# Instructions for lumbar intervertebral disc hernia remedy 'HERNICORE'

'HERNICORE's an injection that lowers the pressure in the intervertebral disc and improves lumbar hernia's symptoms.

Before starting to use, it is necessary to strictly examine its adaptability, therefore a preliminary examination and MRI are essential.

### Indication

- It can only be used when there is no effect in other preservative treatments
- There are roughly 4 types of hernia, but it can be used only for the 'subligamentous extrusion type'.
- Can be administered for nerve root symptoms (with lower leg symptoms) but cannot be used for cauda symptoms (numbness of both lower limbs and patients with urination disorder).
- Treatment can be given only once in a lifetime.

# Ineffective condition:

- Highly degenerated intervertebral discs,
- Spondylolysis/listhesis

Safety and effectiveness unconfirmed for the following

- People with osteoporosis ·
- Rheumatism,
- Under 20 years old, over 70 years old,
- Pregnant or lactating women

### Method:

- 1. A drip infusion is given before treatment begins
- 2. The patient lies on an X-ray image table at an oblique angle and the skin is anesthetized
- 3. A needle is inserted into the intervertebral disc. If it is confirmed that the needle has entered the intervertebral disc, the injection is given.
- 4. To observe the side effect after the injection. It is necessary to rest in the hospital for about 2 hours.
- 5. The patient should avoid taking a bath on the day of the injection
- 6. Do not lift or carry heavy objects (5 kg or more) for 1 week after injection. Avoid strong twisting motion.

7. The effect of the treatment will be checked at least 3 months after its administration, therefore, please revisit Koyama Clinic

## Effects :

Lower leg pain decreases an average of 49.5% 13 weeks after the injection (placebo 34.3%) . Actually, there are individual differences. Please understand that there may not be, or will not be, any effect immediately after the injection. Also, please understand that this treatment may not be a way to completely avoid surgery.

### Side effects :

There is a slight possibility that the needle may hit a nerve, in that case there is a possibility of transient pain radiating.

There is a slight possibility of allergy to medicine (2.6%), in which case appropriate treatment is required.

Lumbar pain (22.3%) and lower limb pain (4.8%) may occur during the course of treatment, and conservative treatment may be necessary.

In part, there is a risk (~ 23%) that the intervertebral disc itself becomes unstable or bone changes, but no treatment is especially necessary

# Cost:

Preliminary examination and MRI: 20,000JPY Hernicore injection; 150,000 JPY Examination after injection:

- Only examination: 2,000JPY
- Examination and MRI: 20,000JPY

Total 172,000-190,000 JPY No refunds will be made

> Koyama Clinic/Kobe Hokuto Hospital Spine Center Certificated Spine Surgeon Toru Takada

# **Consent Form for 'Hernicore'**

- 1. Name of your disease and the surgery : Intervertebral disc hernia
- 2. Current symptoms: Lower leg pain
- 3. Reason for injection: Other treatment was ineffective
- 4. Operative method and anesthesia method: Hernicore therapy
- 5. Scheduled date of surgery (YYY/MM/DD):
- 6. Other:

#### If you agree to have the surgery above, please sign below.

I have received a thorough explanation of the surgery above. As a result, I agree to have the surgery. (Even after you sign, you can withdraw your agreement at any time.) I also agree that appropriate procedures may be taken based on the decision of my doctor.

Date of signature (YYYY/MM/DD): / /
Patient's name : (print)
Patient's signature :
Patient's address :
Representative's name : (print)
Representative's signature : (relationship to patient: )
Representative's address :

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I provided the explanation about the surgery to the person who signed above.

#### Date of explanation (YYYY/MM/DD): // Department:

Attending doctor:

Seal

I confirm that the patient (or his/her representative) above has agreed to have the surgery by signing this document.

Date of confirmation (YYYY/MM/DD): // Department:	
Attending doctor:	Seal