PRODUCT	DESCRIPTION	REF
Winch Kyphoplasty Kit, 15 MM	The kit includes: <ul style="list-style-type: none"> • 1 x Winch Kyphoplasty Balloon Catheter 11G 15MM cod. 900027 • 1 x KeyFix_Direct Access Needle cod. 900103 • 1 x KeyFix_Bone Drill cod. 900141 • 2 x KeyFix_Bone Cement Filler Cannula cod. 900097 • 1 x G21 Kyphoplasty Digital Inflation Device cod. K05-02919 	900016
Winch Kyphoplasty Kit, 20 MM	The kit includes: <ul style="list-style-type: none"> • 1 x Winch Kyphoplasty Balloon Catheter 11G 20MM cod. 900028 • 1 x KeyFix_Direct Access Needle cod. 900103 • 1 x KeyFix_Bone Drill cod. 900141 • 2 x KeyFix_Bone Cement Filler Cannula cod. 900097 • 1 x G21 Kyphoplasty Digital Inflation Device cod. K05-02919 	900018
Winch Bilateral Kyphoplasty Kit, 15 MM	The kit includes: <ul style="list-style-type: none"> • 2 x Winch Kyphoplasty Balloon Catheter 11G 15MM cod. 900027 • 2 x KeyFix_Direct Access Needle cod. 900103 • 1 x KeyFix_Bone Drill cod. 900141 • 2 x KeyFix_Bone Cement Filler Cannula cod. 900097 • 2 x G21 Kyphoplasty Digital Inflation Device cod. K05-02919 	900016B
Winch Bilateral Kyphoplasty Kit, 20 MM	The kit includes: <ul style="list-style-type: none"> • 2 x Winch Kyphoplasty Balloon Catheter 11G 20MM cod. 900028 • 2 x KeyFix_Direct Access Needle cod. 900103 • 1 x KeyFix_Bone Drill cod. 900141 • 2 x KeyFix_Bone Cement Filler Cannula cod. 900097 • 2 x G21 Kyphoplasty Digital Inflation Device cod. K05-02919 	900018B



Winch Kyphoplasty Balloon Catheter is a single use co-axial lumen Catheter with a balloon mounted on its distal tip. The balloon is designed to compress cancellous bone and/or move cortical bone as it inflates. Radiopaque markers located at the proximal and distal end of the deflated balloon allow fluoroscopic visualization of the deflated balloon during its positioning. Available in 15 mm and 20 mm length sizes.Ä



DESCRIPTION	LENGHT (L)	PRESSURE (ATM/PSI)	REF
Winch Kyphoplasty Balloon Catheter 11G 15MM	15 mm	27/400	900027
Winch Kyphoplasty Balloon Catheter 11G 20MM	20 mm	27/400	900028

KEYFIX DIRECT ACCESS NEEDLE

Aggiornare descrizione: The KeyFix Direct Access Needle is intended for percutaneous access to bone, including use during vertebral augmentation procedures, such as kyphoplasty. The device is provided with tracer and bevel tip.



DESCRIPTION

KeyFix_Direct Access Needle with "Bevel" and "Trocar" tip

REF

900103

KEYFIX BONE DRILL

KeyFix Bone Drill is intended for percutaneous access to bone during percutaneous vertebral augmentation, such as kyphoplasty.



DESCRIPTION

KeyFix_Bone Drill

REF

900141

KEYFIX BONE CEMENT FILLER CANNULA

KeyFix Bone Cement Filler Cannula is intended for the delivery of acrylic bone cement during percutaneous vertebral augmentation, such as kyphoplasty. The device is available in different versions:

- 3 pieces with handpiece with normal measure;
- 1 piece with small handpiece to connect it to the V-HP Gun.



DESCRIPTION	REF
KeyFix_Bone Cement Filler Cannula with 3 pieces with handpiece with normal measure	900097
KeyFix_Bone Cement Filler Cannula with 1 piece with small handpiece to connect it to the V-HP Gun	900100

KEYFIX BONE CEMENT FILLER CANNULA FOR SCREW CEMENTATION

The KeyFix Bone Cement Filler Cannula for Screw Cementation has a cannula and a coaxial stylet for bone cement injection in the vertebral body. The device is specifically developed for the injection of bone cement within screws for vertebral fixation.



DESCRIPTION	REF
KeyFix_Bone Cement Filler Cannula for Screw Cementation	900146

KEYFIX WORKING CANNULA

KeyFix Working Cannula consists of an inner cannula which in turn slides in an outer cannula.



DESCRIPTION	REF
KeyFix_Working Cannula	900117

KEYFIX FIRST ACCESS NEEDLE

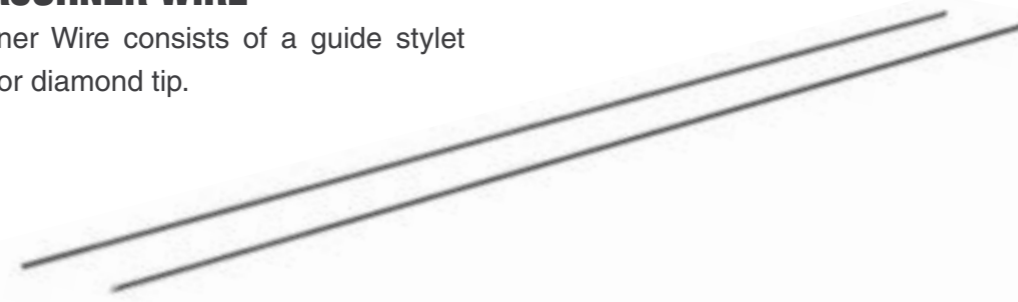
KeyFix First Access Needle is used to obtain access to the bone and is composed of a stylet that slides in a cannula.



DESCRIPTION	REF
KeyFix_First Access Needle 13G	900139
KeyFix_First Access Needle 11G	900140

KEYFIX KIRSCHNER WIRE

KeyFix Kirschner Wire consists of a guide stylet with round tip or diamond tip.



DESCRIPTION

KeyFix_Kirschner Wire with round tip
KeyFix_Kirschner Wire with diamond tip

REF

900119
900121

BIOPSY KIT

The Biopsy Kit is used for tissue sampling. The device has a fishmouth bone biopsy needle, a 3 ml syringe and a tube for tissue sampling in the vertebral body.



LENGHT (mm)

DIAMETER (gauge)

REF

190	Dedicated to 10 gauge cannulas	VV 10 190 8
190	Dedicated to 11 gauge cannulas	VV 11 190 8
190	Dedicated to 13 gauge cannulas	VV 13 190 8

KEYFIX TRADITIONAL ACCESS

The kit includes all the needed instruments to turn Winch Kit Into a traditional access kyphoplasty kit.



PRODUCT

KeyFix_Traditional Access

DESCRIPTION

The kit includes:
 • 2 x KeyFix_Kirshner wires Trocar and Round Tip - Cod. 900119
 • 1 x KeyFix_First Access Needle - Cod. 900139
 • 1 x KeyFix_Working Cannula - Cod. 900117

REF

900174

REFERENCE

- [1] Acrylic bone cement in total joint arthroplasty: A review., Saleh KJ; El Othmani MM; Tzeng TH; Mihalko WM; Chambers MC; Grupp TM, J Orthop Res; 2016 05; 34(5):737-44. PubMed ID: 26852143.
- [2] A randomized trial comparing balloon kyphoplasty and vertebroplasty for vertebral compression fractures due to osteoporosis., M. Dohm, C.M. Black, A. Dacre, J.B. Tillman, G. Fueredi, AJNR Am J Neuroradiol. 2014 Dec;35(12):2227-36.
- [3] Balloon kyphoplasty for osteoporotic spinal fractures with middle column compromise, M. Gan, J. Zou, X. Zhu, G. Wang, H. Yang, Injury, Int. J. Care Injured 45 (2014) 1539–1544.
- [4] Spinal Compression Fracture Management: A Review of Current Treatment Strategies and Possible Future Avenues, I. K. Genev, M. K. Tobin, S. P. Zaidi, S. R. Khan, F. M. L. Amirouche, A. I. Mehta, Global Spine J. 2017 Feb;7(1):71-82.

