

## **APPENDICES TO THE REPORT**

## APPENDIX 1 - MODE OF ACTION AND EFFECTS OF LUMBAR BELTS

The effects of lumbar belts take place on three levels: biomechanical, muscular and subjective.

### 1) The biomechanical action of lumbar belts includes several effects:

#### **- *Increasing intra-abdominal pressure (IAP) with a corollary reduction in intervertebral disc compression.***

The increase in abdominal pressure could engender a redistribution of forces exerted on the lumbar spine. Lumbar belts which increase the rigidity of the abdominal cavity intensify this mechanism (23). Thus, lumbar belts promote an increase in IAP (24) and so have a preventive effect on back injuries incurred when lifting loads.

There is no consensus on the hypothesis that a lumbar belt increases IAP (23, 25).

#### *- Reduction in lumbar spine mobility.*

Most of the studies show that lumbar belts reduce lateral and rotational mobility of the lumbar column but have a lesser limiting effect on extension and flexion of the torso (17, 24, 26, 27, 28).

The beneficial aspects of limiting mobility are often reported in the adoption of safer work postures from the support provided by lumbar belts (29).

The limiting of lumbar mobility explains the analgesic effect of a lumbar belt (30).

Finally, lumbar belts reduce the speed and acceleration of torso movements and require progressive mobilisation (25).

### 2) The muscular effects:

A lumbar belt has three types of effects on the muscular system:

- *Change in electromyographic activity (EMG):* If the lumbar belt increases IAP and this increase results in a reduction of the forces exerted on the lumbar spine, the result must be a reduction in EMG activity of the erector spinae when lifting loads. The studies do not show any effect of the lumbar belt on reducing the EMG activity of the erector spinae (31, 32, 33).
- *Effect on strength and stamina:* the studies conclude that wearing a lumbar belt has no effect on strength or stamina (34, 35, 36).
- *Effect of increasing the maximum ability of lifting a load:* the studies show a trend regarding an increase in the capacity to lift brought about by the wearing of a lumbar belt (37).

### 3) Subjective effects and comfort of a lumbar belt

Immobilisation of the torso has an analgesic effect (38).

In addition to this analgesic effect, lumbar belts induce a feeling of comfort (30, 39). These subjective effects promote use of the lumbar belt; however, since they are subjective, these effects depend on each individual person and each context in which the lumbar belt is used.

## APPENDIX 2 - TESTED DEVICE

### REINFORCED LUMBAR BELT FOR POSTURE SUPPORT

#### **Properties:**

- **(Patented) elastic Combitex® fabric enables optimum removal of perspiration to the outside.**
- Cross-wise fabric straps (postural support).
- Rigid, anatomically shaped reinforcing stays at the rear (made of spring steel)
  
- Adjustable auxiliary device enables the level of dorsal support to be increased.

#### **Indications:**

- Acute and subacute low back pain and ischialgia.
- **Post-intervention and post-immobilization lumbar support.**

#### **Instructions for use:**

- Undo the touch and close (Velcro) fastening straps on the sides.
- Put on the belt, with the inside label facing upwards.
- *Close the belt using the touch and close ventral tab (the touch and close fastening properly fitting without folds or creases).*
- Adjust the dorsal support using the touch and close tabs on the sides.

#### **Precautions:**

Follow the advice of the professional who prescribed or delivered the device. It may be necessary to shape the stays. In case of discomfort, consult this professional.

Store at room temperature, preferably in the original box.

**For reasons of hygiene and performance, we strongly advise against reuse of this device for treating another patient. Any reuse occurs on the sole responsibility of the person making the decision to reuse the device and automatically results in loss of the Thuasne guarantee.**

#### **Care:**

- Wash in soapy water only, without detergent or bleach.
- Wring to remove water.
- Dry away from a heat source.

#### **Materials:**

31 % polyamide, 28 % polyester, 21 % viscose, 20 % spun elastane.

#### **Regulatory aspect:**

**The Lombacross Activity belt is a class 1 medical device, "CE" mark in accordance with Directive 93/42/EEC.**

In France the cost of the belt is refunded by the French national health and pension organisation as a "standard abdominal support belt" ("ceinture de soutien abdominal de série"). List of refundable products, devices and services (Nomenclature Liste des Produits et Prestations Remboursables) (LPPR): Code 201E00.022



Waist measurement	Height
52 – 62 cm	1
63 – 74 cm	2
75 – 89 cm	3
90 – 105 cm	4
106 – 120 cm	5
121 – 140 cm	6

## **APPENDIX 3 - QUESTIONNAIRES**

The questionnaires in this appendix are:

- the initial inclusion questionnaire
- the questionnaire for the D30 visit

The questionnaires used on D60 and D90 are identical with the one used on D30. The only exception at D60 is that the VAS data was not recorded and EIFEL questionnaire was not issued.

**Inclusion Visit****INCLUSION CRITERIA***Tick one box for each question*

- Men or women between 20 and 60 years of age Yes <sub>1</sub> **if No**<sub>2</sub> → **exclusion**
- Care/treatment for an initial or recurring non-specific low back pain Yes <sub>1</sub> **if No**<sub>2</sub> → **exclusion**
- Episode lasting 1 to 3 months Yes <sub>1</sub> **if No**<sub>2</sub> → **exclusion**
- No contraindications to step I or step II analgesics, NSAID, benzodiazepines and thiolchicoside Yes <sub>1</sub> **if No**<sub>2</sub> → **exclusion**
- Agreement to participate in the study (consent form explained and signed) Yes <sub>1</sub> **if No**<sub>2</sub> → **exclusion**

If one of the questions is answered with **NO**, **DO NOT INCLUDE** the patient in the trial

**NON-INCLUSION CRITERIA***Tick one box for each question*

- Patient has used a lumbar belt during the past 6 months No <sub>2</sub> **if Yes**<sub>1</sub> → **exclusion**
- Patient who has low back pain with irradiation beyond the knee and/or accompanied by signs neurological signs, including sciatica No <sub>2</sub> **if Yes**<sub>1</sub> → **exclusion**
- Patient has suffered from a low back pain episode during the 6 months prior to inclusion No <sub>2</sub> **if Yes**<sub>1</sub> → **exclusion**
- Patient has had a spinal operation during the 5 years preceding inclusion No <sub>2</sub> **if Yes**<sub>1</sub> → **exclusion**
- Patient who has low back pain as a side-effect of an accident at work No <sub>2</sub> **if Yes**<sub>1</sub> → **exclusion**
- Patients who have a history of spinal arthrodesis No <sub>2</sub> **if Yes**<sub>1</sub> → **exclusion**
- Patient with a chronic cardiac complaint or respiratory complaint, unbalanced or symptomatic No <sub>2</sub> **if Yes**<sub>1</sub> → **exclusion**
- Patient suffering from low back pain with an inflammatory, tumoural or infectious cause No <sub>2</sub> **if Yes**<sub>1</sub> → **exclusion**
- Patient who has a contraindication to step I or step II analgesic, NSAID, benzodiazepines and thiolchicoside No <sub>2</sub> **if Yes**<sub>1</sub> → **exclusion**
- Patient is pregnant No <sub>2</sub> **if Yes**<sub>1</sub> → **exclusion**
- Patient whose higher functions do not enable them to properly comprehend the protocol or to reliably record the data No <sub>2</sub> **if Yes**<sub>1</sub> → **exclusion**

If one of the questions is answered with **YES**, **DO NOT INCLUDE** the patient in the trial

**Inclusion Visit****Inclusion date**

|\_|\_|/|\_|\_|/|\_|\_|

**(DD/MM/YY)****Date on which consent signed**

|\_|\_|/|\_|\_|/|\_|\_|

**(DD/MM/YY)****Allocation of treatment to the patient takes place exclusively by means of call to vocal server.**

To find out the treatment allocated to your patient, please call the (freephone) green number (follow the instructions opposite) and enter the treatment allocated by the vocal server below.

**Patient is a member of:****Group 1 (TG)** <sub>1</sub>**Group 2 (control)** <sub>2</sub>**Socio-demographic data****Age:** |\_|\_|\_| years**Sex:** Male <sub>1</sub>Female <sub>2</sub>**Marital status:**Married/cohabitation <sub>1</sub>Divorced <sub>2</sub>**Weight (kg):** |\_|\_|\_|. |\_| kgSingle <sub>3</sub>**Height (cm):** |\_|\_|\_| cmWidowed <sub>4</sub>**Occupational status and socio-occupational categories****Current occupational status**<sub>1</sub> In full-time employment<sub>2</sub> In part-time employment<sub>3</sub> Retired (due to ill health)<sub>4</sub> Retired (due to age)<sub>5</sub> Unemployed<sub>6</sub> No paid employment<sub>7</sub> School pupil/Student<sub>8</sub> Other (please specify): \_\_\_\_\_**Socio-occupational category**Farmer <sub>1</sub>Craftsmen, businessmen, heads of companies <sub>2</sub>Executive, professional <sub>3</sub>Managers, senior staff <sub>4</sub>(Salaried) employees <sub>5</sub>Workers <sub>6</sub>Other (please specify) \_\_\_\_\_ <sub>7</sub>

**Inclusion Visit****Level of education**

- <sub>1</sub> Primary school
 <sub>3</sub> Baccaulaureate (A-levels) or final year of secondary school level
- <sub>2</sub> CAP (vocational training certificate) - BEP (vocational studies certificate)
 <sub>4</sub> BAC (baccaulaureate) + 2 (qualification after basic studies)
 <sub>5</sub> Higher than BAC + 2

**Social security cover**♦ **What is the patient's current social security cover?**

- <sub>1</sub> Social security only
- <sub>2</sub> Social security and mutual insurance
- <sub>3</sub> Social security and private insurance
- <sub>4</sub> CMU (Couverture médicale universelle - universal health insurance cover)
- <sub>5</sub> Other (please specify)

**Way of life and general state of health****Smoking**

What is the patient's smoking status?

- Has never smoked <sub>1</sub>
- Former smoker <sub>2</sub>
- Smoker <sub>3</sub>
- } Number of years as smoker | | |
- } Average number of cigarettes smoked per day | | |

**Alcohol consumption**

What is the patient's status vis-à-vis the consumption of alcohol?

- Has never consumed alcohol <sub>1</sub>
- No longer consumes alcohol <sub>2</sub>
- Occasional drinker <sub>3</sub>
- Regular drinker <sub>4</sub>
- } Number of years of consumption | | |
- } Number of units of alcohol consumed per day\* | | |

\* 1 unit of alcohol is about equal to a half a pint (280 ml) of ordinary strength beer or cider, 1 glass (125 ml) of wine, 1 measure (70 ml) of fortified wine (port) or 1 measure (25 ml) of gin or vodka, whisky or other spirits.

**Inclusion Visit****Physical activity**

The patient regularly takes part in one or more sports activity?


<sub>1</sub> Yes

<sub>2</sub> No

If yes, on average, how many hours per week do they take part in this (these) sports activity(ies)?

| | | hours

**Occupational activities**

Does the patient have to carry heavy loads within the scope of their employment?

<sub>1</sub> Yes

<sub>2</sub> No

<sub>3</sub> Not applicable

Does the patient work with strong vibrations within the scope of their employment?

<sub>1</sub> Yes

<sub>2</sub> No

<sub>3</sub> Not applicable
**General state of health**

By and large, the patient considers **their health** to be?

<sub>1</sub> Excellent

<sub>2</sub> Very good

<sub>3</sub> Good

<sub>4</sub> Below average

<sub>5</sub> Bad
**Medical history****Personal medical history**

- ◆ Has the patient already had one or several bouts of sciatica? <sub>1</sub> Yes <sub>1</sub> No
- ◆ Has the patient already had surgical intervention on their spine? <sub>1</sub> Yes <sub>1</sub> No



If yes,

- ◆ When did this intervention take place (including nucleolysis, nucleotomy) ?

(complete with the known accuracy)

| | | / | | | / | | | (DD/MM/YY)



**Inclusion Visit**

- ◆ Has the patient already received medical treatment for these episodes of low back pain?



<sub>1</sub> Yes      <sub>2</sub> No

**If yes**, what preventive and/or therapeutic measures did the patient receive within the scope of their previous episodes (apart from the current episode) ?

	<b>Yes</b>	<b>No</b>
<b>Medical consultations</b> (GP and/or specialist)	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
<b>Additional examinations</b>		
X-rays	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
Biological tests	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
<b>Medication received</b>	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
<i>Step I or II or III analgesics</i>	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
<i>NSAID</i>	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
<i>Spasmolytic drugs</i>	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
<i>Anti-depressants</i>	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
<i>Corticoids</i>	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
<i>Other(s) (please specify).....</i>	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
.....		
<b>Non-medication treatments</b>		
Infiltrations	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
Vertebral manipulations	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
Vertebral traction	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
Kinesitherapy	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
Physiotherapy	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
Course of thermal treatment	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
Wearing a lumbar support belt	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
Acupuncture	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
Wearing a lift insert in the shoe	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
<i>Other(s) (please specify).....</i>	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
.....		

- ◆ Has the patient already been hospitalised for low back pain or as a direct consequence of their low back pain?



<sub>1</sub> Yes      <sub>2</sub> No

**If yes**, please complete the following table:

Main reason for hospitalisation	Duration of hospitalisation (number of nights)
1	
2	
3	

**Inclusion Visit**

♦ Has the patient already had sick leave due to low back pain?

<sub>1</sub> Yes

<sub>2</sub> No

<sub>3</sub> Not applicable



**If yes**, how many sick days has the patient already had due to low back pain | | |

**On average**, how long did these periods of sick leave last? | | | days

**Associated pathologies**

Does the patient currently have one or more associated pathologies (apart from their low back pain)?

<sub>1</sub> Yes

<sub>2</sub> No



**If yes**, please tick the box corresponding to the device/system and state the diagnosis(es)

Cardio-vascular system .....	<input type="checkbox"/> <sub>1</sub>	Psychiatry .....	<input type="checkbox"/> <sub>2</sub>
Respiratory system .....	<input type="checkbox"/> <sub>3</sub>	Skeleton and muscles .....	<input type="checkbox"/> <sub>4</sub>
Urinary and genital system .....	<input type="checkbox"/> <sub>5</sub>	Digestive system .....	<input type="checkbox"/> <sub>6</sub>
Cancer .....	<input type="checkbox"/> <sub>7</sub>	Immune system .....	<input type="checkbox"/> <sub>8</sub>
ENT .....	<input type="checkbox"/> <sub>9</sub>	Central nervous system .....	<input type="checkbox"/> <sub>10</sub>
Skin and appendages .....	<input type="checkbox"/> <sub>11</sub>	Metabolic disorders .....	<input type="checkbox"/> <sub>12</sub>
		Other(s) .....	<input type="checkbox"/> <sub>13</sub>

**Inclusion Visit****Medical data concerning the current low back pain**

- ◆ On which date did the current low back pain episode occur? | \_ | \_ | / | \_ | \_ | / | \_ | \_ | (DD/MM/YY)

(please enter with the known accuracy, at least the year)

- ◆ What factor is responsible for the patient's current low back pain episode?

	<b>Yes</b>	<b>No</b>
Carrying heavy loads	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
Physical effort other than carrying a load	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
Stress and/or anxiety	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
Incorrect movements	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
Accident	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
Nothing in particular	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
Other(s) .....	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>

- ◆ What is the current intensity of the low back pain on the visual analog scale?

.....mm

- ◆ **Description of the low back pain**

		<b>Yes</b>	<b>No</b>
Type	Very localised	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
	Diffuse	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
Seat of the pain	Lower lumbar spine, median	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
	Lower lumbar spine, lateralised	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
Rhythm	Diurnal	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
	Nocturnal	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
	All the time	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
Circumstances at the beginning	Sudden	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
	Progressive	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
	Immobile	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
	During movement	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
Worsening during movements	Anteflexion	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
	Extension	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
	When seated	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
	When lying down	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
Duration	Intermittent	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
	Persistent	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>

**Inclusion Visit**

Other(s)

<sub>1</sub><sub>2</sub>♦ **Physical examinations: Study of lumbar spine mobility**

		<b>No limitation</b>	<b>Limitation without pain</b>	<b>Slightly painful limitation</b>	<b>Painful limitation</b>	<b>Very painful limitation</b>
<b>Flexion mobility</b>	Forward flexion	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>
	Extension	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>
<b>Lateral inclination mobility</b>	Lateroflexion (lateral inclination) to the right	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>
	Lateroflexion (lateral inclination) to the left	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>
<b>Rotational mobility</b>	Rotation to the right	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>
	Rotation to the left	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>

**Inclusion Visit****Patient's current treatment****◆ Consultations**

Since the start of this episode of low back pain, how many times has the patient consulted physicians due to their low back pain or as a direct consequence of their pain (including this consultation) ?

**Number of consultations**

- <sub>1</sub> GP | | |
- <sub>2</sub> Rheumatologist or physical medicine specialist | | |
- <sub>3</sub> Other (s), please specify:..... | | |
- ..... | | |
- <sub>4</sub> No consultation

**◆ Additional examinations (biological tests and/or investigations)**

Since the start of this episode of low back pain, how many examinations from the list given below have been carried out on the patient for their low back pain or as a direct consequence of their pain (apart from the prescribed investigations for during this current consultation) ?

**Number of examinations**

- <sub>1</sub> X-ray of the spine (please specify the incidences)..... | | |
- <sub>2</sub> Bone scintigraphy | | |
- <sub>3</sub> Lumbar MRI | | |
- <sub>4</sub> Computer tomography (CT or CT scan) of the lumbar spine | | |
- <sub>5</sub> CBC (complete blood count) | | |
- <sub>6</sub> Erythrocyte sedimentation rate (ESR) | | |
- <sub>7</sub> Inflammatory protein profile (CRP) | | |
- <sub>8</sub> Other (s), please specify:..... | | |
- ..... | | |
- <sub>9</sub> No examinations/tests

**Inclusion Visit**

♦ **Hospitalisation**

Since the start of this episode of low back pain, has the patient been hospitalised due to their low back pain or as a direct consequence of their pain?



<sub>1</sub> Yes

<sub>2</sub> No

If yes, please complete the following table:

Main reason for hospitalisation	Duration of hospitalisation (number of nights)
1	
2	
3	

♦ **Non-medication treatments**

Since the start of this episode of low back pain, has the patient received any non-medication treatment for their low back pain or as a direct consequence of their pain (apart from those prescribed for during this current consultation)?

<sub>1</sub> Yes

<sub>2</sub> No



If yes, please complete the list given below, specifying the number of sessions that have taken place

**Number of sessions**

<sub>1</sub> Vertebral manipulations

| | |

<sub>2</sub> Vertebral traction

| | |

<sub>3</sub> Kinesitherapy

| | |

<sub>4</sub> Physiotherapy (please specify the nature of the treatment).....

| | |

<sub>5</sub> Infiltrations (epidural or others)

| | |

<sub>6</sub> Other (s), please specify:.....

| | |

..... | | |

<sub>7</sub> No non-medication treatment

Since the start of this episode of low back pain, has the patient received any courses of thermal treatment for their low back pain or as a direct consequence of their pain (apart from any possibly prescribed during this current consultation)?



<sub>1</sub> Yes

<sub>2</sub> No

If yes, please specify the duration of this course of treatment

| | | days

**Inclusion Visit**

- ♦ **Medication taken by the patient since the start of the current low back pain and medication in progress for the low back pain or as a direct consequence of the low back pain**

Class	Brand name	Dosage	Form <sup>1</sup>	Daily dose	Start date (DD/MM/YY)	End date or CONT (DD/MM/YY)	Reason for stopping <sup>2</sup> (circle)
<b>Step I or II or III analgesics</b>				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
<b>NSAID</b>				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
<b>Spasmolytic drugs or Myorelaxants</b>				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A

<sup>1</sup> CP: tablet; GEL: capsule; SI: syrup; SB: solution to be taken orally; PO: ointment; CR: cream; IM: intramuscular; IV: intravenous; SC: subcutaneous; TD: transdermal

<sup>2</sup> Reasons for stopping the treatment: E: Insufficient efficacy; T: Poor tolerance; O: Poor patient compliance; A: Other

## Inclusion Visit

Class	Brand name	Dosage	Form <sup>1</sup>	Daily dose	Start date (DD/MM/YY)	End date or CONT (DD/MM/YY)	Reason for stopping <sup>2</sup>
Corticoids				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
Anti-depressants				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
Gastroprotectants				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
Other (please specify)			Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A	
Other (please specify)			Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A	
Other (please specify)			Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A	
Other (please specify)			Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A	

<sup>1</sup> GEL: capsule; SI: syrup; SB: solution to be taken orally; PO: ointment; CR: cream; IM: intramuscular; IV: intravenous; SC: subcutaneous; TD: transdermal

<sup>2</sup> Reasons for stopping the treatment: E: Insufficient efficacy; T: Poor tolerance; O: Poor patient compliance; A: Other



**Inclusion Visit**

**Treatments prescribed for the low back pain, or as a direct consequence of the low back pain, at the end of this consultation**

♦ **Additional examinations (biological tests and/or investigations) prescribed at the end of this consultation**

- <sub>1</sub> X-ray of the spine (please specify the incidences).....
- <sub>2</sub> Bone scintigraphy
- <sub>3</sub> Lumbar MRI
- <sub>4</sub> Computer tomography (CT or CT scan) of the lumbar spine
- <sub>5</sub> CBC (complete blood count)
- <sub>6</sub> Erythrocyte sedimentation rate (ESR)
- <sub>7</sub> Inflammatory protein profile (CRP)
- <sub>8</sub> Other (s), please specify:.....  
.....
- <sub>9</sub> No examinations/tests

♦ **Non-medication treatment prescribed at the end of this consultation (apart from the lumbar support belt for patients in group 1)**

**Number of sessions**

- <sub>1</sub> Vertebral manipulations | \_ | \_ |
- <sub>2</sub> Vertebral traction | \_ | \_ |
- <sub>3</sub> Kinesitherapy | \_ | \_ |
- <sub>4</sub> Physiotherapy (please specify the nature of the treatment)..... | \_ | \_ |
- <sub>5</sub> Infiltrations (epidural or others) | \_ | \_ |
- <sub>6</sub> Other (s), please specify:..... | \_ | \_ |  
..... | \_ | \_ |
- <sub>7</sub> Course of thermal treatment, if yes, please specify the duration | \_ | \_ | days
- <sub>8</sub> No non-medication treatment

### Inclusion Visit

- ♦ **Medication prescribed to the patient for their low back pain, or as a direct consequence of their low back pain, at the end of this consultation (please also mention any current treatments you stop)**

Class	Brand name	Dosage	Form <sup>1</sup>	Daily dose	Start date (DD/MM/YY)	End date or CONT (DD/MM/YY)	Reason for stopping <sup>2</sup> (circle)
Step I or II or III analgesics				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
NSAID				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
Spasmolytic drugs or Myorelaxants				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A

<sup>1</sup> CP: tablet; GEL: capsule; SI: syrup; SB: solution to be taken orally; PO: ointment; CR: cream; IM: intramuscular; IV: intravenous; SC: subcutaneous; TD: transdermal

<sup>2</sup> Reasons for stopping the treatment: E: Insufficient efficacy; T: Poor tolerance; O: Poor patient compliance; A: Other

## Inclusion Visit

Class	Brand name	Dosage	Form <sup>1</sup>	Daily dose	Start date (DD/MM/YY)	End date or CONT (DD/MM/YY)	Reason for stopping <sup>2</sup>
Corticoids				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
Anti-depressants				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
Gastroprotectants				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
				Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A
Other (please specify)			Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A	
Other (please specify)			Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A	
Other (please specify)			Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A	
Other (please specify)			Dose/day:	_ _ / _ _ / _ _	_ _ / _ _ / _ _	E T O A	

<sup>1</sup> GEL: capsule; SI: syrup; SB: solution to be taken orally; PO: ointment; CR: cream; IM: intramuscular; IV: intravenous; SC: subcutaneous; TD: transdermal

<sup>2</sup> Reasons for stopping the treatment: E: Insufficient efficacy; T: Poor tolerance; O: Poor patient compliance; A: Other

**Inclusion Visit**

♦ **Sick leave prescribed at the end of the present consultation**



<sub>1</sub> Yes

<sub>2</sub> No

<sub>3</sub> Not applicable

**If yes**, please specify the duration (in days) of this sick leave

| \_ | \_ | days

**Date:** / \_ / \_ / / \_ / \_ / \_ / (DD/MM/YY)

**Signature of the investigating physician:**

**Date of the next visit:** / \_ / \_ / / \_ / \_ / \_ / (DD/MM/YY)

**Visit D30**

Date of the visit:D30: | | / | | / | | (DD/MM/YY)

Is the patient continuing with the study? <sub>1</sub> Yes <sub>2</sub>No



If no, please complete the following:

**Reasons for ceasing their participation:**

- Death: <sub>1</sub>

If yes, please specify the date: | | / | | / | | (DD/MM/YY)

Cause of death: .....

- Loss of eyesight: <sub>2</sub>

Date of last contact: | | / | | / | | (DD/MM/YY)

- Other(s) (please specify).....

**Clinical condition of the low back pain**

- ♦ What is the current intensity of the low back pain on the visual analog scale?  
.....mm

☛ If the patient is a member of group G1 with lumbar belt, please answer the questions on the following two pages (pages 20 and 21) and then continue on page 23.

☛ If the patient is a member control group G2, without a lumbar belt, please go directly to page 22.

**Visit D30**

I. ASSESSMENT OF WEARING THE BELT

*To ensure the study is completed smoothly and well and for subsequent interpretation of the results, it is important for the patient to honestly report the true assiduity with which they wear the belt.*

**Patient compliance**

- ◆ During the past four weeks, on average, on how many days **per week** did the patient wear the belt? | \_ |
- ◆ On the days on which the patient wore their belt, how many hours on average did they wear it? | \_ | \_ |
- ◆ On average, how many times a day has the patient had to tighten their belt before an exertion? | \_ | \_ |

**Comfort/discomfort**

- ◆ Does wearing the belt cause the patient any discomfort?

	Yes	No
Persistently	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
At the end of the day	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
At work	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
While carrying out certain daily activities (apart from work)	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
Only during certain movements (please specify) .....	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
Other circumstance(s) (please specify).....	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>

- ◆ Does wearing the belt engender an analgesic effect? <sub>1</sub> Yes <sub>2</sub>No

- ◆ Does wearing the belt result in any of the following effects?:

	Yes	No
Spinal stability	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
A safe/secure feeling	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
Limitation of movement	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
Relaxation/ease	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>

- ◆ Does the patient feel any impression of heat due to wearing the belt? <sub>1</sub> Yes <sub>2</sub>No



**Visit D30**

If yes, is this feeling?

<sub>1</sub> Pleasant

<sub>2</sub> Unpleasant

- ◆ What are the disadvantages for the patient caused by wearing the belt?

	Yes	No
Belt slips upwards	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
Difficult to put on	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
Discomfort during work	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
Unsightly/unaesthetic	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>
Other(s) (please specify)..... .....	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>

**Belt and movements**

- ◆ Wearing the belt enables the patient:

	A lot	A little	Not at all
To move correctly	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>
To maintain a good position	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>
To avoid painful movements	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>

- ◆ The patient appreciates wearing the belt during:

	A lot	A little	Not at all
Handling work	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>
Physical activities	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>
While driving a car	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>
While taking part in sports	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>
Other situation(s) ..... .....	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>

**Overall satisfaction**

- ◆ By and large, how satisfied is the patient with the lumbar belt?

<sub>1</sub> Very satisfied

<sub>2</sub> Fairly satisfied

<sub>3</sub> Fairly dissatisfied

<sub>4</sub> Not at all satisfied

**Wearing the belt**

**Visit D30**

*To ensure the study is completed smoothly and well and for subsequent interpretation of the results, it is important for the patient to honestly report their true attitude to possibly wearing a belt.*

- ◆ Have you used a lumbar belt during the past four weeks?

<sub>1</sub> Yes      <sub>2</sub> No



**If yes,**

- ◆ On average, on how many days during the past four weeks have you worn it?

? | | | days

**Visit D30****Use of treatments since the last visit**♦ **Consultations**

Since the last visit, has the patient consulted a physician concerning their low back pain or as a direct consequence of their pain?

**Number of consultations**

- <sub>1</sub> GP | | |
- <sub>2</sub> Rheumatologist or physical medicine specialist | | |
- <sub>3</sub> Other (s), please specify: ..... | | |
- ..... | | |

♦ **Additional examinations (biological tests and/or investigations)**

Since the last visit, how many of the examinations listed below has the patient had for their low back pain or as a direct consequence of their pain?

**Number of examinations**

- <sub>1</sub> X-ray of the spine (please specify the incidences)..... | | |
- <sub>2</sub> Bone scintigraphy | | |
- <sub>3</sub> Lumbar MRI | | |
- <sub>4</sub> Computer tomography (CT or CT scan) of the lumbar spine | | |
- <sub>5</sub> CBC (complete blood count) | | |
- <sub>6</sub> Erythrocyte sedimentation rate (ESR) | | |
- <sub>7</sub> Inflammatory protein profile (CRP) | | |
- <sub>8</sub> Other (s), please specify: ..... | | |
- ..... | | |
- <sub>9</sub> No examinations/tests

♦ **Hospitalisation**

Since the last visit, has the patient been hospitalised due to their low back pain or as a direct consequence of their pain?

<sub>1</sub> Yes<sub>2</sub> No

**If yes**, please complete the following table:

Main reason for hospitalisation	Duration of hospitalisation (number of nights)
1	
2	
3	

Visit D30

◆ Non-medication treatments

Since the last visit, has the patient received any non-medication treatments for their low back pain or as a direct consequence of their pain?



<sub>1</sub> Yes

<sub>2</sub> No

If yes, please complete the list given below, specifying the number of sessions that have taken place

Number of sessions

<sub>1</sub> Vertebral manipulations

|\_|\_|

<sub>2</sub> Vertebral traction

|\_|\_|

<sub>3</sub> Kinesitherapy

|\_|\_|

<sub>4</sub> Physiotherapy (please specify the nature of the treatment).....

|\_|\_|

<sub>5</sub> Infiltrations (epidural or others)

|\_|\_|

<sub>6</sub> Other (s), please specify:.....

|\_|\_|

.....|\_|\_|

<sub>7</sub> Course of thermal treatment, if yes, please specify the duration |\_|\_| days

<sub>8</sub> No non-medication treatment

## Visit D30

## ♦ Medication received

Since the last visit, has the patient taken medication linked with their low back pain or for a direct consequence of their pain? <sub>1</sub> Yes <sub>2</sub> No



If yes, please give, for each therapeutic category, the commercial name, dosage and duration of the treatment of each specialised field:

Therapeutic category	Brand name	Dose	Form <sup>1</sup>	Daily dosage (e.g.: 2 tablets/day)	Duration of treatment (in days)
<b>Step I or II or III analgesics</b>				..... / day	days
				..... / day	days
				..... / day	days
				..... / day	days
<b>NSAID</b>				..... / day	days
				..... / day	days
				..... / day	days
				..... / day	days
<b>Spasmolytic drugs or Myorelaxants</b>				..... / day	days
				..... / day	days
				..... / day	days
				..... / day	days
<b>Gastroprotectants</b>				..... / day	days
				..... / day	days
				..... / day	days
<b>Corticoids</b>				..... / day	days
				..... / day	days
				..... / day	days
<b>Anti-depressants</b>				..... / day	days
				..... / day	days
				..... / day	days
<b>Other</b> (please specify)				..... / day	days
<b>Other</b> (please specify)				..... / day	days
<b>Other</b> (please specify)				..... / day	days



## APPENDIX 4 - EIFEL QUESTIONNAIRE

### QUESTIONNAIRE FOR ASSESSING THE FUNCTIONAL CAPACITY OF SUFFERERS OF LOW BACK PAIN

#### EIFEL

We would like to find out about the repercussions of your low back pain on your capacity to carry out every day activities.

*If you were confined to your bed due to your low back pain*, tick this box  
and the stop .....

On the other hand, if you can get up and stay standing for at least a few moments, please complete the following questionnaire.

---

A list of sentences is suggested on the following page.

These sentences describe certain *difficulties* experienced in carrying out an *everyday physical activity directly linked to your low back pain*.

Read these sentences carefully, one by one, bearing in mind the condition you are in *today* because of your low back pain.

If you read a sentence which aptly describes a difficulty affecting you *today*, tick it.....

Otherwise, leave the box empty and move on to the next sentence.....

Please remember to only tick the sentences which apply to you *today*.

---

1. I spend virtually all my time at home due to my back.....
2. I often change my position to relieve my back.....
3. Because of my back I walk more slowly than usual .....
4. Because of my back I am unable to do any of the tasks I usually do at home...
5. Because of my back I use the banisters to help me climb the stairs.....
6. Because of my back I often lie down to rest.....
7. Because of my back I have to use a support to get up from a chair.....
8. Because of my back I try to get others to do things instead of me.....
9. Because of my back I get dressed more slowly than usual.....
10. Because of my back I only stay standing for a few moments.....
11. Because of my back I try to neither bend down nor kneel down .....
12. Because of my back I have trouble getting up from a chair.....
13. I have backache most of the time.....
14. Because of my back I have trouble turning over in bed.....
15. Because of my backache I have less appetite.....
16. Because of my backache I have trouble putting on my shoes (or stockings/tights).....
17. Because of my backache I can only walk short distances.....
18. Because of my backache I sleep less .....
19. Because of my backache somebody helps me to get dressed.....
20. Because of my backache I stay seated most of the day.....
21. Because of my back I avoid doing any major work at home.....
22. Because of my back I am more irritable than usual and am in a bad mood with others.....
23. Because of my back I climb the stairs more slowly than usual.....
24. Because of my back I stay in bed most of the time.....

Coste J, Le Parc JM, Berge E, et al. French validation of a functional incapacity scale for assessing low back pain (échelle d'incapacité fonctionnelle pour l'évaluation des lombalgies - EIFEL). Rev Rhum [Ed. Fr.], 1993, 60(5):335-41.

## APPENDIX 5 - LIST OF EXPERTS

### **Steering committee:**

Chairman of the committee: Prof. Claude Le Pen

Scientific advisor: Prof. Patrice Queneau, CHU Bellevue, Saint-Etienne

Main investigating clinical physician: Dr. Paul Calmels, Saint-Etienne

### Other members of the committee:

Prof. Bernard Avouac, Rheumatology Unit, Créteil

Prof. Claude Hamonet, CHU Mondor, Medical Rehabilitation Unit, Créteil

Prof. Philippe Thoumie, Rotschild Hospital, Neuro-Orthopaedic Rehabilitation Unit, Paris 12 ème.

**APPENDIX 6 - OFFICIAL ADMINISTRATIVE DOCUMENTS**  
(CNIL NOTICE, CNOM, CCPRB)

## APPENDIX 7 - REPRESENTATION OF THE INVESTIGATING PHYSICIANS

REGIONS	Lomba-Cross Activity Study				SNIR* - All independent GPs Metropolitan France without Corsica (year 2003)	
	GPs who have agreed to participate		GPs active in the study		Actual (n=53952)	%
	Actual (n=61)	%	Actual (n=44)	%		
Alsace	1	1.6%	1	2.3%	1696	3.1%
Aquitaine	7	11.5%	6	13.6%	3037	5.6%
Auvergne	1	1.6%	1	2.3%	1232	2.3%
Basse Normandie	1	1.6%	1	2.3%	1194	2.2%
Bourgogne	0	0.0%	0	0.0%	1372	2.5%
Bretagne	4	6.6%	3	6.8%	2689	5.0%
Centre	2	3.3%	1	2.3%	1954	3.6%
Champagne-Ardenne	4	6.6%	3	6.8%	1114	2.1%
Franche-comté	0	0.0%	0	0.0%	1073	2.0%
Haute-Normandie	0	0.0%	0	0.0%	1477	2.7%
Île-de-France	3	4.9%	2	4.5%	8368	15.5%
Languedoc-Roussillon	2	3.3%	2	4.5%	2769	5.1%
Limousin	3	4.9%	3	6.8%	820	1.5%
Lorraine	3	4.9%	1	2.3%	2065	3.8%
Midi-Pyrénées	2	3.3%	1	2.3%	2820	5.2%
Nord-Pas-de-Calais	1	1.6%	0	0.0%	3852	7.1%
PACA	10	16.4%	6	13.6%	5387	10.0%
Pays de la Loire	7	11.5%	4	9.1%	2772	5.1%
Picardie	1	1.6%	1	2.3%	1488	2.8%
Poitou-charentes	1	1.6%	1	2.3%	1556	2.9%
Rhone-Alpes	8	13.1%	7	15.9%	5217	9.7%
<b>Total</b>	<b>61</b>	<b>100.0%</b>	<b>44</b>	<b>100.0%</b>	<b>53952</b>	<b>100.0%</b>

\*IRDES-EcoSante2005-Régions

## APPENDIX 8 - ITT POPULATION/ PP POPULATION

The main results in PP are presented below.

### Socio-demographic data of the lumbar belt group

Belt group		PP		Non-PP	
Variables		N=102	n1=90	n2=12	P
<b>Age</b>	Average (ET)	43 (11.0)	44 (10.5)	42 (14.6)	0.550
	Median	47	47	44	
<b>Sex</b>	Male	56 (54.9%)	53 (58.9%)	3 (25.0%)	<b>0.027 *</b>
	Female	46 (45.1%)	37 (41.1%)	9 (75.0%)	
<b>Weight</b>	Average (ET)	75 (16.6)	76 (16.9)	72 (13.8)	0.550
	Median	74	74	70	
<b>Height</b>	Average (ET)	170 (8.7)	171 (8.7)	166 (8.5)	0.067
	Median	170	171	168	
<b>Marital status</b>					
	Married / cohabitation	75 (73.5%)	67 (74.4%)	8 (66.7%)	0.204
	Divorced	9 (8.8%)	9 (10.0%)	0 (0.0%)	
	Single	18 (17.6%)	14 (15.6%)	4 (33.3%)	
	Widowed				

Social security cover		PP		Non-PP	
Variables		N=102	n1=90	n2=12	P
<b>Social security cover</b>					
	Social security only	4 (3.9%)	3 (3.3%)	1 (8.3%)	0.837
	Social security & mutual insur'	84 (82.4%)	75 (83.3%)	9 (75.0%)	
	Social security & private insurance	7 (6.9%)	6 (6.7%)	1 (8.3%)	
	CMU (universal medical cover)	7 (6.9%)	6 (6.7%)	1 (8.3%)	

<b>Level of education, occupational status and SOC</b>				
<b>Variables</b>	<b>N=102</b>	<b>PP (n=90)</b>	<b>Non-PP (n=12)</b>	<b>P</b>
<b>Level of education</b>				
Primary school	8 (7.8%)	8 (8.9%)	0 (0.0%)	0.791
CAP-BEP	52 (51.0%)	45 (50.0%)	7 (58.3%)	
Bac or final year of sec.ed	15 (14.7%)	13 (14.4%)	2 (16.7%)	
BAC+2	14 (13.7%)	13 (14.4%)	1 (8.3%)	
Higher than BAC+2	13 (12.7%)	11 (12.2%)	2 (16.7%)	
<b>Occupational status</b>				
In full-time employment	64 (62.7%)	60 (66.7%)	4 (33.3%)	0.133
In part-time employment	12 (11.8%)	9 (10.0%)	3 (25.0%)	
Retired (due to ill health)	3 (2.9%)	3 (3.3%)	0 (0.0%)	
Retired (due to age)	6 (5.9%)	4 (4.4%)	2 (16.7%)	
Unemployed	10 (9.8%)	8 (8.9%)	2 (16.7%)	
No occupational activity	4 (3.9%)	4 (4.4%)	0 (0.0%)	
School pupil/Student	1 (1.0%)	1 (1.1%)	0 (0.0%)	
Other	2 (2.0%)	1 (1.1%)	1 (8.3%)	
<b>SOC (socio-occupational category)</b>				
Missing	6	6	0	0.877
Farmer	4 (4.2%)	4 (4.8%)	0 (0.0%)	
Craftsmen, businessmen, company	8 (8.3%)	7 (8.3%)	1 (8.3%)	
Executives, professionals	12 (12.5%)	11 (13.1%)	1 (8.3%)	
Other	5 (5.2%)	4 (4.8%)	1 (8.3%)	
(Salaried) employees	34 (35.4%)	29 (34.5%)	5 (41.7%)	
Workers	17 (17.7%)	16 (19.0%)	1 (8.3%)	
Managers, senior staff	16 (16.7%)	13 (15.5%)	3 (25.0%)	
Other	10 (5.5%)	5 (5.2%)	5 (5.7%)	

**Socio-demographic data of the control group**

<b>Control group</b>		<b>PP</b>		<b>Non-PP</b>	
<b>Variables</b>		<b>N=95</b>	<b>n1=81</b>	<b>n2=14</b>	<b>P</b>
<b>Age</b>	Average (ET)	43 (10.5)	44 (10.0)	39 (12.1)	0.067
	Median	45	45	41	
<b>Sex</b>	Male	52 (54.7%)	43 (53.1%)	9 (64.3%)	0.437
	Female	43 (45.3%)	38 (46.9%)	5 (35.7%)	
<b>Weight</b>	Average (ET)	71 (13.9)	71 (14.1)	73 (12.9)	0.676
	Median	69	68	72	
<b>Height</b>	Average (ET)	169 (8.7)	169 (8.9)	171 (7.4)	0.524
	Median	170	170	172	
<b>Marital status</b>					
	Married / cohabitating	70 (73.7%)	61 (75.3%)	9 (64.3%)	0.716
	Divorced	7 (7.4%)	6 (7.4%)	1 (7.1%)	
	Single	15 (15.8%)	12 (14.8%)	3 (21.4%)	
	Widowed	3 (3.2%)	2 (2.5%)	1 (7.1%)	

<b>Social security cover</b>		<b>PP</b>		<b>Non-PP</b>	
<b>Variables</b>		<b>N=102</b>	<b>n1=90</b>	<b>n2=12</b>	<b>P</b>
<b>Social security cover</b>					
	Social security only	4 (4.2%)	3 (3.7%)	1 (7.1%)	0.537
	Social security & mutual insur'	81 (85.3%)	68 (84.0%)	13 (92.9%)	
	Social security & private insurance	7 (7.4%)	7 (8.6%)	0 (0.0%)	
	CMU (universal medical cover)	3 (3.2%)	3 (3.7%)	0 (0.0%)	

Level of education, occupational status and SOC		Belt group		
Variables	N=102	PP (n=90)	Non-PP (n=12)	P
<b>Level of education</b>				
Primary school	5 (5.3%)	4 (4.9%)	1 (7.1%)	0.972
CAP-BEP	48 (50.5%)	41 (50.6%)	7 (50.0%)	
Bac or final year of sec.ed	12 (12.6%)	10 (12.3%)	2 (14.3%)	
BAC+2	11 (11.6%)	9 (11.1%)	2 (14.3%)	
Higher than BAC+2	19 (20.0%)	17 (21.0%)	2 (14.3%)	
<b>Occupational status</b>				
In full-time employment	71 (74.7%)	59 (72.8%)	12 (85.7%)	0.828
In part-time employment	8 (8.4%)	8 (9.9%)	0 (0.0%)	
Retired (due to age)	4 (4.2%)	3 (3.7%)	1 (7.1%)	
Unemployed	3 (3.2%)	3 (3.7%)	0 (0.0%)	
No occupational activity	7 (7.4%)	6 (7.4%)	1 (7.1%)	
School pupil/Student	1 (1.1%)	1 (1.2%)	0 (0.0%)	
Other	1 (1.1%)	1 (1.2%)	0 (0.0%)	
<b>SOC (socio-occupational category)</b>				
Missing	8	7	1	0.614
Farmer	1 (1.1%)	1 (1.4%)	0 (0.0%)	
Craftsmen, businessmen, company	10 (11.5%)	10 (13.5%)	0 (0.0%)	
Executives, professionals	14 (16.1%)	12 (16.2%)	2 (15.4%)	
Managers, senior staff	13 (14.9%)	11 (14.9%)	2 (15.4%)	
(Salaried) employees	24 (27.6%)	20 (27.0%)	4 (30.8%)	
Workers	20 (23.0%)	15 (20.3%)	5 (38.5%)	
Other	5 (5.7%)	5 (6.8%)	0 (0.0%)	

**Current medical data - responsible factors: belt group**

Variables	N=102	PP		Non-PP	P
		n1=90	n2=12		
<b>Duration since episode started</b>					
Average (ET)	49.86 (18.392)	50.03 (18.975)	48.58 (13.813)		0.799
Median	45.50	45.50	46.50		
<b>Carrying a heavy load</b>	46 (45.1%)	39 (43.3%)	7 (58.3%)		0.327
<b>Physical effort other than carrying a load</b>	30 (29.4%)	25 (27.8%)	5 (41.7%)		0.321
<b>Stress and/or anxiety</b>	20 (19.6%)	19 (21.1%)	1 (8.3%)		0.295
<b>Incorrect movements</b>	31 (30.4%)	26 (28.9%)	5 (41.7%)		0.366
<b>Accident</b>	0	0	0		
<b>Nothing in particular</b>	12 (11.8%)	10 (11.1%)	2 (16.7%)		0.575
<b>Other(s)</b>	13 (12.7%)	13 (14.4%)	0 (0.0%)		0.159

**Current medical data - responsible factors: Control group**

Variables	N=102	PP		Non-PP	P
		n1=90	n2=12		
<b>Duration since episode started</b>					
Average (ET)	49.83 (16.857)	49.69 (17.039)	50.64 (16.359)		0.846
Median	46.50	46.00	48.50		
<b>Carrying a heavy load</b>	32 (33.7%)	28 (34.6%)	4 (28.6%)		0.661
<b>Physical effort other than carrying a load</b>	25 (26.3%)	20 (24.7%)	5 (35.7%)		0.387
<b>Stress and/or anxiety</b>	19 (20.0%)	17 (21.0%)	2 (14.3%)		0.563
<b>Incorrect movements</b>	35 (36.8%)	29 (35.8%)	6 (42.9%)		0.613
<b>Accident</b>	0	0	0		
<b>Nothing in particular</b>	16 (16.8%)	15 (18.5%)	1 (7.1%)		0.294
<b>Other(s)</b>	7 (7.4%)	7 (8.6%)	0 (0.0%)		0.253

### Associated pathologies: Belt group

Associated pathologies	PP		Non PP	
Variables	N=95	n1=81	n2=14	P
<b>Associated pathology?</b>	38 (37.6%)	34 (38.2%)	4 (33.3%)	
Missing	1	1	0	0.744
<b>Cardio-vascular system</b>	13 (12.7%)	12 (13.3%)	1 (8.3%)	0,626
<b>Psychiatry</b>	5 (4.9%)	4 (4.4%)	1 (8.3%)	0.558
<b>Respiratory system</b>	4 (3.9%)	3 (3.3%)	1 (8.3%)	0.402
<b>Skeleton and muscles</b>	2 (2.0%)	2 (2.2%)	0 (0.0%)	0.602
<b>Urinary and genital system</b>	1 (1.0%)	1 (1.1%)	0 (0.0%)	0.714
<b>Digestive system</b>	7 (6.9%)	7 (7.8%)	0 (0.0%)	0.317
<b>Cancer</b>	0	0	0	NS
<b>Immune system</b>	0	0	0	NS
<b>ENT</b>	1 (1.0%)	1 (1.1%)	0 (0.0%)	0.714
<b>Central nervous system</b>	1 (1.0%)	1 (1.1%)	0 (0.0%)	0.714
<b>Skin and appendages</b>	1 (1.0%)	1 (1.1%)	0 (0.0%)	0.714
<b>Metabolic disorders</b>	17 (16.7%)	16 (17.8%)	1 (8.3%)	0.410
<b>Other(s)</b>	2 (2.0%)	1 (1.1%)	1 (8.3%)	0.090

### Associated pathologies: Control group

Associated pathologies	PP		Non PP	
Variables	N=95	n1=81	n2=14	P
<b>Associated pathology?</b>	33 (34.7%)	29 (35.8%)	4 (28.6%)	0.600
<b>Cardio-vascular system</b>	9 (9.5%)	9 (11.1%)	0 (0.0%)	
<b>Psychiatry</b>	4 (4.2%)	4 (4.9%)	0 (0.0%)	
<b>Respiratory system</b>	1 (1.1%)	0 (0.0%)	1 (7.1%)	
<b>Skeleton and muscles</b>	2 (2.1%)	2 (2.5%)	0 (0.0%)	
<b>Urinary and genital system</b>	1 (1.1%)	1 (1.2%)	0 (0.0%)	
<b>Digestive system</b>	4 (4.2%)	4 (4.9%)	0 (0.0%)	
<b>Cancer</b>	0	0	0	NS
<b>Immune system</b>	0	0	0	NS
<b>ENT</b>	2 (2.1%)	1 (1.2%)	1 (7.1%)	
<b>Central nervous system</b>	3 (3.2%)	2 (2.5%)	1 (7.1%)	
<b>Skin and appendages</b>	3 (3.2%)	2 (2.5%)	1 (7.1%)	
<b>Metabolic disorders</b>	10 (10.5%)	9 (11.1%)	1 (7.1%)	
<b>Other(s)</b>	0	0	0	NS

**APPENDIX 9 – MEDICAL HISTORY:**  
**Medical treatment received for previous episodes**

Medical treatment received for previous episodes

Treatment for previous episodes (1)		<i>Belt group</i>		<i>Control group</i>		
Variables		N=197	n1=102	n2=95		P
<b>Medical treatment for this pain</b>	Yes	153 (78.1%)	73 (72.3%)	80 (84.2%)		<b>0.044 *</b>
	Missing	1	1	0		
<b>Medical consultations</b>	Yes	147 (74.6%)	70 (68.6%)	77 (81.1%)		0.125
	Not applicable	43 (21.8%)	28 (27.5%)	15 (15.8%)		
<b>Additional examinations X-rays</b>	Yes	117 (59.4%)	55 (53.9%)	62 (65.3%)		0.127
	Not applicable	43 (21.8%)	28 (27.5%)	15 (15.8%)		
<b>Additional examinations Biol. tests</b>	Yes	72 (36.5%)	39 (38.2%)	33 (34.7%)		0.051
	Not applicable	43 (21.8%)	28 (27.5%)	15 (15.8%)		
<b>Medical treatment</b>	Yes	142 (72.1%)	68 (66.7%)	74 (77.9%)		0.139
	Not applicable	43 (21.8%)	28 (27.5%)	15 (15.8%)		
<b>Analgesics I and II</b>	Yes	148 (75.1%)	72 (70.6%)	76 (80.0%)		0.107
	Not applicable	43 (21.8%)	28 (27.5%)	15 (15.8%)		
<b>NSAID</b>	Yes	132 (67.0%)	63 (61.8%)	69 (72.6%)		0.138
	Not applicable	43 (21.8%)	28 (27.5%)	15 (15.8%)		
<b>Spasmolytic drugs</b>	Yes	126 (64.0%)	60 (58.8%)	66 (69.5%)		0.137
	Not applicable	43 (21.8%)	28 (27.5%)	15 (15.8%)		
<b>Antidepressants</b>	Yes	11 (5.6%)	5 (4.9%)	6 (6.3%)		0.139
	Not applicable	43 (21.8%)	28 (27.5%)	15 (15.8%)		
<b>Corticoids</b>	Yes	12 (6.1%)	6 (5.9%)	6 (6.3%)		0.139
	Not applicable	43 (21.8%)	28 (27.5%)	15 (15.8%)		
<b>Other(s)1</b>	Yes	3 (1.5%)	2 (2.0%)	1 (1.1%)		0.114
	Not applicable	43 (21.8%)	28 (27.5%)	15 (15.8%)		
<b>Other(s)2</b>	Yes	5 (2.5%)	3 (2.9%)	2 (2.1%)		0.121
	Not applicable	43 (21.8%)	28 (27.5%)	1 5 (15.8%)		

Treatment for previous episodes (2)		<i>Belt group</i>		<i>Control group</i>	
Variables		N=197	n1=102	n2=95	P
<b>Infiltrations</b>	Yes	11 (5.6%)	5 (4.9%)	6 (6.3%)	0.139
	Not applicable	43 (21.8%)	28 (27.5%)	15 (15.8%)	
<b>Vertebral manipulations</b>	Yes	40 (20.3%)	12 (11.8%)	28 (29.5%)	<b>0.004 *</b>
	Not applicable	43 (21.8%)	28 (27.5%)	15 (15.8%)	
<b>Vertebral traction</b>	Yes	10 (5.1%)	5 (4.9%)	5 (5.3%)	0.140
	Not applicable	43 (21.8%)	28 (27.5%)	15 (15.8%)	
<b>Kinesitherapy</b>	Yes	100 (50.8%)	48 (47.1%)	52 (54.7%)	0.141
	Not applicable	43 (21.8%)	28 (27.5%)	15 (15.8%)	
<b>Physiotherapy</b>	Yes	40 (20.3%)	13 (12.7%)	27 (28.4%)	<b>0.010 *</b>
	Not applicable	43 (21.8%)	28 (27.5%)	15 (15.8%)	
<b>Courses of thermal treatment</b>	Yes	(2.5%)	1 (1.0%)	4 (4.2%)	0.062
	Not applicable	43 (21.8%)	8 (27.5%)	15 (15.8%)	
<b>Wearing a lumbar support belt</b>	Yes	17 (8.6%)	5 (4.9%)	12 (12.6%)	<b>0.037*</b>
	Not applicable	43 (21.8%)	28 (27.5%)	15 (15.8%)	
<b>Acupuncture</b>	Yes	10 (5.1%)	5 (4.9%)	5 (5.3%)	0.140
	Not applicable	43 (21.8%)	28 (27.5%)	15 (15.8%)	
<b>Wearing a shoe lift insert</b>	Yes	14 (7.1%)	8 (7.8%)	6 (6.3%)	0.109
	Not applicable	43 (21.8%)	28 (27.5%)	15 (15.8%)	

## APPENDIX 10 – MEDICATION INTAKE

### Medication intake: Analgesics

		<i>Belt group</i>		<i>Control group</i>	
<b>Analgesics</b>	<b>N=197</b>	<b>n1=102</b>	<b>n2=95</b>	<b>P</b>	
<b>D30 n (%)</b>	<b>129 (65.5%)</b>	<b>61 (59.8%)</b>	<b>68 (71.6%)</b>	0.538	
No. of days' intake					
Avg (ET)	19 (11.1)	19 (9.9)	19 (12.2)	0.842	
In medication intake	15	15	15		
No. of days' intake	12 (12.7)	11 (11.9)	14 (13.4)	0.173	
Total medication population	10	8	10		
<b>D60 n (%)</b>	<b>102 (51.8%)</b>	<b>47 (46.1%)</b>	<b>55 (57.9%)</b>	0.428	
No. of days' intake					
Avg (ET)	17 (11.6)	15 (9.9)	19 (12.8)	0.087	
In medication intake	15	10	15		
No. of days' intake	9 (12.1)	7 (10.2)	11 (13.6)	<b>0.017*</b>	
Total medication population	2	0	6		
<b>D90 n (%)</b>	<b>79 (40.1%)</b>	<b>30 (29.4%)</b>	<b>49 (51.6%)</b>	<b>0.033*</b>	
No. of days' intake	16 (10.8)	12 (9.2)	18 (11.2)	<b>0.013*</b>	
In medication intake	15	8	15		
No. of days' intake	6 (10.2)	3 (7.3)	9 (12.0)	<b>&lt;0.001*</b>	
Total medication population	0	0	1		

### Medication intake: NSAID

		<i>Belt group</i>		<i>Control group</i>	
<b>NSAID</b>	<b>N=197</b>	<b>n1=102</b>	<b>n2=95</b>	<b>P</b>	
<b>D30 n (%)</b>	<b>87 (44.2%)</b>	<b>35 (34.3%)</b>	<b>52 (54.7%)</b>	0.068	
No. of days' intake					
Avg (ET)	15 (8.4)	13 (6.6)	16 (9.2)	0.079	
In medication intake	10	10	10		
No. of days' intake	7 (9.2)	4 (7.2)	9 (10.5)	<b>&lt;0.001*</b>	
Total medication population	0	0	7		
<b>D60 n (%)</b>	<b>29 (14.7%)</b>	<b>8 (7.8%)</b>	<b>21 (22.1%)</b>	<b>0.016*</b>	
No. of days' intake	17 (9.4)	12 (8.5)	19 (9.0)	0.057	
In medication intake	15	10	15		
No. of days' intake	3 (7.1)	1 (3.9)	4 (9.0)	<b>&lt;0.001*</b>	
Total medication population	0	0	0		
<b>D90 n (%)</b>	<b>23 (11.7%)</b>	<b>4 (3.9%)</b>	<b>19 (20.0%)</b>	<b>0.002*</b>	
No. of days' intake	13 (7.1)	11 (2.5)	13 (7.8)	0.637	
In medication intake	10	10	10		
No. of days' intake	1 (4.8)	0 (2.2)	3 (6.3)	<b>0.001*</b>	
Total medication population	0	0	0		

**Medication intake: Spasmolytic drugs**

		<i>Belt group</i>		<i>Control group</i>	
<b>Spasmolytic drugs</b>		<b>N=197</b>	<b>n1=102</b>	<b>n2=95</b>	<b>P</b>
<b>D30 n (%)</b>		<b>72 (36.5%)</b>	<b>29 (28.4%)</b>	<b>43 (45.3%)</b>	0.099
No. of days' intake	Avge.(ET)	21 (13.9)	22 (13.9)	21 (14.1)	
					0.841
In medication intake		15	15	15	
No. of days' intake	Avge.(ET)	8 (13.2)	6 (12.2)	9 (14.1)	
					0.078
Total medication population		0	0	0	
<b>D60 n (%)</b>		<b>35 (17.8%)</b>	<b>13 (12.7%)</b>	<b>22 (23.2%)</b>	0.128
No. of days' intake	Avge. (ET)	21 (11.1)	18 (7.9)	23 (12.4)	
					0.212
In medication intake		20	15	25	
No. of days' intake	Avge.(ET)	4 (9.2)	2 (6.5)	5 (11.2)	
					<b>0.023*</b>
Total medication population		0	0	0	
<b>D90 n (%)</b>		<b>25 (12.7%)</b>	<b>5 (4.9%)</b>	<b>20 (21.1%)</b>	<b>0.003*</b>
No. of days' intake	Avge.(ET)	21 (9.6)	28 (9.1)	20 (9.1)	
					0.065
In medication intake		20	30	20	
No. of days' intake	Avge. (ET)	3 (7.9)	1(6.4)	4 (9.0)	
					<b>0.015*</b>

## APPENDIX 11 – CONSULTATION

### Consultation at D30

		<i>Belt group</i>		<i>Control group</i>	
Variables		N=197		n1=102	n2=95
P					
<b>General physician</b>	Avge (ET)	1 (0.5) (n= 55)	1 (0.4) (n=21)	1 (0.5) (n=34)	0.442
<b>Rheumatologist</b>	Avge (ET)	1 (0.0) (n=4)	(n=0)	1 (0.0) (n=4)	
<b>Others</b>		(n= 0)	(n=0)	(n=0)	

### Consultation at D60

		<i>Belt group</i>		<i>Control group</i>	
Variables		N=195		n1=101	n2=94
P					
<b>General physician</b>	Avge (ET)	1 (0.2) (n=32)	1 (0.3) (n=13)	1 (0.0) (n=19)	0.233
<b>Rheumatologist</b>	Avge (ET)	1 (0.0) (n=4)	(n=0)	1 (0.0) (n=4)	
<b>Others</b>	Avge (ET)	2 (.) ( n=1)	(n=0)	2 (.) (n=1)	

### Consultation at D90

		<i>Belt group</i>		<i>Control group</i>	
Variables		N=195		n1=101	n2=94
P					
<b>General physician</b>	Avge (ET)	1 (0.3) (n=27)	1 (0.0) (n= 8)	1 (0.4) (n=19)	0.250
<b>Rheumatologist</b>	Avge (ET)	1 (0.0) (n=3)	(n=0)	1 (0.0) (n=3)	
<b>Others</b>	Avge (ET)	1 (.) (n=1)	1 (.) (n=1)	(n=0)	

## APPENDIX 12 – EXAMINATIONS/TESTS

### Examinations/Tests D30

Variables		Belt group		Control group	P
		N=196	n1=102	n2=94	
<b>X-ray of the spine</b>	Avge (ET)	2 (1.5)	2 (1.2)	2 (1.6)	
0.827		(n=18)	(n= 6)	(n=12)	
<b>Bone scintigraphy</b>		(n=0)	(n=0)	(n= 0)	
<b>Lumbar MRI</b>	Avge (ET)	1 (0.0)	1 (0.0)		
		(n=2)	(n=2)	(n=0)	
<b>Computer tomography</b>	Avge (ET)	1 (0.0)	1 (.)	1 (0.0)	
		(n=4)	(n=1)	(n= 3)	
<b>CBC</b>	Avge (ET)	1 (0.0)	1 (0.0)	1 (0.0)	
		(n=11)	(n=4)	(n=7)	
<b>Erythrocyte sedimentation rate</b>	Avge (ET)	1 (0.0)	1 (0.0)	1 (0.0)	
		(n= 8)	(n=3)	(n= 5)	
<b>Inflammatory protein profile</b>	Avge (ET)	1 (0.0)	1 (0.0)	1 (0.0)	
		(n=8)	(n=4)	(n=4)	
<b>Other(s)</b>	Avge (ET)	2 (.)		2 (.)	
		(n=1)	(n= 0)	(n=1)	

### Examinations/tests at D60

		<i>Belt group</i>		<i>Control group</i>
Variables		N=195	n1=101	n2=94
<b>X-ray of the spine</b>	Avge (ET)	1 (0.0) (n=3)	1 (0.0) (n=2)	1 (.) (n=1)
<b>Bone scintigraphy</b>		(n=0)	(n=0)	(n=0)
<b>Lumbar MRI</b>	Avge (ET)	1 (.) (n=1)	(n=0)	1 (.) (n=1)
<b>Computer tomography</b>	Avge (ET)	1 (.) (n=1)	1 (.) (n=1)	(n=0)
<b>CBC</b>	Avge (ET)	1 (.) (n=1)	(n=0)	1 (.) (n=1)
<b>Ethrocyte sedimentation rate</b>	Avge (ET)	1 (.) (n=1)	(n=0)	1 (.) (n=1)
<b>Inflammatory protein profile</b> (n=1)	Avge (ET)	1 (.)	(n=1)	1 (.) (n=0)
<b>Other(s)</b>	Avge (ET)	1 (.) (n=1)	(n=0)	1 (.) (n=1)

### Examinations/tests D90

		<i>Belt group</i>		<i>Control group</i>
Variables		N=191	n1=98	n2=92
<b>X-ray of the spine</b>	Avge (ET)	1 (0.0) (n=3)	1 (.) (n=1)	1 (0.0) (n=2)
<b>Bone scintigraphy</b>		(n=0)	(n=0)	(n=0)
<b>Lumbar MRI</b>		(n=0)	(n=0)	(n=0)
<b>Computer tomography</b>		(n=0)	(n=0)	(n=0)
<b>CBC</b>	Avge (ET)	1 (0.0) (n=3)	1 (.) (n=1)	1 (0.0) (n=2)
<b>Ethrocyte sedimentation rate</b>	Avge (ET)	1 (0.0) (n=3)	1 (.) (n=1)	1 (0.0) (n=2)
<b>Inflammatory protein profile</b> 1 (.)	Avge (ET)	1 (0.0) (n=2)	1 (.) (n=1)	1 (.) (n=1)
<b>Other(s)</b>		(n=0)	(n=0)	(n=0)

## APPENDIX 13 – NON-MEDICATION TREATMENTS

### Non-medication treatments D30

		<i>Belt group</i>		<i>Control group</i>	
Variables		N=196	n1=102	n2=94	P
<b>Has the patient received any non-medication treatments?</b>					
Yes		63 (32.1%)	23 (22.5%)	40 (42.6%)	<b>0.003*</b>
<hr/>					
<b>Vertebral manipulations</b>	Avge (ET)	2 (0.5) (n=6)	2 (.) (n=1)	1 (0.5) (n=5)	0.374
<b>Vertebral traction</b>		(n=0)	(n=0)	(n=0)	
<b>Kinesitherapy</b>	Avge (ET)	7 (2.9) (n=55)	7 (3.1) (n=20)	7 (2.8) (n=35)	0.945
<b>Physiotherapy</b>	Avge (ET)	6 (3.5) (n=2)	3 (.) (n=1)	8 (.) (n=1)	
<b>Infiltrations</b>	Avge (ET)	1 (.) (n=1)	(n=0)	1 (.) (n=1)	
<b>Other(s)</b>	Avge (ET)	1 (0.0) (n=3)	1 (0.0) (n=2)	1 (.) (n=1)	
<b>Course of treatment</b>		(n=0)	(n=0)	(n=0)	

### Non-medication treatments D60

		<i>Belt group</i>	<i>Control group</i>		
Variables	N=195	n1=101	n2=94	P	
<b>Has the patient received any non-medication treatments?</b>					
Yes	51 (26.2%)	17 (16.8%)	34 (36.2%)		<b>0.002*</b>
<b>Vertebral manipulations</b>	Avge (ET)	1 (.) (n=1)	(n=0)	1 (.) (n=1)	
<b>Vertebral traction</b>		(n=0)	(n=0)	(n=0)	
<b>Kinesitherapy</b>	Avge (ET)	6 (3.2) (n=45)	6 (3.1) (n=16)	6 (3.2) (n=29)	0.649
<b>Physiotherapy</b>	Avge (ET)	5 (3.6) (n=4)	3 (0.7) (n=2)	8 (2.8) (n=2)	0.116
<b>Infiltrations</b>	Avge (ET)	1 (0.0) (n=2)	(n=0)	1 (0.0) (n=2)	
<b>Other(s)</b>	Avge (ET)	2 (0.6) (n=3)	2 (.) (n=1)	2 (0.7) (n=2)	0.667
<b>Course of thermal treatment</b>		(n=0)	(n=0)	(n=0)	

### Non-medication treatments D90

		<i>Belt group</i>	<i>Control group</i>		
Variables	N=191	n1=98	n2=92	P	
<b>Has the patient received any non-medication treatments?</b>					
Yes	34 (17.8%)	9 (9.2%)	25 (27.2%)		<b>0.001*</b>
<b>Vertebral manipulations</b>	Avge (ET)	3 (1.0) (n=4)	2 (1.4) (n=2)	3 (0.0) (n= 2)	0.423
<b>Vertebral tractions</b>	Avge (ET)	1 (.) (n= 1)	1 (.) (n=1)	(n=0)	
<b>Kinesitherapy</b>	Avge (ET)	7 (3.4) (n=31)	6 (3.2) (n=8)	8 (3.5) (n=23)	0.297
<b>Physiotherapy</b>	Avge (ET)	8 (3.5) (n=2)	10 (.) (n=1)	5 (.) (n=1)	
<b>Infiltrations</b>		(n=0)	(n= 0)	(n=0)	
<b>Other(s)</b>	Avge (ET)	1 (.) (n=1)	(n=0)	1 (.) (n=1)	
<b>Course of treatment</b>		(n=0)	(n=0)	(n=0)	

## APPENDIX 14 – COSTS PERSPECTIVE OF PAYING BODIES IN A BROAD SENSE

### Costs of medication intake

		<i>Belt group</i>	<i>Control group</i>	
Variables n2=95	P	N=197	n1=102	
<b>D30</b>				
Avge. (ET)	19.87 (24.902)	15.32 (19.214)	24.75 (29.152)	<b>0.008 *</b>
Median	12.10	8.66	19.62	
Range	[0.00 - 197.03]	[0.00 - 80.60]	[0.00 - 197.03]	
<hr/>				
<b>D60</b>				
Avge. (ET)	8.88 (13.499)	5.91 (10.218)	12.06 (15.747)	<b>0.001*</b>
Median	2.50	0.18	4.35	
Range	[0.00 - 57.48]	[0.00 - 46.22]	[0.00 - 57.48]	
<hr/>				
<b>D90</b>				
Avge. (ET)	6.03 (10.824)	3.21 (7.670)	9.06 (12.773)	<b>&lt;0.001*</b>
Median	0.00	0.00	2.22	
Range	[0.00 - 72.39]	[0.00 - 40.84]	[0.00 - 72.39]	

### Total medication costs in €

		<i>Belt group</i>	<i>Control group</i>	
Variables n2=95	P	N=197	n1=102	
<b>Total medical costs in €</b>				
<b>D30</b>				
Avge. (ET)	63.80 (73.479)	46.88 (68.327)	81.97 (74.813)	<b>&lt;0.001 *</b>
Median	33.60	15.20	57.59	
Range	[0.00 - 321.86]	[0.00 - 313.64]	[0.00 - 321.86]	
<hr/>				
<b>D60</b>				
Avge. (ET)	34.23 (51.109)	22.80 (41.295)	46.50 (57.621)	<b>0.001 *</b>
Median	6.92	3.16	23.05	
Range	[0.00 - 212.92]	[0.00 - 170.58]	[0.00 - 212.92]	
<hr/>				
<b>D90</b>				
Avge. (ET)	27.20 (51.321)	12.75 (33.155)	42.71 (61.976)	
	<b>&lt;0.001*</b>			
Median	1.74	0.00	13.44	
Range	[0.00 - 260.28]	[0.00 - 185.37]	[0.00 - 260.28]	
<hr/>				
<b>Cumulative costs over the 3 months of the follow-up monitoring</b>				
Avge. (ET)	127.85 (138.06)	81.00 (109.61)	179.90 (148.07)	<b>&lt;0.001 *</b>
Median	76.67	29.32	142.80	
Range	[0.00 - 513.02]	[0.00 - 487.77]	[0.00 - 513.02]	

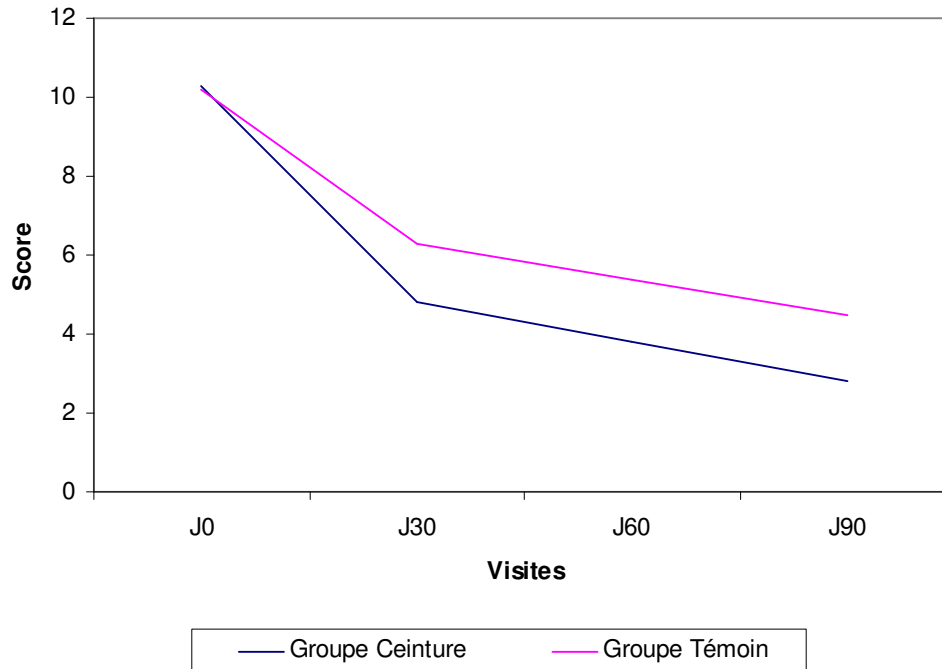
**Other medical costs**

<i>Belt group</i>	<i>Control group</i>			
<b>Variables n2=95</b>	<b>P</b>	<b>N=197</b>	<b>n1=102</b>	
<b>D30</b>				
Avge. (ET)	43.93 (64.366)	31.55 (58.463)	57.22 (67.980)	<b>0.005 *</b>
Median	0.00	0.00	25.00	
Range	[0.00 – 311.22]	[0.00 – 243.23]	[0.00 – 311.22]	
<b>D60</b>				
Avge. (ET)	25.35 (45.445)	16.89 (36.199)	34.44 (52.318)	<b>0.006 *</b>
Median	0.00	0.00	0.00	
Range	[0.00 – 191.36]	[0.00 – 142.80]	[0.00 – 191.36]	
<b>D90</b>				
Avge. (ET)	21.17 (47.454)	9.55 (29.889)	33.65 (58.579)	
	<b>&lt;0.001*</b>			
Median	0.00	0.00	0.00	
Range	[0.00 – 239.20]	[0.00 – 167.80]	[0.00 – 239.20]	

## APPENDIX 15 – MAIN RESULTS: PP (per protocol) POPULATION

### Change in Eifel score

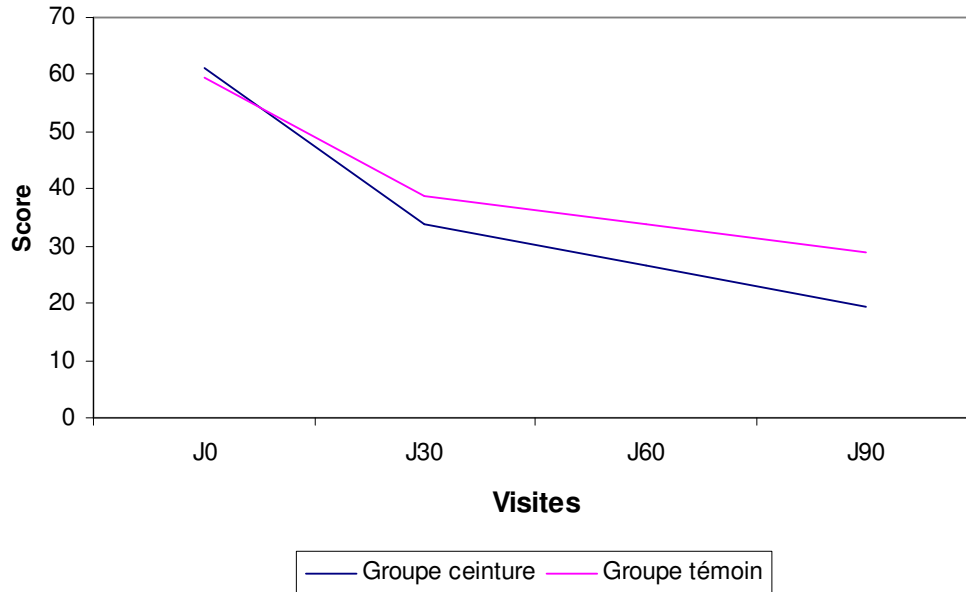
Evolution du score EIFEL entre J0 et J90 - Population PP



Change in EIFEL score		<i>Belt group</i>	<i>Control group</i>	
Variables	N=171	n1=90	n2=81	P
<b>D0 score</b>				
Average (ET)	10.3 (4.66)	10.3 (4.63)	10.2 (4.72)	0.835
Median	10.0	10.0	10.0	
Range	[0.0 - 24.0]	[1.0 - 21.0]	[0.0 - 24.0]	
<b>Change D0-D30</b>				
Average (ET)	4.7 (4.60)	5.5 (4.43)	3.9 (4.66)	<b>0.021 *</b>
Median		5.0	5.0	3.0
Range	[-8.0 - 17.0]	[-4.0 - 17.0]	[-8.0 - 16.0]	
<b>Change D0-D90</b>				
Average (ET)	6.7 (4.97)	7.5 (4.77)	5.7 (5.05)	<b>0.019 *</b>
Median	6.0	7.5	5.0	
Range	[-8.0 - 18.0]	[-3.0 - 18.0]	[-8.0 - 17.0]	
<b>Proportion responding</b>	134 (78.4%)	77 (85.6%)	57 (70.4%)	<b>0.016 *</b>

## Change in VAS score

### Evolution Score EVA entre J0 et J90 - Population PP



Change in VAS score		<i>Belt group</i>		<i>Control group</i>	
Variables	N=171	n1=90	n2=81	P	
<b>VAS score (D0)</b>					
Average (ET)	60.3 (19.17)	61.0 (18.85)	59.6 (19.62)	0.636	
Median	60.0	67.0	60.0		
Range	[8.0 - 100.0]	[10.0 - 100.0]	[8.0 - 95.0]		
<b>Change D0-D30</b>					
Average (ET)	24.2 (19.95)	27.2 (19.42)	20.8 (20.13)	<b>0.038 *</b>	
Median	23.0	29.0	20.0		
Range	[-37.0 - 70.0]	[-20.0 - 70.0]	[-37.0 - 70.0]		
<b>Change D0-D90</b>					
Average (ET)	36.5 (22.79)	41.7 (22.89)	30.7 (21.36)	<b>0.001 *</b>	
Median	37.0	40.0	30.0		
Range	[-20.0 - 89.0]	[-18.0 - 89.0]	[-20.0 - 80.0]		

## Costs

Costs of medication intake in €: Health insurance perspective

Variables	N=171	Belt group		Control group	P
		n1=90	n2=81		
<b>D30</b>					
Avg. (ET)	11.70 (15,577)	8.95 (11,050)	14.76 (19,023)		<b>15*</b>
Median	6.92	5.22	9.96		
Range	[0.00 - 127.36]	[0.00 - 44.90]	[0.00 - 127.36]		
<hr/>					
<b>D60</b>					
Avg. (ET)	5.40 (8,250)	3.43 (5,853)	7.59 (9,865)		<b>&lt;0.001 *</b>
Median	1.44	0.56	2.59		
Range	[0.00 - 34.92]	[0.00 - 28.42]	[0.00 - 34.92]		
<hr/>					
<b>D90</b>					
Avg. (ET)	3.80 (6,894)	1.93 (4,797)	5.88 (8,191)		<b>&lt;1*</b>
Median	0.00	0.00	2.27		
Range	[0.00 - 46.04]	[0.00 - 26.55]	[0.00 - 46.04]		

Other medical costs in €: Health insurance perspective

Variables	N=171	Belt group		Control group	P
		n1=90	n2=81		
<b>D30</b>					
Avg. (ET)	27.19 (41,899)	19.11 (37,634)	36.17 (44,720)		<b>0.007 *</b>
Median	0.00	0.00	13.00		
Range	[0.00 - 217.85]	[0.00 - 152.13]	[0.00 - 217.85]		
<hr/>					
<b>D60</b>					
Avg. (ET)	15.94 (28,406)	9.33 (20,732)	23.27 (33,659)		<b>0.001 *</b>
Median	0.00	0.00	0.00		
Range	[0.00 - 115.82]	[0.00 - 85.68]	[0.00 - 115.82]		
<hr/>					
<b>D90</b>					
Avg. (ET)	13.83 (29,918)	6.51 (19,226)	21.97 (36,926)		<b>&lt;0.001 *</b>
Median	0.00	0.00	0.00		
Range	[0.00 - 145.02]	[0.00 - 102.18]	[0.00 - 145.02]		

Total medical costs in €: Health insurance perspective

Total medical costs in €		<i>Belt group</i>	<i>Control group</i>	
Variables	N=171	n1=90	n2=81	P
<b>D30</b>				
Avge. (ET)	38.89 (47.025)	28.06 (42.601)	50.92 (49.007)	<b>0.001 *</b>
Median	19.92	7.29	32.93	
Range	[0.00 - 224.77]	[0.00 - 190.40]	[0.00 - 224.77]	
<hr/>				
<b>D60</b>				
Avge. (ET)	21.34 (31.969)	12.76 (23.819)	30.86 (36.958)	<b>&lt;0.001 *</b>
Median	4.41	1.57	13.36	
Range	[0.00 - 125.97]	[0.00 - 100.84]	[0.00 - 125.97]	
<hr/>				
<b>D90</b>				
Avge. (ET)	17.63 (32.110)	8.44 (20.822)	27.84 (38.834)	<b>&lt;0.001 *</b>
Median	1.20	0.00	8.82	
Range	[0.00 - 154.26]	[0.00 - 107.69]	[0.00 - 154.26]	
<hr/>				
<b>Cumulative costs over the 3 months of the follow-up monitoring: health insurance perspective</b>				
Avge. (ET)	77.86 (84,841)	49.27 (66,599)	109.63 (91,758)	<b>&lt;0.001 *</b>
Median	43.76	19.06	85.68	
Range	[0.00 - 327.73]	[0.00 - 293.56]	[0.00 - 327.73]	

Costs of sick leave in €: Health insurance perspective

Costs of sick leave in €		<i>Belt group</i>	<i>Control group</i>	
Variables	N=171	n1=90	n2=81	P
<b>D30</b>				
Avg. (ET)	67.88 (282.45)	34.52 (144.23)	104.95 (379.13)	0.104
Median	0.00	0.00	0.00	
Range	[0.00 - 2459.6]	[0.00 - 819.85]	[0.00 - 2459.6]	
<b>D60</b>				
Avg. (ET)	29.27 (210.44)	0.00 (0.000)	61.80 (303.43)	0.055
Median	0.00	0.00	0.00	
Range	[0.00 - 2200.7]	[0.00 - 0.00]	[0.00 - 2200.7]	
<b>D90</b>				
Avg. (ET)	16.15 (128.43)	0.00 (0.000)	34.09 (185.56)	0.083
Median	0.00	0.00	0.00	
Range	[0.00 - 1208.2]	[0.00 - 0.00]	[0.00 - 1208.2]	

Total costs per period in €

Total medical costs in €		<i>Belt group</i>	<i>Control group</i>	
Variables	N=171	n1=90	n2=81	P
<b>D30</b>				
Avg. (ET)	63.62 (75,255)	45.90 (69,013)	83.32 (77,394)	1 *
Median	32.77	14.60	57.59	
Range	[0.00 - 321.86]	[0.00 - 313.64]	[0.00 - 321.86]	
<b>D60</b>				
Avg. (ET)	35.14 (52.789)	21.16 (39.934)	50.68 (60.690)	<0.001 *
Median	[0.00 - 212.92]	[0.00 - 170.58]	[0.00 - 212.92]	
Range	6.92	3.16	23.52	
<b>D90</b>				
Avg. (ET)	29.08 (53,124)	13.94 (35,010)	45.91 (63,945)	<1*
Median	2.04	0.00	15.88	
Range	[0.00 - 260.28]	[0.00 - 185.37]	[0.00 - 260.28]	