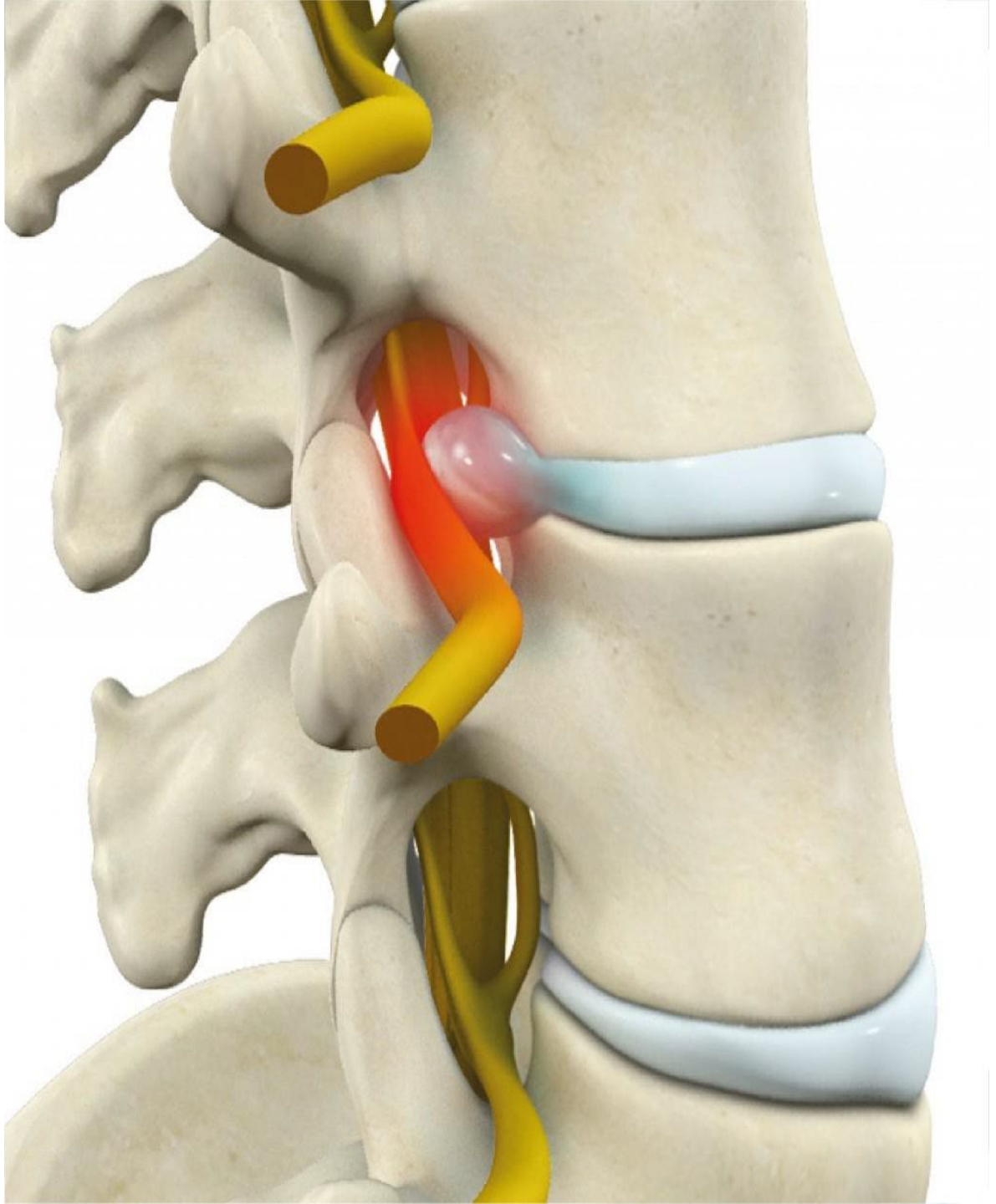
# DISKOM™

Percutaneous mechanical discectomy probe for *cervical approach*

Key Features & characteristics



# CERVICAL HERNIA

A **cervical hernia,** also known as a cervical disc herniation, is a protrusion of intervertebral disc material or other spinal structures through a tear or defect in the cervical vertebral column.
These herniations can occur at any level of the cervical spine.
Cervical herniations may be congenital or acquired due to degeneration or trauma.

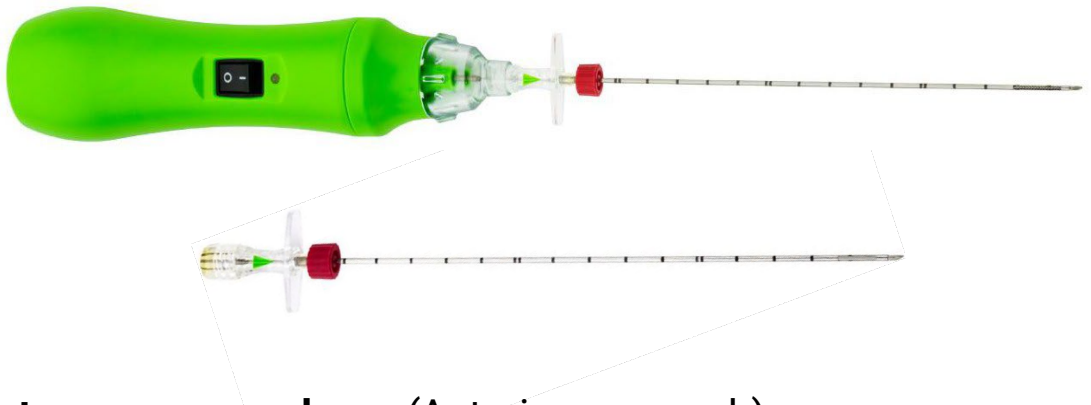
Symptoms of cervical herniations can vary depending on the location and size of the herniation and can include **neck pain, weakness, numbness, tingling in the arms or legs, headaches, or difficulty swallowing.**
In asymptomatic cases, the herniation may be found incidentally on imaging.

**If left untreated, cervical herniations can lead to serious complications** such as spinal cord compression, which can cause permanent nerve damage.

Treatment options for cervical herniations include **percutaneous discectomy,** a minimally invasive procedure performed by a small needle and a special instrument that removes or shrinks the herniated portion of the disc, reducing pressure on the spinal cord or nerve root and relieving symptoms.

# DISKOM™ - Percutaneous discectomy probe

**17 G x 16 cm -> for Lumbar/thoracic percutaneous procedures** (Posterior, lateral approach, 7/8 cm from midline, 45° angulation)



**19 G x 8 cm - > for Cervical percutaneous procedures** (Anterior approach)

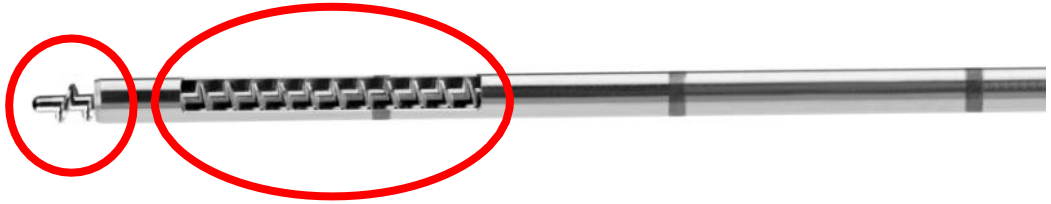
# DISKOM™- FUNCTIONALITY

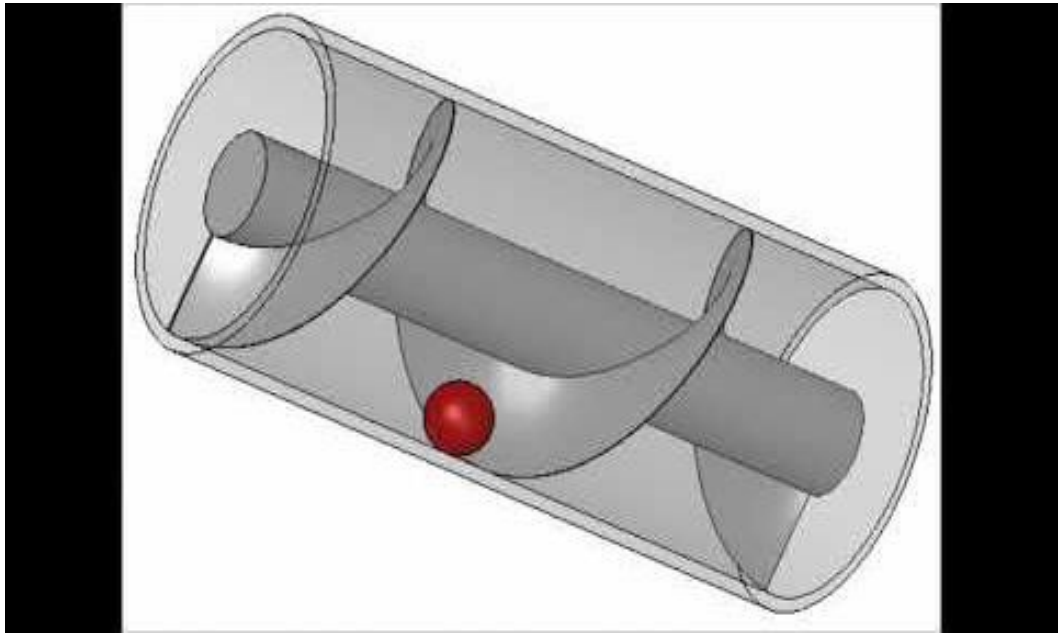
How does DISKOM™ work?

It's a **mechanical** removal procedure, based on Archimedes' screw.
It does NOT make use of either radiofrequency or laser.

DISKOM™ has a **cochlear tip with both distal and side openings.**

Thanks to its design, as the device rotates, it removes disc material outwards, relieving pressure on the spinal cord.

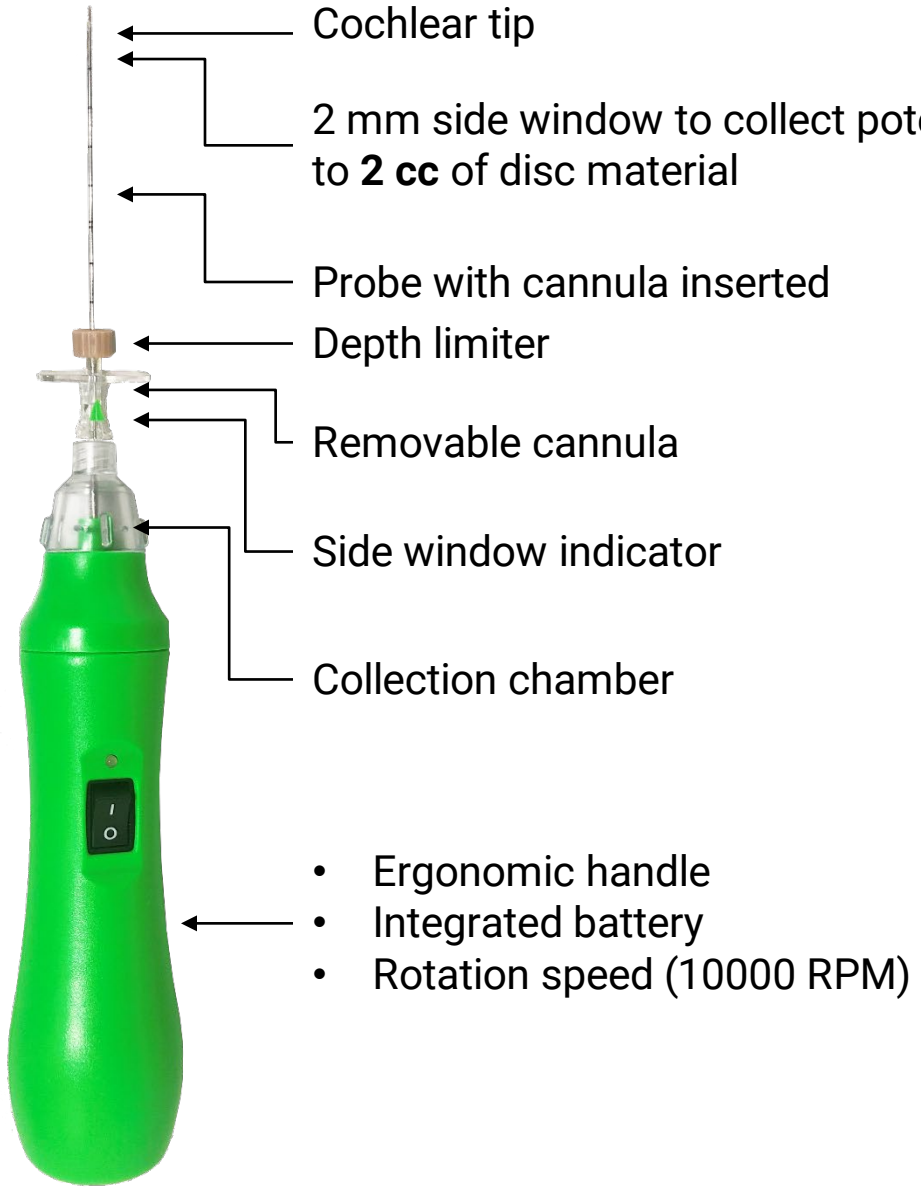




# DISKOM™: BENEFITS

- Allows to collect potentially **up to 2 cc of disc material**
- Annular integrity preservation
- No thermal damage to the nerve roots and surrounding tissues
- Percutaneous access: MIS procedure
- Total procedure time: 10/15 minutes
- Just local anaesthesia needed
- Fast recovery after treatment
- Immediate visual confirmation of the collected amount of disc material
- Allows bioptic procedures on the collected disc material
- Immediate reduction of the pressure on the nerve roots
- No further equipment is needed
- No capital investment is required
- Single-use device
- Available for thoracolumbar or cervical spine
- Packaged with its introducer needle

# DISKOM™: FEATURES AND USE




**SURGICAL TECHNIQUE**:

• Introduce the access needle under fluoroscopy guidance into the disc. Contrast liquid might be injected through the cannula.

• Remove the stylet, introduce the probe into the cannula, and connect the collection chamber to the access needle cannula, through the Luer-lock connection.

• Switch the probe on.

• Perform a backward and frontward movement, for 2/3 minutes combining it with a rotational movement.

• Disc material is then removed and collected along the probe stylet or into the collection chamber.

• After switching off, remove the device.

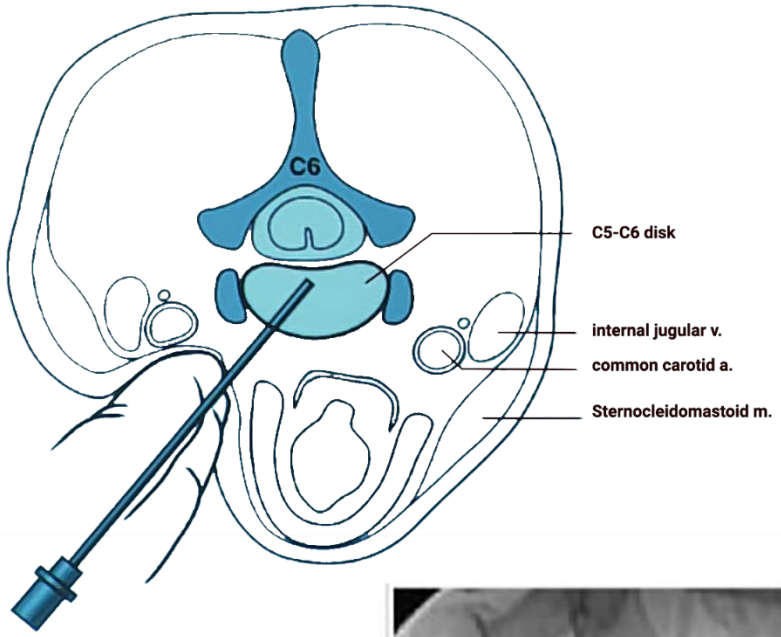
# DISKOM™: patient selection and access

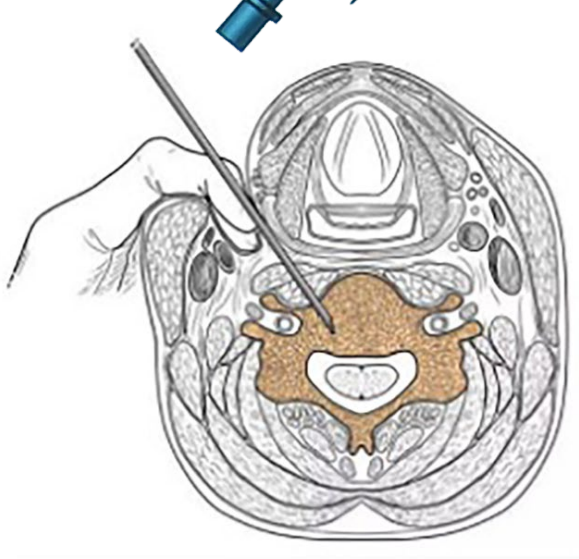
## Patient selection:

- Radicular pain
- MRI consistent with contained disc herniation
- MRI demonstrating 50% preserved disc height
- Failed conservative treatment
- Facet pain excluded
- Positive low-volume diagnostic selective nerve root block
- Discogram and post-disco CT consistent with the above (optional)

## Access:

Currently, **anterior access** in cervical discectomy is regarded as the gold-standard surgical option for cervical disc herniation.
Place the patient in the supine position, with the neck slightly extended (this position allows for better visualization of the cervical spine) and proceed as per side figures.
The procedure is usually done on an outpatient basis, so patients are able to go home the same day.
The procedure may vary depending on the patient's specific condition and the surgeon's preference.



# Cervical DISKOM™: clinical studies to support the effectiveness

https://doi.org/10.1007/s11547-020-01133-x
MUSCULOSKELETAL RADIOLOGY
***Percutaneous cervical discectomy: retrospective comparison of two different techniques***
Anna Maria Ierardi · Aldo Carnevale · Alberto Cossu · Andrea Coppola · Enrico Maria Fumarola · Enrico Garanzini · Salvatore Silipigni · Alberto Magenta Biasina · Aldo Paolucci · Melchiore Giganti ·Gianpaolo Carrafiello

DOI: 10.23750/abm.v91i10-S.10247
ACTA BIOMED
***Image-guided percutaneous mechanical disc decompression for herniated discs: a technical note***
Alessandro Liguori, Marco Pandolfi, Martina Gurgitano, Antonio Arrichiello, Letizia Di Meglio, Salvatore Alessio Angileri, Anna Maria Ierardi, Aldo Paolucci, Federica Galli, Elvira Stellato, Gianpaolo Carrafiello

# DISKOM™: CONTRAINDICATIONS AND COMPLICATIONS

## CONTRAINDICATIONS

**Absolute**

- As the Archimedes' screw works best with fluid or granular material, if the disc is completely dehydrated (black hernia) this principle cannot be applied.
- A totally extruded hernia is also a contraindication
- Sequestered (free) disc fragment
- Segmental instability (spondylolisthesis)
- Stenosis of neural foramen or spinal canal
- Asymptomatic intervertebral disc bulging was discovered as an incidental finding
- Active infection and/or discitis
- Pregnancy (radiation exposure of the fetus must be avoided)

**Relative**

- Haemorrhagic diathesis (should be corrected before the operation)
- Anticoagulant therapy (should be interrupted before the operation)
- Severe degenerative disc disease with more than 2/3 disc height decrease
- Primary or metastatic malignancy

## POSSIBLE COMPLICATIONS:

- Intra-operative complications are related to the technique itself as well as the instrumentation (e.g. catheter breakage, nerve root injury), whilst postoperative complications include bleeding, infection and other general complications.
- Discitis is the most common complication of percutaneous disc decompression techniques occurring in up to 0,24% per patient
- Less frequently encountered complications of the technique include reflex sympathetic dystrophy, puncture of the thecal sac with accompanying headache, haemorrhage and neurologic injury, allergic reactions to any of the agents during the procedure and vasovagal reactions (in case of cervical intervertebral disc decompression

# DISKOM™: competitive advantages

## DISKOM™ benefits compared to Dekompressor

- More powerful engine
- Rotation speed is maintained constant
- 2 collection sides: distal and lateral
- Allows to collect up to 2cc of disc material

## DISKOM™ benefits compared to De-ko / Herniatome

- More powerful engine
- Rotation speed maintained constant
- 2 collection sides: distal and lateral
- Allows to collect up to 2cc of disc material
- No glued / sealed parts → safer and more resistant device
- No need for extra components or surgical steps such as the k-wire → product ready to use

## DISKOM™ benefits compared to RF, laser discectomy, Discogel

- Avoid possible iatrogenic endplate oedema
- Avoid possible leakage in the surrounding tissues
- Immediate visual confirmation of the collected amount of disc material → up to 2 cc
- Immediate reduction of the pressure on the nerve roots
- No further equipment needed such as the generator

# DISKOM™: lengths and sizes

| Procedure | Sizes | Product Code | Packaging |
|---|---|---|---|
| Cervical | 19G x 8cm | DKR1908CDFL10 | Single unit |
| Thoracic/Lumbar | 17G x 16cm | DKR1716CDFL10 | Single unit |

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OVER

# 50

YEARS

**OF EXPERIENCE IN THE BIOMEDICAL SECTOR**

# OUR PLANT


## OFFICES

- DOMESTIC SALES
- INTERNATIONAL SALES
- MARKETING
- PRODUCTION DEPARTMENT
- TECHNICAL OFFICE
- QUALITY & REGULATORY
- FINANCIAL DEPARTMENT
- HR

## PRODUCTION

- CLEANROOM
- METAL PROCESSING DEPARTMENT
- MOLDING DEPARTMENT

## DEPOSIT

- WAREHOUSE: 400 MQ
- STERILE PRODUCTS DEPOSIT
- LOGISTIC & PACKAGING DEPARTMENT

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## STATE-OF-THE-ART
**production machinery**

## ENTIRE IN-HOUSE
**production process**

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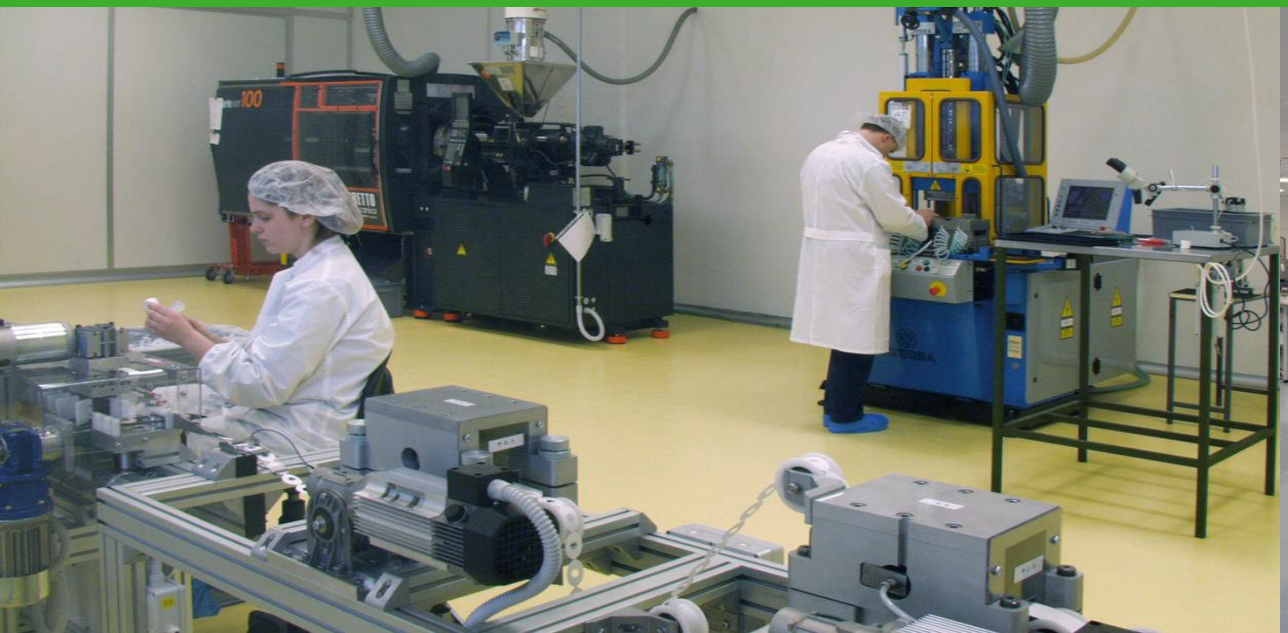

# OUR SERVICES

## PRODUCTION PROCESS CONTROL

Complete manufacturing process carried out internally (from the design to the final packaging) with state-of-the-art production machinery and equipment.

## RESEARCH & DEVELOPMENT

We conduct constant research to increase production and quality standards and develop new products. With an internal R&D team, we can offer our customers full support to meet their needs.

## OEM SERVICES

Being a manufacturing company, we can offer **OEM and Private label services** for companies who wants products under their brand name or with their custom colour.

## MARKETING SUPPORT

We provide our customers with video tutorials and surgical video procedures, case reports, literature, presence at major medical congresses, organization of events, laboratory training and courses.

## REGULATORY & QUALITY DEPARTMENTS

Our primary aim is product quality and to provide painstaking service to the clientele. Our regulatory and quality teams conduct rigorous tests for this purpose, from the raw materials to the equipment and the finished product.

## FOUR WEEKS DELIVERY

Thanks to the control of the production process, we satisfy our customers orders whithin 4 weeks (on average)

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# OUR PRODUCT LINES

**Biomedical products and single use devices for:**

## SPINE SURGERY

- Kyphoplasty kit
- Vertebroplasty set
- Mechanical percutaneous discectomy
- Minimally invasive spine accessories

## ORTHO-BIOLOGICS

- Adipose tissue stem cells kit
- Bone marrow stem cells kit
- Subchondral bone plasty
- Metaphyseal fractures augmentation

## BIOPSY

- Soft tissue biopsy needles
- Bone marrow biopsy needles
- Bone marrow aspiration needles
- Explant needles
- Mammary lesion localization needles

## ASSISTED REPRODUCTION TECHNOLOGIES

- Ovum Pick-up needles
- Embryo transfer catheters
- Vitrification Straws
- Prenatal diagnosis

## INTENSIVE CARE

- Tracheostomy filter and cannula fastening ties

## AESTHETIC

- Adipose tissue for applications in modern dermatology, plastic and aesthetic surgery

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# OUR CERTIFICATIONS

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EN ISO 13485
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FDA CLEARED

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