e-NABLE Device Safety Guidelines

Statement

Based on preliminary testing and observations on the functionality and capabilities of our experimental 3D printed prosthetic devices it is felt that they are currently not safe for operation of heavy machinery, tools, equipment, and vehicles due to low grip strength development. These prosthetic devices have shown, however, to provide some functionality for gross grasp activities of light and pliable objects, but it is in no way a substitute for a fully functioning hand. In addition, we don't recommend the use of our experimental 3D printed prosthetic devices for small children (i.e., under 3 years of age) due to greater fall rate and the need of sensory input through oral stimulation. Furthermore, it is unknown if our experimental 3D printed prosthetic devices are able to sustain a small child's bite without breaking. Please review and consider the following recommendations and precautions regarding the 3D printed prosthetic device

General Recommendations for experimental 3D printed prosthetic device

Physical Safety

1. Work with your doctor or medical professional for appropriate use and wearing schedule of your experimental 3D printed prosthetic device.
2. These devices are made with low temperature plastic and should not be exposed to temperatures over 120° degrees. A 3D printed prosthetic device left in a car on a hot day may be damaged.
3. With any prosthetic there is a possibility to develop pressure sores. If redness develops after wearing for the 15-20 minute trial please contact provider of the device, to reevaluate fit. If redness persists please contact your healthcare provider.
4. Monitor your device for wear and tear and contact your provider for assistance with replacing worn or broken parts.
5. Users should assume that the device could break at any moment, even while using it for tasks that have worked in the past, because the rate at which the plastic parts fatigue and need to be replaced is unknown.
6. Do not use the device to lift boiling water off the stove (e.g. cooking pasta) or to lift dishes of very hot food out of a microwave oven or out of a hot oven or any other situation in which a failure of the experimental device could cause injury indirectly if the hot material is dropped or spilled.

Health Safety

7. Allow the mechanical hand breathing room as excessive sweat and other components may cause poor hygiene and lead to skin problems.

8. The use of a prosthetic sock is recommended for individuals with sensitive skin.
9. Make sure you have no allergic reactions to the material used to print the mechanical hand or any other component.
10. Make sure the mechanical hand is comfortable.
11. Ensure the mechanical hand is functioning for the correct purpose.
12. Start using the hand in a progressive manner. If the muscles of your wrist joint are tired, it would be a good idea to take a break and continue using the mechanical hand the next day.

Child Safety

13. The child needs to be supervised at all times while using these mechanical hands.
14. Young children cannot be trusted to watch out for the Health Safety items listed above. It is the responsibility of the caretaker to check for any problems with the child using an experimental 3D printed prosthetic device.
15. Let the child use/play with the device in a very conservative, progressive schedule: just 5-10 minutes at a time, or even less. If the child likes the device and is eager to use it, let them work up to using it for longer periods of time gradually. Talk with a pediatrician or other medical professional about how much use is safe for the child, and what other problems to watch out for.
16. If your child feels pain on the wrist or elbow joint, please stop using the mechanical hand. This may be a sign of an overuse injury.
17. If any component of the mechanical hand breaks, please stop using it.
18. Ensure that the hardware and other moving parts are not loose, especially for children young enough to be at risk of choking on foreign objects.
19. The use of the 3D printed prosthetic device should be coordinated with the child's teacher and health care providers.
20. The 3D printed prosthetic device is not made for weight-bearing or supporting body weight, so outdoor or rough play with the prosthetic should be closely monitored.
21. Children who are not walking or are unsteady on their feet may not be appropriate for this device as falling on the 3D printed prosthetic device may result in further injury.

Cleaning instructions:

22. The 3D printed prosthetic device can be surface cleaned with warm water and a mild detergent. If an odor develops on the device, cleaning with shaving cream may help to dissipate the odor. If Velcro straps become worn or ineffective, please contact the provider of your prosthetic hand for replacement.

Disclaimer

By accepting any design, plan, component or assembly related to the so called "e-NABLE Hand", I understand and agree that any such information or material furnished by any individual

associated with the design team is furnished as is without representation or warranties of any kind, express or implied, and is intended to be a gift for the sole purpose of evaluating various design iterations, ideas and modifications. I understand that such improvements are intended to benefit individuals having specific disabilities and are not intended, and shall not be used, for commercial use. I further understand and agree that any individual associated with the e-NABLE organization shall not be liable for any injuries or damages resulting from the use of any of the materials related to the e-NABLE Hand.