Exoskeleton Gait Training Medical Clearance Form



Patient data (Name and Address or Label):	Please answer the following questions thoroughly, so we can better judge the use of the ReWalk. Please tick, underline or complement. If required, we are happy to help you fill out. (n = no y = yes)
Phone number:	E-mail address;
Gender: □ Male □ Female	Date of birth:
Height: cm Weight:	kg Shoe size:
Contact details OP&R Shop (If, available):	Payer's contact details: (If, available):

Description oft he ReWalk Exoskeleton

The **ReWalk**-System is a wearable robotic exoskeleton.

People with paraplegia, a spinal cord injury resulting in complete or incomplete paralysis of the legs, can use the ReWalk exoskeleton in an urban terrain (stand, walk on level surfaces and mild slopes, ascend and descend stairs). The ReWalk is not intended for sports or aggressive use.

The system uses patented motion sensing technology along with battery-powered motorized legs powering knee and hip movement which is controlled by proprietary on-board computers and software.

The system allows an user self-initiated independent locomotion. The **ReWalker** controls movement using subtle changes in his/her center of gravity. A forward tilt of the upper body is sensed by the system, which initiates the first step. Repeated body shifting generates a sequence of steps which mimics a functional natural gait

of the legs with walking speeds as high as 0.71 m/s (1.6 mph/ 2.6 km/h).

The new ReWalk System is designed for all day use at home and in the community. It is the most used and most studied exoskeleton system of its kind via clinical studies and extensive laboratory testing.

Apart from social and psychological benefits, of being able to walk again, are Clinical studies* showing that standing and ambulation in the ReWalk is providing potential health benefits, such as:

Reduction of some medications for certain ailments, improved bowel and bladder function, improved mental health, improved sleep and reduced fatigue, decreased body fat, decreased pain, improved posture and balance.

*Interim Data, Presented at 2014 AAPM&R Annual Assembly-Exoskeletal- Assisted Walking for Spinal Cord Injury.

Medical Diagnosis

1) Lesion height	t □ C7 or above		De e.g	e significant orthopedic formities present? g. leg length discrepancy, scoliosis, tational deformities	□n	□у
□ TH 1			If yes,	which?		
	□ TH 2 □ TH 3 □ TH 4 □ TH 5 □ TH 6 □ TH 7			Does the patient suffer from uncontrolled Spasm , Ashworth > 3?	□n	□у
	□ TH 8 □ TH 9		b.	Is the mobility of Hip, Knee or Ankle significant limited?	□n	□у
	□ TH 10 □ TH 11 □ TH 12		If yes,	which?		
	☐ L1 or below		C.	Is there an extension deficit in the Knee joint > 10 degree?	□n	□у
	(Please tick)		d.	Is the Neutral 0 position of the Ankle joint reached?	□n	□у
			e.	Is the Neutral 0 position in the Hip joint reached?	□n	□у
2) Degree of inj ASIA Scale:	□ A □ B			Can the patient stand-up and actively stand, even with aids? e.g. crutches or standing frame	□n	□у
Alternative to	☐ C ☐ D D D ASIA Scale ☐ Complete ☐ Incomplete		g. If yes	Does the patient stand regularly? e.g. with standing aids :	□n	□у
3) Date of injur	y 	-	h.	Are trunk control and body consciousness existing?	□n	□у
4) Are the actual of yes, which?	al diseases?	□ n □ y	i.	Are the functionality of the upper extremities and the range of motion good?	□n	□у
5)Was one of the following diseases diagnosed in the past? Multiple Sclerosis (MS) Stroke Cerebral Sclerosis Parkinson Disease Trauma Brain Injury (TBI) Amyotrophic Lateral Sclerosis (ALS) Cerebral Palsy		-	j.	Does the patient use the wheelchair independently?	□n	□у
			k.D	oes the patient transfer independently? e.g. car - wheelchair - massage bank	□n	□у
			l.	Other limitations , which could be of a concern related to a secure walking with the ReWalk using crutches ?	□n	□у
			If yes	, which?	_	

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(This section must be completed only by a physician)

Inclusion Criteria

- 1. Hands and shoulders can support crutches or a walker
- 2. Healthy bone density
- 3. Skeleton does not suffer from any fractures
- 4. Able to stand using a device such as EasyStand
- 5. In general good health
- 6. Height of 160 to 190 cm (5'3" 6'2") Depending on leg length:

- Lower leg length: 43,5 to 56 cm - Upper leg length: 36 to 48,5 cm

7. Weight does not exceed 100 kg (22lbs)

Exclusion Criteria

- 1. History of severe neurological injuries other than SCI (MS, CP, ALS, TBI etc)
- 2. Severe concurrent medical diseases: infections, circulatory, heart or lung
- 3. Pressure sores
- 4. Severe spasticity (Modified Ashworth 4)
- Unstable spine or unhealed limbs or pelvic fractures
- 6. Heterotopic ossification that impair joint mobility
- Significant contractures (plantar flexion > 0°, knee > 10°, hip flexion >0°)
- 8. Psychiatric or cognitive situations that may interfere with proper operation of the device
- 9. Pregnancy
- 10. Incapable of holding crutches

Physician data (Name and Address):							
	-						
Phone number:	e-mail address:						
In accordance with the appended inclusion and exclusion criteria, there are no concerns for the patient,							
to perform a gait training with ReWalk exoskeleton.							
Physician signature:	Date / Stamp						
i iiyaldan algirature.	Date / Stamp						

Please return the completed, signed and stamped form to:

ReWalk Robotics GmbH

Leipziger Platz 15 10117 Berlin Germany www.rewalk.com **Fax** +49 (0) 30 2589 4100 or **E-Mail** kontakt@rewalk.com