Spinevisc®

The proven hyaluronic acid treatment for facet joint arthrosis.

Hyaluronic Acid, Sodium Salt 1.0 %
Dear user,

The prevalence of specific and non-specific back pain is constantly increasing. Acute pain often disappears on its own in most cases. The rest, however, persist for several months, so that one can speak of chronic back pain. A possible trigger for pain is the facet syndrome. The facet syndrome (Fig. a) is a chronic pain syndrome caused by irritation of the nociceptors in the joint capsule. The main causes are chronic overload, facet joint incongruence due to disc degeneration or arthrosis. The lumbar spine is most frequently affected. Patients mostly complain of long-lasting and often difficult to treat pain.

The clinical diagnosis of the facet syndrome is difficult to determine. Typical features are painful muscle tension, local pressure and/or knocking pain over the spinous processes as well as motion-dependent pain in the area of the paravertebral muscles.

In early stages of facet joint arthrosis, conservative treatment is indicated (physiotherapy, possibly supported by oral analgesics or anti-inflammatory drugs). Further treatment options are facet joint infiltrations with local anaesthetics and/or corticosteroids. In addition, procedures such as percutaneous thermo- and cryodenervation are also available.

The treatment with Spinevisc® hyaluronic acid is particularly successful in early stages of facet joint arthrosis. It is recommended to repeat the Spinevisc® treatment 3 – 5 times in weekly intervals to achieve a successful clinical outcome. The treatment can be repeated several times within 12 months.

Fig. a: Facet syndrome
**What is Spinevisc®?**
- A highly pure, non-crosslinked hyaluronic acid with an average molecular weight of 1.2 – 1.4 Mio. kD (Kilodalton), similar to the body’s own hyaluronic acid
- Biotechnologically, fermentatively produced in a patented process in Europe (Pharm.-Eur.)
- Purely biomimetic hyaluronic acid without any microbiological impurities
- Very well tolerated and physiologically degradable
- An alternative to corticosteroids, percutaneous thermo, cryo- and sodium chloride infiltration
- Another option in the treatment cascade of the facet syndrome

**Why Spinevisc®?**
- CE certified for the treatment of facet joint arthrosis
- Clinically tested and proven for the use on facet joints
- 90% proven patient satisfaction
- Improves the lubricating and shock-absorbing properties of the body’s own synovial fluid and is anti-inflammatory
- Clinically effective alternative to anti-inflammatory drugs and antirheumatic drugs
- The Spinevisc® treatment may be repeated 3 – 5 times in weekly intervals (depending on the patient’s pain level). The treatment can be repeated several times within 12 months

**Clinical Efficacy Assessment**
- 37% freedom from symptoms vs. 49% clear improvement (N = 79 patients)
Assessment of individual pain status, criteria rest pain and movement pain

The symptoms of pain and discomfort decreased continuously during the 3-week treatment cycle with Spinevisc® for all criteria. Therapy success continued with most patients even after completion of the 3-week treatment cycle.

### VAS – Rest Pain (N = 79 patients)

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<thead>
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<th>Time</th>
<th>Arithmetical Mean</th>
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<td>T0: Prior Therapy</td>
<td>5.78</td>
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<tr>
<td>T1: Prior Injection 1</td>
<td>4.02</td>
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<tr>
<td>T2: Prior Injection 2</td>
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<td>T4: After Therapy</td>
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(T1 – T3: after denervation before injection 1, 2 and 3)

### VAS – Movement Pain (N = 79 patients)

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<td>T4: After Therapy</td>
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(T1 – T3: after denervation before injection 1, 2 and 3)
Exemplary infiltration technique with Spinevisc®

For the treatment of facet joint arthrosis (Fig. b), which is often referred to as the „facet syndrome“ and which leads to severe back pain, intra-articular facet joint infiltration with Spinevisc® can be performed.

Fig. b: Lumbar facet joints

The facet joints contain opposite cartilage surfaces (Fig. c), which reduce friction between the bones.

Fig. c: Cartilage surfaces of the facet joints

The joint is surrounded by a capsule filled with a small amount of synovial fluid (Fig. d). The synovial fluid acts as a lubricant to reduce friction between the rubbing facet joints. Healthy facet joints support the spine while allowing a wide range of rotational and bending movements (flexion/extension).

Fig. d: Capsule with synovial fluid
The facet joints can become inflamed and painful due to a variety of diseases such as arthrosis. (Fig. e)

Fig. e: Vertebral facet joints affected by facet joint arthrosis

Before a facet joint infiltration with Spinevisc® hyaluronic acid, the facet joints should be diagnosed as the source of pain. If local anaesthetics or corticosteroids are contraindicated, sodium chloride solution alone may be injected under aseptic conditions. (Fig. f)

Fig. f: Lumbar facet joint diagnosis

The patient is brought into the abdominal or knee position.
A needle is then guided into the facet joints using fluoroscopy under aseptic conditions. (Fig. g)

Fig. g: Needle guidance into the facet joints

Contrast dye can be injected to confirm that the needle is properly positioned into the facet joints.

Note: This surgical step is recommended but not mandatory if a contrast dye intolerance is indicated.

Fig. h: Injection of contrast dye
After confirmation of the needle positioning, a mixture of anaesthetics and anti-inflammatory drugs is slowly injected into the facet joints. (Fig. i)

After the injection of the anaesthetics and anti-inflammatory drugs, the needle positioning and direction in the facet joints should be reconfirmed under fluoroscopy.

The injection needle is placed on the cone of the Spinevissc® syringe and the hyaluronic acid is then slowly injected into the facet joints under fluoroscopic control.

Note: It is recommended to inject 1 ml Spinevissc® per facet joint.

After the facet joint infiltration with Spinevissc® it is recommended to monitor the patient for about one hour by means of electrocardiogram (ECG) and blood pressure measurement, to pay attention to physical reactions and to check the physical mobility of the patient. It is not recommended to drive a motor vehicle directly after the procedure.

It is recommended to repeat the Spinevissc® treatment 3 – 5 times in weekly intervals (depending on patient’s pain level) to achieve a successful clinical outcome. The treatment can be repeated several times within 12 months.
Disclaimer
This document is intended exclusively for experts in the field, i.e. physicians in particular, and is expressly not for the information of laypersons.

The information on the products and/or procedures contained in this document is of a general nature and does not represent medical advice or recommendations. Since this information does not constitute any diagnostic or therapeutic statement with regard to any individual medical case, individual examination and advising of the respective patient are absolutely necessary and are not replaced by this document in whole or in part.

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Literature
10 Spinevisc® Instructions For Use