

**Collective Information Notice Regarding the SNDS Post-Registration Study for the Monitoring of Patients Who Underwent Arthroplasty with the MOBI-C® PLUG&FIT Cervical Disc Prosthesis (MOBI-C® PLUG&FIT EPI)**

In accordance with the provisions of Article 14 GDPR, this collective information notice describes the measures implemented for studies that do not permit personal information and that require access to data from the SNDS (*Système National des Données de Santé* — National Health Data System).

**- Data Controller**

LDR Médical SAS, a single-shareholder simplified joint-stock company, with a capital of 280,591.40 euro, with its registered address at Parc d'Entreprises du Grand Troyes, Quartier Europe de l'Ouest, 5 rue de Berlin, 10300 Sainte-Savine, France, registered in the Troyes Trade and Companies Register under number Troyes B 433 924 529, in its capacity as data controller, is conducting a study using medical administrative databases.

**- Legal Basis**

In accordance with Article 6 GDPR and Article 5 of the French Data Protection Act, the data handled for this study is based on the legitimate interest of LDR Médical SAS, as a healthcare company, in pursuing objectives related to healthcare research, studies, evaluations and innovation.

In accordance with Article 9 GDPR, the processing of such personal data concerning health is for scientific research purposes; on April 25, 2024, the CESREES (*Comité Ethique et Scientifique pour les Recherches, les Etudes, et les Évaluations en Santé* — Ethics and Scientific Committee for Research, Studies and Evaluations in Healthcare) stated that the study was in the public interest (dossier number 17130925).

The study was authorized by the CNIL (*Commission Nationale de l'Informatique et des Libertés* — National Commission for Information and Freedoms) in accordance with Article 66 of Law no. 78-17, referred to as the "Data Protection Act," of January 6, 1978, as amended (Decision DR-2024-215; August 13, 2024).

**- Purpose of Processing**

The objective of this project is to provide additional real-life safety information in order to assess the outcomes of patients who underwent a cervical arthroplasty with the MOBI-C® PLUG&FIT prosthesis, and to compare the efficacy and healthcare resource use in these patients against those who underwent more conventional treatment in the form of ACDF (anterior cervical discectomy and fusion).

**- Data Source and Categories of Data**

This notice concerns all health-related research, studies and evaluations that use data from the SNDS related to healthcare expenditure in outpatient and inpatient settings for 99% of the French population. The SNDS includes:

- Outpatient care reimbursement data and reference data (SNIIRAM [*Système National d'Information Inter Régimes de l'Assurance Maladie* — Inter-Plan National Information System for Health Insurance] database),
- Hospital data (PMSI [*Programme de Médicalisation des Systèmes d'Information* — IT System Medicalization Program]).

The data processed in the SDNS is data relating to hospitalizations (condition responsible for hospitalization and associated comorbidities) and/or data relating to reimbursed outpatient care (medical consultations, treatment delivery, medical procedures, etc.).

In accordance with the requirements of the CSP (*Code de la Santé Publique* — French Public Health Code), the personal data contained in these databases do not identify the individuals that they relate to.

Additionally, the studies are only conducted through research laboratories or research offices that comply with the requirements of the CNIL.

Only the staff of the research laboratory and the research office may access the data, in accordance with professional secrecy and in accordance with Articles 226-13 and 223-14 of the French Penal Code. Under no circumstances will the data controller have direct or indirect access to such personal data.

- **Data Retention Period**

In relation to conducting SNDS projects, the data retention period is 8 years, covering the duration of the project.

- **Data Processor and Recipients**

The data is made available by the CNAM (*Caisse Nationale d'Assurance Maladie* — National Health Insurance Fund) on the CNAM secure IT portal for the designated data processor, HORIANA. Only those who are authorized to process SNDS data and authorized to process project data will be able to access it.

- **Data Transfer**

The individual data will only be accessible via the CNAM secure IT portal and will not be transferred outside the European Union.

- **Exercise of Rights and Complaints**

You have the right of access, rectification, objection and erasure relating to your data, as well as a right to restrict the processing of your data.

In accordance with the CSP, to exercise your rights and if you wish to object to the processing of your data for the purposes of this project, please contact the director of your regional health insurance fund directly.

You also have the right to file a complaint with the CNIL online or by mail to 3 Place de Fontenoy — TSA 80715 — 75334 PARIS CEDEX 07 — France.

Finally, the data controller has appointed a personal data protection officer, who can be contacted at the following address: [privacy.emea@highridgemedical.com](mailto:privacy.emea@highridgemedical.com)