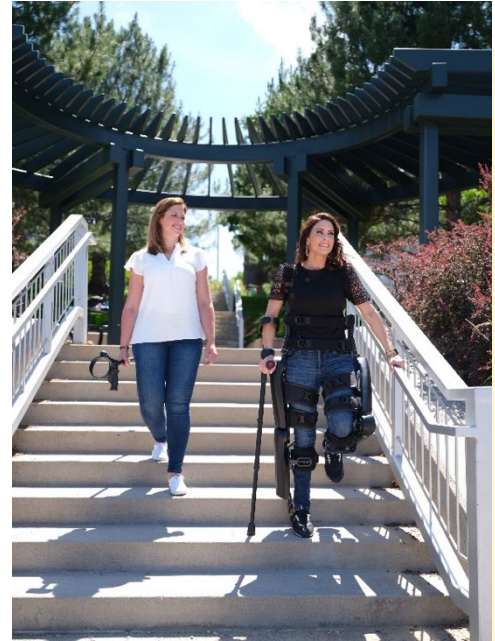


System Description

The ReWalk® P6.0 Exoskeleton is a prescription device which enables individuals with spinal cord injuries to perform ambulatory functions and is composed of an external, powered, motorized frame that fits to the lower limbs and part of the upper body.

Control of the device is achieved through a wrist-worn User-operated wireless remote controller, tilt sensor and specific body movements. The gait movements are performed by a set of gears and motors at the knee and the hip joints. The ReWalk system includes Remote control Communicator, Exoskeleton (Inc. Rigid Frames, Waistpack and Straps), Battery charger and Laptop, and off the shelf crutches. The device is intended for indoor and outdoor use: including standing and walking on level surfaces and mild slopes and ascending and descending stairs and curbs for users who are at least 18 years old.



Indications For Use

The ReWalk® P6.0 fits to the lower limbs and part of the upper body and is **intended to enable individuals with spinal cord injury at levels T7 to L5 to perform ambulatory functions in home and community settings** with supervision of a specially certified companion in accordance with the User assessment and training certification program. The device is also intended to enable individuals with spinal cord injury at levels T4 to T6 to perform ambulatory functions in rehabilitation institutions in accordance with the User assessment and training certification program. The ReWalk P6.0 is intended for indoor and outdoor use: including standing and walking on level surfaces and mild slopes and ascending and descending stairs and curbs.

Before using the device, confirm that the following prerequisites are met by the User:

- ⦿ Hands and shoulders can support crutches or a walker
- ⦿ Healthy bone density, meaning sufficient bone density according to the judgement of the prescribing physician after clinical examination of the patient – including radiological proof if needed
- ⦿ Skeleton does not suffer from any fractures
- ⦿ In general good health
- ⦿ Height is between 160 cm and 190 cm (5' 3" - 6' 2")
- ⦿ Weight does not exceed 100 kg (220 lbs)
- ⦿ At least 18 years old



Contraindications

People with the following conditions should not use the ReWalk:

- ⦿ History of severe neurological injuries other than SCI (MS, CP, ALS, TBI, etc.)
- ⦿ Severe concurrent medical conditions that would interfere with safe device use or walking (e.g. infections, respiratory issues, severe visual impairment, pain, or joint instability, severe arthritis, acute arthritis, or synovitis after total or partial lower limb joint replacement; Severe integumentary system issues in areas of device contact; myocardial infarction or angina or ischemic heart disease within the last 6 months; uncontrolled diabetes; unresolved deep vein thrombosis; a history of renal dialysis, orthostatic hypotension, essential hypertension, uncontrolled blood pressure, colostomy bag, III-IV spine scoliotic deformity)
- ⦿ Uncorrectable equinovarus foot deformation
- ⦿ Severe spasticity (Modified Ashworth 4)
- ⦿ Unable to tolerate standing position in a supported standing device (e.g. due to orthostatic hypotension)
- ⦿ Amputations and lower limb prostheses
- ⦿ Unstable or unhealed fractures of the spine, pelvis and/or lower extremities
- ⦿ Uncorrectable leg length discrepancy over 2 cm when using additional correction tools
- ⦿ Heterotopic ossification that impairs joint mobility
- ⦿ Significant arthritis or contractures that limit lower limb range of motion necessary for adequate walking (flexion $>0^{\circ}$ at hips, $>10^{\circ}$ at knees, $>0^{\circ}$ at ankle plantar flexors)
- ⦿ Psychiatric or cognitive disorders that may interfere with proper operation of the device
- ⦿ Pregnancy

