Operating Manual
Pin 0.2ml / FehrFix
Pin 0.2ml / FehrFix - System for nucleus reinforcement

GENERAL DESCRIPTION:
- The Pin 0.2ml system for nucleus reinforcement is intended for the treatment of the degenerative spinal disk syndrome. The implant can be implanted by a posterolateral puncture access.
- The Pin 0.2ml implant consists of a biologically compatible and biostable hydrogel and is inserted with a cannula in a length of 15 mm. This cannula is supplied with the system.
- The size of the supplied cannulas matches perfectly with the Pin 0.2ml. These cannulas have to be used in order to ensure a proper function.

INDICATION:
The Pin 0.2ml system for nucleus reinforcement is indicated for the treatment of:
- pains that have existed for at least 12 weeks in the area of the lumbar, thoracic and cervical vertebrae;
- exhausted pain therapy and physiotherapeutic treatment without any clear improvement
- small or no radicular pains;
- as a consequence of a degenerative disk disease
- diagnosed by means of black disk in the MRI and anamnesis of the patient
- with incomplete or without disruption of the annulus fibrosus or enclosed prolapse (contained disk)
- adjacent segment degeneration after fusion surgery or surgery for the erection of the vertebral body

CONTRAINDICATIONS:
Pin 0.2ml implant is not suitable for the treatment of patients with:
- radiculopathy caused by a nerve root compression;
- acute spinal disk herniation with extruded or sequestered parts of cartilage, prolapse > 3 mm;
- rupture of the annulus fibrosus with a severity level of 4 (modified Dallas discogram)
- partial rupture of the annulus fibrosus or rupture of the annulus fibrosus extending over the entire thickness;
- disk height 50% of the original height
- severe symptoms of a central, foraminal or lateral recessive stenosis, spondylolisthesis, acute fractures, broken or heavily worn zygapophysial joints or Bechterew syndrome;
- 12 months after previous spinal surgeries with opening of the annulus fibrosus in the area concerned;
- metabolic dysfunctions of the bones;
- pregnant women, breastfeeding mothers,
- active system infection or localized infection of the implant site,
- discography with contrast agent influences the swelling of the material.

WARNINGS:
The Pin 0.2ml implant may only be inserted by physicians who have broad experience with such implants and who have sufficient knowledge regarding the required special surgical technique.
Physicians have to work in a strictly aseptic way in order to minimize the risk of infection. In case of an infection, it must be fought by means of an aggressive treatment.
The Pin 0.2ml - implant is for single use and may not be sterilized a second time. The reuse of this implant may cause dysfunctions of the implant or complications during the surgery, including infections.
Irrespective of these warnings, there are the general risks of undesirable effects which may occur during any surgery. Before the surgery, patients have to be informed about the general surgical risks.

POTENTIAL COMPLICATIONS AND SIDE EFFECTS:
Due to the nucleus reinforcement with Pin 0.2ml, the following potential undesirable side effects may occur:
In connection with the Pin 0.2ml - implant:
- migration of the implant;
- incorrect positioning of the implant;
- necessary revision surgery, perhaps in order to remove the Pin 0.2ml - implant;
- foreign body reaction
- ineffectiveness of the implant/the treatment as there is no improvement with respect to the symptoms/the function.

In connection with the surgery:
- reactions to the anesthetic or contrast agent;
- myocardial infarction;
- infection;
- damage to blood vessels/bleedings;
- deep vein thrombosis;
- hematoma;
- pneumonia;
- impairment of the nervous system;
- stroke
- damage of nerves or injury of the spinal cord;
- paralysis;
- thrombus formation;
- wound dehiscence or delayed wound healing;
- pain/problems at the puncture site;
- death

Note: With respect to the treatment of some of these potential effects, a medical treatment or a revision surgery may become necessary.

PACKAGING AND STERILIZATION OF THE IMPLANT:
The Pin 0.2ml implants have been sterilized twice when they are delivered for single use. The packaging of the implant must not be damaged. Damaged products or products the packaging of which have been damaged have to be returned to Aureus Medical GmbH. Products which have passed their expiry dates must not be used, but have to be disposed of in accordance with the provisions.
Explanted parts of the product or parts which have not been used have to be regarded as hazardous waste and have to be disposed of according to the applicable provisions.

INSTRUCTIONS FOR USE:
There is no guarantee that each application of the Pin 0.2ml - implant brings the desired success. Reference is made to the potential complications and side effects and the general warnings on the package insert which contains a comprehensive list of the potential risks.

The use of a Pin 0.2ml implant should only be approved if the following conditions are met before, during and after the surgery.

Before the surgery:
1. Only those patients who meet the indication cri-

teria and with respect to whom there are no contraindications may receive the implant.
2. Careful handling and safe storage of the system are required in order to avoid any scratches, notches, unintended moistening and contaminations.
3. The surgeon must be familiar with the parts of the system. Before each surgery, he has to ensure that all implants and all instruments are available.
4. For any use, all implants and surgical instruments have to be in perfect and undamaged condition, clean and sterile.

During the surgery:
1. The surgeon has to follow the surgical instructions. In the area of the spinal cord and of the nerve roots, extreme caution should be exercised.
2. During the surgery, an imaging technique is to be used.

After the surgery:
1. The patient has to receive precise instructions regarding the correct use as well as information about the limits of the implant. In addition, the patient should be informed about the restrictions he or she has to observe after the surgery. The patient should be warned that he or she may not fall or strain his or her back too much.
2. Any decision concerning the removal of the implant should also include the taking into account of the risks relating to any new surgery.

Instructions for surgeries:
1. Position the patient in prone or lateral position (depending on the preference of the surgeon).
2. Ensure that the imaging equipment may be used smoothly for the setting of the segments.
3. Generously disinfect the puncture site with a suitable disinfectant and observe the prescribed exposure time.
4. Cover the surgical field with sterile material.
5. Now position the spinal needle using a posterolateral access and an imaging technique.
   Attention: Only the supplied spinal needle is compatible with the implant. Do not bend or break the needle.
6. A discography is contraindicated as the contrast agent influences the swelling behavior of the implant.
7. After an optimal placement of the spinal needle (centered in the spinal disk in anterior-posterior position and lateral path of rays) please check the patency of it by completely pulling out and reinserting the stylet several times. Leave the stylet in the needle until the placement of the implant.
8. Pull the stylet out of the needle and place the implant individually in the needle.
9. Using the stylet, push the implant stick right up to the spinal disk.
10. Repeat step 8 and 9 in order to insert the remaining implant sticks into the spinal disk.
11. After the placement of the last implant stick, pull out the spinal needle and cover the puncture site with a sterile patch (adhesive dressing)

osmed gmbh
Ehrenbergstraße 11
98693 Ilmenau
Phone: +49 3677/668631
Fax: +49 3677/668639

Distribution Aureus Medical GmbH
Schatzbogen 33
81829 Munich
Phone: +49 89 4568940-0
Fax: +49 89 4568940-10

EXPLANATION OF THE GRAPHIC SYMBOLS:

Symbol	Meaning
	Do not reuse
	Caution, consult accompanying documents.
	Use before
	Manufacturer
LOT	Batch number
REF	Article number
STERILE R	Sterilized by means of radiation
STERILE EO	Sterilized using ethylene oxide
	Do not sterilize again
	Do not use if packaging is damaged
CE	CE Marking
	Phone number
	Fax number
16G	Spinal cannula size 16 ITP Bochum