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TheraSuit® Orthosis



I. The History and Development of TheraSuit®:

TheraSuit, a soft, dynamic, proprioceptive orthotic, is a full-featured dynamic correction clothing. The invention of the Therasuit can be tracked back since the 1960s, when the United States and the Soviet Union competed to develop space science and technology (the so-called Space-Age). The Soviet Union's space science laboratories found that astronaut's physical and neurological condition had been changed after staying in a gravity-free environment for an extended period of time. Without the affect of gravity, the astronaut's spinal cords elongated about 2 inches. There was no doubt that astronauts suffered a neurological change in their body, as well as the musculoskeletal change of not using their muscles to fight against gravity in order to move around for their activities of daily living. After returning to the Earth, the astronauts suffered muscle atrophy, loss of muscle strength, osteoporosis (bone demineralization), decreased cardiopulmonary function, reduced joint mobility, and change in proprioception.

In view of these observations, the Soviet space scientist designed and developed a fully functional prototype of the dynamic correction clothing- called "**PENGUIN SUIT**". By wearing this "Penguin Suit", it provided deep compression force on the skin, muscle, and bone even in weightlessness. Thus the astronauts would not suffer from the effects of extended staying in a gravity-free environment. Also the scientists and the rehab-medicine team also developed a set of intensive training program to restore and build up the astronauts' physical and sensor-motor function.

In 1971, professor Siemionowa, the Soviet space medical expert, improved and modified the "PENGUIN SUIT", called "**ADELI SUIT**" and used it for the astronauts. Due to suffering a lot of the same effects of difficulty of movement, the astronauts and children with cerebral palsy (neuro-muscular disorders or developmental delays) had the same physical and neurological changes in decreased range of motion of joint mobility, reduced muscle strength, and difficulty of movement against the gravity. At the Pediatric Institute of the Russian Academy of Science, a team developed and modified the first "Adeli Suit"- renamed it as the "**LK Adeli 92**". This was the early prototype "suit" developed and used for the various populations with cerebral palsy or neuro-muscular disorders. They soon discovered that the "LK Adeli 92" worked well for children with

cerebral palsy, and was mainly designed for the functional movement in an upright position liked standing and walking due to the original setting and design of the bungee cords. The bungee cords provided the resistance only in the upright position.

In 1994, because of the limitation of the “LK Adeli 92”, an improved “Suit” was re-developed and called “**LK Adeli 94**”. It consisted of a vest, shorts, headpiece, knee pieces, padding, and special shoes with hooks for wearing. In 1997, a trained Poland physical therapist couple, Richard and Izabela Koscielnny- parents of a disabled child, first introduced the “Adeli Suit”, “Universal Exercise Unit”, and the “Intensive Training Program”, and was used in pediatric physical therapy rehabilitation in the United States. Later in 2002, further improvement of the re-designed “Suit” by Richard and Izabela was patented “**TheraSuit**®”. The new version of the “**TheraSuit**®” added padding for comfort, Velcro closure for increased efficiency in application, and covering with variety of hooks in optimal locations for more options of bungee cord attachments. TheraSuit® is the only one of a device in the United States registered with the FDA (defined as a soft, dynamic proprioceptive orthotic) and meeting all requirements and regulations (U.S. Patent US 7,153,246, International Patent PCT/US2008/051458). In 2007, Kevin Huang, PT, MA, , the trained and certified instructor (by TheraSuit® LLC), first introduced the " TheraSuit® ", "Universal Exercise Unit (UEU)", and "Intensive Therapy Program" into Taiwan, and used in pediatric physical therapy rehabilitation. Later in 2009, further registered and approved with Department of Health in Taiwan, R.O.C. - ” **TheraSuit® Orthosis** ” (DHA04400754801), as well as registered Patent of " TheraSuit® " in Taiwan and in China.

II. The Components of the TheraSuit® :

- Cap
- Vest
- Shorts
- Knee Pads
- Shoe Attachments
- Elastic Bands
- Plastic/Metal Hooks
- Arm Attachments



The above elements of the suit are connected with each other through a system of elastic bands.

III. The Sizes of the TheraSuit® :

<u>Sizes</u>	<u>Model</u> (SKU)	<u>Colors</u>	<u>Suggested Age</u>	<u>Suggested Height</u>
X-Small	TH6	Yellow/Red	2.5-4 y/o (petite)	less than 34”
Small	TH1	Yellow	3-5 y/o	34”-44” tall
Medium	TH2	Red	5-8 y/o	44” -51” tall
Large	TH3	Green	8-12 y/o	51” -56” tall
X-Large	TH4	Blue	12-18 y/o	56” -66” tall
XX-Large	TH5	Blue/Yellow	Adult	more than 66”

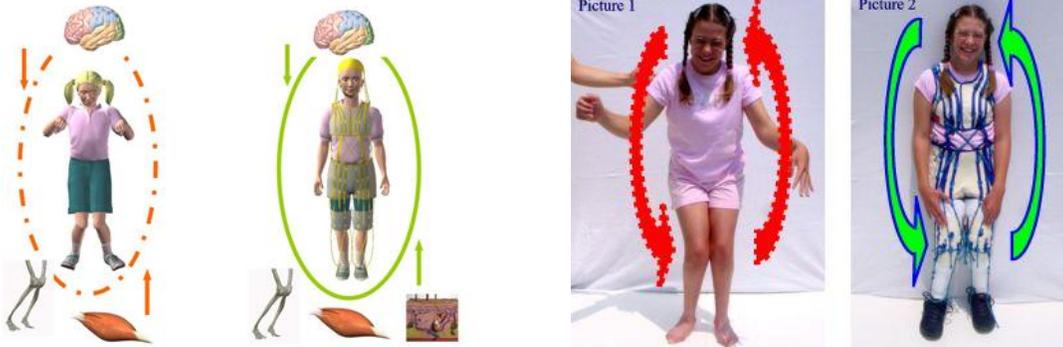


IV. The Concepts of TheraSuit®:

The TheraSuit® is defined by the FDA as a soft, dynamic, proprioceptive orthosis constructed of a breathable but highly durable fabric. It is derived from the space rehabilitation medicine, and is a safe and effective treatment tool that acts as an external set of muscles. By way of adjusting the length of the elastic bands (tension and force adjustment) and the location and direction of the elastic bands' attachment (three dimensional correction of posture and movement), the TheraSuit® provides three major goals: 1) to provide support and stability during positioning and posture, 2) to provide dynamic assistance or resistance during muscle strengthening, and 3) to promote facilitation or acceleration in functional skill training.

By wearing the TheraSuit®, it provides dynamic compression and loading force on our body (skin, muscles, and joints) for the following outcomes: 1) to correct body alignment as closely to normal as possible in static posture or during dynamic transitions, 2) to re-train the central nervous system and to normalize muscle tone for new functional skill learning, 3) to reduce abnormal pathological reflexes, 4) to restore proper physiological synergy movement pattern. According to the “Feedback Theory”, those normalized tactile and proprioceptive stimulations are afferent to the vestibular system. Then the vestibular system processes,

integrates all the peripheral information from our body. Finally, the central nervous system conducts normal and proper efferent message to muscles, tendons, and joints for correct posture, proper transitions, graded balance, coordination or functional skills. In summery, the TheraSuit[®] can normalize muscle tone, and promote or re-store balance, coordination, body awareness and space orientation (the position of the body in space).



According to the “Motor Learning Theory”, the vicious cycle can be interrupted, and replaced by “new” corrected information. It means that the more correct proprioceptive inputs the central nervous system receives from the joints, ligaments, muscle, tendons, and joint’s capsule, etc., the more correct alignment, proper postures, and actively graded movement patterns our body can perform. For example, as a regular individual, we all have a “magic” number (maybe hundred, or a few hundred repetitions) to learn a new skill or a new movement pattern. A child diagnosed with cerebral palsy or other neuro-motor disorders might require more (maybe hundreds or thousands of repetitions) to learn even any particular movement. A baby trying to push himself/herself up off the floor will need to repeat this movement pattern a few hundred times in order to master it. Another one may need either more or less repetitions to learn the same skill. For a child with cerebral palsy; however, he/she might have a “magic” number grow to a thousand or more repetitions to learn and master a new skill. Wearing the TheraSuit[®] over a prolonged period of time while practicing the new skills will also help to accelerate the progress and become more fluent, and might need less and less effort. Therefore, the TheraSuit facilitates the development of new gross and fine motor skill like sitting, standing, and walking.

V. The Benefits of TheraSuit®:

- Provide the dynamic tactile and proprioceptive inputs to influence the vestibular system and normalize the muscle tone.
- Improve the body awareness and spatial orientation.
- Reduce the abnormal pathological reflexes and stereotyped movement pattern.
- Provide the dynamic correction of body alignment to as close to normal as possible in static posture and dynamic transitions.
- Provide the external support/stabilization to the weak muscles or muscle groups.
- Reduce the compensatory movement pattern to lower the energy consumption during transitions and locomotion.
- Re-train the central nervous system.
- Improve the graded balance and coordination control.
- Speed up the new movement patterns and functional skills learning and development.
- Decrease involuntary and uncontrolled movements in Ataxia and Athetosis.
- Improve the fluency of airway and speech production.

VI. The Indications of TheraSuit®:

- Cerebral Palsy
- Neuro-muscular Disorders (Spasticity/ Hypotonia)
- Muscular-skeletal Disorders
- Developmental Delays
- Post Stroke (CVA) Patient
- Spinal Cord Injuries and Spina Bifida
- Traumatic Brain Injury
- Ataxia
- Athetosis

VII. The Contraindications of TheraSuit®:

- Hip subluxation greater than 33%-50%.
- Severe scoliosis (exceeding 25 degrees).
- Fixed joint contractures in hip joint and lower extremities.
- Younger than 2.5 year-old.

VIII. The Precautions of TheraSuit®:

- Heart conditions
- Uncontrolled seizure activities
- Hip subluxation (20%-33%)
- Hydrocephalus (VP shunts)
- Diabetes
- Kidney problems
- High blood pressure
- Height of less than 34 inches (85 cm)

The TheraSuit® meets all requirements of FDA regulations and is FDA listed and registered. There is no age limit to use TheraSuit® (please review the contraindications and precautions of the TheraSuit®). Although the clinical concepts of TheraSuit® to be very simple, professional certified training is require to ensured the safety of the patient and quality of treatment.

