



Procedural kit for Vertebroplasty

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.

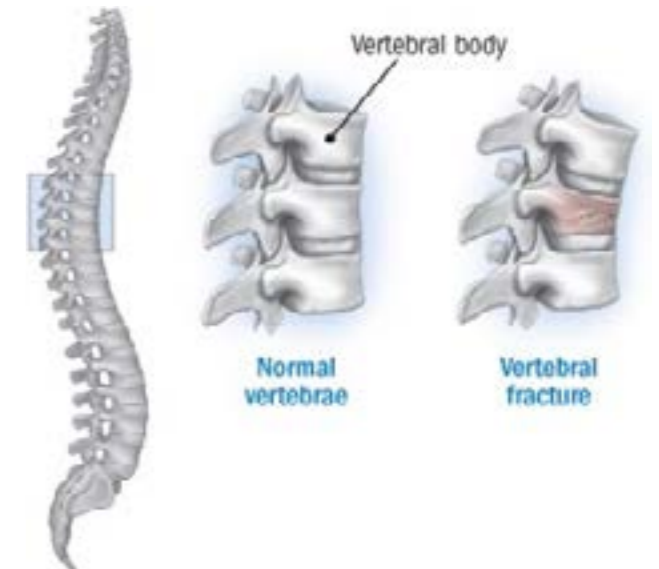
Since 2010 G21 has been operating according to a quality system in compliance with EN ISO 13485 "Quality Management Systems - Requirements for regulatory purposes applicable to Medical Devices".

V-KIT 01 4
NEEDLES FOR VERTEBROPLASTY AND BONE BIOPSY 5
V-HP GUN 6
BIOPSY-KIT 7

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 [1-4].

Vertebroplasty is intended to relieve the pain and prevent further vertebral collapse. Collapsed vertebrae are stabilized with injections of bone cement into the vertebral body [1-4].



Fluoroscopy permits direct control of the injection. G21 bone cements for verberal consolidation contains a contrast agent (Barium Sulphate for V-FIX and Zirconium Oxide for V-FAST and V-STEADY) that makes them visible during the pocedures.



The V-KIT for vertebroplasty includes V-HP Gun and one V-ACCESS needle. It is recommended to use them in combination with G21 bone cements for vertebral consolidation.



| PRODUCT | DESCRIPTION | REF |
|----------|---|---------------|
| V-KIT 01 | V-HP Gun + V-ACCESS bevel tip 11G 120 mm | VK01 11 120 5 |
| V-KIT 01 | V-HP Gun + V-ACCESS bevel tip 11G 150 mm | VK01 11 150 5 |
| V-KIT 01 | V-HP Gun + V-ACCESS bevel tip 13G 120 mm | VK01 13 120 5 |
| V-KIT 01 | V-HP Gun + V-ACCESS bevel tip 13G 150 mm | VK01 13 150 5 |
| V-KIT 01 | V-HP Gun + V-ACCESS bevel tip 15G 120 mm | VK01 15 120 5 |
| V-KIT 01 | V-HP Gun + V-ACCESS bevel tip 15G 150 mm | VK01 15 150 5 |
| V-KIT 01 | V-HP Gun + V-ACCESS trocar tip 11G 120 mm | VK01 11 120 6 |
| V-KIT 01 | V-HP Gun + V-ACCESS trocar tip 11G 150 mm | VK01 11 150 6 |
| V-KIT 01 | V-HP Gun + V-ACCESS trocar tip 13G 120 mm | VK01 13 120 6 |
| V-KIT 01 | V-HP Gun + V-ACCESS trocar tip 13G 150 mm | VK01 13 150 6 |

The bevel V-Access was designed to perform percutaneous vertebroplasty procedures facilitating pedicle access into the vertebral body thanks to the double sharpened tip. The bevel tip combined with the handle indicator allows the cement flow directioning. The diamond V-Access was designed to perform pedicle access and percutaneous targeting.



The V-Access needle is available with two different tip types:

| BEVEL TIP | | |
|-----------|-------------|-------------|
| GAUGE | LENGHT (mm) | REF |
| 11 | 120 | VV 11 120 5 |
| 11 | 150 | VV 11 150 5 |
| 13 | 120 | VV 13 120 5 |
| 13 | 150 | VV 13 150 5 |
| 15 | 120 | VV 15 120 5 |
| 15 | 150 | VV 15 150 5 |

| TROCAR TIP | | |
|------------|-------------|-------------|
| GAUGE | LENGHT (mm) | REF |
| 11 | 120 | VV 11 120 6 |
| 11 | 150 | VV 11 150 6 |
| 13 | 120 | VV 13 120 6 |
| 13 | 150 | VV 13 150 6 |

High pressure gun for radiopaque bone cement injection

The V-HP GUN is intended to be used during vertebral consolidation procedures, such as vertebroplasty and kyphoplasty.



CHARACTERISTICS

1. The ergonomic handle, screwing plunger and light weight, make the V-HP Gun a user-friendly injection device.
2. High volume capacity up to 15,00 ml, quick and safe luer-lock direct connection to G21 closed mixing system (PicoMix V). V-HP Gun can also be loaded from open bone cement mixing bowl by using the nozzle which keeps the luer-lock from cement residuals.
3. The 30 cm (12 in) angle-tip injecting pipe keeps the operator away from direct X ray irradiation during cement injection under fluoroscopy.

| PRODUCT | DESCRIPTION | REF |
|----------|--|--------|
| V-HP GUN | High pressure gun for radiopaque bone cement injection | 900165 |

The Biopsy Kit is used for tissue sampling. The device has a fishmouth bone biopsy needle, a 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 |

REFERENCES

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- [3] Percutaneous Access to the Vertebral Bodies: A Video and Fluoroscopic Overview of Access Techniques for Trans-, Extra-, and Intrapedicular Approaches, A. J. Ringer, S. V. Bhamidipaty, World Neurosurg. (2013) 80, 3/4:428-435.
- [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.

