

	<p style="text-align: center;"><b>MEDIOX GmbH.</b> D-82166 Gräfelfing, Am Kirchhölzl 14.</p>	<p style="text-align: center;"><b>PMCF-S-INFO ENG v01</b></p>
<p><b>Released: 2016.01.01.</b></p>	<p style="text-align: center;"><b>Mediox Products follow up protocol Spine</b></p>	<p style="text-align: center;"><b>Page:1/1</b></p>

## Information about Mediox Products follow up protocol

The details of the patient pre and post op follow up should be recorded to the Mediox's Medical Record form (**PMCF-S-MR**). The following forms should be given to the doctor who is filling out the medical record:

- Medical Record form – **PMCF-S-MR**
- Information about Mediox Products follow up protocol – **PMCF-S-INFO**
- Neck Disability Index Questionnaire – **PMCF-S-NDI (in case of cervical products)**
- Oswestry Disability Index Questionnaire – **PMCF-S-ODI**
- Visual Analogue Scale – **PMCF-S-VAS**

Due to protection of personal data the patient has to have a unique id number. This id number should be generated in the following way:

The first two letters are the patient's monogram, then the birth year in 4 digits followed by the exact date of the operation. *(E.g. If the patient was born in 1960 and the monogram is KJ and the operation was performed in 2013.01.20. then the patient id is : KJ1960130120)*

Controlling protocol after the operation:

1. OP – day 0
2. 6 weeks X-ray control, maybe CT
3. 3 months X-ray control, maybe CT
4. 6 months X-ray control, maybe CT
5. 12 months X-ray control, maybe CT
6. Yearly X-ray control, maybe CT

The radiological evaluation should be performed at the time of injury or in case of chronic degeneration at the time of affiliation, then after the operation evaluate the results.

The records should be provided to Mediox after all control examination.

***The manufacturer has to be informed in occurrence of the following events:***

- Breakage of implant or external fixation device
- Allergic reaction to the implant
- Frequent operation failure (more than 5%)
- Early implant loosening
- Frequent septic complications (more than 5 %).
- Bad bone healing result, significantly higher complication rate than the other methods, which is described in the scientific literature.