**Informed Consent of the Patient to Perform Selective Nerve Root Blocks or Facet Denervation under CT Control by the Composition of Ozone and Oxygen**

**on……………………………………………..**

**Mr/Ms……………………………………………**

**Birth Certificate Number …………………………………………**

**Weight………………… kg Height…………………… cm**

**Examining Physician…………………………………….**

**This is to confirm that MUDr……………………………….. requested for you the above-mentioned special interventional procedure which is carried out by a qualified radiologist.**

**Information on the Nature of the Disease:**

**The patient claims that he/she has been informed about the nature of their disease by their examining (attending) physician and that they have been explained the reasons why they should undergo the examination.**

 **The patient also declares that all possible further questions have been answered by the physician performing the procedure.**

**Nature and Aim of the Examination: the essence is targeted application of the healing composition of 27 µg/ml of ozone and oxygen into the nerve root which causes clinical difficulties or medical procedure on the intervertebral joint causing difficulties. The effect should be reduction or disappearance of the symptoms.**

**Expected Benefits: reduce the pain that is caused by the irritation of the affected nerve root or inflammation in the facet joint. It should be noted that the effect is usually not permanent, but can be long-lasting.**

**Description of the Procedure: The procedure is performed in local anesthesia. The patient lies still, it takes about 20 minutes. First, by using computerized tomography, the place causing difficulties is found. The competent nerve root or intervertebral joint is inserted with a needle and healing composition. The insertion of the needle and application of the composition may be accompanied by pain which disappears when the procedure finishes. After the examination, if there are no complications, the patient stays still on their back for about 30 minutes and after that they can leave.**

**Risks and Complications during the Procedure:**

* **application of the healing composition intrathecally (into the dural sac) with the following temporary flaccid paralysis of the relevant place and necessary short-term hospitalization at neurosurgical or neurology department (mostly overnight)**
* **inflammatory complications are extremely rare**
* **unwanted application of the healing composition into a blood vessel has minimal risk, although there may occur occasional toxic and allergic reactions**

**Pregnancy:**

**Women aged 15 – 45 hereby confirm by their signature that they are not pregnant nor are likely to be pregnant, as this is a procedure associated with ionizing radiation and there is a risk of serious harm to the fetus.**

**Alternative Possibilites:**

**The root injection under CT control is performed when non-invasive medical and rehabilitation procedures are no longer effective. The alternative to the indicated cases could be open neurosurgical procedure or classical injection of the composition of anesthetics and corticosteroids.**

**The patient confirms that they have been informed about the advantages and disadvantages of the alternative procedures by their attending physician.**

**Additional Questions of the Patient:**

**The right to refuse the proposed procedure: after talking to your doctor you have the right to disagree with the proposed procedure. If you do not give your consent, your physician will you all the possible consequences and will make a record which you both sign.**

**Consent of the Patient:**

1. **I confirm that I have answered all the questions of the examining physician truthfully and have not withheld anything.**
2. **I confirm that I have been thoroughly informed about the above-mentioned procedure, its side effects and in case of complications I agree with all interventions necessary to remove them and thus to save my life or health.**
3. **I confirm that I have been given the possibility to ask the staff follow-up questions that have been satisfactorily answered.**
4. **I confirm that I have been given the possibility:**
* **to give up the information about my health**
* **to identify persons to whom such information may be provided**
* **to express prohibition on the provision of such information to another person.**
1. **I agree with sending my medical report or image documentation electronically to the physician who requested the examination.**
2. **I have been informed about the amount of the payment.**

**I confirm that I have been informed by the above-mentioned physician about the nature and expected outcome of the procedure. I have been given to ask questions and all of them have been satisfactorily answered. Based on the discussion and this information I confirm that I fully understand the proposed procedure.**

**I agree with the implementation of the above-mentioned procedure and I have been informed about its possible risks. Because of the side-effects it is not recommended to drive a motor vehicle within 24 hours after the procedure.**

**I have been informed about the fact that the proposed method of treatment may cause health complications or consequences.**

**I agree with the publication of the data collected during the treatment, in scientific publications, exclusively anonymously. I agree with transfer of findings and data to other physicians, healthcare facilities, health insurances to the extend permitted by the law on data protection should my next treatment require it.**

**Based on this instruction I declare that I fully understand the proposed procedure. I leave the choice of the process which should lead to better treatment to the physician – radiologist and cooperating staff.**

**In ……………. on……………. …………………………………………..**

**Patient’s Signature (guardian for minors)**

**The statement of the examining (attending) physician: I declare that I have the aforementioned patient (or their guardian) informed in an understandable manner about the nature of the disease, the expected outcome of the procedure including alternative options and their advantages and disadvantages.**

**On………………….. Physician’s Name, Surname and Signature ……………………………………**

**The statement of the physician performing the procedure: I declare that I have the aforementioned patients (or their guardian) informed in an understandable manner about the planned procedure including warnings about possible complications. All questions have been answered.**

**On……………………. Physician’s Name, Surname and Signature……………………**