Production List

	OMOM No	SSI No	Sandhill No	MMS No	MMS新设型号	JS代工MMS型号	SynMed P No	Name - Internal reference	Diameter
Adult	JSIpC-8Z1P-21	not known	ZAN-BS-01	MMS-Z1-A	MMS-6Z1P-A01	JSIpC-8Z1P-57	SYAN-BS-01	Single use OESO length more than 18cm 6 impedance, spacing at 2cm, 1pH channel, non infused catheter (10pcs)	6.0FR/2.0mm
Adult	JSIpC-8Z2P-23	900003	ZAN-BG-44	MMS-Z2G-A	MMS-6Z2P-A02	JSIpC-8Z2P-55	SYAN-BG-44	Single use OESO length more than 18cm 6 impedance, spacing at 2cm, 2pH channels, Gastric and OESO -15 & 0 , non infused catheter (10pcs)	6.0FR/2.0mm
Paediatric	JSIpC-7Z1P-13	900004	ZPN-BS-46	MMS-Z1-P-7R	MMS-6Z1P-P01	JSIpC-7Z1P-53	SYPN-BS-46	Single use OESO length 15- 18cm 6 impedance, spacing at 2cm, 1pH channel non infused catheter (10pcs)	6.0FR/2.0mm
Adult	JSIpC-8Z2P-25	not known	ZAN-BD-31	NOT Done	NOT Done	NOT Done	SYAN-BD-31	Single use OESO length more than 18cm 6 impedance, spacing at 2cm, 2pH channels OESO, 0 &15cm non infused catheter (10pcs)	6.0FR/2.0mm
Paediatric	JSIpC-7Z2P-15	not known	ZPN-BG-07	MMS-Z2G-P	MMS-6Z2P-P02	JSIpC-7Z2P-59	SYPN-BG-07	Single use OESO length 15-18cm 6 impedance, spacing at 2cm, 2pH channels Gastric and OESO -12 & 0cm, non- infused sensor catheter (10pcs)	6.0FR/2.0mm
Infant	JSIpC-7Z1P-14	900005	ZIN-BS-51	MMS-Z1-I	MMS-6Z1P-I01	JSIpC-7Z1P-54	SYIN-BS-51	Single use OESO length less than 15cm, 6 impedance, spacing at 1.5cm, 1pH channel OESO, non infused catheter (10pcs)	6.0FR/2.0mm
Adult	JSIpC-8Z2P-22	NOT Done	NOT Done	NOT Done	MMS-6Z2P-A03	JSIpC-8Z2P-52	NOT Done	Single use OESO length more than 18cm 6 impedance, spacing at 2cm, 2pH channels, esophagealnon 0&16, infused catheter (10pcs)	6.0FR/2.0mm
Adult	JSIpC-8Z2P-21	NOT Done	NOT Done	NOT Done	MMS-6Z2P-A04	JSIpC-8Z2P-51	NOT Done	Single use OESO length more than 18cm 6 impedance, spacing at 2cm, 2pH channels, esophagealnon 0&15, infused catheter (10pcs)	6.0FR/2.0mm
	OMOM No	SSI No	Sandhill No	MMS No	MMS新设型号	JS代工MMS型号	SynMed P No	Name - Internal reference	Diameter
Paediatric	JSIpC-0Z1PT-20	SYNIS	PHNS-P	MMS-pH-SD	NOT Done	NOT Done	SYNPH-P	Single use Paediatric 1 ph channel catheter (10pcs)	5FR/1.67mm
Adult	JSIpC-0Z1P-20	SYNIS	PHNS	MMS-pH	MMS-0Z1P	JSIpC-0Z1P-58	SYNPH	Single use 1 ph channel catheter (10pcs)	6.0FR/2.0mm
Adult	JSIpC-0Z2P-21	SYNID05	PHN05	MMS-pH-5	MMS-0Z2P-05	JSIpC-0Z2P-60	SYNPH05	Single use 2 ph channels 5cm spacing catheter (10pcs)	6.0FR/2.0mm
Adult	JSIpC-0Z2P-22	SYNID10	PHN10	MMS-pH-10	MMS-0Z2P-10	JSIpC-0Z2P-61	SYNPH10	Single use 2 ph channels10cm spacing catheter (10pcs)	6.0FR/2.0mm
Adult	JSIpC-0Z2P-27	SYNID15	PHN15	MMS-pH-15	MMS-0Z2P-15	JSIpC-0Z2P-56	SYNPH15	Single use 2 ph channels15cm spacing catheter (10pcs)	6.0FR/2.0mm
Adult	JSIpC-0Z2P-24	SYNID18-ENT	PHN18	NOT Done	NOT Done	NOT Done	SYNPH18	Single use 2 ph channels18cm spacing catheter (10pcs)	6.0FR/2.0mm
Adult	JSIpC-0Z2P-23	SYNID21-ENT	PHN21	MMS-pH-21	MMS-0Z2P-21	JSIpC-0Z2P-62	SYNPH21	Single use 2 ph channels 21cm spacing catheter (10pcs)	6.0FR/2.0mm
Paediatric	JSIpC-0Z2PT-22	Not known	PHN10-P	NOT Done	NOT Done	NOT Done	SYNPH10-P	Single use Paediatric 2 ph channels 10cm spacing catheter (10pcs)	5FR/1.67mm
Paediatric	JSIpC-0Z2PT-27	Not known	PHN15-P	NOT Done	NOT Done	NOT Done	SYNPH15-P	Single use Paediatric 2 ph channels 15cm spacing catheter (10pcs)	5FR/1.67mm

V 47. PH /impedansometrijos matavimo kateteris V

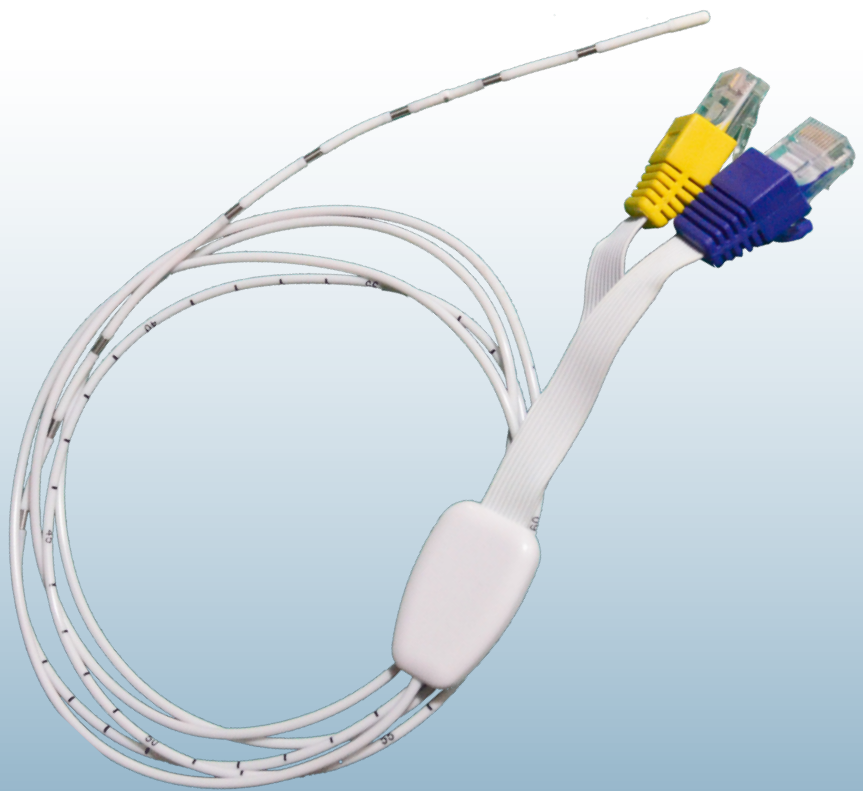
2014.9.19

JINSHAN | Life Insights

alpHaFLEX

pH-Impedance/ pH Catheter

Catalogue



Overview

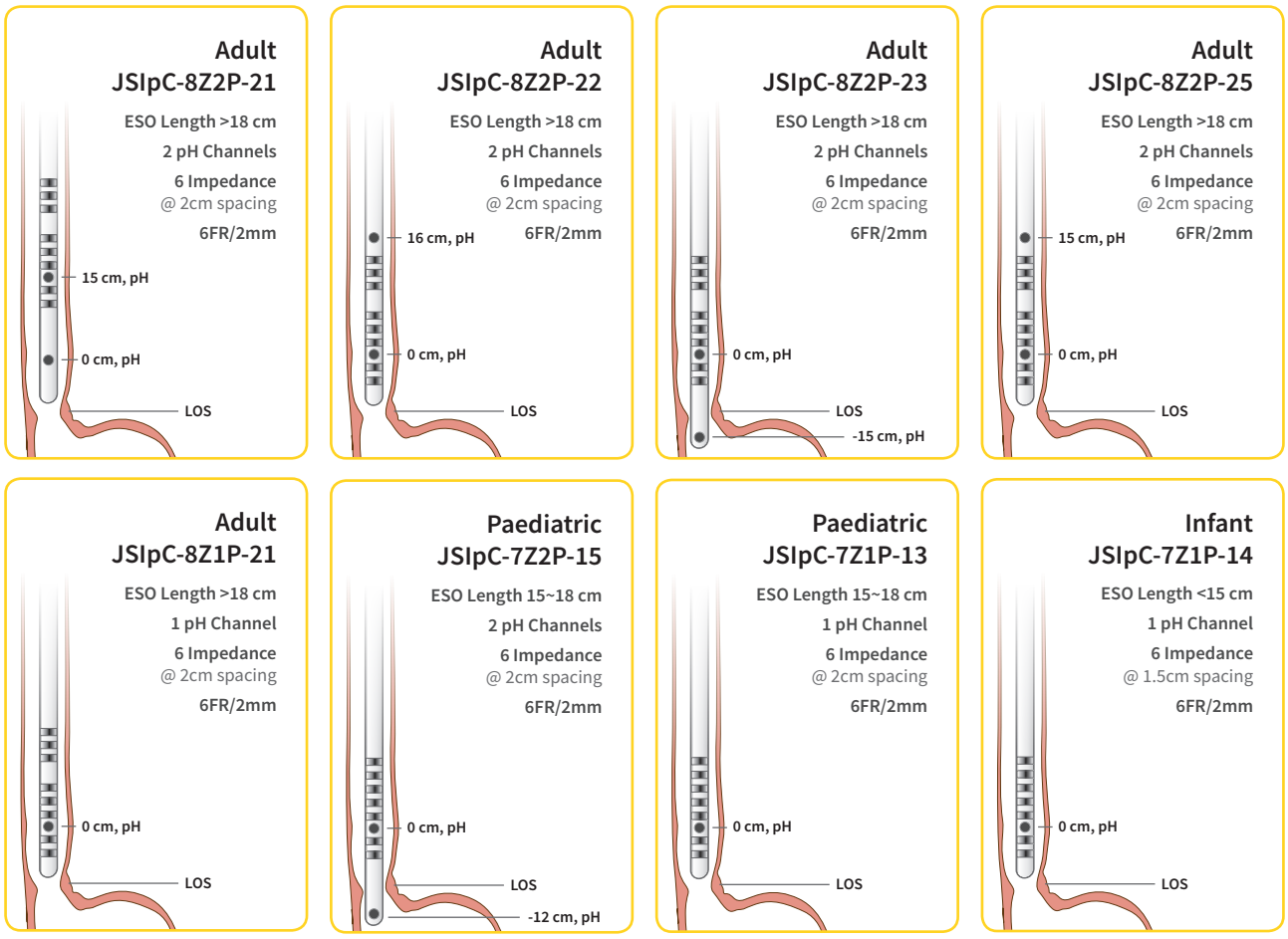
At JINSHAH, we provide a wide range of varieties to healthcare professionals. Designed with precision, accessibility and patient comfort in mind, these are your perfect choices to pH and impedance measurement.

For more information on price and customization, please contact our sales representative in your region.

47. PH /impedansometrijos matavimo kateteris:
- skirtas atlikti ambulatorinius pH ir impedanso matavimus stemplje;- vienkartinis (pažymta simboliu);- 6 Fr;- kateteryje integruoti 8 varžos matavimo davikliai;- kateteryje integruotas 1 pH matavimo daviklis;- pagamintas nenaudojant natralios gumos latekso;
- vidinio standarto (neturi klijuojamo išorinio standarto elektrodo);- ant kateterio pažymtas / sugraduotas gylis stemplje kas 1 cm;
- tinkamas naudoti su Ohmega pH/impedansometrijos matavimo sistema „Medical Measurment Systems (MMS)“ .

Single-use Impedance-pH Catheters

Code	Type	Impedance channels	Spacing imp. channels	pH channels	Reference	Location Channels	Diameter
JSIpC-8Z2P-21	Adult	6	2 cm	2	Internal	Esophageal	6 FR/2 mm
JSIpC-8Z2P-22	Adult	6	2 cm	2	Internal	Esophageal	6 FR/2 mm
JSIpC-8Z2P-23	Adult	6	2 cm	2	Internal	Esophageal, Gastric	6 FR/2 mm
JSIpC-8Z2P-25	Adult	6	2 cm	2	Internal	Esophageal	6 FR/2 mm
V JSIpC-8Z1P-21	Adult	6 V	2 cm V	1 V	Internal	Esophageal	6 FR/2 mm V
JSIpC-7Z2P-15	Paediatric	6	2 cm	2	Internal	Esophageal, Gastric	6 FR/2 mm
JSIpC-7Z1P-13	Paediatric	6	2 cm	1	Internal	Esophageal	6 FR/2 mm
JSIpC-7Z1P-14	Infant	6	1.5 cm	1	Internal	Esophageal	6 FR/2 mm



Drawing not to scale

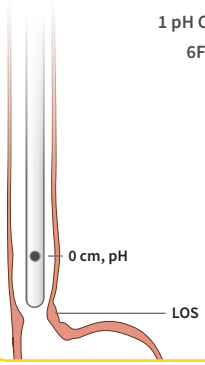
Features

- 2-year long shelf life.
- High precision electrodes
- Stiff end to facilitate easier catheter insertion.
- Minimized diameter and flexible materials to ensure patient comfort.
- Customizable length and configurations to your demand.

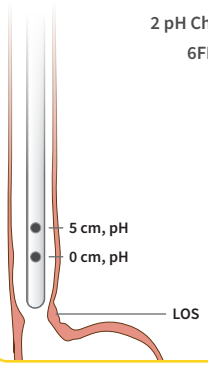
Single-use pH Catheters

Code	Type	pH channels	pH channel Spacing	Reference	Location Channels	Diameter
JSIpC-0Z1P-20	Adult	1	n/a	Internal	Esophageal	6 FR/2 mm
JSIpC-0Z2P-21	Adult	2	5 cm	Internal	Esophageal	6 FR/2 mm
JSIpC-0Z2P-22	Adult	2	10cm	Internal	Esophageal	6 FR/2 mm
JSIpC-0Z2P-27	Adult	2	15 cm	Internal	Esophageal	6 FR/2 mm
JSIpC-0Z2P-24	Adult	2	18 cm	Internal	Esophageal	6 FR/2 mm
JSIpC-0Z2P-23	Adult	2	21 cm	Internal	Esophageal	6 FR/2 mm
JSIpC-0Z1PT-20	Paediatric	1	n/a	Internal	Esophageal	5 FR/1.67 mm
JSIpC-0Z2PT-22	Paediatric	2	10 cm	Internal	Esophageal	5 FR/1.67 mm
JSIpC-0Z2PT-27	Paediatric	2	15 cm	Internal	Esophageal	5 FR/1.67 mm

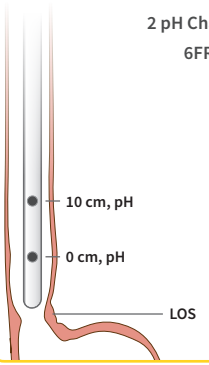
Adult
JSIpC-0Z1P-20
1 pH Channel
6FR/2mm



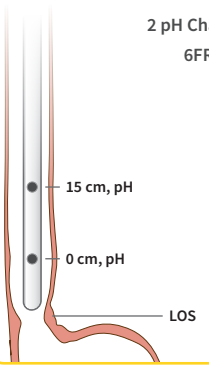
Adult
JSIpC-0Z2P-21
2 pH Channels
6FR/2mm



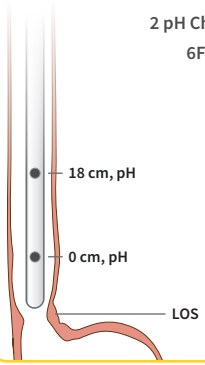
Adult
JSIpC-0Z2P-22
2 pH Channels
6FR/2mm



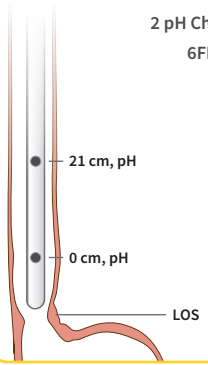
Adult
JSIpC-0Z2P-27
2 pH Channels
6FR/2mm



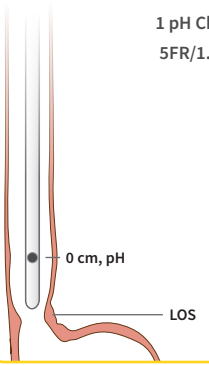
Adult
JSIpC-0Z2P-24
2 pH Channels
6FR/2mm



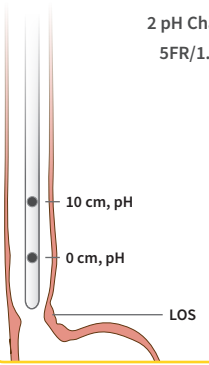
Adult
JSIpC-0Z2P-23
2 pH Channels
6FR/2mm



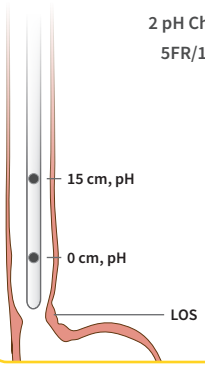
Paediatric
JSIpC-0Z1PT-20
1 pH Channel
5FR/1.67mm



Paediatric
JSIpC-0Z2PT-22
2 pH Channels
5FR/1.67mm



Paediatric
JSIpC-0Z2PT-27
2 pH Channels
5FR/1.67mm



Drawing not to scale

Chongqing Jinshan Science & Technology (Group) Co., Ltd.

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CE Registration No: HD 60132692 0001

To whom it may concern:

Date 04.06.2024

Declaration

We Chongqing Jinshan Science & Technology (Group) Co., Ltd (hereinafter referred to as “Jinshan Group”) is a national high-tech enterprise that integrates research and development, manufacturing, marketing and service of digital medical devices.

We declare that our product alpHaFLEX disposable impedance-pH catheter REF JSIpC-8Z1P-57 has 1 pH channel and 6 impedance channels with 8 resistance measurement sensors integrated in the catheter . There are marked depth in the esophagus every 1 cm on the catheter.

Yours sincerely,
Chongqing Jinshan Science & Technology (Group) Co., Ltd.

重庆金山科技(集团)有限公司
CHONGQING JINSHAN
SCIENCE & TECHNOLOGY (GROUP) CO., LTD
WANG JINSHAN
(president)

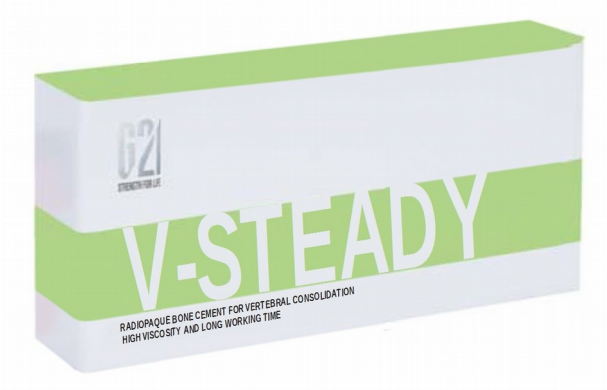
47. PH /impedansometrijos matavimo kateteris:
- skirtas atlikti ambulatorinius pH ir impedanso matavimus stemplje;
- kateteryje integruoti 8 varžos matavimo davikliai;
- kateteryje integruotas 1 pH matavimo daviklis;
- ant kateterio pažymtas / sugraduotas gylis stemplje kas 1 cm;
-

G21
STRENGTH FOR LIFE

76.1. – 76.3. Vertebroplastikos rinkinys:
76.1. . Vertebroplastikai skirtas cementas ir ranga:
- komplekte pateikiama aukšto klampumo 26 g cemento milteli ir 10 ml sterilaus skysio-monomero;
- rentgenokontrastinis, kontrastins medžiagos kiekis cemento mišinyje 45%;
- darbo laikas su cementu 9 min prie 21° C (kad bt galima atlikti keli slanksteli vertebroplastik);
- vienkartin uždara mechanin cemento maišymo ir išstmimo sistema, kurioje cementas pilnai išmaišomas sukamaisiais judesiais iki vientisos mass, paruoštos injekavimui;
- cementas iš maišymo sistemos saugiai aspiruojamas cemento injektori per "luer lock" arba lygiaverte jungt;
- cemento injektorius patogus naudoti, su varžto tipo arba lygiaveriu stmokliu, užtikrinaniu reikiam slg bei kontroliuojam cemento suleidim, su cemento suleidimui skirtu prailginimo vamzdeliu, kuris patikimai tvirtinasi prie vertebroplastikos adatos;
- speciali vertebroplastikai pritaikyta adata, pritaikyta atlikti vertebroplastik visose stuburo dalyse;
- btinas adatos diametr pasirinkimas - 10G, 11G
- adatos distalinis galiukas nuožulnus, leidžiantis suleisti kaulin cement pasirinkta kryptimi;

BONE CEMENTS FOR VERTEBRAL CONSOLIDATION

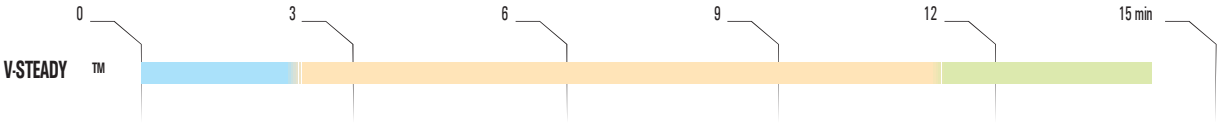
HIGH VISCOSITY CEMENT: V-STEADY™



WORKING PROPERTIES AT 23°C ACCORDING TO ISO 5833 (1)

V-STEADY ™(2)

1. ISO 5833, Implants for surgery - Acrylic resin cements (2002).
2. Data on file at G21 S.r.l.



PREPARATION	from the moment that liquid and powder are mixed to the time until when the cement is ready for use
WORKING	the period during which the cement maintains a viscosity suitable to be injected into the bone
HARDENING	the time during which the cement hardens to form the final, hard PMMA

Notes:
Timings obtained using systems for controlled injection of high-viscosity cements.
Timings may vary as a function of temperature and humidity. The higher the temperature, the shorter the phases.
Refer to Instruction for use for information on the duration of each period relative to temperature.

V-STEADY ™

Acrylic-based radiopaque bone cement with **immediate development of viscosity** and **long working time**. Ready for use immediately after mixing (in less than two minutes), it maintains this consistency for approximately **9 minutes** thanks to a specific formulation that controls the polymerisation reaction.

Ideal to perform procedures on several vertebral levels and for those surgeons that want a high-viscosity cement that **maintains its plasticity throughout a useful working time**. The cement completely hardens in 14 minutes (at 23°C).

It can be manually prepared (open bowl and spatula) or mixed using closed or vacuum systems. Because of its fluidity, it can be easily applied with specific systems for controlled injection of high-viscosity cement.

CHARACTERISTICS

1. reduced mixing time (45 seconds to obtain an homogeneous product)
2. **zero waiting time**
3. optimal control of the injection
4. **working time: 9 minutes** (using bone fillers)
5. excellent mechanical properties (especially the compression strength)
6. **high concentration of contrast medium** (45,00% of $Zr0_2$)
7. **low polymerisation temperature** so as to reduce the risk of thermal shock on the tissues.

ACCESSORIES

V-HP Gun ™

High pressure system dedicated to the injection of radiopaque bone cement

The large winged screws allows a perfect handling and a complete control during the injection when applying pressure. V-HP Gun™ gives the surgeon a larger working window to perform the procedure.
The light weight allows a easy control during the whole procedure. The syringe, completely separated from the handle, allows an easy aspiration of cement. Thanks to the ON-OFF buttons it is possible to interrupt the flowing of cement with immediate decrease of the pressure.

PRODUCT	DESCRIPTION	REF
V-HP Gun ™	High pressure system dedicated to bone cement injection during vertebral consolidation procedures	900165

- cemento injektorius patogus naudoti, su varžto tipo stūmokliu, užtikrinančiu reikiamą slėgį bei kontroliuojamą cemento suleidimą, su cemento suleidimui skirtu prailginimo vamzdeliu, kuris patikimai tvirtinasi prie vertebroplastikos adatos;

PicoMix ™ V

Bone cement closed mixing system with delivery syringe

PicoMix™ V includes the MiniMix™ mixer, a funnel, a spatula and 4 syringes (with rigid plunger) for cement injection. Allows the preparation of up to 40g of acrylic-based bone cement (PMMA) and then the transfer in a practical and safe manner directly into the syringes provided through the Luer-lock connection.
PicoMix™ V is latex free and 100% compatible with MMA.

- - vienkartinė uždara mechaninė cemento maišymo ir išstūmimo sistema, kurioje cementas pilnai išmaišomas sukamaisiais judesiais iki vientisos masės, paruoštos injekavimui;

PRODUCT	DESCRIPTION	REF
PicoMix ™ V	Mixer and delivery syringes with rigid plunger	900129

V-Mix ™

Bone cement with mixer and delivery syringes

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

V-Mix™ 01

V-Mix™ 02

V-Mix™ 03

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

V-STEADY

DE

Röntgenpositiver Knochenzement für perkutane Wirbelsäulenaugmentations-Verfahren

EN

Radiopaque bone cement for Percutaneous Vertebral Augmentation (PVA) procedures

ES

Cemento óseo radiopaco para los procedimientos percutáneos de aumento vertebral

FR

Ciment osseux radiopaque pour les procédures percutanée d'augmentation vertébrale

IT

Cemento osseo radio-opaco specifico per procedure di consolidamento vertebrale

TR

Perkutan omurga dolgu uygulamalari için röntgen altinda görünür kemik çimentosu

EN (US)

Radiopaque bone cement for Percutaneous Vertebral Augmentation (PVA) procedures

Caution: Federal Law (USA) restrict this device to sale by or on the order of a surgeon.

V-STEADY main characteristics

Intended use

V-STEADY is a dedicated radiopaque bone cement, specifically formulated to perform percutaneous vertebral augmentation procedures, such as vertebroplasty or kyphoplasty.

V-STEADY bone cement main features are:

- appropriate viscosity to perform vertebral augmentation procedures, allowing application using a cannula, but, in the same time, enabling the operator to control cement distribution inside vertebral body;
- optimal application time;
- high concentration and homogeneous distribution of contrast medium, for an optimal visibility under RX monitoring devices;
- high mechanical performance and limited polymerization heat generation rate (versus ISO 5833:2002 – "Implant for surgery-Acrylic resin cements").

V-STEADY bone cement shall be prepared immediately before its application, using two sterile components, liquid and powder in predefined quantities, respectively contained in a vial and in a gas-permeable paper bag. Preparation consists in pouring the liquid content of the vial into the powder content of the bag, then stirring, following manufacturer's instructions. Both primary containers of cement components are totally sterile, also externally, to be possible to transfer them inside operating field, within a primary blister, also externally sterile. Primary blister is supplied inside a secondary blister which allows an easy handling and opening. Preparation, handling and application of ***V-STEADY*** bone cement must be performed only by qualified healthcare professionals, specifically trained to the procedure and under the direct supervision of the physician responsible for the procedure.

The manufacturer declines any liability in case of use of ***V-STEADY*** bone cement not strictly corresponding to specified intended use, or the use of ***V-STEADY*** bone cement by personnel not adequately qualified and trained.

- komplekte pateikiama aukšto klampumo 26 g cemento miltelių ir 10ml sterilaus skysčio-monomero

Composition

Powder component - 26,0 g bag contains :
Poly(methacrylic acid methyl ester)
Zirconium dioxide
Dibenzoyl peroxide
Liquid component - 10 ml vial contains:
Methacrylic acid methyl ester stabilized with 1,4-Dihydroxybenzene
Benzenamine, N,N,4-trimethyl

Packaging and sterility

Manufacturing and packaging process of ***V-STEADY*** is performed under strict quality procedures in controlled environment, which conforms to most stringent applicable international standards.

Liquid component is sterilized by filtration, powder component is sterilized by ethylene oxide. The sterile liquid is contained in an amber glass vial packed in a blister pack in sterile conditions and subsequently sterilized by ethylene oxide. The powder is packed in two bags in sterile conditions. The internal bag in medical-grade paper and polyethylene containing the powder component is inserted in another bag in Tyvek and polyethylene and both are sterilized by ethylene oxide. The two bags are packed in a non-sterile protective aluminium wrapping.

Before using ***V-STEADY*** it is necessary to verify carefully the integrity of the packaging. If the packaging is uncompleted, damaged, unsealed, the cement cannot be used and must be discarded. After the opening of the package on, it is mandatory, and responsibility of the operator, to use an aseptic handling technique. Any error in handling and during the transfer into the sterile field might affect bone cement sterility, the sterility of the surgical intervention and imply the risk of severe complications for the patient, such as infections and sepsis.

Activation process

When the liquid and the powder components are mixed, the benzenamine, N,N,4-trimethyl activates the catalyst dibenzoyl peroxide. This starts the polymerization process of methacrylic acid methyl ester. The result is an homogeneous fluid and then a dough. This dough, introduced as stabilizing medium inside the vertebral body, within the limit working time prescribed by the manufacturer (see fig.1), will become solid, obtaining the fixation and stabilization of the broken vertebral body.

Clinical indications

Bone cement ***V-STEADY*** is intended to stabilize and reinforce vertebral body structure in percutaneous vertebroplasty and kyphoplasty procedures, 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 tumors in the vertebral body (metastatic carcinomas or myelomas);

osteolysis coming from symptomatic vertebral hemangiomas.

It should be observed that vertebral augmentation procedures, such as percutaneous vertebroplasty and kyphoplasty are only palliative treatments for stabilizing the vertebral bodies and release pain. They do not treat the underlying illness (osteoporosis or tumor-related illness).

V-STEADY is neither intended to treat acute traumatic fractures of vertebral body, nor as prophylaxis on osteopoenic patients, in absence of fractures on the vertebras to treat.

Contraindications

Do not use ***V-STEADY*** when it is known a patient's hypersensitivity to the constituents of bone cement or to the contrast medium (Zirconium dioxide).

Absolute contraindications are:

- pregnancy or breast feeding;
- local or systemic infections not completely resolved;
- non controllable hemorrhagic diseases.
- Main relative contraindications to the use of ***V-STEADY*** are:

- tumors of vertebral body extended to epidural space;
- tumors extended to spinal canal, with occlusion greater than 20%;
- bone fragment affecting the spinal cord;
- vertebras' anatomic damage causing unsafe access into vertebral body.

Other relative contraindications are:

- non collaborating patient, patient unable to follow operator's instructions;
- metabolic diseases which interfere with bone cement polymerization reaction;
- osteomalacia;
- non local infection foci potentially interesting implant;
- hypotension;
- congestive heart disease;
- renal failure.

Familiarization with *V-STEADY* bone cement

Before using ***V-STEADY*** the surgeon should become familiar with its properties, handling, application during vertebral augmentation procedures, and with the handling of other devices which come in contact with the bone cement, or are going to be used during vertebral augmentation. The surgeon shall perform simulations of the procedure following the correct medical practice and the instructions of the involved devices manufacturers. It is also recommended for surgeons to practice mixing, handling and application prior to the use. The characteristics of the bone cement, the timing of the different phases are functions of ambient temperature, humidity and depend on mixing technique. The surgeon shall simulate the entire process of mixing, handling and application in similar environmental conditions to the operating room.

Warnings when using *V-STEADY* bone cement

- Monitor the patient carefully for any change in blood pressure during and immediately following the application of bone cement. Adverse patient reactions affecting the cardiovascular system have been associated with the use of bone cements. Hypotensive reactions have occurred between 10 and 165 seconds following application of bone cement; they have lasted from 30 seconds to 5 or more minutes. Some have progressed to cardiac arrest. Patients should be monitored carefully for any change in blood pressure during and immediately following the application of bone cement
- Cement leakage may cause tissue damage, nerve or circulatory problems, and other serious adverse events.
- Serious adverse events, some with fatal outcome, associated to the use of bone cements for vertebroplasty or kyphoplasty include myocardial infarction, cardiac arrest, cerebrovascular accident, pulmonary embolism, and cardiac embolism. Although the majority of these adverse events present early within the post-operative period, there have been some reports of diagnoses beyond a year or more after the procedure.
- Other reported adverse events for acrylic bone cements intended for vertebroplasty or kyphoplasty include: Leakage of the bone cement beyond the site of its intended application with introduction into the vascular system resulting in embolism of the lung and/or heart or other clinical sequelae.
- In case of cardiovascular or pulmonary complications it is necessary to control and re-establish an appropriate level of volemia.
- In case of acute respiratory or cardiac failure, apply appropriate resuscitation techniques to restore vital functions
- Prior to implanting bone cement it is necessary to exclude risky or contraindicating conditions (see absolute and relative contraindications). In particular an accurate RX control of vertebral fracture morphology, of fractured vertebral body possible vascularization or presence of eodema.
- Prior to implanting bone cement, as safeguard measure, it should be previewed the possibility of an immediate surgical action to correct percutaneous procedure complications.
- It is mandatory to execute vertebral augmentation procedure under real time RX imaging guidance, to see the distribution of bone cement in the entire extension of vertebral body and enabling the operator to avoid leakage outside of vertebral body.
- Uncompleted filling of vertebral body may imply insufficient symptoms corrections and long term reduced stability of the treated vertebra.
- In case of bone cement leakage outside vertebral body, paravertebral structures may be damaged, potentially causing spinal cord compression, intercostal pain, leakage in the intervertebral space, perivertebral blood vessels filling, with risk of embolism, infections and post surgical pain.
- In case of treatment of hemangioma, a preliminary vascular sclerotization with percutaneous alcohol application may help in preventing bone cement penetration in blood vessels.
- Be careful during bone cement mixing phase and strictly follow the instructions.
- Avoid direct operator's skin or eye contact of liquid component of dough and reduce as possible the exposition to monomer vapors, which may cause irritation of airways, of eyes and, in rare cases, affect liver.
- Ventilate the room to eliminate monomer vapors. Liquid component is volatile and flammable . In presence of monomers vapors do not use electrocautery instruments or other high temperature sources.
- Do not use latex gloves or other latex devices. Liquid component is a lipid solvent which can cause glove perforation and may damage exposed tissues. PVP gloves (three layers: polyethylene, vinyl copolymer, polyethylene) or Viton®-butile gloves give an adequate protection for a long period. In case surgical synthetic rubber gloves are going to be used, it is advisable to wear a second pair of gloves upon, adapted to bone cement handling.
- Operators wearing contact lenses shall not mix bone cement or be exposed to monomer vapors.

- Polymerization of bone cement is an exothermic reaction which finish only when bone cement becomes hard inside vertebral body. Respect waiting time before application (fig. 1) and consider that generated heat may damage bone tissue o other tissues in contact with bone cement.
- **Do not add any other material to *V-STEADY* bone cement.** Addition of non approved ingredients (powder, water solutions,…) severely compromises physical and chemical characteristics of bone cement both in preparation phase and after implant.
- **Use always the entire content of one powder bag mixed with the entire content of one single vial. It is not allowed mixing of more than one powder bag and one vial at a time.**
- The quantity of bone cement to be implanted is related to the number of vertebras to be treated and depends on the anatomic proportions of each individual patient.
- Single use device. This device cannot be re-used.

Application instructions

When using ***V-STEADY*** respect normal application rules for bone cements to limit unpredicted effects and guarantee a stable and long lasting fixation to vertebral body. Bone cement implant need to be performed by a specialist physician, specifically trained on vertebral augmentation procedures. Application must be only performed using approved devices for vertebroplasty or kyphoplasty procedures.

Preliminary work process

A dose is prepared by pouring the entire content of powder-included in one bag in a bowl containing the entire quantity of liquid component contained in a vial.
To prepare bone cement it is necessary:

- sterile working surface;
- sterile bowl made of ceramic, stainless steel, polypropylene or other material specifically approved to get in contact with bone cement dough;
- sterile spoon or spatula made of ceramic, stainless steel, polypropylene or other material specifically approved to get in contact with bone cement dough;

Only after a verification of the integrity of the entire packaging, an assistant will open the external non-sterile aluminum laminated envelope, then will open only the contained outer pouch, which is the sterility barrier, and then internal pouch, containing the powder, can be laid on the sterile working surface using an aseptic technique. Similarly the assistant will open the blister containing the vial and then place the glass vial in the sterile field using aseptic technique.
Any error in handling and during the transfer into the sterile field might affect bone cement sterility, the sterility of the surgical intervention and imply the risk of severe complications for the patient, such as infections and sepsis.
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Preparation and application

Preparation and application of ***V-STEADY*** bone cement is performed through four subsequent phases:

I. mixing;
II. waiting (in this phase bone cement, when touched, sticks to the gloves);
III. application (in this phase bone cement has the aspect of a fluid dough, it does not stick and can be handled, injected by a syringe and a cannula);
IV. setting (in this phase bone cement should have been already implanted and completes its hardening. Non implanted bone cement has reached in this phase too high viscosity to be injected by syringe and cannula, it cannot be used anymore and must be disposed).

Duration of phases from II to IV is function of ambient temperature and humidity. Higher temperature accelerates hardening, while lower slow it down (see fig. 1).
Mix by hand inside the sterile bowl using a sterile spoon or spatula conforming materials specifications. Apply a regular stirring action, not too fast, and continue for one minute. Do not exceed mixing time.
Viscosity increases progressively as a consequence of polymerization reaction, during the phases from II to IV.
The cement needs to be aspired into a syringe approved for vertebral augmentation treatments immediately after mixing phase, because in this phase the viscosity is low and the fluid can be easily transferred into the syringe.
Keep waiting until completion of phase II (waiting phase) and then proceed with the application (phase III, the cement has become dough).
Use cannula needles with mandrel, with internal diameter higher than 1.8 mm,
V-STEADY bone cement shall be introduced into vertebral body by a syringe approved for percutaneous vertebral augmentation treatments, which allows to inject the cement with constant and regular flow and to verify total volume injected. Follow syringe and access devices manufacturer's instructions.
During applications it is mandatory to be supported by a real time RX (laterolateral) monitoring. In case of paravertebral escape of bone cement, operator must interrupt immediately cement injection, wait, and continue only when the cement has reached a higher viscosity. If the filling of vertebral body is insufficient and not correctly distributed, it is advisable to proceed with a contralateral access and complete filling of vertebral body. When cement injection is concluded, introduce the mandrel into the cannula needle, in such a way that, after taking out the needle (and the mandrel), there will be no cements residuals in contact with the soft tissues of access canal. Patient is required to remain motionless until bone cement is completely set (end of phase IV).

Dose

The content of the package is normally enough to perform vertebroplasty or kyphoplasty in the vast majority of clinical cases. As preventive measure, it is advisable to keep at hand at least a second package of ***V-STEADY*** bone cement to be able to prepare an extra quantity of bone cement, if this need will emerge during the procedure.

Other uses

V-STEADY is intended only for procedures of vertebroplasty or kyphoplasty. Any different use is absolutely excluded.

Storage

V-STEADY bone cement must be stored in its sealed original package, inside a dry and clean storage room, at a storage temperature not lower than 5°C and not higher than 25°C.

Expiry date, sterility, disposal

Expiry date is written on the external box and on the secondary outer blister labels.
V-STEADY .cannot be used after expiry date.
V-STEADY cannot be used if the package is unsealed or the secondary blister is not present or damaged.
Opened or damaged ***V-STEADY*** packages must be disposed with all their content.
V-STEADY is sterilized by ethylene oxide and cannot be re-sterilized.
A yellowish colour of the powder or of the liquid are not normal, in this case the cement cannot be used and must be disposed.
Dispose the remaining of ***V-STEADY*** bone cement and the content of partially utilized, expired, not usable or damaged packages, following rules and procedures applicable to this kind of hospital waste.

CE 0476

- darbo laikas su cementu 8,5 min prie 21° C

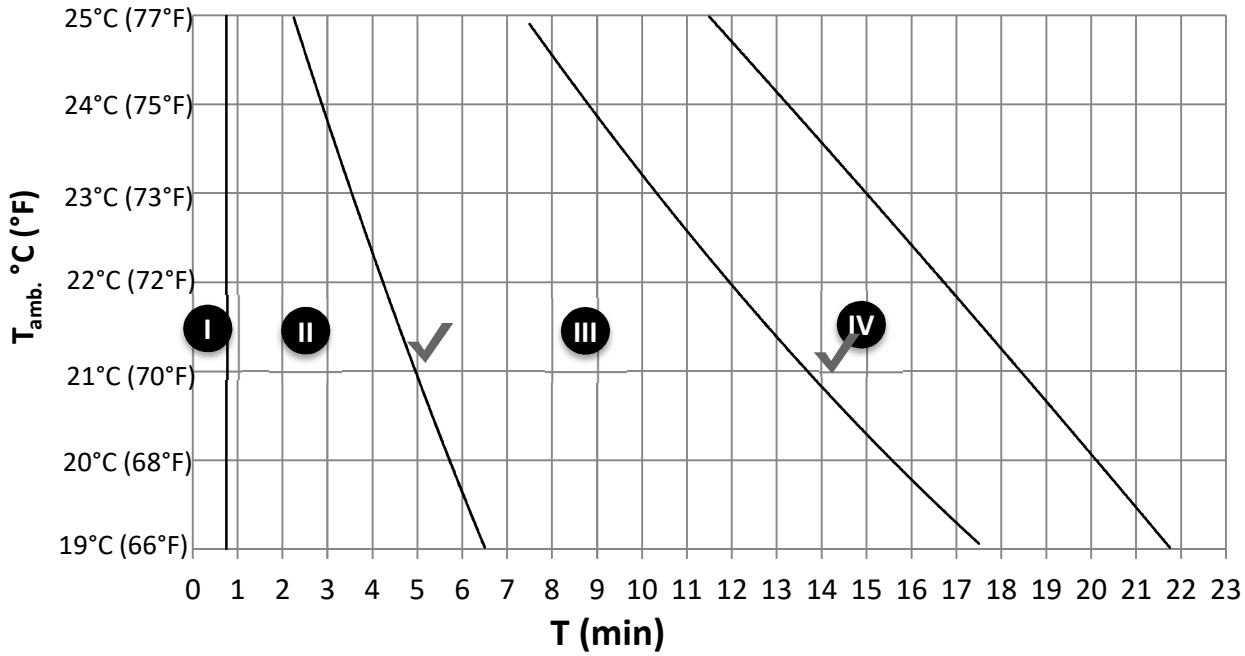


Fig. 1

KeyFix™

DIRECT ACCESS NEEDLE

TROCAR AND BEVEL TIP ✓

10 GAUGE ✓

REF **900103** ✓

EN(US)

INSTRUCTIONS FOR USE

IT

ISTRUZIONI PER L'USO

ES

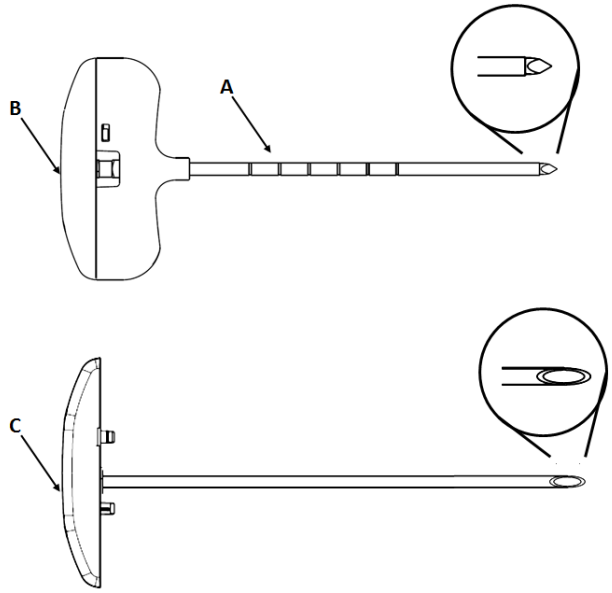
INSTRUCCIONES DE USO

76.2. Vertebroplastikos adata:
- sterili (simbolis ant pakuots);
- vienkartin (pažymta simboliu);
- adatos distalinis galiukas nuožulnus, leidžiantis suleisti kaulin cement pasirinkta kryptimi;
- adatos rankenl pagaminta iš specialios plastmass , mažinanios artefakt galimyb tiriant rentgeno ar ašpari plaktuko smgiams, patogi vedimui, sukiojimui, ištraukimui;
- adatos storis 10G, ilgis 12 cm;
- adat kaina turi bti vienoda, nepriklausomai nuo dydži;
- su numatyta pakuots atidarymo vieta;
- ant pakuots pažymtas galiojimo laikas.

Indications for use

KeyFix_Direct Access Needle, 10 Gauge is intended for percutaneous access to bone, including use during percutaneous vertebral augmentation, such as kyphoplasty.

Device description



The device is composed of:

A) Access cannula – A hollow needle, with a 120 mm working length, designed to provide and maintain access to the vertebral body. The length of the access cannula is marked in 1 cm increments to aid in access cannula placement. A Luer connector at the proximal end of the access cannula can be connected to a cement delivery device.

B) Trocar tip stylet – A solid rod with a sharp, forur-facet point used to penetrate tissue and the vertebral body when installed in the access cannula.

C) Bevel tip stylet – An optional Tip Stylet with a sharp, wedge-shaped point.

Contraindications

- Instability of posterior wall and/or pedicles.
- Infections.
- Bleeding disorders or treatment that increase the chance of bleeding.
- Severe bleeding.
- Pregnancy.
- Vertebral height loss of 68% or greater or alternatively, vertebral body collapse to less than 1/3 (33%) of the original height.
- Vertebral plana (collapse >90%).
- Pedicle width smaller than 5 millimeters.

Warnings

- Only trained and experienced healthcare professionals should use this equipment. Before using the device read and understand the instructions. Become familiar with the device prior to use.
- The healthcare professional performing any procedure is responsible for determining the appropriateness of this device and the specific procedure used for each patient. G21, as manufacturer, does not recommend surgical procedure or technique.
- Upon initial receipt and before use, inspect the package for damage and confirm the integrity of the sterile barrier. DO NOT use if package is damaged.
- Upon initial receipt and before use, inspect the device for damage. DO NOT use if any component is damaged.
- DO NOT use this device after the expiration date printed on the packaging. The components of this device may not be safe or effective after the expiration date.
- DO NOT reuse, reprocess, or repackage the device. This device is intended for a single use only. Reuse may create a serious risk of contamination and may compromise the structural integrity of the device resulting in operational failure.
- The device should be manipulated only while under fluoroscopic guidance with radiographic equipment providing high quality images.
- The marks on the length of the access cannula are for reference only and are not intended to replace the use of fluoroscopic guidance.
- If using a transpedicular approach, pedicle fracture may occur if the pedicle is not large enough or stable enough to withstand the procedure.
- Incorrect placement of the access cannula/stylet assembly may result in rupture of the aorta and/or nerve damage.
- If using parapedicular approach, complications that may occur include pneumothorax and bleeding.
- Follow the current local protocol governing the preparation of the patient for percutaneous bone cement delivery.

- Always remove the access cannula from the vertebral body immediately after bone cement injection. If the bone cement is allowed to harden, the access cannula may be difficult to remove and/or a cement spike may be created.
- DO NOT allow the balloon to contact the access cannula and stylet. The balloon component may fail due to contact with surgical tools.
- Use only G21-approved components and accessories, unless otherwise specified. DO NOT modify any components or accessories.
- Follow the current local regulations governing the handling and disposal of sharps and potential biohazard waste.

Adverse events

Adverse events potentially associated with use of the device include but are not limited to the following:

- Embolism of fat, thrombus or other materials resulting in symptomatic pulmonary embolism or other clinical sequelae.
- Deep or superficial wound infection.
- Retropulsed vertebral body bone fragments, which may cause injury to the spinal cord or nerve roots resulting in radiculopathy, paresis or paralysis.
- Incorrect placement of the access cannula/stylet assembly, possibly resulting in rupture of the aorta and/or nerve damage.
- Bleeding or hematoma.
- Pneumothorax.
- Pedicle fracture.
- Rib fracture.
- Re-fracture of treated vertebral body.
- Adjacent level vertebral fracture.
- Paravertebral abscess formation.
- Urinary tract infection.
- Spinal tuberculosis.
- Pyogenic spondylitis.
- Transient hyperalgia.
- Vertebral osteitis.
- Dyspnea.
- Chest pain.
- Pneumonia.

Instructions

Notes:

- If desired, incise the surgical site to facilitate insertion of the access cannula/stylet assembly.
- If use of the bevel tip stylet is desired, unlock and remove the trocar tip stylet from the access cannula and install the bevel tip stylet prior to insertion.

1. Remove the protective sheath from the access cannula/stylet assembly.
2. Under fluoroscopic guidance, insert the access cannula/stylet assembly into the surgical site.
3. Twist the access cannula/stylet assembly or use a gentle hammering technique to advance the access cannula/stylet assembly into the cortical bone of the vertebral body.
4. Unlock and remove the stylet from the access cannula.

How supplied

KeyFix_Direct Access Needle, 10 Gauge is supplied sterile (ethylene oxide) for single use in a double peel-open pouch. Do not use if the package is damaged.

Storage

KeyFix_Direct Access Needle, 10 Gauge should be stored in the original shipping materials.

Proper care should be taken to ensure that ***KeyFix_Direct Access Needle, 10 Gauge*** will not be damaged.

Store in a cool and dry place.

KITS FOR VERTEBROPLASTY

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

V-KIT 01 ™

Needle for vertebroplasty V-ACCESS™	x1
V-HP Gun™	x1

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

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

76.3. Biopsijos rinkinys:

- sterilus (simbolis ant pakuotės)
- su numatyta pakuotės pakuotės atidarymo vieta;
- ant pakuotės pažymėtas galiojimo laikas;
- vienkartinis (pažymėta simboliu);
- rinkinį sudaro:

 13 G storio kaniulė audinių paėmimui iš stuburo, tinkanti naudoti per 11 G storio vertebroplastikos adatos spindį;

 3 ml vienkartinis švirkštas, skirtas įtraukti biopsinę medžiagą;

 švirkštas tinka prie 13 G storio kaniulės;

 plastikinis medžiagos indelis bioptatui

VERTEBROPLASTIC

VERTEBROPLASTY NEEDLE – PLASTIC HANDLE

VERTEBROPLASTY NEEDLE WITH PLASTIC HANDLE

VERTEBROPLASTIC is used in Vertebroplasty procedures to inject cement into the vertebral body. Vertebroplasty is a very well established technique for treating back pain caused by severe osteoporosis or tumors with consequent loss of height or fracture of the vertebral body. Coaxial biopsy can also be performed.

FEATURES:

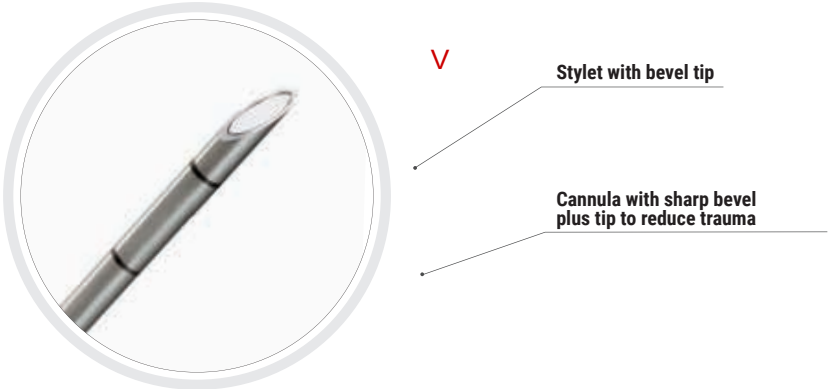
1. ERGONOMIC GRIP WITH LOCKING SYSTEM
2. THE ENHANCED DESIGN OF THE PLASTIC HANDLE ALLOWS EASY HANDLING OF THE NEEDLE
3. TIP DIRECTION INDICATOR
4. AISI 304 STAINLESS STEEL CANNULA AND STYLET

AGO PER VERTEBROPLASTICA CON IMPUGNATURA IN PLASTICA

VERTEBROPLASTIC viene utilizzato nelle procedure di vertebroplastica per iniettare cemento nel corpo vertebrale. La vertebroplastica è una tecnica consolidata per il trattamento delle fratture vertebrali causate da grave osteoporosi o da patologie tumorali con conseguente perdita di altezza del corpo vertebrale. È possibile effettuare una biopsia coassiale.

CARATTERISTICHE:

1. IMPUGNATURA ERGONOMICA CON SISTEMA DI BLOCCAGGIO
2. IL DESIGN MIGLIORATO DELL'IMPUGNATURA IN PLASTICA AGEVOLA L'UTILIZZO DELL'AGO
3. INDICATORE DI DIREZIONE PUNTA
4. CANNULA E STILETTO IN ACCIAIO AISI 304



GAUGE / CALIBRO	DIAMETER / DIAMETRO	LENGHT		
11G	3,00	100 mm	120 mm	150 mm
13G	2,50	100 mm	120 mm	150 mm
15G	1,80	100 mm	120 mm	150 mm

BIOPSYBELL S.R.L.
Via Aldo Manuzio 24, 41037 Mirandola (MO) - Italy
Tel. +39 0535 27850 - Fax. +39 0535 33526
international1@biopsybell.it - www.biopsybell.it

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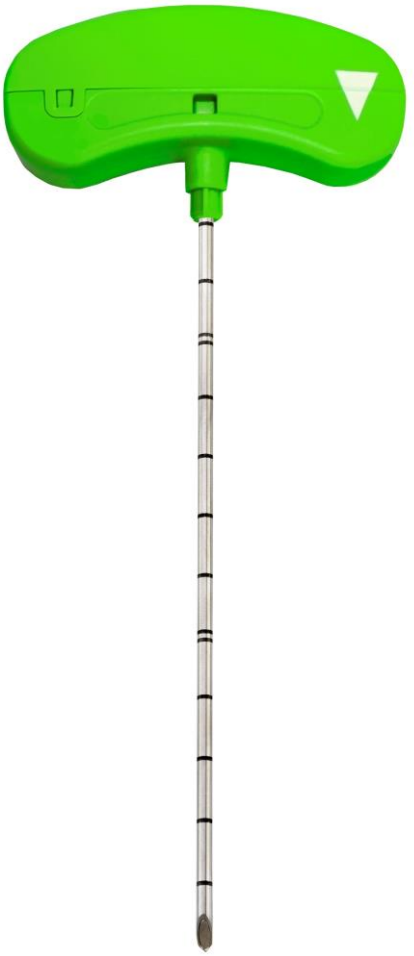
Rev.00 31/07/2020

VERTEBROPLASTIC

VERTEBROPLASTY NEEDLE – PLASTIC HANDLE



EN **VERTEBROPLASTIC** is used in vertebroplasty procedures for cement injection into the vertebral body.
Vertebroplasty is a very well-established technique for treating back pain caused by severe osteoporosis or tumors with consequent loss of height or fracture of the vertebral body.

Coaxial biopsy needle compatible with VERTEBROPLASTIC available for vertebral biopsy.

MAIN FEATURES

1. Easy handling of the needle thanks to its handle design
2. Tip direction indicator
3. Hammerable handle
4. Ergonomic grip with locking system
5. Cannula and stylet with sharp bevel plus tip to reduce trauma

76.2. Vertebroplastikos adata:
- sterili (simbolis ant pakuots);- vienkartin (pažymta simboliu);
- adatos distalinis galiukas nuožulnus, leidžiantis suleisti kaulin cement pasirinkta kryptimi;
- adatos rankenl pagaminta iš specialios plastmases , mažinanios artefakt galimyb tiriant rentgenu , atspari plaktuko smgiams, patogi vedimui, sukiojimui, ištraukimui;

AVAILABLE SIZES

- adatos storis 10; 11G, ilgis 12, 15 cm;- adat kaina turi bti vienoda, nepriklausomai nuo dydži;
- su numatyta pakuots atidarymo vieta;- ant pakuots pažymtas galiojimo laikas.

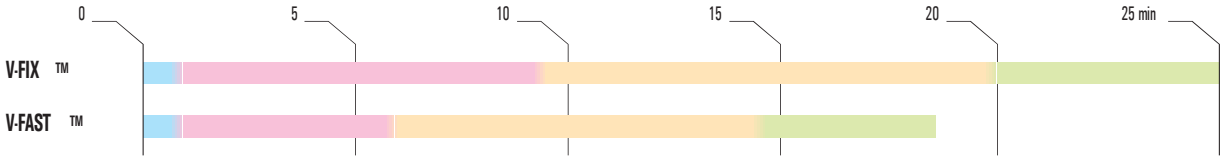
GAUGE	DIAMETER	LENGHT		
11G	3,00 mm	100 mm REF. KRVT1110200CBP-A	120 mm REF. KRVT1112200CBP-A	150 mm REF. KRVT1115200CBP-A
13G	2,50 mm	100 mm REF. KRVT1310200CBP-A	120 mm REF. KRVT1312200CBP-A	150 mm REF. KRVT1315200CBP-A
15G	1,80 mm	100 mm REF. KRVT1510200CBP-A	120 mm REF. KRVT1512200CBP-A	150 mm REF. KRVT1515200CBP-A

LOX VISCOSITY CEMENTS: V-FIX™ and V-FAST™

WORKING PROPERTIES AT 23°C ACCORDING TO ISO 5833 (1)

V-FIX ™(2) V-FAST™(2)

1. ISO 5833, Implants for surgery - Acrylic resin cements (2002).
2. Data on file at G21 S.r.l.



MIXING	from the moment that liquid and powder are mixed to the time at which the mixture is homogeneous
WAITING	the period until when the mixture does not stick to the glove
WORKING	the period during which the cement maintains a viscosity suitable to be injected into the bone
HARDENING	the time during which the cement hardens to form the final, hard PMMA

Notes:
Timings may vary as a function of temperature and humidity. The higher the temperature, the shorter the phases.
Refer to Instruction for use for information on the duration of each period relative to temperature.

V-FIX ™ and V-FAST ™

Acrylic-based radiopaque bone cements with a **low initial viscosity** and a **long working time**. They are particularly suitable when the procedure requires the consolidation of multiple vertebral levels.

V-FIX™ is characterised by the longest working time among the cements available in our range. V-FAST™ has got a shorter waiting and working times and it is indicated when a quicker cement is needed.

They can be manually prepared (open bowl and spatula) or mixed using closed or vacuum. Because of the fluidity, they can be easily applied with syringes or specific controlled injection systems.

CHARACTERISTICS

1. reduced mixing time (45 seconds to obtain an homogeneous product)
2. optimal control of the injection
3. **working times: V-FIX™ 11 MIN - V-FAST™ 8 MIN**
4. excellent mechanical properties (especially the compression strength)
5. V-FIX™ **high concentration of contrast medium** (30% of $BaS0_4$)
6. V-FAST™ **high concentration of contrast medium** (45% of $Zr0_2$)

ORDERING INFORMATION

PRODUCT	COMPOSITION	CONTENTS	REF
V-STEADY ™	High viscosity radiopaque bone cement for vertebral consolidation	1 x 20 g	800039
V-FIX ™	Low viscosity radiopaque bone cement for vertebral consolidation	1 x 20 g	800037
V-FAST ™	Low viscosity radiopaque bone cement for vertebral consolidation	1 x 20 g	800036
V-FIX DH ™	Low viscosity radiopaque bone cement for vertebral consolidation - Two half doses	2 x 10 g	800017
V-FAST DH ™	Low viscosity radiopaque bone cement for vertebral consolidation - Two half doses	2 x 10 g	800016