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Description

The Dilator is composed of dilator sleeve and dilator core. The metal material is stainless steel. The material of the handle is acrylonitrile butadiene styrene (ABS) resin. The product is supplied in sterilized condition and is sterilized by ethylene oxide. The sterilization is valid for 2 years. Single use.

Intended purpose

The device is used in percutaneous vertebroplasty (PVP) or percutaneous kyphoplasty (PKP) to create a dilatation channel for subsequent injection of bone cement.

Indications

Vertebral fractures (VF) caused by tumours, osteoporosis, or trauma.

Contraindications

Contraindications may be relative or absolute. The choice of a particular procedure must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chances of a successful outcome:

- Asymptomatic VFs
- Complete vertebral collapse
- Uncorrectable coagulopathy
- Allergy to bone cements
- Infection
- Pregnancy
- Patient's condition improving with medical therapy
- Severe cardiorespiratory disease
- Instability of posterior wall and/or pedicles
- Tumour mass with spinal canal involvement
- Retropulsion of a fracture fragment causing severe spinal canal compromise

Intended target population

Patients should be skeletally mature and have six weeks of non-operative therapy.

Intended user

The device must be performed by experienced spine surgeons who have the necessary specialized training in the use of PVP or PKP.

General conditions of use

PVP or PKP is a technically demanding procedure presenting a risk of serious injury to the patient. The information contained in the IFU is necessary but not sufficient for the use of the device. This information is in no sense intended as a substitute for the professional judgment, skill and experience of the surgeon in careful patient selection, preoperative planning and product selection, knowledge of the anatomy and biomechanics of the spine, understanding of the materials and the mechanical characteristics of the device used, training and skill in spinal surgery, securing the patient's cooperation in following an appropriately defined post-operative management program and conducting scheduled post-operative follow-up examinations.

Expected clinical benefits

By using Dilator and other products in the Vertebral Working Channel System, patients' pain and dysfunction can be improved significantly, as well as the Oswestry Disability Index (ODI) and Visual Analog Scale (VAS) score.

Performance characteristics

Dilator is designed to form and serve as a working channel for subsequent devices to enter the vertebral body and exert their effects

Adverse events

The surgeon shall warn the patient of all the potential adverse events. They include but are not limited to:

- Cement leakage
- Vertebral fractures
- Pain
- Paravertebral hematoma
- Psoas hematoma
- Cement pulmonary embolism
- Neurological deficits
- Anterior spinal artery syndrome
- Paraplegia

Sterilization

Ethylene Oxide Sterilization

Warnings and precautions

- The surgeon using the product is required to be experienced and have undergone the necessary professional training. Before the operation, according to the patient's symptoms, signs, segments and the results of imaging tests to determine the surgical plan;
- Select the appropriate specifications and models of products, cannot be used in conjunction with other companies' products;
- The sterilized packaged products have been sterilized by ethylene oxide and do not need to be sterilized again before use;
- It is essential to maintain strict sterile technique during the procedure and during all phases of handling all products;
- Although the products have been strictly inspected, the sterilized packaged products may still have the risks of

broken packages and scratches on the surfaces, etc. Before surgery, please carefully check whether the aseptic packages are intact, if they are broken, they cannot be used in clinic;

- Please check the validity period of the sterilized products, if they are not in the validity period, they cannot be used in clinic;
- All products are **Single Use**. Repeated use will lead to shorten the life of the products and cross infection, so it is strictly prohibited to be reused;
- Always use appropriate imaging techniques with high quality imaging to avoid patient injury and place products right.

Allergy and hypersensitivity to foreign bodies

When hypersensitivity is suspected or proven, it is highly recommended that the tolerance of the skin to the materials that make up the products or bone cement be checked before they are used.

Treatment before device is used

The devices are provided sterile. Remove products from the package in an aseptic manner.
Store sterile devices in their original protective packaging.
Do not remove them from the packaging until immediately before use.
Prior to use, check the product expiration date and verify the integrity of the sterile packaging by visual inspection:
– Inspect the entire area of sterile barrier package including the sealing for completeness and uniformity.
– Inspect the integrity of the sterile packaging to ensure there are no holes, channels or voids.
Do not use if the package is damaged or expired.

Surgical approach

Under the guidance of the guide pin, insert the dilator into the vertebral body. Then, remove the guide pin and dilator core, and leave the dilator sleeve in the body as a working channel for subsequent devices, such as bone drill, bone guide and vertebroplasty balloon catheter.

Combination of medical devices

Dilator is intended to be used with legally-marketed guide pin, bone drill, bone guide and/or vertebroplasty balloon catheter adequately indicated for use in PVP or PKP. Please refer to the associated product information for details on its use, indication, contraindications, precautions, warnings, potential adverse events, undesirable side effects and residual risks.
Dilator has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Clinician training

The company's Marketing Department/Foreign Trade Department will travel to hospitals to train doctors in the use of the device prior to surgery, which will need to be carried out by an orthopaedic surgeon specially trained in the Vertebral Working Channel System products.

Single Use

Never reuse the device. It could become contaminated resulting in infection. In addition, even though the device

appears undamaged, it may have small defects which could compromise structural integrity reducing its service life and/or leading to patient injury.
Surgeons must verify that the device is in good condition and operating order prior to use during surgery.

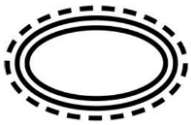
Shelf life
Shelf life of 2 years.

Disposal requirement
Dispose of used product per local, state and federal blood borne pathogen controls including biohazard sharps container and disposal procedures.

Complaints
Any health professional having a complaint or grounds for dissatisfaction relating to the identity, quality, durability, reliability, safety, effectiveness or performance of a product should notify Fule or its representative. Moreover, if a product has malfunctioned, or is suspected of having malfunctioned, Fule or its representative must be advised immediately.
If a Fule product has ever worked improperly and could have caused or contributed to the death of or serious injury to a patient, the distributor or Fule must be informed as soon as possible by telephone, fax or in writing.
For all complaints, please include the name and reference along with the batch number of the product(s), your name and address and an exhaustive description of the event to help Fule understand the causes of the complaint.

Label graphs, symbols and abbreviations
For the explanation of general graphs and symbols, please refer to EN ISO 15223-1, Symbol for Use in the Label of Medical Devices.

Symbol	Explanation	Symbol	Explanation
	Humidity limitation		Caution
	Do not reuse		Manufacturer
	Batch code		Temperature limitation
	Date of manufacture		Authorised representative in the European Union
	Ethylene Oxide Sterilization		Unique device identifier

Symbol	Explanation	Symbol	Explanation
	Medical device		CE mark
	Consult instructions for use or consult electronic instructions for use		Use by date
	Catalogue number		Do not use if package is damaged and consult instructions for use
	Double sterile barrier system with protective packaging outside		
Transportation packaging identification			
Symbol	Explanation	Symbol	Explanation
	Country of manufacture		This way up
	Keep away from sunlight		Keep dry
	Fragile, handle with care		

Maintenance and storage methods of products

The product shall be stored in a ventilated, non-corrosive gas room with the relative humidity no more than 80% and temperature between 10℃ to 30℃.

The products should be stored and transported gently, forbidden to collide or scratch each other, prevent the packaging from breaking or the products from being damaged, otherwise it is forbidden to use them.

The product should be protected from rain, corrosion and sunlight during transportation.

Electronic instruction website:

https://www.fulekejiorthopedic.com/instruction-for-use-1/

Product specifications and model

Name	Model	Specification	Remark
Dilator	FQNK01	d: 3.1, 3.5 L: 141	Hollow