# Product Design Specification

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**Project title: Knee Crutch**

**Group members:**

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**Function:**

Patients with an injury below the knee are often asked to utilize crutches or a cane when ascending and descending stairs, but when patients are unable to use these devices, there isn't an effective medium. A stair chair works for many wheelchair users, but when they are only temporarily wheelchair bound, it is not plausible to install one in their homes for a brief period of time. There are similar devices to such physical constraints on the market; however, these aids are intended for walking, not stair usage, and lack the offset height necessary to accommodate for the lack of a knee joint in use. Additionally, many are difficult to put on and remove, making stair ascension a more time consuming task than necessary [1]. The Knee Crutch is a necessary solution to this problem; it will allow users to climb stairs efficiently with a mechanically tested, stable, light, and height-adjustable frame. Additionally, it will utilize a handle component to allow ease in transferring the device to the next stair, and the knee support will be comfortable, with a length that does not encumber an area of injury.

**Client requirements:**

- The product's frame should be height adjustable and made of steel, with a material stability component at the foot.
- The knee rest should be concave and fitted with padding to allow comfortable, lateral support of the knee
    A. It should be a length that does not encumber the area of injury
- The product should be mechanically stress tested

- The product should be about 5 lb with a handle to allow users to move it up stairs

**Design requirements:**

1. **Physical and Operational Characteristics**
    a. *Performance requirements*

The knee crutch will be used anytime the patient ascends or descends stairs. The device is used and moved for every step the patient takes up the stairs, around 10 steps at a time. The crutch should be able to bear the full weight of a patient, over 200 pounds, for 5-15 seconds as they lift themselves to the next step.

*b. Safety*

In order to avoid exceeding a weight limit of 300 pounds, a warning label will be needed to ensure proper stability and function of the device. When testing and designing the knee crutch, regulations and quality standards from ISO 13485 must be followed to ensure the device is safe for its intended use [7].

*c. Accuracy and Reliability*

This device must have a yield strength of 17 MPa +/- 2.5 MPa, as a result of a 1,334.4 newton (300 pound) axial stress test.

Additionally, as a result of the stress test, the device will maintain a factor of safety of at least 2.

The device should withstand daily use for 6-8 weeks

*d. Life in Service*

The knee crutch device should be durable and ideally last for many years with numerous patients. The device is expected to be used to assist in ascending and descending fewer than ten steps at a time, and therefore should not experience significant wear and tear. However, the device should still be inspected before use to ensure the stabilizing factors of the device are operating correctly. The target life in service is 5 years.

*e. Shelf Life*

The final design must be able to withstand room temperature conditions and must be able to stay in storage for the entirety of its life in service.

*f. Operating Environment*

The device will be used by patients with non-weight bearing injury below the knee. Users' ages will range from 50 to 70 years old, but the device should be suitable for use by patients of all ages. The device will be used in outdoor and indoor environments and should be suitable for temperatures 0°C-40°C.

*g. Ergonomics*

The height adjustability of the leg should be located in an easily accessible area for the user of heights ranging from 5'2" to 5'9". Additionally, the base of the device should incorporate a shock absorbing mechanism and significant friction to avoid slipping and ensure comfort during use. Lastly, the leg rest component should possess concavity to provide lateral support to the knee for users with varying degrees of instability.

*h. Size*

The device should be slightly shorter than the shin of the patient's uninvolved leg, allowing the patient to easily maneuver it up each step. Most patients fall between the heights of 5' 2" to 5' 9", so the device should be adjustable enough to cover this range. The handle of the device should correspond with anthropometric ratios so that the patient can grasp and position it without discomfort.

*i. Weight*

The product's weight should be slightly lighter than the current prototype, similar to the weight of the competitors. The device should weigh approximately five pounds.

*j. Materials*

The device needs to be sturdy enough to support patients over 200 pounds. Aluminum will be used for the leg and foot of the device. The foot should include a soft or rubber-like base in order to provide some give to keep the device stable on uneven surfaces.

*k. Aesthetics, Appearance, and Finish*

The device will have a relatively simple design, similar to a small chair. The main components will be the single leg and large foot, the brace for the knee to be placed, and the handle for the patient to move the crutch up and down. The area for the knee to be placed should be slightly concave to provide lateral support to the knee. The foot should be small enough to comfortably fit on a standard stair tread- about 10".

2. **Production Characteristics**
    a. *Quantity*

The developed knee crutch should be adjustable, so only one prototype will be required. This product should also have the ability to be quickly produced as the client will require one per patient.

    b. *Target Product Cost*

A competing design called the iWalk [1] retails for around $179 dollars. Our product will be similarly priced. Our target product cost range will be $100-$150.

3. **Miscellaneous**
    a. *Standards and Specifications*
        i. Must meet ISO 7176-24:2004 [4]
        ii. Must meet ASTM F3580-24 [5]
    b. *Customer*
        i. Knee Crutch is intended for individuals with lower limb injuries who need to briefly be able to go up and down a small set of stairs.
    c. *Patient-related concerns*
        i. Device must be stable and not heavy
        ii. Device must be able to be moved with arms
        iii. Patient must be able to kneel on the device
    d. *Competition*
        i. iWalk Hands Free Crutch [1]
        ii. Stair Chair
        iii. Freedom Leg [3]

**References**

[1] iWALKFree, “Clinical Research,” *iWALKFree*. Accessed Sep. 14, 2025. [Online]. https://iwalk-free.com/clinical-research/

[2] W. B. Johnson *et al.*, “Exoskeletal solutions to enable mobility with a lower leg fracture in austere environments,” *Wearable Technologies*, vol. 4, p. e5, Feb. 28, 2023, doi: 10.1017/wtc.2022.26.

[3] “Hands Free Crutch - Crutch Alternative - Freedom Leg.” Freedom Leg Brace, 3 Sep. 2025, https://www.freedomleg.com/.

[4] “Wheelchairs - Part 28: Requirements and Test Methods for Stair-Climbing Devices.” *Compass. https://compass.astm.org/content-access?contentCode=ISO%7CISO%207176-28%3A2012%7Cen-US. Accessed 18 Sep. 2025.*

[5] ASTM Standards “Standard Test Method for Exoskeleton Use: Stairs.” Book of Standards Volume: 15.13. Developed by Subcommittee: F48.03. Accessed Sep. 18, 2025 [Online]. https://compass.astm.org/content-access?contentCode=ASTM%7CF3580-24%7Cen-US.

[7] *ISO 13485:2016*. (n.d.). ISO. Retrieved September 15, 2025, from https://www.iso.org/standard/59752.html