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Official Title of the Study: Validation of Point Partial User Needs With Partial Finger Amputees

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Statistical Analysis Plan

This is not a statistically powered study. This is a device feasibility test with pass/fail results for objective tasks. The validation methods described in Table 1 will be implemented to confirm the user needs of the *Point Partial*. A simple pass/fail result will be recorded for each user need for each subject. No formal outcome measures nor data analysis will be performed during this sub-aim (a statistically powered study is presented in Aim #2.2). Here, we are focused on confirming that the product suits our user needs in its first use by human subjects. An overall passing rate above 80% across all user needs and subjects will be considered a success.

Table 2. User Needs and Validation Methods for *Point Partial*

User Need		**Validation Method**	
ID #	**Description**	**ID #**	**Description**
UN-1	*Point Partial* shall be comfortable for a full day's use	VAL-1	User wears *Point Partial(s)* for a full day
UN-2	*Point Partial* shall allow the user to flex and extend finger without their contralateral hand	VAL-2	User flexes and extends the *Point Partial(s)* without using contralateral hand
UN-3	*Point Partial* shall be robust enough to operate in challenging environments	VAL-3.1	User lifts a 25 lb. bag with *Point Partial(s)*
		VAL-3.2	User grips a hammer with *Point Partial(s)* and drives a nail into a piece of wood
UN-4	*Point Partial* shall be releasable while performing active grasps	VAL-4	User releases *Point Partial(s)* while performing an active grasp by pressing the dorsal button
UN-5	*Point Partial* shall have a durable ratcheting mechanism	VAL-5	User positions *Point Partial(s)* into each of the locking positions
UN-6	*Point Partial* shall have a reliable auto spring-back mechanism	VAL-6	User activates spring-back mechanism by using (1) contralateral hand, (2) tabletop, and (3) side or thigh
UN-7	*Point Partial* shall have high friction	VAL-7	User grips a 5 lb. cylindrical smooth object using *Point Partial(s)* for 10 seconds
UN-8	*Point Partial* shall have a pronounced fingernail	VAL-8	User picks up 1 coin from a smooth tabletop
UN-9	*Point Partial* shall be robustly attached to mounting system	VAL-9	User performs VAL-1 through VAL-8