Device Safety Guidelines

Statement

Based on preliminary testing and observations on the functionality and capabilities of our experimental 3D printed assistive 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 assistive 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 assistive 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 assistive 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 assistive device

**General Recommendations for experimental 3D printed assistive device**

**Physical Safety**

1. Work with your doctor or medical professional for appropriate use and wearing schedule of your experimental 3D printed assistive device.
2. These devices are made with low temperature plastic and should not be exposed to temperatures over 120° degrees.  A 3D printed assistive device left in a car on a hot day may be damaged.
3. With any assistive device 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**

1. Allow the mechanical hand breathing room as excessive sweat and other components may cause poor hygiene and lead to skin problems.
2. The use of a prosthetic sock is recommended for individuals with sensitive skin.
3. Make sure you have no allergic reactions to the material used to print the mechanical hand or any other component.
4. Make sure the mechanical hand is comfortable.
5. Ensure the mechanical hand is functioning for the correct purpose.
6. 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**

1. The child needs to be supervised at all times while using these mechanical hands.
2. 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 assistive device.
3. 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.
4. 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.
5. If any component of the mechanical hand breaks, please stop using it.
6. 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.
7. The use of the 3D printed prosthetic device should be coordinated with the child’s teacher and health care providers.
8. The 3D printed assistive device is not made for weight-bearing or supporting body weight, so outdoor or rough play with the assistive device should be closely monitored.
9. Children who are not walking or are unsteady on their feet may not be appropriate for this device as falling on the 3D printed assistive device may result in further injury.

**Cleaning instructions:**

1. The 3D printed assistive 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 assistive device for replacement.

Any use of these devices is subject to the Disclaimer on the following pages.

**Release and Waiver of Liability and Hold Harmless Agreement**

You acknowledge that you understand that the e-NABLE Community Foundation (“Foundation”) is a non-profit foundation to encourage the development and dissemination of prosthetics for children and adults using 3D printer technology.  The Foundation generally does not create the design or plans (“Designs”) nor manufacture or print the components, assemblies or final prosthetics based on the Designs (“Components”), nor does it certify the Designs or Components operate properly or satisfy any regulatory requirements.  This Release and Waiver of Liability and Hold Harmless Agreement (“Agreement”) is meant to reflect the limited role of the Foundation in the development of the Design and Components. The person signing below (“You”) is either the individual recipient of the Design or Component if the individual recipient is an adult under the laws of the relevant jurisdiction or the parent or legal guardian of the child if the individual recipient is a child under the laws of the relevant jurisdiction.

You agree that any Design or Component furnished to me by the Foundation or by any individual associated with the Foundation is provided “AS IS” and without representations or warranties of any kind, express or implied, and is intended to be a gift.  By accepting any Design or Component, I further acknowledge that such Design or Component, has not been evaluated or approved by any regulatory authority.  Generally, the Design has been developed by a person or a company who may be a member of the e-NABLE community but is not an employee or contractor of the Foundation. Similarly, the Component has generally not been manufactured or printed by a person or company who is a member of the e-NABLE community but once again is not an employee or independent contractor of the Foundation.

You understand that any Design or a Component furnished by the Foundation is meant to benefit an individual recipient who has need of an assistive hand technology, and is not intended, and shall not be used, for commercial use.  If You are an adult under the laws of the relevant jurisdiction and are the individual recipient, You acknowledge that You understand the potential risks of the use of the Design or Component and expressly assume such risks.  If the individual recipient is a child under the laws of the relevant jurisdiction, You represent that You are the parent or legal guardian of the child and that You understand the potential risks of the use of the Design or Component and expressly assume such risks on behalf of the individual recipient.

Furthermore, You (either for yourself or your child)  release and forever discharge the Foundation and its  officers, employees, contractors, subcontractors, volunteers and agents (“Releasees”) from any and all liability for acts or omissions— including negligent acts or omissions—causing damage, loss, injury, or death to the individual recipient from the use of the Design or the Component. You agree to defend, indemnify and hold the Releasees harmless from any and all liability or loss— including liability for negligence—arising in conjunction with or resulting from the individual recipient’s use of a Design or Component (including all attorney's fees and expenses incurred by the Releasees).

You further understand and agree that the Foundation and any individual associated with the Foundation shall ***not*** be liable for any injuries or damages, including any consequential, incidental, indirect, punitive or special damages, resulting from or arising out of the use of the Design or Component provided by the Foundation or any individual associated with the Foundation.

Any information provided by the Foundation and any individual associated with the Foundation is not intended to be used or relied upon to diagnose or treat a health problem or disease and the Foundation makes no claims regarding the Design or the Components.  You should consider consulting with a qualified health care provider prior to fitting the Component.  Carefully read all labels and heed all directions and cautions that accompany the Components.  Any statements made by the Foundation are for informational purposes only and are not meant to replace the services or recommendations of a physician or other qualified health care practitioner.

You acknowledge that this Agreement is governed by the laws of the State of Delaware (without reference to its conflict of law provisions) and the parties intend that this Agreement to be as broad and inclusive as permitted by law. If any portion of this Agreement is found to be invalid for any reason, the remainder of the Agreement shall continue to remain in full force and effect and shall continue to be binding.

You have carefully read the foregoing provisions and understand their contents.

READ AND AGREED

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