

A Retrospective and prospective, observational (non-interventional), post-authorization Safety cohort study to evaluate the incidence of the breakages and insertion/Removal complications of buprenorphine implants in routine clinical care (RE-START)

**First published:** 19/04/2024

**Last updated:** 09/02/2026

Study

Discontinued

## Administrative details

**EU PAS number**

EUPAS1000000092

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**Study ID**

1000000092

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**DARWIN EU® study**

No

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## Study countries

Italy

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## Study description

RE-START study, under real world conditions, aims to describe the rate of breakage of Sixmo® implants occurring during the observation period. The study population consists of adult patients with a diagnosis of opioid dependence and treated with Sixmo® as part of their routine clinical care, according to the approved Summary of Product Characteristics (SmPC).

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## Study status

Discontinued

# Research institutions and networks

## Institutions

L. Molteni & C. dei Fratelli Alitti Società di Esercizio  
S.p.A.

## Contact details

### Study institution contact

RE-START study Team RE-START@moltenifarma.it

**Study contact**

[RE-START@moltenifarma.it](mailto:RE-START@moltenifarma.it)

## Primary lead investigator

Claudio Leonardi

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 03/05/2024

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### Study start date

Actual: 10/06/2024

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### Date of final study report

Planned: 31/12/2026

Actual: 30/01/2026

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

The Sponsor of RE-START study is L. Molteni & C. dei Fratelli Alitti Società di Esercizio S.p.A.

(Address: Strada Statale 67 - Loc. Granatieri 50018 Scandicci (Fi), Italy)

## Regulatory

**Was the study required by a regulatory body?**

Yes

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**Is the study required by a Risk Management Plan (RMP)?**

EU RMP category 1 (imposed as condition of marketing authorisation)

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**Regulatory procedure number**

EMA/H/C/PSA/S/0097

Methodological aspects

Study type

Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Safety study (incl. comparative)

**Study design:**

Multi-centre, retrospective and prospective cohort, observational (non-interventional) PASS

**Main study objective:**

The primary objective is:

- To describe the rate of breakage of Sixmo® implants (endpoint: all implant breakages reported as occurring during the treatment period, whether or not associated with adverse events linked to Sixmo® implant).

## Study Design

### **Non-interventional study design**

Cohort

## Study drug and medical condition

### **Medicinal product name**

SIXMO

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### **Study drug International non-proprietary name (INN) or common name**

BUPRENORPHINE

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### **Anatomical Therapeutic Chemical (ATC) code**

(N07BC01) buprenorphine

buprenorphine

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### **Additional medical condition(s)**

Opioid dependence

## Population studied

## Short description of the study population

Study population will consist of alive male and female patients aged 18 years or over, with a diagnosis of opioid dependence and treated with Sixmo® as part of their routine clinical care, according to the approved Summary of Product Characteristics (SmPC).

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## Age groups

- **Adult and elderly population ( $\geq 18$  years)**
    - Adults (18 to < 65 years)
      - Adults (18 to < 46 years)
      - Adults (46 to < 65 years)
    - Elderly ( $\geq 65$  years)
      - Adults (65 to < 75 years)
      - Adults (75 to < 85 years)
      - Adults (85 years and over)
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## Estimated number of subjects

120

## Data management

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Use of a Common Data Model (CDM)

## **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

Unknown