eksoNR

About EksoNR

EksoNR© is a wearable robotic exoskeleton that enables individuals to stand up and walk over ground with a full weight bearing, reciprocal gait in a clinical setting. It is the only FDA approved exoskeleton for acquired brain injury and multiple sclerosis and was the first exoskeleton to be approved for stroke and spinal cord injury. EksoNR with SmartAssist software, which was designed for rehabilitation institutions, provides adaptive amounts of power to both sides of the patient's body, engaging the patient throughout his or her continuum of care.

The technology provides the ability to mobilize patients early in their recovery, offering many repetitions of intense, quality, task specific steps.

Intended Use

EksoNR is intended to perform pre-gait and ambulatory functions in rehabilitation institutions under the supervision of a trained physical therapist for individuals with:

Acquired brain injury, including traumatic brain injury (upper extremity motor functions of at least 4/5 in at least one arm).

Stroke (upper extremity motor functions of at least 4/5 in at least one arm).

Spinal cord injuries at levels T4 to L5 (upper extremity motor function of at least 4/5 in both arms) and individuals with spinal cord injuries at levels of C7 to T3 (ASIA D with upper extremity motor function of at least 4/5 in both arms).

Multiple sclerosis (upper extremity motor function of at least 4/5 in at least one arm).

Limitations

Users should have the following characteristics:

Skeleton does not suffer from any unhealed fractures of the pelvis or lower limbs.

Able to tolerate the upright standing position

Hip width or leg segment lengths are within the range of adjustability (height between approximately 5′ and 6′4″).

Weight does not exceed 220lbs.

The therapist must complete a training program prior to the use of the device. The devices are not intended for sports or stair climbing.

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Contraindications

People with the following conditions should not use this device:

- Severe concurrent medical diseases: infections, circulatory, heart or lung
- Severe spasticity (Modifed Ashworth 4)
- Unstable spine or unhealed limb or pelvic fractures
- Heterotopic ossification
- Psychiatric or cognitive situations that may interfere with operation
- Decreased standing tolerance due to orthostatic hypotension
- Cognitive impairments resulting in inability to follow directions
- Pregnancy
- Poor skin integrity in contact areas
- Certain range of motion (ROM) restrictions
- Unresolved deep vein thrombosis
- Lower limb prosthesis

Research Summary

CVA

Increased number of steps and distance walked for patients being treated with Ekso versus standard of care when time spent in therapy is equal (Karunakaran 2021, Nolan 2020)

Improved non-motor outcomes when compared to standard of care when time spent in therapy is equal (De Luca 2020)

Improved gait outside of the Ekso including improved 6MWT, 10mWT, TUG, TCT, and FAC (Goffredo 2019)

Bilateral hemisphere improvements in connectivity and neuroplasticity (Calabro 2018)

SCI

Cardiac responses comparable to exercise noted when patients walking in Ekso (Corbianco 2021, Faulkner 2019, Escalona 2018)

Trunk muscle activation below level of injury while walking in Ekso (Alamro 2018)

Improved non-motor outcomes (pain, spasticity, bowel function, bladder management, self care) (Baunsgaard 2018, Stampacchia 2017, Hong 2017)

Improved gait outside of the Ekso (Baunsgaard 2017)

ABI

Improvements in gait symmetry after using Ekso (Karunakaran 2019, Nolan 2018)

Increased activation in prefrontal cortex, M1, and premotor cortex when walking in Ekso versus walking with no device (Karunakaran 2020)

MS

Improved gait outside of the Ekso including improved 10MWT, TUG, FAC, BBS (Russo 2021)

Improved cognitive processing speed and thalamocortical resting-state functional connectivity (Androwis 2021)

Improved perception of physical and mental well-being (Russo 2021)

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Contact Name
Role / Job Title
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Email Address

Indications For Use (USA)

EksoNR is intended to perform ambulatory functions in rehabilitation institutions under the supervision of a trained physical therapist for the following populations:

Individuals with multiple sclerosis (upper extremity motor function of at least 4/5 in at least one arm)

Individuals with acquired brain injury, including traumatic brain injury and stroke (upper extremity motor functions of at least 4/5 in at least one arm)

Individuals with spinal cord injuries at levels T4 to L5 (upper extremity motor function of at least 4/5 in both arms)

Individuals with spinal cord injuries at levels of C7 to T3 (ASIA D with upper extremity motor function of at least 4/5 in both arms)

The therapist must complete a training program prior to the use of the device. The devices are not intended for sports or stair climbing

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FDA clearance
for clinical use

CE 0044