Format for CSR Proposals of Social Relevance

1. Title of Project: Affordable Personalized 3D Printed Lower Limb Prosthesis

2. Background/Motivation: Customized lower limb prosthesis is an unmet need in India, and the demand for such prosthesis is increasing rapidly. Statistics show that tens of thousands of amputees are being added to the population in India every year [1]. As part of the rehabilitation of the lower limb, the missing part is replaced by a prosthesis which consists of a socket, pylon, and foot. A socket is an interface between the residual stump and the prosthesis. The volume of a residual stump shrinks continuously over the first few months after amputation. It may take up to two years to stabilize, and the shape of the residual stump may vary depending on the weight gain or loss by the amputee. These above situations demand a new prosthetic socket frequently. This causes a heavy financial burden on the amputee. Approx. 55% of lower limb amputees are not satisfied with their sockets because of low comfort, residual limb pain, skin breakdown [4], and 30 million people are not having access to assistive devices globally [5]. A well functional prosthesis can help an amputee to overcome his disability, and it will enhance his confidence and social status. A socket is the only component of the prostheses that is not suitable for mass production and must be tailored for each amputee. Since the socket is the interface between residual stump and prostheses, it needs to be changed as the shape or volume of the stump changes. On the other hand, conventional socket fabrication is laborious and time-consuming. Highly skilled laborers are required to develop a well-fitting socket. This will, in turn, increase the cost. Studies show that a shortage of 40,000 technicians exists in this area [5]. Hence, additive manufacturing combined with CAD/CAM technology can mitigate the gravity of the drawbacks mentioned above. Fused Deposition Modeling 3D printers, a relatively cost-effective technique, can produce personalized products with high accuracy and are widely used for various applications. Another way to reduce the cost of production of a socket is using cheaper raw material. Expensive sockets made from Carbon fiber reinforced composites are available in the market but cannot afford by the economically weaker group.

3. Objectives of the project:

This project aims to develop a low-cost, well-fitting, cosmetically pleasing, well-functioning socket, which helps the medical community provide customized sockets at an affordable price to needy people. The following objectives are set to fulfill the aim.

1. A clinical study on lower limb amputated persons and 3D scanning of the stump and development of the CAD model of the socket from the 3D scanned data
2. FEM analysis of designed sockets (CAD model) and performance evaluation
3. 3D Printing of a customized socket with natural fiber reinforced composite filament
4. A fully integrated prosthetic socket design and manufacturing solution with prototype devices

4. Brief Methodology:

The prosthesis should be supplied to a suitable person by assessing one's K Level seeing rehabilitation potential. For this, we need to work along with clinicians. We will take the help of our existing hospital collaborators for amputee data acquisition. The academic partner will work on developing protocols to print NFC filaments using FDM. Thermo-mechanical, biological property evaluation, and printability of the produced natural fiber-reinforced composite material are studied, and outcomes are already communicated by the BioFab TE group led by Dr. Falguni Pati. We are working on scaling up the printing process now. Fabrication will be carried out in IIT Hyderabad. Mechanical properties will be tested, and reliability will be assessed. A socket must be tested for both static and dynamic conditions to evaluate its performance. After supplying the socket to the amputee, feedback will be taken; based on the inputs, follow up will be performed. We will also take the lead in getting requisite feedbacks from amputees. The same will be further analyzed to optimize the parameters to improve the product. Development of final protocol and product, filing a patent application for regulatory support or approval will be followed.

5. Target population/Beneficiaries:

In India, the available sockets are complete solid sockets with minimum ventilation. After conventional Jaipur foot prosthesis, genuine attempts made in the invention and innovation of designs for prosthesis were scarce in India. India is a country less focused on rehabilitation. A combined effort and tuning of industry, academia, and social service organizations are needed to fill this gap. Removing the hitch and uplifting of the amputee to make them productive is also essential for the world's fastest-growing economy.

We still see many disabled individuals who are using the old conventional artificial limb, which has limited degrees of freedom. Since they could not spare the price of a new prosthesis, the Alliance of an amputee with prostheses will last for a long duration. The success rate of a prosthesis has a solemn dependence on the person's comfort. A socket will decide the comfort level of the lower limb amputee while wearing the prosthesis. We will be able to uplift a vast population of amputees still in a dream of a well-fitted, light, aesthetic, functional, low-cost socket. Moreover, the environmental impact caused by the carbon fiber materials, synthetic fibers can be eliminated. Usually, it takes 15-30 days to supply a socket to an amputee by the conventional method. We will be able to reduce the duration to 4-5 days. Computer-based model generation and 3D printing will reduce the intervention required by a skilled person, and hence productivity can be increased.

6. Expected Outcome/Deliverables:

Printing of novel natural fiber reinforced composite will be an outcome of this study. This will thrive in several related research areas and the application of composites. This low-cost prosthetic socket will attract a huge no of amputees. We will be able to uplift a vast population of amputees still in a dream of a well-fitted, light, aesthetic, functional, low-cost socket. By joining with nonprofit organizations, we will make sure that the outcome of this research has been reached to the amputees who cannot afford a prosthesis.

• Development of novel natural fiber-reinforced composite (NFC) filament for 3D printing
• Technology for production of custom-made personalized 3D printed prosthetic socket with NFC

7. Timeline and Budget:

	Year 1	Year 2	Year3
Budget (in Rs lakhs)	10 Lakhs	10 Lakhs	10 Lakhs
Milestones	Meeting clinician and selection of lower limb amputees. 3D scanning of the residual limb Development of CAD model of the socket from scanned images	FEM analysis to predict the design feasibility and optimization of the final design Fabrication of prosthesis and their static and dynamic testing	Supplying the prosthesis to amputee and feedback collection, optimize the final product The patent filing, publication of results, and funding regulatory approval required

8. Proposer Name & Designation:

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