Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 011099 0060 Rev. 01

Manufacturer:

ulrich GmbH & Co. KG
Buchbrunnenweg 12
89081 Ulm
GERMANY

Facility(ies):

ulrich GmbH & Co. KG
Buchbrunnenweg 12, 89081 Ulm, GERMANY

ulrich GmbH & Co. KG
Mergelgrube 1, 89081 Ulm, GERMANY

Product Category(ies): **surgical instruments, implants for osteosynthesis, interbody fusion devices, vertebral body replacements, spinal plate systems, spinal rod-screw-systems, contrast media injectors, disposables for contrast media injectors, surgical tourniquets, disposables for surgical tourniquets**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713159589

Valid from: 2020-01-15
Valid until: 2024-05-26

Date, 2020-01-15

Digitally signed by Dubalari Pavel
Date: 2022.12.12 09:57:41 EET
Reason: MoldSign Signature
Location: Moldova

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 011099 0059 Rev. 01

Holder of Certificate: **ulrich GmbH & Co. KG**
Buchbrunnenweg 12
89081 Ulm
GERMANY

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Surgical Instruments, Implants for Osteosynthesis, Interbody Fusion Devices, Vertebral Body Replacements, Spinal Plate Systems, Spinal Rod-Screw-Systems, Contrast Media Injectors, Disposables for Contrast Media Injectors, Surgical Tourniquets, Disposables for Surgical Tourniquets; Installation of Contrast Media Injectors; Servicing of Contrast Media Injectors and Surgical Tourniquets**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 011099 0059 Rev. 01

Report No.: 713212284

Valid from: 2022-04-01
Valid until: 2025-03-31

Date, 2022-03-31

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 011099 0059 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

ulrich GmbH & Co. KG
Buchbrunnenweg 12, 89081 Ulm, GERMANY

Design and Development, Production and Distribution of Surgical Instruments, Implants for Osteosynthesis, Interbody Fusion Devices, Vertebral Body Replacements, Spinal Plate Systems, Spinal Rod-Screw-Systems, Contrast Media Injectors, Disposables for Contrast Media Injectors, Surgical Tourniquets, Disposables for Surgical Tourniquets; Installation of Contrast Media Injectors; Servicing of Contrast Media Injectors and Surgical Tourniquets

ulrich GmbH & Co. KG
Mergelgrube 1, 89081 Ulm, GERMANY

Production and Distribution of Surgical Instruments, Implants for Osteosynthesis, Interbody fusion Devices, Vertebral Body Replacements, Spinal Plate Systems, Spinal Rod-Screw-Systems, Contrast Media Injectors, Disposables for Contrast Media Injectors, Surgical Tourniquets, Disposables for Surgical Tourniquets

./.

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TÜV®

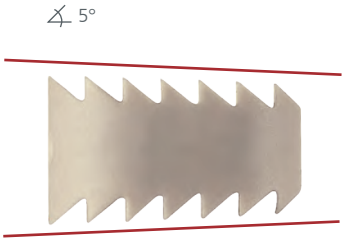
cerv-X™

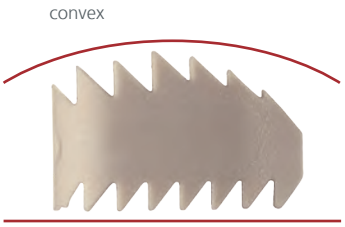
cervical cage

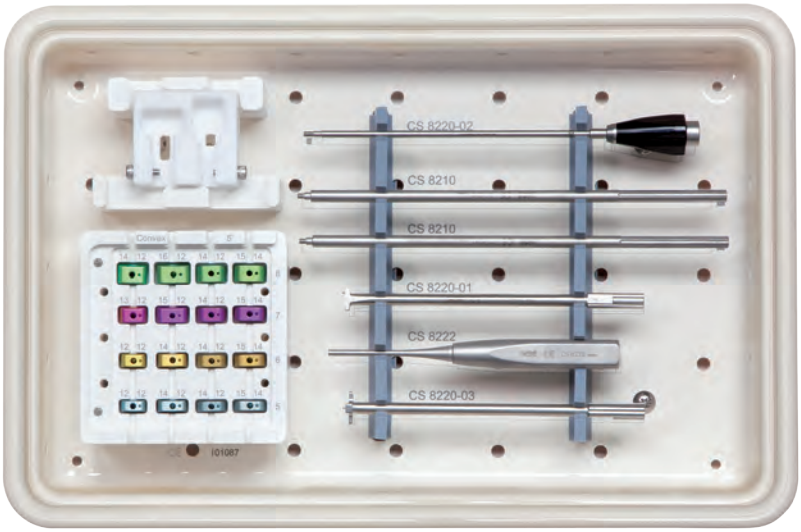
ulrich medical

System

- Cage for cervical interbody fusion
- Radiolucent PEEK Optima® LT1
- Two different shapes allow adaptation to end plates







Clearly arranged tray and sterile packaged implants

Advantages

- Simple handling and easy placement
- Tantalum x-ray marker for position control
- Sterile packaged implants

cerv-X™ and mambo™

cerv-X™

Components

Implants	Product number
cerv-X, height 5 mm, width 14 mm, length 12 mm, angle 5°	CS 8200-05
cerv-X, height 6 mm, width 14 mm, length 12 mm, angle 5°	CS 8200-06
cerv-X, height 7 mm, width 14 mm, length 12 mm, angle 5°	CS 8200-07
cerv-X, height 8 mm, width 14 mm, length 12 mm, angle 5°	CS 8200-08
cerv-X, height 9 mm, width 14 mm, length 12 mm, angle 5°	CS 8200-09
cerv-X, height 10 mm, width 14 mm, length 12 mm, angle 5°	CS 8200-10
cerv-X, convex, height 4 mm, width 12 mm, length 12 mm	CS 8201-04
cerv-X, convex, height 5 mm, width 12 mm, length 12 mm	CS 8201-05
cerv-X, convex, height 6 mm, width 12 mm, length 12 mm	CS 8201-06
cerv-X, convex, height 7 mm, width 13 mm, length 12 mm	CS 8201-07
cerv-X, convex, height 8 mm, width 14 mm, length 12 mm	CS 8201-08
cerv-X, convex, height 9 mm, width 14 mm, length 12 mm	CS 8201-09
cerv-X, convex, height 10 mm, width 14 mm, length 12 mm	CS 8201-10
cerv-X, height 5 mm, width 15 mm, length 14 mm, angle 5°	CS 8202-05
cerv-X, height 6 mm, width 15 mm, length 14 mm, angle 5°	CS 8202-06
cerv-X, height 7 mm, width 15 mm, length 14 mm, angle 5°	CS 8202-07
cerv-X, height 8 mm, width 15 mm, length 14 mm, angle 5°	CS 8202-08
cerv-X, convex, height 4 mm, width 14 mm, length 12 mm	CS 8203-04
cerv-X, convex, height 5 mm, width 14 mm, length 12 mm	CS 8203-05
cerv-X, convex, height 6 mm, width 14 mm, length 12 mm	CS 8203-06
cerv-X, convex, height 7 mm, width 15 mm, length 12 mm	CS 8203-07
cerv-X, convex, height 8 mm, width 16 mm, length 12 mm	CS 8203-08

Over a Century of Innovation

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Phone: +49 (0)731 9654-0 | Fax: +49 (0)731 9654-2705
spine@ulrichmedical.com | www.ulrichmedical.com

WS 8200-EN R4/2018-11

tezo®

titanium cages

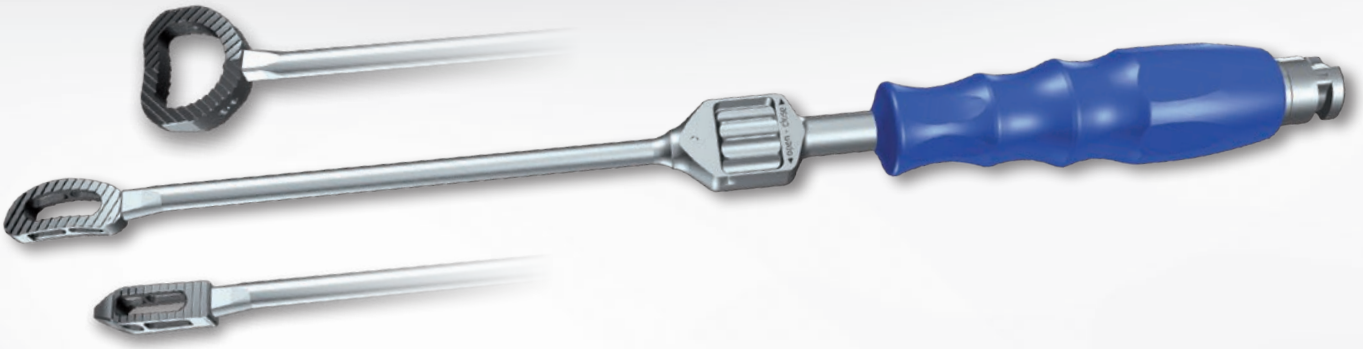
100 Years

Over A Century Of Innovation

ulrich medical USA

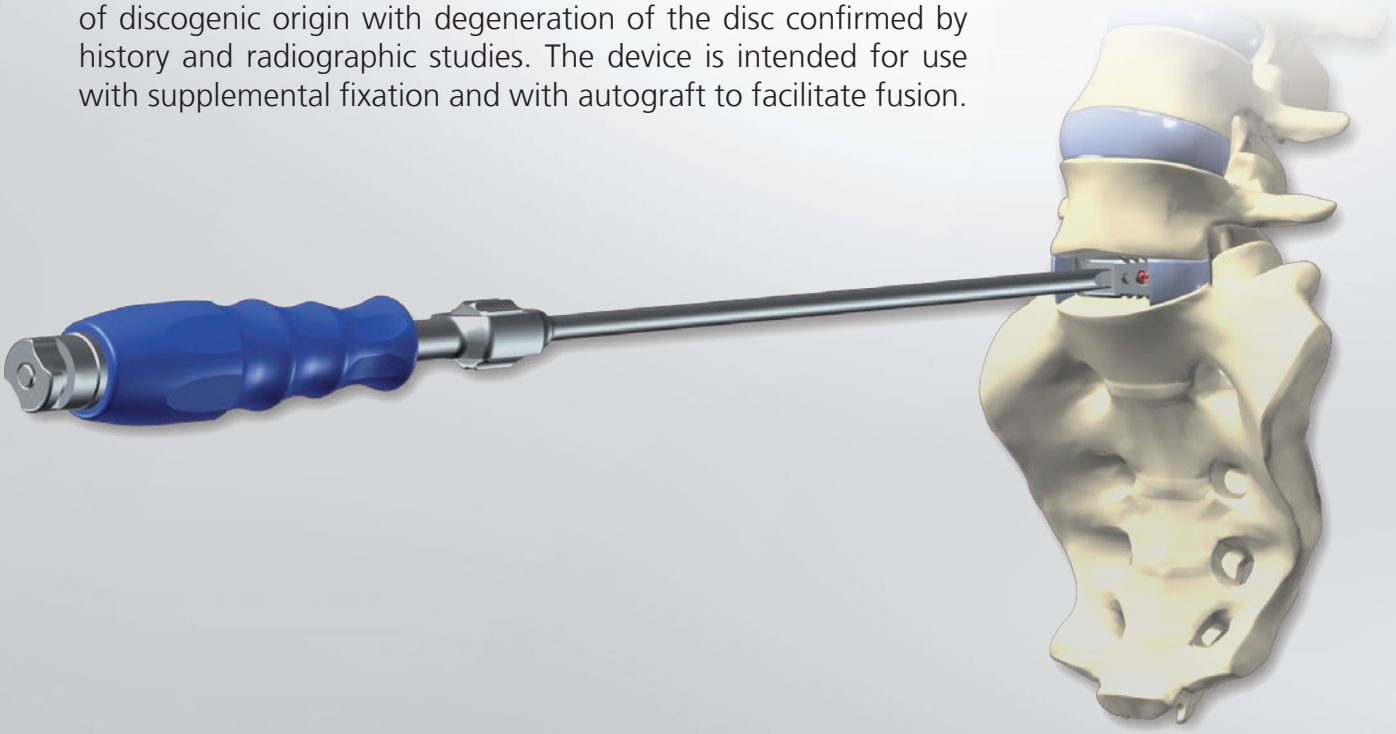
System

- Titanium implants for lumbosacral interbody fusion
- 3 cage types: tezo-P, tezo-T, tezo-A
- Inner roughened surface with porous structure
- Sterile packaging: 10 year shelf life



Indications

tezo is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with supplemental fixation and with autograft to facilitate fusion.



Advantages

Unique implant design

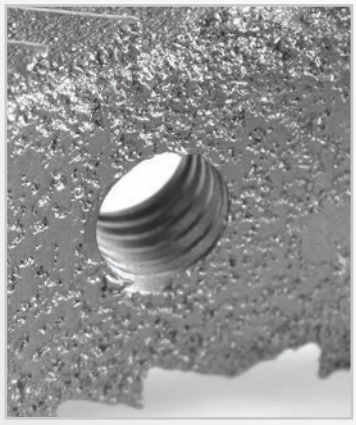
- Inner wall designed with porous roughened surface structure to allow for improved boney adherence and osseointegration
- Titanium alloy design for stability and boney adherence
- Implants will accommodate all surgical approaches (PLIF, TLIF, ALIF, lateral)
- Optimal tooth design for stability and to minimize implant migration
- Large graft windows for improved fusion response

Unique footprint options

- Large TLIF cage at 34 x 16mm, 5° angulation
- Unique PLIF cage at 29mm, 12° angulation (L4, L5, S1)
- Multiple connection points on ALIF cage (0°, 30°, 45°, 90°)

Streamlined instrument set

- One set of instruments accommodates PLIF or TLIF approaches
- Full set of disc preparation instruments available with PLIF and TLIF sets



Inner wall surface

Components

Implants	Length x Width	Height	Angle	Product Number
tezo-P	24 x 10mm	7 – 14mm*	5°	CS 3401-07 to -14
tezo-P	29 x 10mm	7 – 14mm*	5°	CS 3402-07 to -14
tezo-P	29 x 10mm	8 – 14mm*	12°	CS 3403-08 to -14
tezo-T	29 x 11mm	7 – 14mm*	5°	CS 3415-07 to -14
tezo-T	29 x 14mm	7 – 14mm*	5°	CS 3416-07 to -14
tezo-T	34 x 16mm	7 – 14mm*	5°	CS 3417-07 to -14
tezo-A	28 x 22mm	8 – 16mm**	8°	CS 3431-08 to -16
tezo-A	31 x 25mm	8 – 16mm**	0°	CS 3432-08 to -16
tezo-A	31 x 25mm	8 – 16mm**	8°	CS 3433-08 to -16
tezo-A	31 x 25mm	8 – 16mm**	12°	CS 3434-08 to -16
tezo-A	34 x 28mm	8 – 16mm**	0°	CS 3435-08 to -16
tezo-A	34 x 28mm	8 – 16mm**	8°	CS 3436-08 to -16
tezo-A	34 x 28mm	10 – 16mm**	12°	CS 3437-10 to -16

* Standard equipment for tezo-P and tezo-T up to 13mm height (14mm upon request)
** Standard equipment for tezo-A up to 16mm height (18mm upon request)

US0207 R3 / 2017-01

100 Years

Over A Century Of Innovation

ulrich medical USA

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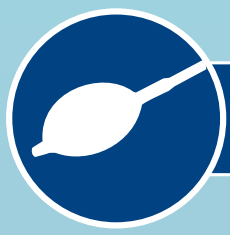
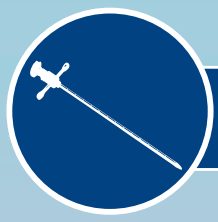
G21

STRENGTH FOR LIFE

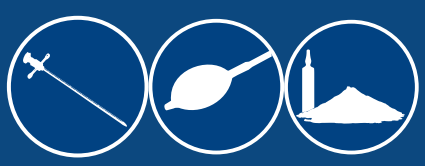
BONE CEMENTS



KYPHOPLASTY



VERTEBROPLASTY



SPINE LINE

BONE CEMENTS
FOR VERTEBRAL CONSOLIDATION

G21 bone cements are intended to stabilize and reinforce vertebral body structure in percutaneous vertebroplasty and kyphoplasty procedures [1, 2, 3], when treating painful pathologic compression fractures of vertebral body, which do not respond to anthalgic therapy, and are caused by:

- primary and secondary osteoporosis;
- osteolysis coming from tumours in the vertebral body (metastatic carcinomas or myelomas);
- osteolysis coming from symptomatic vertebral haemangiomas [1, 2, 3].

G21 bone cements are dedicated radiopaque bone cements, specifically formulated to perform percutaneous vertebral augmentation procedures, such as vertebroplasty or kyphoplasty [1, 2, 3].

The G21 bone cements for vertebral consolidation come in the form of a two-component system (powder and liquid) to be mixed at the time of application in the operating room. They are formulated to develop the right viscosity for the type of application and such that, once hardened, they assume a compact structure which enhances the mechanical strength of the implant.

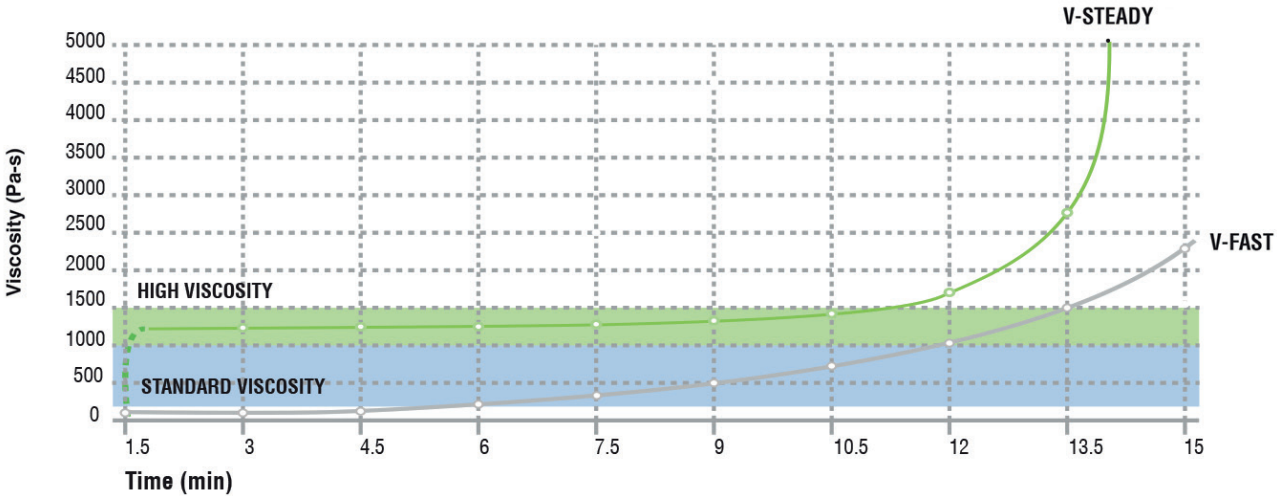
In order to respond to the specific needs of individual health professionals, the cements differ between them in useful working time and viscosity, designed to exclude the risk of leakage and the related complications [4-7].

G21 bone cements for vertebral consolidation are available in different viscosities:

- V-FIX and V-FAST: low viscosity bone cements.
- V-STEADY: high viscosity bone cement.

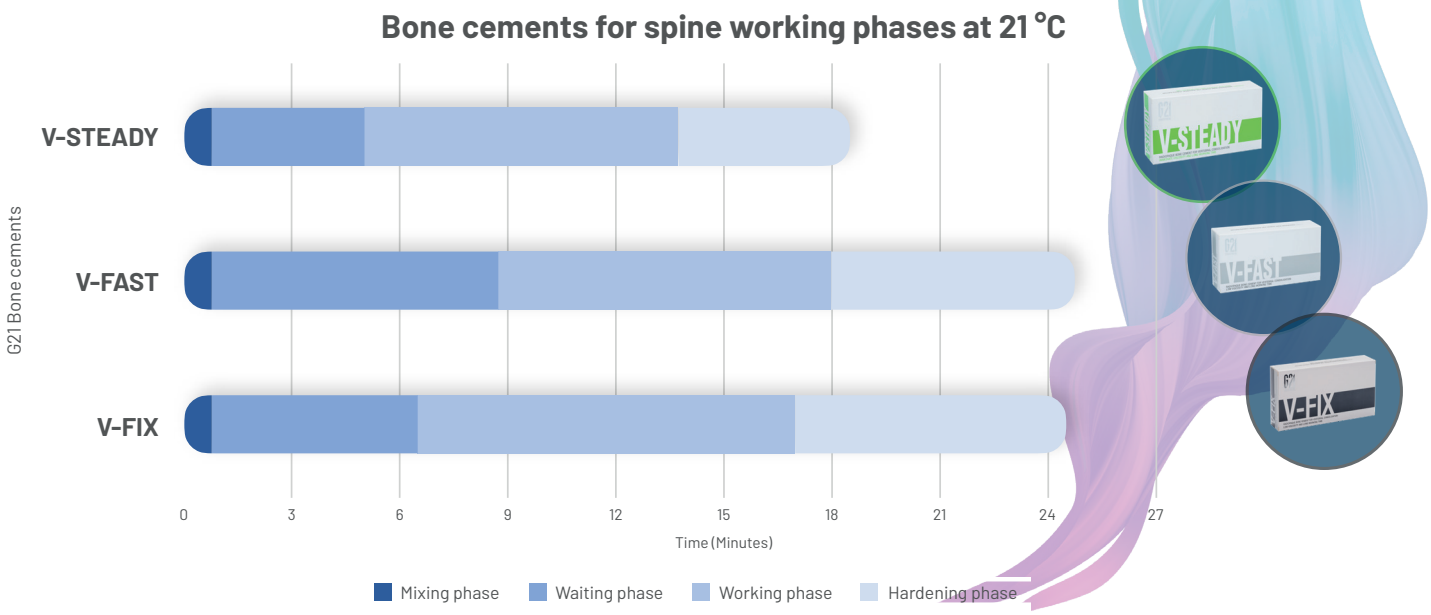
Viscosity VS Time

Data on file at G21 S.r.l. [8]



Working Times

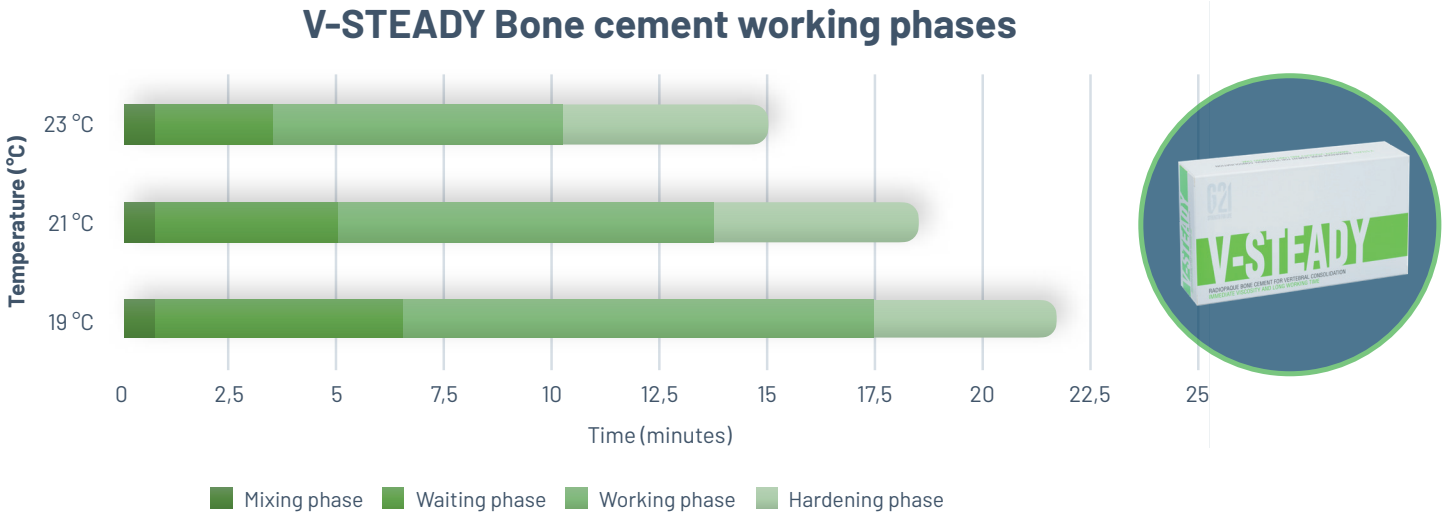
V-FIX, V-FAST and V-STEADY are a radiopaque bone cements for dedicated use, specifically formulated for the execution of percutaneous vertebroplasty or kyphoplasty procedures [4-7].



HIGH VISCOSITY BONE CEMENT: V-STEADY

V-STEADY is a high viscosity bone cement. It is characterized by:

- Prolonged maintenance of the high calibrated viscosity suitable for kyphoplasty and vertebroplasty procedures;
- High concentration and homogeneous distribution of the contrast medium that allows an optimal visualization on the radioscopic monitoring devices;
- Specifically formulated to give the surgeon the risk of cement leakage from the vertebral body, thanks to its high viscosity immediately after the mixing phase;
- Obtaining high viscosity with reduced waiting time. During the phases of aspiration of the cement and preparation of the accessories, after the mixing phase, the same time is used;
- Low polymerisation temperature so as to reduce the risk of thermal shock on the tissues [8].



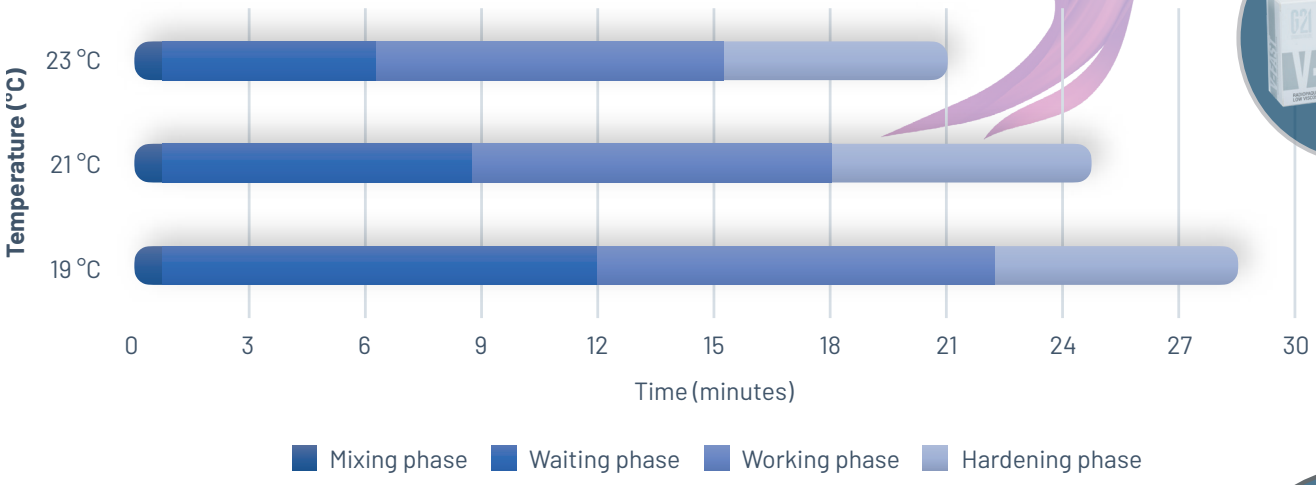
BONE CEMENTS
FOR VERTEBRAL CONSOLIDATION

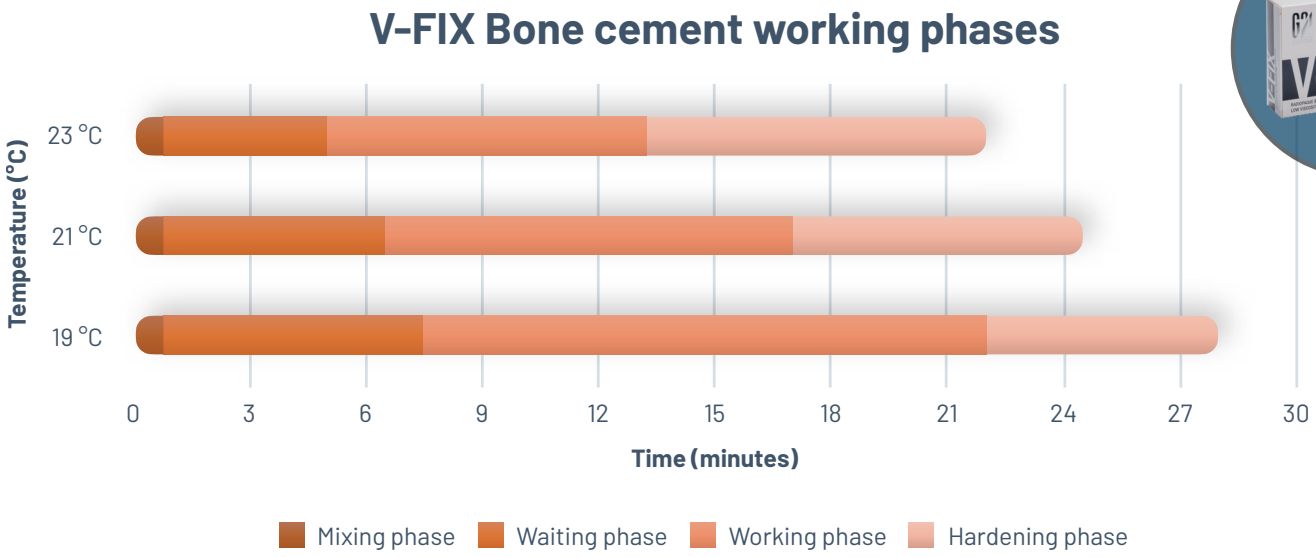
Working Times

LOW VISCOSITY BONE CEMENTS: V-FIX and V-FAST

V-FIX and V-FAST are low viscosity bone cements. They are characterized by:

- Prolonged maintenance of the viscosity property, developed in such a way that it remains constant during the surgical application, guaranteeing the operator the control of the cement distribution inside the vertebral body.
- Extended usage time (V-FAST bone cement is characterized by a reduced time of polymerization compared to V-FIX bone cement).
- High concentration and homogeneous distribution of the contrast agent which allows an optimal visualization on the radioscopic monitoring devices.
- Low polymerisation temperature so as to reduce the risk of thermal shock on the tissues [8].





Clinical Evidence

BONE CEMENTS
FOR VERTEBRAL CONSOLIDATION

Polymethylmethacrylate (PMMA), commonly known as bone cement, is widely used in vertebral consolidation procedures and in vertebral fracture stabilization procedures.

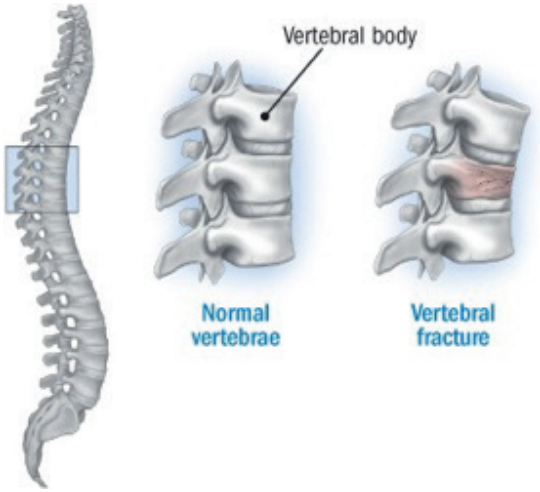
As the population ages, the incidence of osteoporotic vertebral compression fractures (OVCF) is increasing. This is also aggravated by the appearance of the intravertebral fissure (IVC), which is not uncommon after OVCF.
IVC is considered an important risk factor as it causes prolonged back pain, severe vertebral collapse, progressive kyphosis, and even neurological deficit.

Percutaneous vertebroplasty (PVP) is a minimally invasive technique to treat painful OVCF with IVC. Numerous clinical studies have illustrated that this treatment can quickly relieve pain by partially restoring vertebral height and providing stable biomechanics through the injection of bone cement into the fractured vertebrae. [16]

To make the cement radiopaque and therefore visible in fluoroscopy during the injection phases, a contrast agent (barium sulfate for V- Fix and zirconium oxide for V- Fast and V- Steady) is added. [9]

The addition of zirconium dioxide significantly improves tensile strength, fracture toughness and fatigue crack propagation resistance. On the contrary, the addition of barium sulfate produces a decrease in tensile strength but does not affect fracture toughness and improves crack propagation resistance. [16]

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 [12].



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 [12].

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. [12-15].

Thanks to the contrast agent contained in G21 Bone Cement (Barium sulphate for V-Fix or Zirconium Oxide for V-Fast and V-Steady) it's possible to directly control the injection through fluoroscopy.

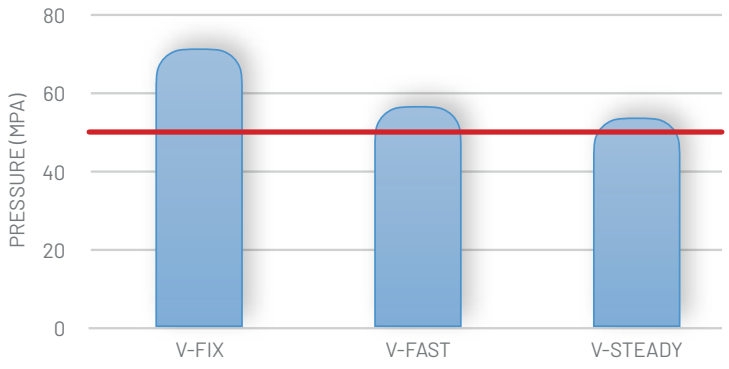
BONE CEMENTS
FOR VERTEBRAL CONSOLIDATION

Mechanical Properties

Following the implantation of a cemented prosthesis, bone cement is subjected to different stresses.

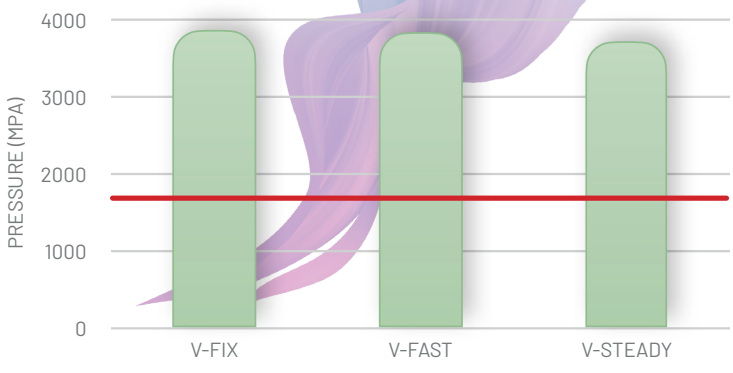
In order to demonstrate that the mechanical characteristics of the G21 bone cements for vertebral consolidation comply with the international standard for Acrylic Bone cements [11], G21 has performed the following tests:

Determination of bending strength of polymerized cements [8]:



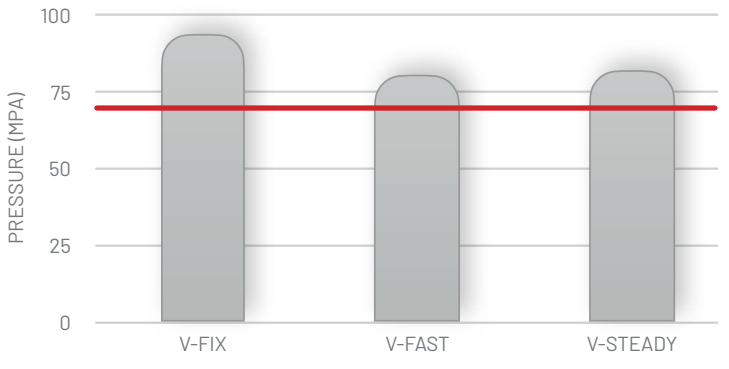
50 MPa minimum request from ISO 5833

Determination of bending modulus of polymerized cements [8]:



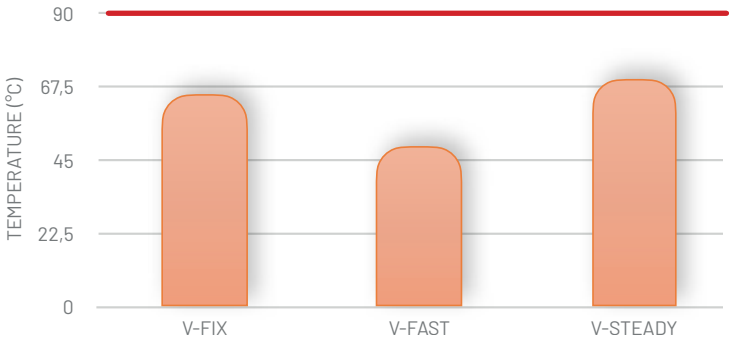
1800 MPa minimum request from ISO 5833

Determination of compressive strength of polymerized cements [8]:



70 MPa minimum request from ISO 5833

Determination of maximum temperature of polymerized cements [8]:



90°C maximum request from ISO 5833

Ordering Informations

BONE CEMENTS
FOR VERTEBRAL CONSOLIDATION

G21 BONE CEMENTS FOR VERTEBRAL CONSOLIDATION

PRODUCT	DESCRIPTION	REF
V-FIX	Low viscosity radiopaque bone cement	**800037**
V-FAST	Low viscosity radiopaque bone cement	**800036**
V-STEADY	High viscosity radiopaque bone cement	**800039**

V- FIX dh and V-FAST dh bone cements have the same functional characteristics of V-FIX and V-FAST bone cements.
They differ only in packaging distribution: the standard amount of powder and the liquid indeed are divided into two distinct packages.

PRODUCT	DESCRIPTION	REF
V-FIX DH	Low viscosity radiopaque bone cement	**800017**
V-FAST DH	Low viscosity radiopaque bone cement	**800016**

Accessories

PICOMIX V

Closed system to mix and dispense bone cement

The PicoMix V is designed to mix, aspirate and inject bone cement. It consists of a semi-manual mixer that allows a homogeneous mixing of the cement by avoiding direct contact with the cement itself and 4 x 5 ml syringes with a rigid plunger used for the aspiration and subsequent injection of cement.
Inside the package there are also a funnel and a spatula, to facilitate any powder addition operation.

PRODUCT	DESCRIPTION	REF
PicoMix V	Closed system to mix and dispense bone cement	**900129**

DISP MIXING BOWL-V

Open mixing system to prepare the bone cement

The device is used to mix the powder and the liquid that make up the standard viscosity sterile radiopaque bone cements.
Latex free disposable plastic bowl is supplied sterile and packed with a spatula for mixing, a surgical drape and 3 syringes (5 ml) with rigid plunger and aspiration tips [8].

PRODUCT		REF
DISP MIXING BOWL - V	Open mixing system to prepare the bone cement	**900051**

Accessories

V-MIX

Bone cement with closed mixing system

V-Mix includes the PicoMix V, a funnel, 4 syringes (with rigid plunger) for cement injection and bone cement for vertebral consolidation.

PRODUCT	DESCRIPTION	REF
V-MIX 01	V-FIX bone cement with mixer and syringes with rigid plunger	**800045**
V-MIX 02	V-FAST bone cement with mixer and syringes with rigid plunger	**800046**
V-MIX 03	V-STEADY bone cement with mixer and syringes with rigid plunger	**800047**

SPINE LINE

V-HP Gun

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. Hight volume capacity (up to 15,00 ml), plus 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**

V-Access

The V-Access Vertebroplasty needle has been developed to perform percutaneous vertebroplasty procedures, which ease the access to the vertebral body thanks to the double sharpening design of the tip. V-Access needles are available in two different models, which are characterized by different tips:

- The bevel tip needles allow to direct cement flow during injection in combination with the tip design and the indicator on the handpiece,
- Diamond tip V-Accesses have been developed to perform pedicular access and percutaneous positioning.

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**

VERTEBROPLASTY

VKIT-01

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**

Winch Kit

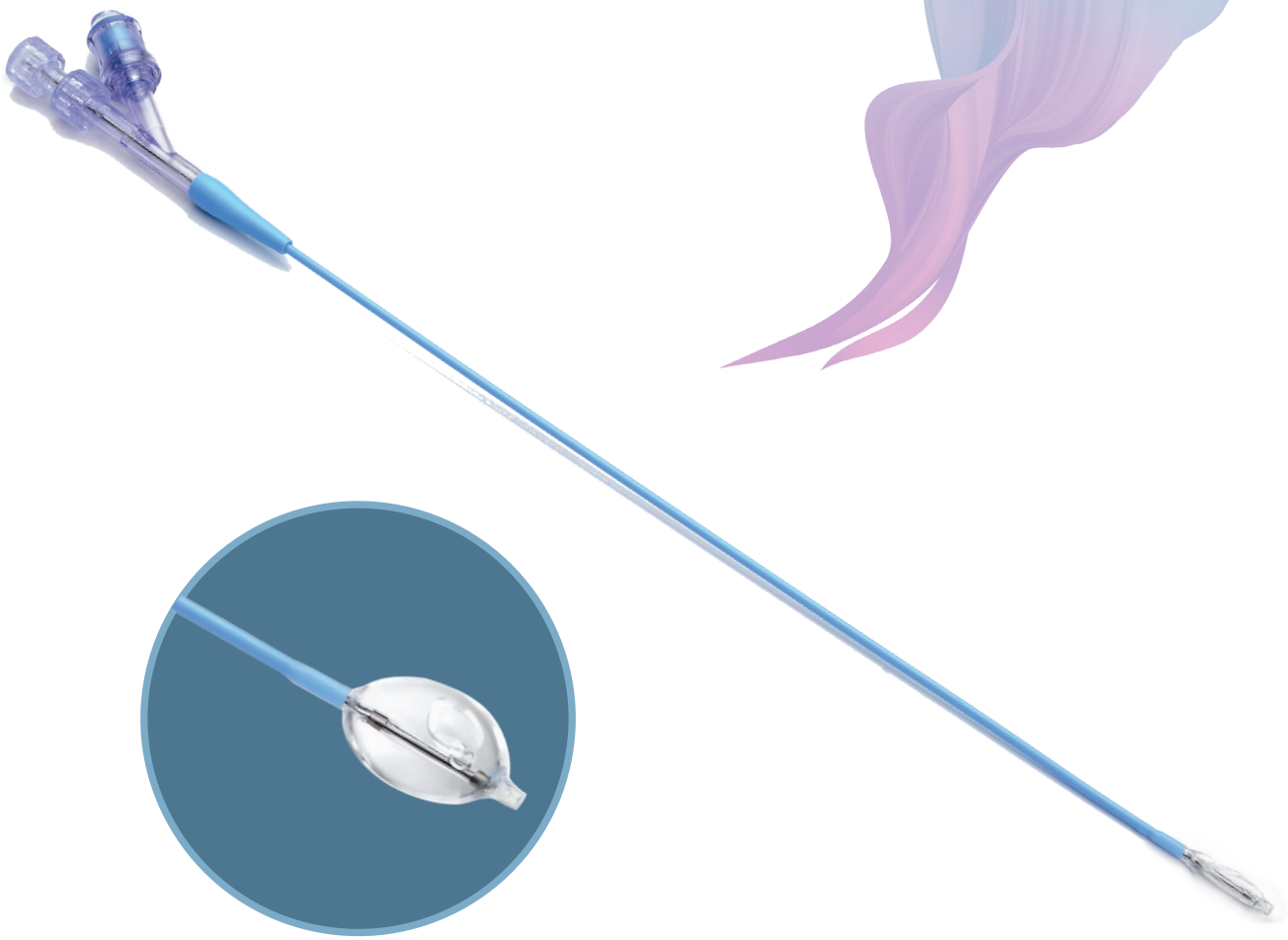
The kit includes all the needed instruments for a minimally invasive (10 gauges) direct access kyphoplasty procedure. Integrated, one-step design for quick and efficient percutaneous access to the bone and creation of the working channel. No change of cann ulated needle and smaller diameter allow to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

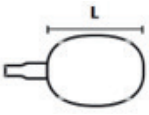
PRODUCT	DESCRIPTION	REF
Winch Kyphoplasty Kit, 15 MM	The kit includes: • 1 x Winch Kyphoplasty Balloon Catheter 11G 15MM cod. 900027 • 1 x KeyFix Direct Access Needle cod. 900103 • 1 x KeyFix Bone Drill cod. 900141 • 2 x KeyFix Bone Cement Filler Cannula cod. 900097 • 1 x G21 Kyphoplasty Digital Inflation Device	**900016**
Winch Kyphoplasty Kit, 20 MM	The kit includes: • 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	**900018**
Winch Bilateral Kyphoplasty Kit 15 MM	The kit includes: • 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	**900016B**
Winch Bilateral Kyphoplasty Kit 20 MM	The kit includes: • 2 x Winch Kyphoplasty Balloon Catheter 11G 15MM 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	**900018B**
Easy Winch, 15 MM **Easy Winch, 20 MM**	The kit includes: • 1 x Winch Kyphoplasty Balloon Catheter 11G (15 MM / 20MM) • 1 x KeyFix Direct Access Needle cod. 900103 • 1 x G21 Kyphoplasty Digital Inflation Device	**900198** **900199**

KYPHOPLASTY

Winch Kyphoplasty Balloon

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 on 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.



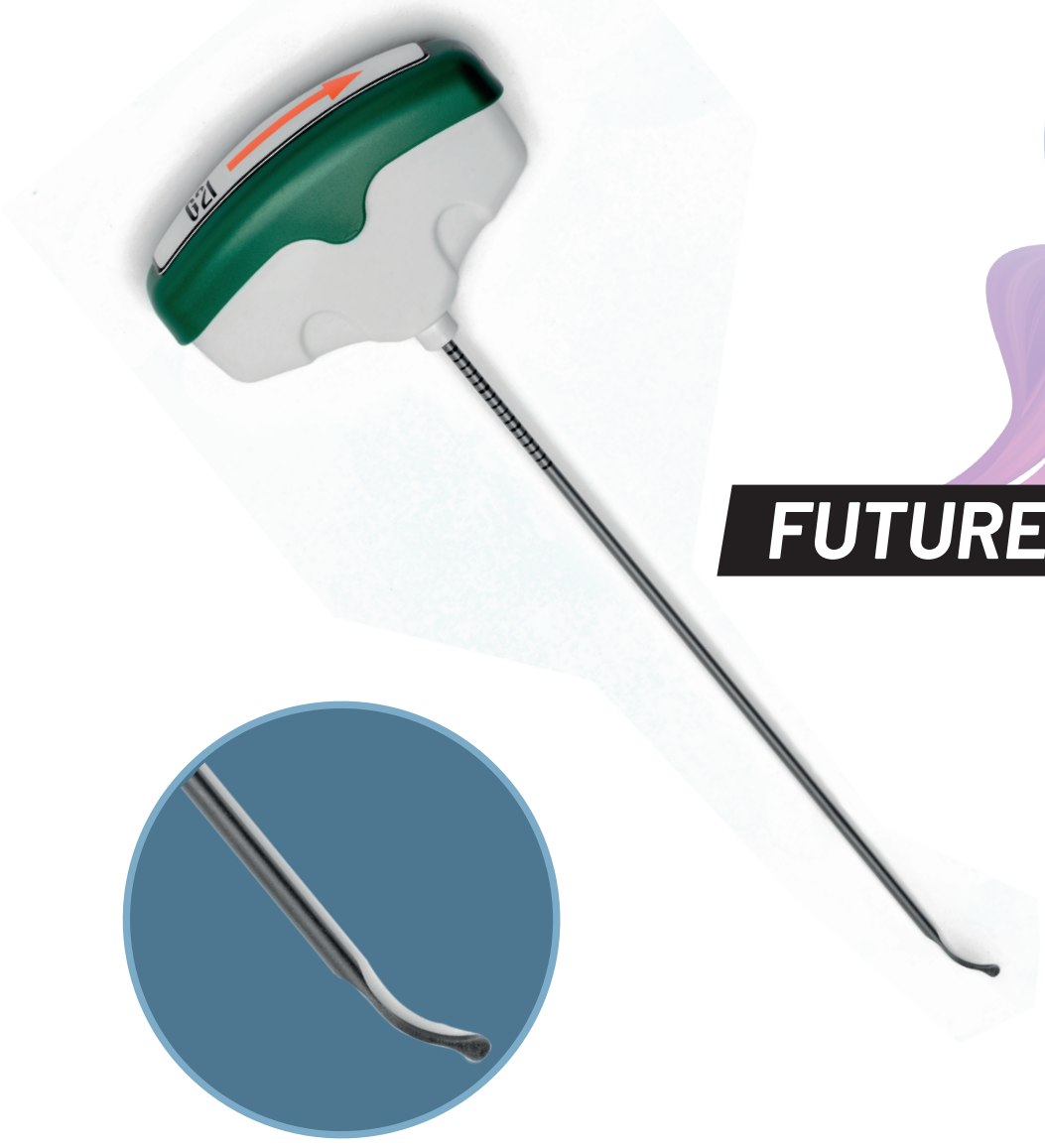


DESCRIPTION	LENGHT (L)	PRESSURE (ATM/PSI)	REF
Winch Kyphoplasty Balloon Catheter 11G 15MM	15MM	27/400	**900027**
Winch Kyphoplasty Balloon Catheter 11G 20MM	20MM	27/400	**900028**

Flex Drill

KYPHOPLASTY

A flexible drill made of medical grade nitinol that can be used to create a cavity suitable for the kyphoplasty balloon catheter in the vertebra.



FUTURE IS FLEX

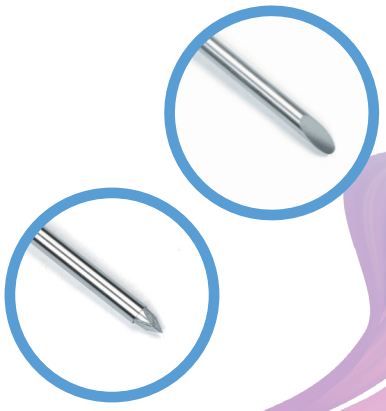
PRODUCT	REF
Flex Drill	**900212**

KYPHOPLASTY

Accessories

KEYFIX DIRECT ACCESS NEEDLE

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 trocar and bevel tip.



DESCRIPTION	REF
KeyFix Direct Access Needle with “Bevel” and “Trocar” tip	**900103**

KEYFIX BONE DRILL

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

DESCRIPTION	REF
KeyFix Bone Drill	**900141**

Accessories

KEYFIX BONE CEMENT FILLER CANNULA

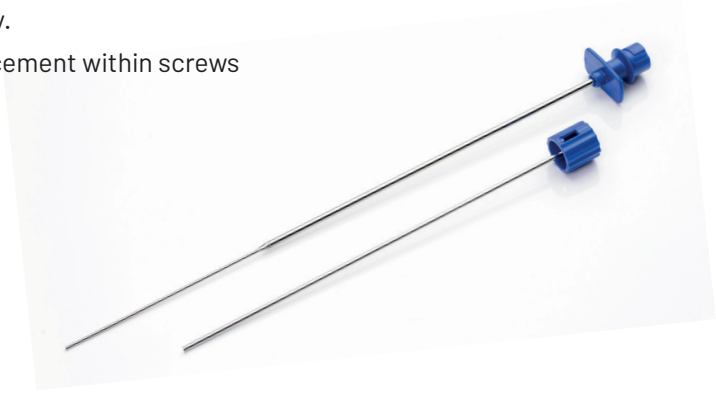
KeyFix Bone Cement Filler Cannula is intended for the delivery of acrylic bone cement during percutaneous vertebral augmentation, such as kyphoplasty. The device is available in different versions:

- 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 hanpiece 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

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**

KYPHOPLASTY

Accessories

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 11G	**900140**
KeyFix First Access Needle 13G	**900139**

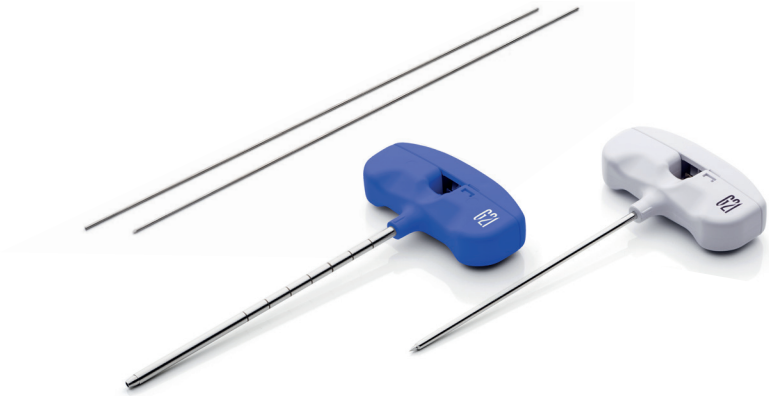
KEYFIX KIRSCHNER WIRE

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

DESCRIPTION	REF
KeyFix Kirschner Wire with round and diamond tip	**900119**
KeyFix Kirschner Wire with diamond tip	**900121**

Accessories

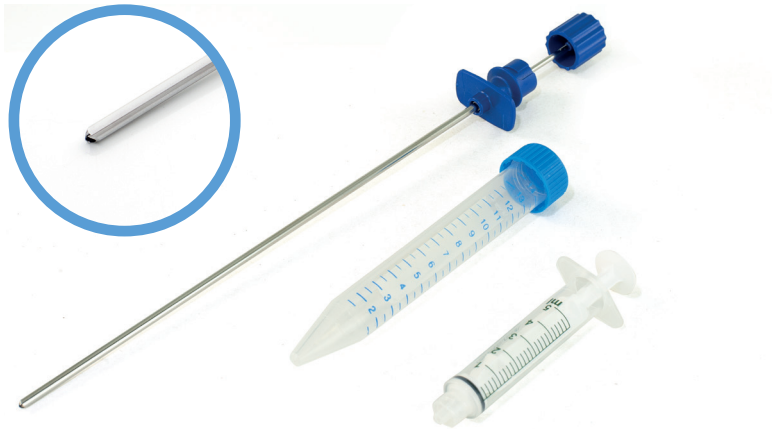
KEYFIX TRADITIONAL ACCESS



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

PRODUCT	DESCRIPTION	REF
KeyFix Traditional Access	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	**900174**

BIOPSY KIT



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 ve rtebral 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**

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