

CLINICAL VALUATION REPORT

Medical device: **FABRIC WITH BIOMOLECULES**

1) RATIONAL STUDY

The clinical study described here was intended to evaluate the clinical efficacy and safety of the BIOMOLECULES FABRIC devices.

2) DESIGN OF THE STUDY

The study duration of 8 weeks, was conducted on 20 subjects, male and female, between the ages of 25 and 74 years.

The study was conducted in the period between 10th of January and 10th of March 2015 at VIGNALI PHYSIOTHERAPIC CENTER.

The examined patients have the following symptoms and diseases.

ID SAMPLES	PATHOLOGY	DEGREE/ SYMPTOMS	AREA	SEX	N° PATIENTS
A	Sciatica	Medium/Serious	Lumbo-sacral	M/F	5
B	Neck Pain	Medium/Serious	Cervical spine	M/F	3
C	Post-Traumatic Pain	Medium/Serious	Small Joints	M/F	2
D	Osteoarthritis	Medium/Serious	Extended	M/F	7
E	Chronic tendinopathy	Medium/Serious	Extended	M/F	3

Patients applied 1 sample of the device in the area that was suffering, for a period from 15 to 20 days.

The conditions of the patients were reevaluated at a distance of 30 days from the first device apply.

3) RESULTS

Treatment outcomes, with reference to the standard of table 1, are briefly summarized in the following table.

ID SAMPLES	N° IMPROVED PATIENTS	N° STABLE PATIENTS	N° WORSENEED PATIENTS	NOTES
A	100,00%	0	0	/
B	100,00%	0	0	/
C	0,00%	100,00%	0	/
D	57,00%	43,00%	0	/
E	33,00%	66,00%	0	/

4) CONCLUSIONS

On the basis of the results, including the Tab 2, it can be concluded that the medical device is effective on the control of painful symptoms.

No patient showed side effects.

No patient showed worsening of symptoms.

