



PROCEDURAL KITS FOR KYPHOPLASTY

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Osteoporosis and metastasis may weaken the vertebrae to such a point that they fracture by effect of the compression generated by normal everyday activities, causing pain and difficult of movement in the patients.

Compared to vertebroplasty, which is aimed solely at symptomatic treatment of pain, kyphoplasty encourages restoration of the height of the vertebral body.

This is a **minimally invasive percutaneous procedures** whereby a balloon catheter is inserted into the vertebra to

be treated through a channel created with a small-gauge cannula. The balloon is then filled with liquid containing the contrast medium in order to restore the height of the collapsed vertebral body bringing it back to its natural position.

Once removed the balloon, in the created cavity, a specific bone cements with optimized radiopacity is injected in order to obtain the vertebral consolidation.

It is highly recommended to **use KeyFix™ Kyphoplasty Kit in combination with G21's resins for vertebral consolidation.**

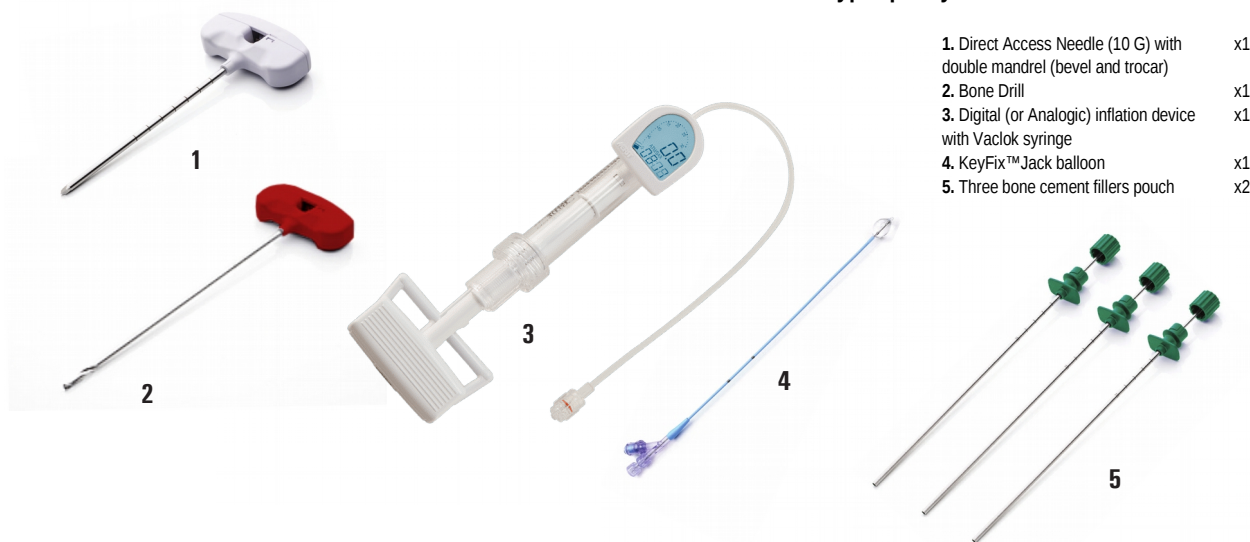
KeyFix™ KIT FOR DIRECT ACCESS MININVASIVE KYPHOPLASTY

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.

Three different size of the balloon (**10, 15 and 20 mm**) are available, so that the surgeon can choose the most suitable for each case.

Direct access needle is available with double mandrel "**bevel**" and "**trocar**" tips to suit physician preference, customizing the treatment approach.

KeyFix™ Kit for Direct Access mininvasive Kyphoplasty



- 1. Direct Access Needle (10 G) with double mandrel (bevel and trocar) x1
- 2. Bone Drill x1
- 3. Digital (or Analogic) inflation device with Vaclok syringe x1
- 4. KeyFix™ Jack balloon x1
- 5. Three bone cement fillers pouch x2

BALLOON LENGHT mm	DESCRIPTION	REF	DESCRIPTION	REF
10	Digital Inflating device	900176	Analogic Inflating device	900175
15	Digital Inflating device	900172	Analogic Inflating device	900170
20	Digital Inflating device	900173	Analogic Inflating device	900171

CATHETERS WITH BALLOON FOR KYPHOPLASTY PROCEDURES

Inflation of the kyphoplasty balloon creates a cavity and compacts cancellous bone in the vertebral body for delivering bone cement.

Low pre-inflation profile allows an accurate positioning inside the vertebral body through smaller diameter cannulas.

High quality manufacturing, range of shapes and sizes to fit patient anatomy.

Radiopaque markers allow for accurate visualization during positioning prior to inflation with contrast medium.



KeyFix™ Jack Balloons, 11 Gauge

The reduced diameter allows accurate placement even in small vertebral bodies and in the upper thoracic levels. Lower pre-inflation profile enables insertion into 10 gauge working cannulas.

Exerted pressure up to 367 psi.

Available in 10, 15 and 20 mm length sizes.

(L) LENGTH (mm)	EXERTED PRESSURE (atm / psi)	REF
10	25 / 367	900130
15	25 / 367	900131
20	25 / 367	900132

DIGITAL INFLATION DEVICE

A portable inflation device and fluid dispensing syringe for creating and real-time monitoring of the pressure.

It is a 20-ml disposable device with an integral pressure transducer, microcomputer, threaded plunger assembly with lock/release bar, a flexible high pressure extension tube and

a three-way medium pressure stopcock.

The scale on the syringe indicates the volume of contrast medium used to inflate the balloon, which corresponds to the quantity of cement to be injected into the cavity.



CHARACTERISTICS

1. atm / bar or psi reading
2. pressure range: -1 to +30.0 atm/bar (-7 to 441 psi)
3. volume dispensed: 0.45ml ± 0.07 ml per 360° handle rotation
4. male luer-lock connector
5. VacLok syringe and 3-way stopcock included
6. easy-to-read backlit LCD display
7. length of the extension tube: 61 cm

PRODUCT	DESCRIPTION	REF
Digital inflation device	Inflation device with digital display	K05 - 02919 - Can not be ordered separately

ANALOGIC INFLATION DEVICE

Analogic inflation device featuring a spring loaded locking mechanism which allows users to easily prep the device and quickly deflate a balloon, even from max pressure.

Other benefits include: ergonomic grip, clear barrel, luminescent pressure gauge, T-Handle, compact design and the ability to rapidly generate pressure.

CHARACTERISTICS

1. atm / bar or psi reading
2. pressure range: -1 to +30.0 atm/bar (-7 to 441 psi)
3. male luer-lock connector
4. 3-way stopcock included
5. easy-to-read analogic display
6. length of the extension tube: 35 cm



PRODUCT	DESCRIPTION	REF
Analogic inflation device	Inflation device with analogic display	100391 - Can not be ordered separately

TOOLS FOR KYPHOPLASTY AND BONE BIOPSY

Direct Access
Needle



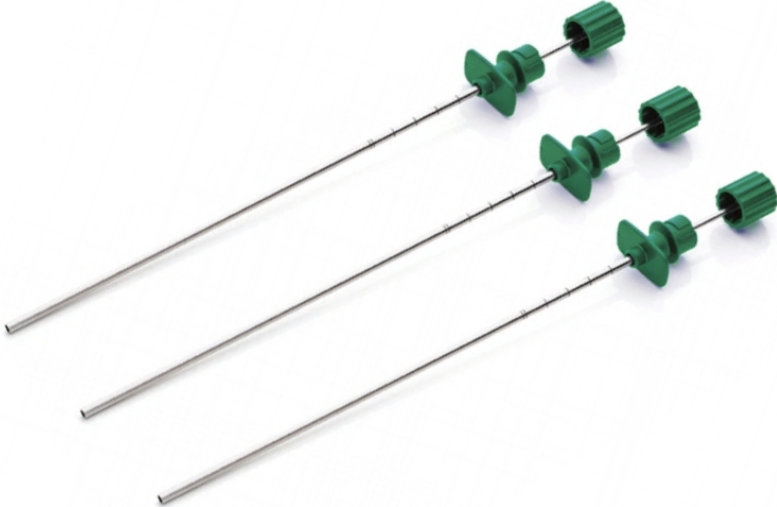
LENGTH (mm)	DIAMETER (mm)	DESCRIPTION	REF
120	3.5	Trocar and bevel mandrel included with one cannula	900103

Bone Drill



LENGTH (mm)	DIAMETER (mm)	DESCRIPTION	REF
212	3.0		900141

Bone Cement
Filler Cannula



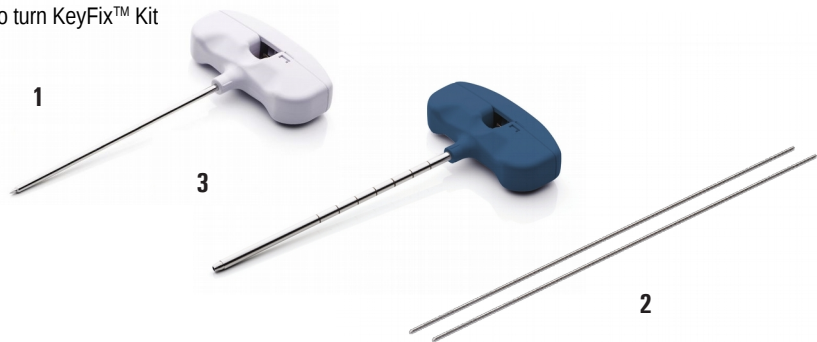
LENGTH (mm)	DIAMETER (mm)	DESCRIPTION	REF
195	3.0	3 bone fillers for each sterile pouch	900097

KeyFix™ KIT FOR TRADITIONAL ACCESS KYPHOPLASTY

The kit includes all the needed instruments to turn KeyFix™ Kit into a traditional access Kyphoplasty kit

Kit KeyFix™ Kit for Traditional Access Kyphoplasty

- 1. First access needle(13G) with trocar tip x1
- 2. Kirshner guide wire x2
- 3. Working cannula (10G) x1



PRODUCT

KeyFix™ Traditional Access

REF

900174

BIOPSY KIT



Biopsy KIT With 3-ml syringe and sampling tube

LENGTH (mm)	DIAMETER (gauge)	REF
190	Dedicated to 11 gauge cannulas	VV11 190-8
190	Dedicated to 13 gauge cannulas	VV13 190-8

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