

# PHYSIUM

## Observational Safety Study

Our purpose was to evaluate the incidence of adverse reactions from 2011 to 2013 and the safety of FISIUM into the miofascial lesions.

We conducted a retrospective observational study of a selected group of Spanish physiotherapists that agreed to participate in the study in their physiotherapeutic centers.

Incidents were collected with use of a multifaceted approach including direct continuous observation. 17 physicians independently assessed incident type, severity, and preventability as well as systems-related and individual performance failures.

FISIUM Safety Study was conducted as part of the FISIUM Safety Report from January 2011 to January 2013. The study occurred in the physiotherapeutic centers. Patients who needed a therapy massage for their myofascial lesions were included. Patient-related data were confidential. Patients were treated with FISIUM, in sessions of 60 minutes once a week. The primary method of data collection was the direct continuous observation method. Physiotherapists experienced in direct observation, and they followed the on-call continuously. The primary outcomes of interest were the incidence and rates of adverse events. . All available US cases reported during the period of the study were reviewed and analysed for this safety report. A descriptive statistical analysis was performed. We calculated the number, percentage, and type of patient safety incidents identified.

### RESULTS

A total of 9.411 patients in 14 Spanish physiotherapeutic centers were studied. 41.677 physiotherapy sessions were applied. Each patient received an average of 4,6 treatment sessions.

We observed a total of 202 (2,15 %) adverse events.

	<b>Total</b>
Number of physiotherapists	<b>14</b>
Patients included	<b>9411</b>
Total number of sessions	<b>41677</b>
Sessions per patient (average)	<b>4,5</b>

<b>Adverse events</b>	<b>Total</b>	<b>Incidence (per 10.000 patients)</b>	<b>Incidence (per 10.000 sessions)</b>
Pain during treatment	84	89,26	20,51
Hematomas	22	23,38	5,28
Dermal injury by applicators	19	20,19	4,56
Lace	10	10,63	2,4
Cefalea	8	8,52	1,92
Tiredness	50	53,13	12
Paresthesia	4	4,25	0,96
Visceral sensitivity	2	2,13	0,48
Dizziness	1	1,06	0,24
Vomit	1	1,06	0,24
Vertigo	1	1,06	0,24
<b>Total adverse events /Physiotherapist</b>	<b>202</b>	<b>214,65</b>	<b>48,5</b>

No adverse effects that threaten life or safety of the patient were reported. The most common side effects were pain during treatment in 84 patients (89,3 per 10.000 patients) reported by 11/14 physiotherapists, dermal injury by applicators 19 (20,2 per 10.000 patients) reported by 6/14 physiotherapists and hematomas 22 (23,4 per 10.000 patients) reported by 5/14 physiotherapists. The 84 patients (89,3 per 10.000 patients) who presented pain at the onset of the first session of treatment were mild and improve or disappear after the second session. A physiotherapist has indicated that occurs during the execution of stretching. Some therapists hypothesized that the pain is due to the application of inappropriate pressure (too high) and consider the pain a result of misuse of FISIUM. The 19 (20,2 per 10.000 patients) of dermal injury are produced by the applicators, especially in those patients with sensitive skin and/ or poorly hydrated ones. This dermal lesion is also observed in patients treated with more massage intensity. 22 (23,4 per 10.000 patients) hematomas are minor and occurred more frequently with the use of head rolling aesthetic, and most frequently in areas like psoas, abductors near groin or popliteal area.

The other injuries like lace, tiredness, paresthesia, visceral sensitivity, dizziness, vomits and vertigo were reported only for only 1/14 physiotherapists.

These AE must be interpreted in the context of the limitations of all day-to-day data collection, such as uncertain causality, incomplete medical information, under-reporting, unverified diagnoses, duplicate reports, and confounders (for example, disease severity, concomitant medications).

### **Conclusions:**

This study help characterize the safety profile of FISIUM in this group of patients with miofascial lesions.

This study suggests that massage therapy with FISIUM is a well-tolerated, safety option in patients with miofascial lesions that need to be treated with massage.