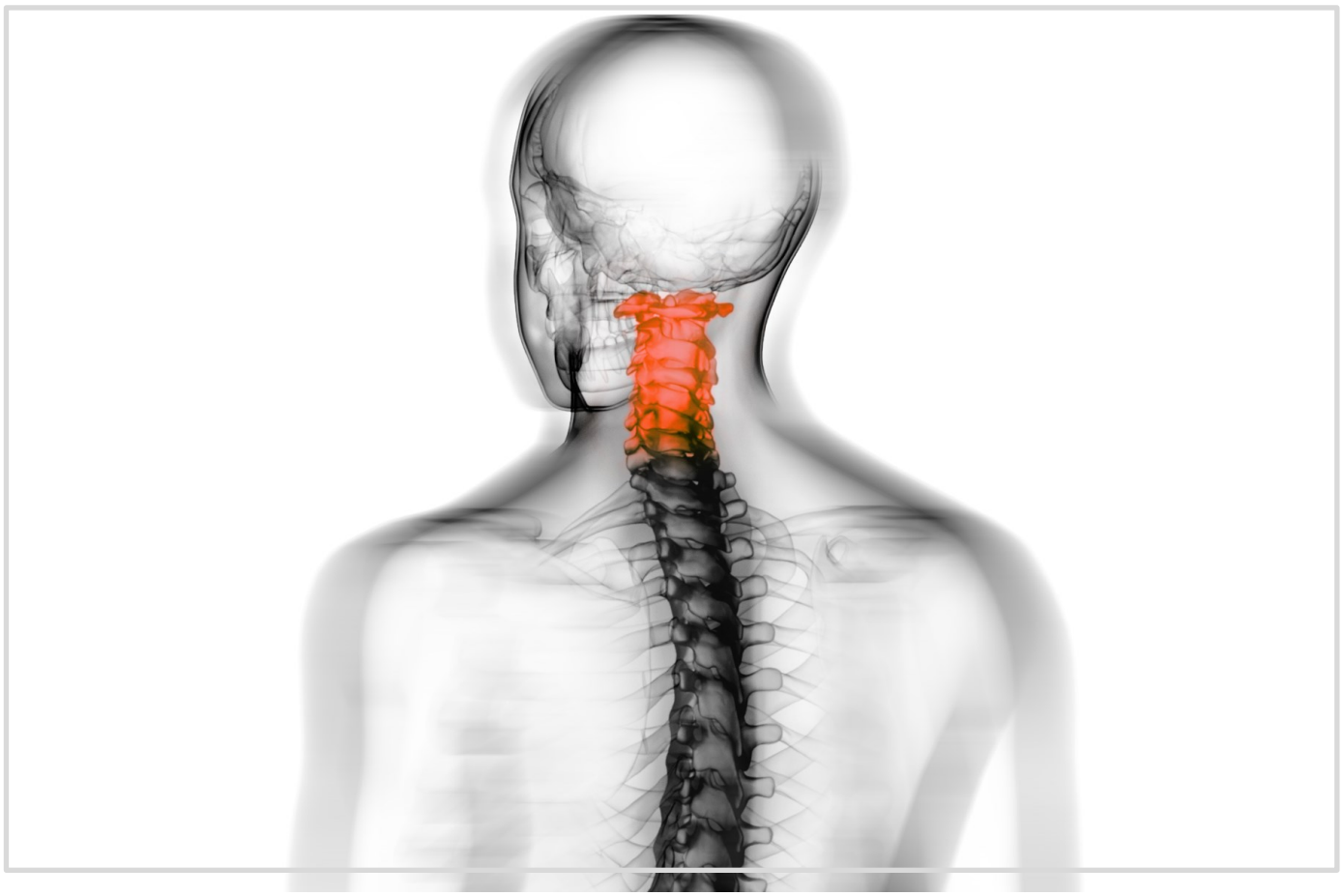
DISKOM™

Percutaneous discectomy device



Cervical Surgical Technique

bpb medica


medica

Our company

BPB MEDICA™ is an Italian manufacturing company specializing in the design, production and marketing of high-quality healthcare products for medical use and medical surgery devices.

BPB MEDICA™ was founded in 1999 by the Bellini family, boasting thirty year's experience in the biomedical sector. The founder, Carlo Bellini Sr., started the business in 1968 and has passed down ethics, integrity and spirit of sacrifice to his heirs. Today BPB MEDICA™ has leveraged its **50 years of experience** to develop new innovative product lines, growing the company on the international level.

BPB MEDICA™'s philosophy is to grow alongside the needs of patients, doctors and hospital staff in general. Backed by the experience acquired by the company's specialized technical personnel and thanks to newly-adopted technologies, BPB MEDICA™ has quickly managed to make a name for itself in the domestic and international markets.

50
YEARS
OF EXPERIENCE

70
COUNTRIES SERVED

OUR PRODUCT LINES:

SPINE

ORTHO-BIOLOGICS

ASSISTED REPRODUCTION

BIOPSY

INTENSIVE CARE

AESTHETIC

Our company

Cutting department

Moulding department

BPB MEDICA™ operates with state-of-the-art production machinery and equipment and **the entire production process is carried out in-house** (from design to final packaging).
As a manufacturing company, besides the traditional business model (BPB MEDICA™ -> DISTRIBUTOR), BPB MEDICA™ can also offer **OEM and private label services**.

Thanks to the **internal R&D Department** BPB MEDICA™ conducts constant research on the reference pathologies to ever-better qualifying, improving its production standards and aiding the development of new products.

BPB MEDICA™ provides painstaking service to its clientele and its primary aim is product quality. The **internal Regulatory and Quality Departments** conduct rigorous tests, from the raw materials to the equipment and the finished product. This allowed the company to obtain **CE, ISO 13485** and the establishment registration by **FDA**.

Cleanroom

OUR SERVICES:

- **ENTIRE IN-HOUSE PRODUCTION**
- **RESEARCH & DEVELOPMENT**
- **OEM & PRIVATE LABEL SERVICES**
- **MARKETING SUPPORT**
- **INTERNAL REGULATORY AND QUALITY DEPARTMENTS**
- **FOUR WEEKS DELIVERY**

DISKOM™

DISKOM™ is a single-use device that allows **percutaneous discectomy** of the cervical region of the spine. In the case of a painful hernia, it significantly relieves the pressure on the nerve roots and surrounding tissues by removing the material of the nucleus pulposus from the intervertebral disc with a minimally invasive approach.

The technique consists of a **mechanical removal procedure** of the nucleus pulposus, does not involve the use of radiofrequency or laser and is based on the use of an Archimedean screw.

The greater the hydration of the disc, the greater the suction capacity of the cochlea (a totally dehydrated disc or high-grade black disc does not allow suction and constitutes a contraindication, as for an expelled hernia).

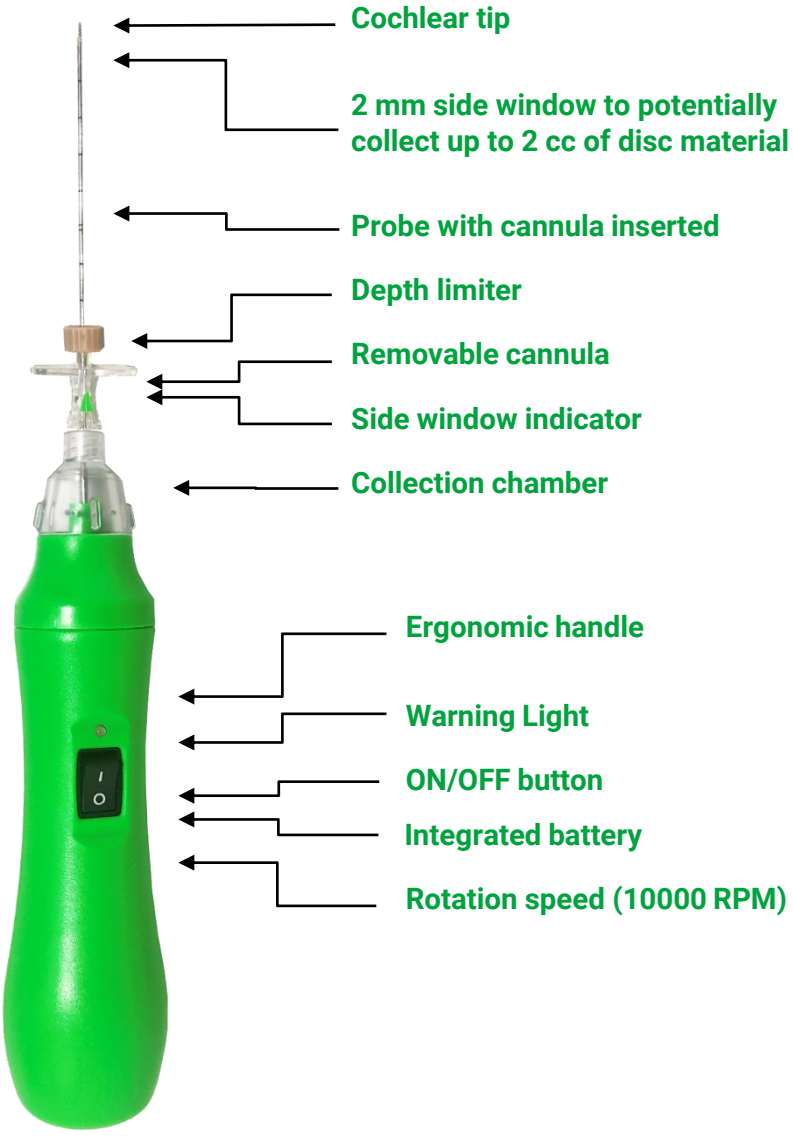
The large side fenestration allows the removal of up to 2 cc of disc material.

MAIN FEATURES

Cochlear Tip
The cochlea, being firmly connected to the other components of the device, is almost impossible to be detached.

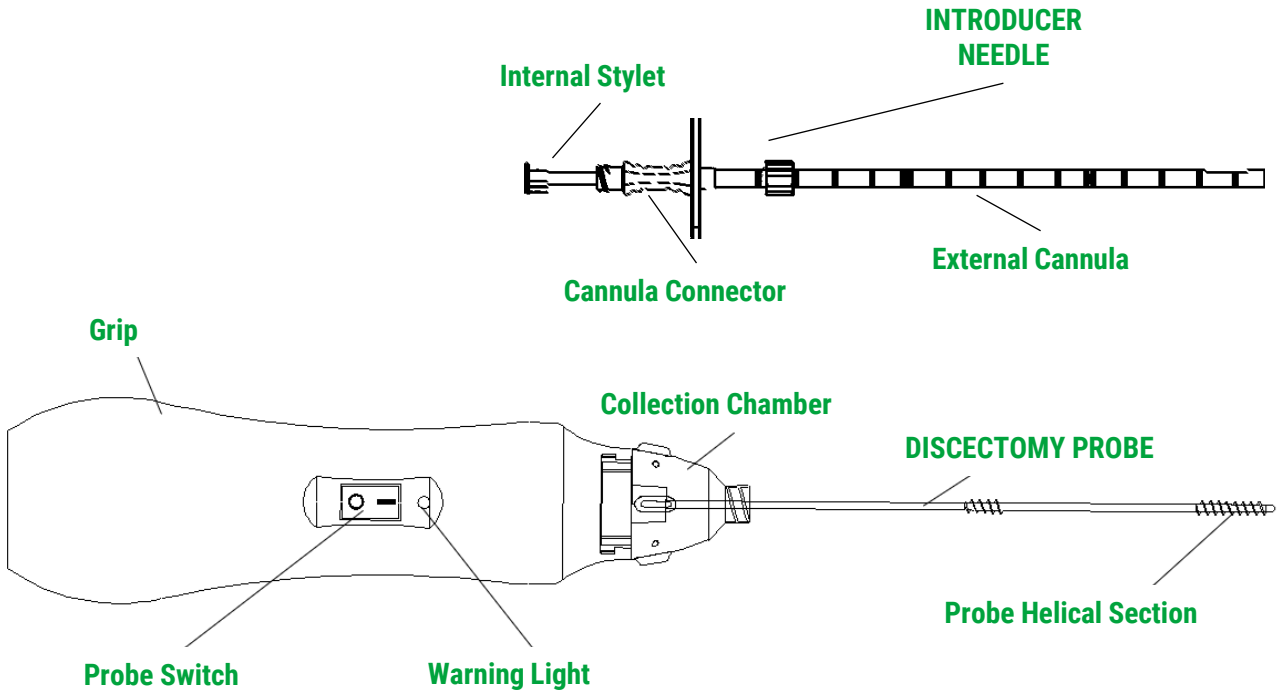
This unique feature is a guarantee of safety and effectiveness.

Procedure	Size	Length
Cervical	19 G	8 cm



Displayed device colours are indicative.

How does it work?



DISKOM™ consists of an introducer needle and a percutaneous discectomy device.

The introducer needle is composed of a suction cannula and an introducer stylet, both made of stainless steel. The suction cannula has an open tip and a lateral fenestration to allow aspiration of the nucleus pulposus material.

The discectomy device is instead composed of a handle directly connected to a rod with a screw and containing a 9V battery, the electrical circuit and the DC motor, which is activated by the power button. The rod with screw is made of titanium and comes with a double Archimedean screw.

The nucleus pulposus material aspirated from the intervertebral disc during the procedure can also be contained in the transparent collection chamber, which can be disassembled after the aspiration procedure to allow biopsy of the aspirate.

ADVANTAGES

- DISKOM™ preserves the integrity of the disc annulus
- It allows rapid rehabilitation
- Procedure time: 10 to 15 minutes
- Only local anaesthesia is required
- Instant visual confirmation of the amount of disc material collected
- Immediate lowering of pressure on the nerve roots and tissues surrounding the hernia
- It collects up to 2 cc of disc material
- The warning light gives notice of any exceeding of the maximum amount of aspirated material or any difficulty in suctioning
- The collected sample can be used for biopsy tests
- DISKOM™ is compatible with thoracolumbar and cervical procedures

Pre-operative plan

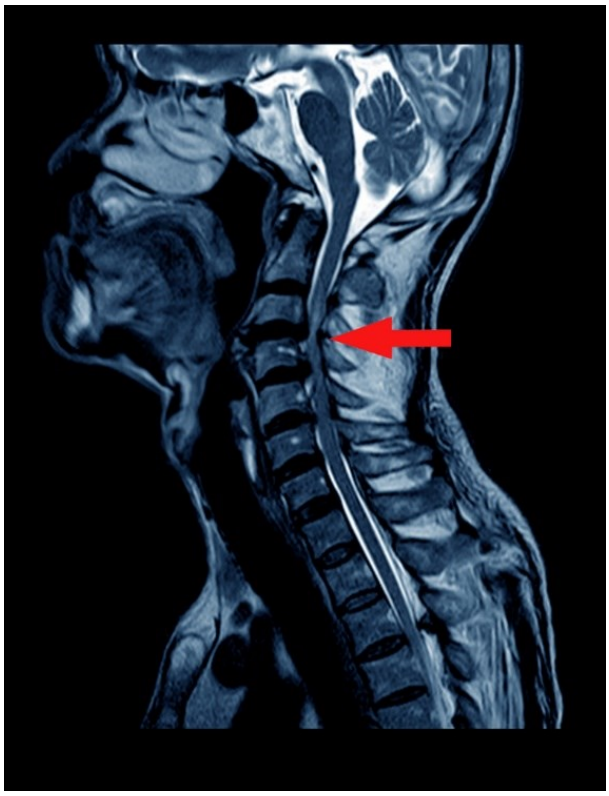
CLINICAL INDICATIONS

The indication for discectomy is a non-expelled herniated (extruded) intervertebral disc.

DISKOM™ is intended for professional use by qualified and trained interventional radiologists, neuroradiologists, neurosurgeons, orthopaedic surgeons and pain therapists, fully familiar with the indications, contraindications, limitations, typical results and possible side effects related to percutaneous discectomy devices, particularly those related to the lumbar and thoracic regions of the spine. The procedure must comply with antisepsis regulations.

PATIENT SELECTION

Discectomy may be considered medically necessary for the treatment of a non-expelled herniated (extruded) intervertebral disc when the following criteria are met:



- Signs and symptoms of radiculopathy and/or myelopathy on history and physical examination (persistent and debilitating neck, back or leg pain refractory to at least 6 weeks of conservative therapy, rapidly progressing neurological deficits, persistent or progressive symptoms of myelopathy refractory to at least 6 weeks of conservative therapy).
- Documentation of nerve root compression on imaging (MRI or computed tomography) consistent with contained disc herniation, which confirms the correspondence between the level involved and the patient's symptoms and which detects a preserved disc height of at least 50% with satisfactory hydration of the disc.
- Failed conservative treatment.
- Facet joint pain excluded based on diagnostic documentation and physical examination.
- Positive low-volume diagnostic SNRB (Selective Nerve Root Blocks).
- Discogram and post-disco CT consistent with the above (optional).

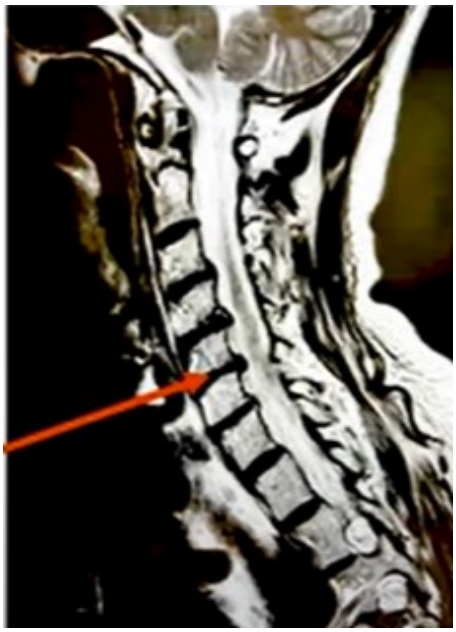
The choice of the patient and the decision to perform a discectomy must be made by medical staff taking into account the full clinical and physical picture of the patient.

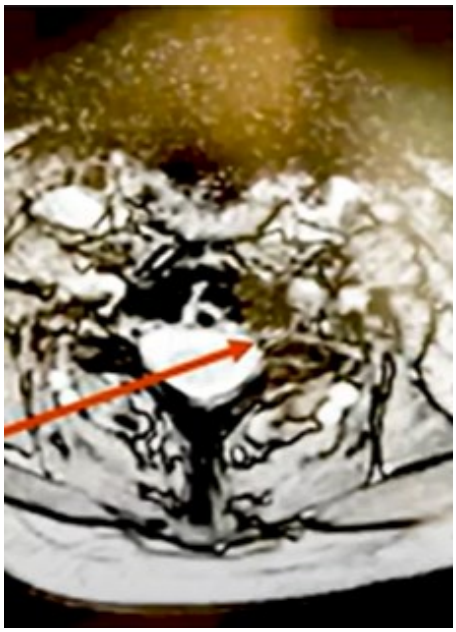
The choice must be made evaluating various aspects, for example, weight/fat mass of the patient, type of patient and any other physical/clinical characteristic of the patient that may have an impact on the discectomy result.

Based on these data the expert and trained surgeon may decide if to perform the discectomy on the patient and which needle is more suitable to do it.

Surgical technique

The DISKOM™ procedure is typically performed under fluoroscopic or CT guidance with a prone approach to treat the intervertebral discs of the cervical spine.

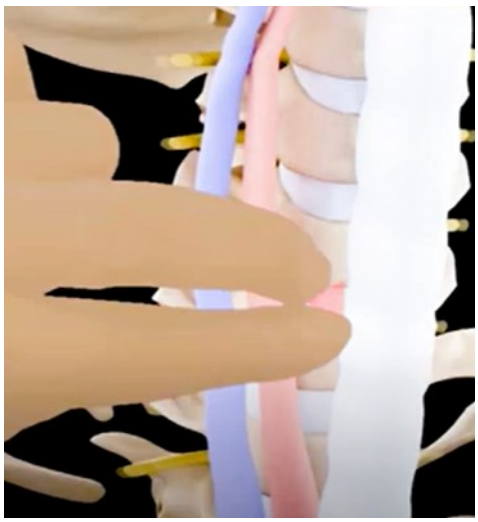


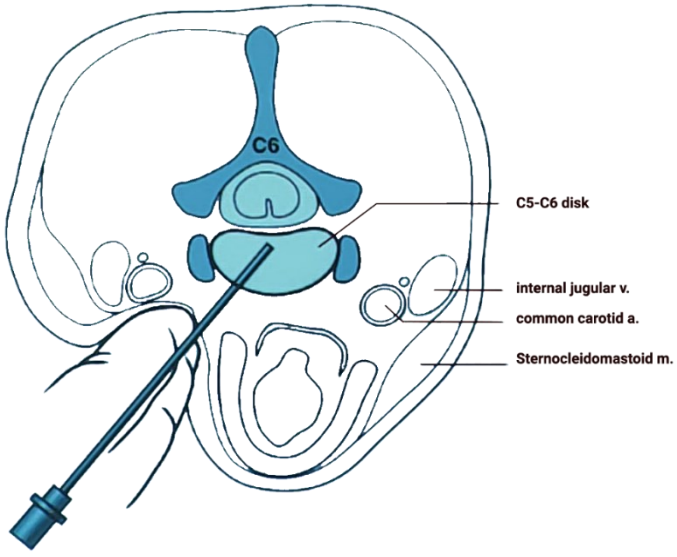


Before starting the procedure, it is strictly essential to carefully sterilise the surgical area.

Before positioning the introducer, exclusively conscious sedation or local anaesthesia is performed by inoculating the anaesthetic only into the skin and subcutaneous soft tissues (taking care not to involve the nerve root to allow monitoring of the patient for signs of irritation of the segmental spinal nerves.

CERVICAL LEVELS ACCESS



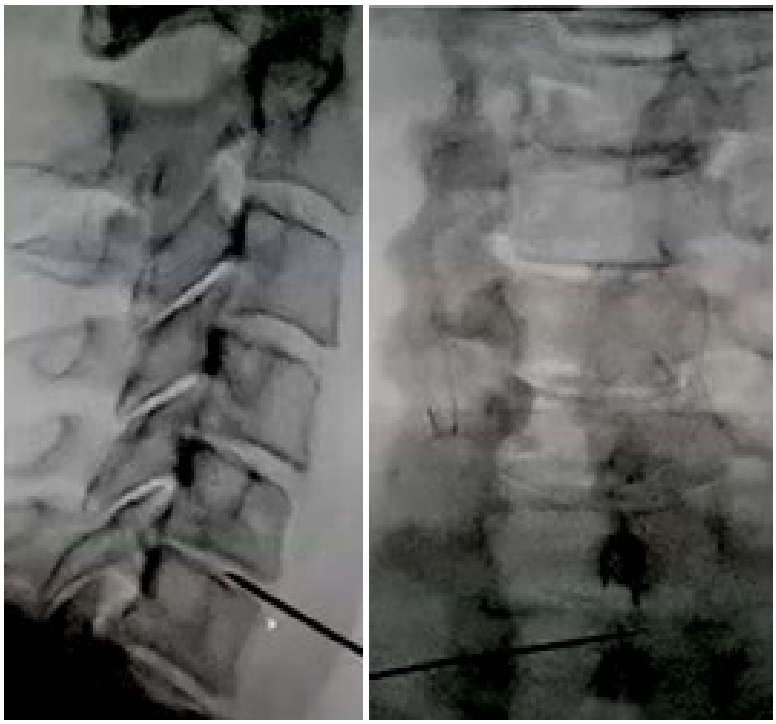


- Access to the disc occurs through an anterior approach.
- Keep the neck in a hyperextended position by placing pillows under the upper part of the thoracic spine.
- The carotid artery and jugular vein should be moved laterally by pressing two fingers against the spine.
- Access the disc of interest by inserting the introducer needle between the two fingers.
- Allow the introducer needle to pass between the oesophagus medially and the major cervical vessels laterally.
- Once the disc has been targeted, perform both AP and lateral views to confirm the correct introducer needle positioning. If deemed necessary, perform a discography of the affected level to verify the exact placement of the introducer needle.

Surgical technique

PROCEDURE

- Once the intervertebral disc has been accessed with the introducer needle, remove the introducer stylet.
- Insert the helical stylet of the discectomy probe into the cannula of the introducer needle.
- Connect the discectomy probe to the introducer needle by the Luer-Lock connection.
- Activate the device using the ON/OFF button.
- Alternate anteroposterior movements with rotational movements for approximately 2/3 minutes.
- The disc material is removed and collected along the stylet of the device or within the collection chamber.
- Turn off the device using the ON/OFF button.
- Remove DISKOM™ taking care not to remove the introducer needle without its stylet or helical stylet inside.



If the warning light turns red during the procedure (giving notice of exceeding the maximum amount of aspirated material or difficulty in suctioning), the device has to be turned off immediately and the aspiration from the nucleus pulposus is interrupted.

Disc material collected along the probe stylet

Contraindications and warnings

CONTRAINDICATIONS

- Use of the device is contraindicated in the case of **traumatic vertebral fractures, infection, tumour, pregnancy and coexisting severe diseases.**
- The probe is not suitable for the treatment of patients in whom pain symptoms are not caused by herniated discs. Patients that have **free fragments**, **severe bone stenosis** or **severe degenerative discopathies** must be excluded.
- This device is not suitable for use in patients with **severe neurologic deficiency** and rapid progression.
- The operation is to be performed under local anaesthesia or conscious sedation to allow monitoring of the patient for signs of segmental spinal nerve irritation. **General anaesthesia is contraindicated**.
- **Non-contained disc herniation (disc extrusion), sequestered disc or asymptomatic intervertebral disc bulging incidentally discovered at computed tomography or MR imaging.**
- **Segmental instability** as spondylolisthesis or deformity of the spine.
- **Haemostasis disorders** or anticoagulant therapy.

WARNINGS, PRECAUTIONS AND SIDE-EFFECTS

- The needle has to be used exclusively by suitably trained expert medical staff.

- The device is single-use and must be destroyed after use. Reuse is strictly prohibited. Reuse or resterilization may compromise the structural integrity of the device and/or cause damage to the device which may cause injury, disease or death to the patient. Reuse or resterilization may also create a risk of device contamination and/or cause infection of the patient or cross-infection, including but not limited to transmission of infectious diseases from one patient to the next or discitis or epidural abscesses. Device contamination may cause harm, disease or death to the patient.

- After use, it may constitute a risk of contamination and/or infection, therefore, handle with care and dispose of the needle following the regulations in force and medical practice.

- Do not use the device in contact with the central nervous system (do not under any circumstances use a transdural approach) or the central circulatory system.

- This device is intended for access to only one vertebral disc. Do not use it on several intervertebral levels.

- Do not immerse the device in liquids.

- Use under fluoroscopic guidance.

- Use the device according to the electromagnetic compatibility (EMC) guidelines indicated in the information leaflet. Portable and mobile RF communications equipment may cause increased emissions and/or reduced immunity of the device.

- Do not bend, straighten or modify the shape of the introducer cannula in any way. Failure to follow this instruction may result in the breakage of the screw stem during use. A fragment of this stem might remain in the surgical site after pulling out the cannula with the consequent need to intervene to remove it.

- Do not use during pregnancy and between 0 and 18 years of age.

- Follow instructions carefully and do not perform dangerous manoeuvres that could lead to nerve or nerve root injury.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