

## Procurement of Cochlear Implant for next 5 years

Name of Organization – Artificial Limbs Manufacturing Corporation of India.

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<b>Sr. No.</b>	<b>Financial Year</b>	<b>Description of item</b>	<b>Broad Specification Parameters</b>	<b>Tentative Required Qty.</b>	<b>Accounting Unit (Nos.)</b>	<b>Estimated Value of Procurement inclusive all taxes. (Rs. In Cr.)</b>
1	2021-22	Cochlear Implant	As per annexure A	1000	Nos.	34.94
2	2022-23	Cochlear Implant	As per annexure A	1100	Nos.	38.44
3	2023-24	Cochlear Implant	As per annexure A	1210	Nos.	42.28
4	2024-25	Cochlear Implant	As per annexure A	1330	Nos.	46.47
5	2025-26	Cochlear Implant	As per annexure A	1460	Nos.	51.02

## Annexure 'A'

Item : Cochlear Implants Consisting of Items & as per details/Specification given below ALIMCO Code : LH91		
Sl. No.	Material Description	
A	Cochlear Implants Consisting of Items and as per details/Specifications given below	
Sl. No.	PARAMETER	QUALITATIVE REQUIREMENT
i	Number of Channels/Electrodes	16 or above
ii	Implant Casing	Hermetically sealed titanium or ceramic casing.
iii	Accessories	To include all following accessories – Three Short Cords for speech processor, One coil/antenna, Two Magnets, One Tester, Two Holding Buckle / Snug Fit, Extra Hooks, One Processor Clip-On Cover, Audio / headphone cable, Electronic Dry Aid Kit, One External Hard Case, One Bag Organizer, Non rechargeable batteries for one year of use, Rechargeable battery pack with charger – 01 Set, Rechargeable battery pack – 03 nos. Various Manuals complete both in Hindi & English language (List of standard accessories to be provided by the manufacturer/Tenderer in format at Annexure 'C-1')
iv	Speech Processor	Behind the Ear (BTE) with ability to store multiple programs
v	Speech Coding strategy	Proven and internationally accepted speech-coding strategies.
vi	Implant integrity testing ability	Ability to test implant and electrode integrity and function both intra-operatively and post-operatively. Ability to measure action potential of auditory nerve.
vii	Safety MRI compatibility	Minimum MRI Compatibility without removal of the magnet-1.5Tesla.
viii	FM compatibility	Compatibility with standard FM based systems and FM transmitters.
ix	Tele coil/Telephone compatibility	Telephone compatibility with inbuilt telecoil.
x	Battery Type	(a) Rechargeable Battery with suitable charger. Rechargeable battery should last minimum 14 Hrs in single charge and shall have life of 02 years minimum.  (b) Non Chargeable Type/Zinc Air Battery

xi	Regulatory approval	<p>(i) CE marked or US FDA and must be approved by Drug Controller General of India (DCGI)</p> <p>(ii) The tenderer should submit an undertaking that tenderer shall provide valid Import License issued under the provisions of the Drug and Cosmetic Act, 1940 and Rules 1945 issued by Central Drug Standard Control Organization (DGCI) Directorate General of Health Services, Ministry of Health and Family Welfare in the name of tenderer valid for at-least 90 days from date of opening of TC bid.</p>
xii	Bone Evacuation (Maximum)	1.00 cubic centimeters.
xiii	Infrastructure support	a) All necessary hardware and software required for preoperative, intra-operative and post-operative testing and programming for the implanted should be provided at hospital/centre impaneled under ADIP scheme.
		b) To impart training of professional at Hospital centre identified by AYJNISHD Mumbai prior to Cochlear Implant surgery.
xiv	Technical Support	On-site technical support for hardware/software programming related problem should be provided as and when required within three working days.
xv	Service Support	Provision of spares/ loaners for equipment defects/ malfunctions within five working days.
xvi	Warranty	<p>Replacement/ repair warranty is to be provided as follows</p> <p>(i) Cochlear implant :10 Years from the date of surgery including surgery cost shall be borne by the Supplier in case of failure,</p> <p>(ii) External components - Processor 3 years + extended warranty of 2 years; rechargeable battery unit, coil, magnet, battery charger– 1 year each</p>
xvii	Reliability Factor	Reliability factor should be 95% and above with published /data based evidence to be attached
xviii	Has any of your CI models ever been recalled by any regulatory authority	<p>Yes/ No If Yes</p> <p>Furnish the details and reasons for recall</p> <p>Corrective Action taken thereafter</p>
xix	Experience	(a) The Company should have been in the business of supply of Cochlear Implant for a period of minimum two years in India as on date. Necessary acceptable documentary proof need to be provided.
		(b) The Company must have supplied a minimum of 250 Cochlear Implant in India as on date. The copies of Purchase Order for the said quantity need to be provided.
		(c) The Company should have been in the business of supply of Cochlear Implant for a period of minimum ten years world wide as on date. Necessary acceptable documentary proof need to be provided.
		(d) The Company must have supplied a minimum of 5000 Cochlear Implant worldwide as on date. The copies of Purchase Order for the said quantity need to be provided
		(e) Minimum average turnover in last 3 years shall be Rs. 1400.00 Lakhs. A Certificate with UDIN by practicing Chartered Accountant to be provided.

xx	Implant Shelf life	Two years minimum.
xxi	Product support	Lifelong product support for the product including implanted and external component, software and hardware, Free upgrade of software & hardware support for product in case existing implant system is discontinued by manufacturer.
xxii	Training	Training of medical and paramedical personnel and continuing education to be provided by supplier as and when required.
xxiii	AMC/Extended Warranty	Extended warranty of 2 years for sound processor over the existing warranty of 3 years.
xxiv	Performance Guarantee	Irrevocable Bank Guarantee of 5% of Purchase Order value from a Nationalized Bank for warranty period for 10 years, subject to maximum of Rs. 50.00 Lakhs
xxv	Service Network	(a) Details of Marketing/Sales Offices in India
		(b) Details of Service Support Centers in India