Tri-Axial Ergonomic Knee Brace Hinge Product Design Specification

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Function:

The function of the design project is to improve the current knee brace model of Mueller Sports Medicine Inc. The company currently uses a straight tri-axial hinge in their brace that mimics the motion of the knee well; however, the straight shape does not match the profile of the leg. The client, Dr. Sarah Kuehl, desires a knee brace hinge that more closely conforms to the shape of the leg in relation to the thigh and calf while still generic enough to fit a variety of users. In order to design such a hinge, data will need to be collected in order to determine an average leg size. Using this "ideal" leg, the knee brace will be designed to more accurately match the distal portion of the thigh, the knee, and the posterior portion of the calf.

Client Requirements:

- Made out of aluminum
- Lightweight
- Using the tri-axial hinge requirement
- Conform to as many patient's legs as possible
- Prevent leg movement in lateral direction and hyperextension
- Allowing for proper range and motion of flexion
- Comfortable for patients to wear
- Durable

Design requirements:

1. Physical and Operational Characteristics

a. **Performance Requirements**: The knee brace will be used daily, so it should be able to bend at the hinge 1000's of times a day and prevent lateral movement of the knee under normal gait conditions. The hinge itself will experience little loading because it only restricts motion in the lateral and hyperextension directions.

b. **Safety**: Cannot catastrophically break under corrosion and prolonged wear. The hinge should not protrude too far from the leg.

c. **Accuracy and Reliability**: Should not inhibit normal gait of the patient

d. **Life in Service**: Should be able to be used everyday for one year and then reused by another patient afterwards.

e. **Operating Environment**: It will be attached to the leg surrounding the knee and will be worn during everyday activities, both inside and outside.

f. **Ergonomics**: Augment the current design with a hinge that more effectively conforms to the patient's leg and provide natural motion for knee flexion.

g. **Size**: One size should fit most, accounting for variable thigh and calf circumferences.

h. **Weight**: As light as possible since it must be easily wearable by the patient and less impactful on their stride.

i. **Materials**: Aluminum, prototype can be made out of plastic

j. **Aesthetics, Appearance, and Finish**: Should match the aesthetics of the current knee brace. Should be sleek without rough finish.

2. Production Characteristics
a. **Quantity**: 1

b. **Target Product Cost**: <$500

3. Miscellaneous
a. **Standards and Specifications**: Knee braces do require FDA approval. Also need to meet any Mueller SOP or Quality Requirements.

b. **Customer**: Mueller Sports Medicine

c. **Patient-related concerns**: Should be comfortable, easily removable and adjustable, supportive but allowing of flexion.

d. **Competition**: Ossur, Breg, DonJoy