The Indian Association of Dermatologists, Venereologists and Leprologists (IADVL)-Industry Liaison Committee – Year 2024-2025

“Check list before buying Laser Instruments”

NOTE: This checklist is useful once you have decided what laser technology to buy. There is no discussion about the physics and decision making about technology.

DISCLAIMER: IADVL, Industry Liaison Committee ’23, provides this checklist as a general guideline for dermatologists considering the purchase of a medical laser device. This checklist is meant for informational purposes only and does not constitute professional advice or endorsement of any specific laser device or manufacturer.

- **Consultation with a Senior Dermatologist**:
  Before making any decisions related to the purchase of a medical laser device, it is crucial to consult with a qualified senior dermatologist who is experienced in dermatology and using same laser device or used other machine from same distributor, this is very important first step.
- **Regulatory Compliance**:
  The purchase, ownership, and use of medical laser devices are subject to various local, state, and federal regulations and licensing requirements. It is the responsibility of the dermatologist to ensure compliance with all applicable laws and regulations.
- **Manufacturer and Device Research**:
  Dermatologists should thoroughly research and evaluate different manufacturers and laser devices to determine which one best suit their clinical needs. **IADVL does not endorse or recommend any specific manufacturer or product.**
- **FDA Approval**:
  Ensure that any medical laser device being considered for purchase is approved by the U.S. Food and Drug Administration (FDA) or the relevant regulatory authority and other FDA certificates , CE certificate (Always ask to add some reference clinician of their countries).

- **Insurance and Liability**:
  Dermatologists should have appropriate liability insurance coverage to protect themselves and their practice in case of any unforeseen events or complications related to laser treatments. Take advice of current office bearers of IADVL regarding this. Is DVL welfare trust will give you protection by enrolling your device, Take advice of current DVL welfare trust office bearers also.
- **Make sure to get registered** with parent organisation without fail, which will allow you to be in touch with parent organisation.(company)
- **Certificates**:
  Certificate of origin, Certificate of Manufacturing Plants (If manufacturing is done abroad and device assembled in India/Bharat – ask for place of assembly.)
- **Registration of Company**:
  From Where or whom you are buying, country of origin of the company, whether it's registered under company act or working as M/s or middle man/distributer.
  At the same time ask also whether the company sales same device to non-qualified cosmetologist or others who have not having medical regulatory registration number.
- Ask for **demo** of the same device before buying. The machine should be kept in clinic for 2-3 treatment sessions because it is not possible to assess the result in single session. The machine should be tried for various indications.
- **Cost of consumable Parts**:
  Before buying any system always verify availability, durability and cost of consumable parts. Ask for how many years from installation date company will provide parts and if that particular distributor terminate to sale that particular device then who will provide after-sales services? How the person currently dealing with you will help you regarding the same device, in future?
- **Transportation breakage:**
  Pre-decide terms and conditions of Repair or replacement of Breakage happening during and after transportation and faulty or malfunctional device after installation. Ask for installation charges.
- **Bills and GST**:
  Ask for a detailed bill and calculate GST as per Government rules and regulations. Quote price and final deal may be different that to be specified as per discussion with distributor.
- **Breakage & maintenance policy**:

Ask about warranty and/or guarantee. What and how will they replace or repair any damages, occurring during or after warranty period? How many routine maintenance visits will be provided in a year? And for how many years? Inquire about warranty extension. Ask about software updates, maintenance and their charges. Make sure you sign a contract with the distributor for maintenance that includes all terms and condition.. Clarify whether it is AMC (Annual Maintenance contract) or CMC (comprehensive maintenance contract) and clearly mention all terms, conditions and promises discussed verbally is mentioned on paper , with the distributor. Check for validity of contract signed. Ask for charges of repair, after the end of contract.

- **Laser safety equipment**:
  Laser safety glasses and other safety material should be provided by Distributor. Inquire about that before final deal. Ask whether it is included in the price quoted or any extra charges are there. Inquire if they will provide any marketing material and will they provide customized brochure or not? In what quantity? Always ask for original user manual, installation manual/reports and video of procedure by parent company.
- **Power-supply & Suitable clinic environment:**
  Air-conditioned room, Cooling system, Smoke evacuator, Power back up, Stable power supply UPS, , three phase connection, Invertor and battery back up at installation site should be checked priorly and confirmation by engineer of that particular company is must.
- Make sure everything is on paper before installation of machine or Laser device.

*Ask for promotion activities by the company

Take full advantage of that. Ask for the company for standees or brochures with your clinic name and logo to be printed. Many companies provide it. Make use of it.

*While checking with senior dermatologist be polite and make sure you ask all your doubts, but also value their time and be concise with it.

Be prepared with your doubts

*Regulatory compliance, cross check with the actual regulatory authority website. Often some companies may provide bogus certificate.

*Make sure you know the higher persons in the distributor company and get their number. Regional representative may misrepresent the device details for a sale.

Consumer Protection Act, 2019, has provisions that protect buyers of LASER instruments in India. Some of the key rights include:

1. Right to Safety: The instrument must meet safety standards and not pose any risk to the consumer's health or property.

2. Right to Information: Consumers have the right to accurate and clear information about the LASER instrument, including its specifications, potential hazards, and proper usage instructions.

3. Right to Choice: Consumers can choose from a variety of LASER instruments available in the market, ensuring they find the product that best meets their needs.

4. Right to Redressal: If the LASER instrument is defective, does not meet the promised specifications, or causes harm, consumers have the right to seek remedies such as refund, replacement, or repair under the provisions of the Act.

5. Right to Consumer Education: Consumers have the right to be educated about the safe and proper use of LASER instruments, as well as their rights and options in case of any issues.

These rights aim to protect consumers and ensure fair and transparent transactions when purchasing Click Here LASER instruments in India.

The Guidelines issued by Ministry of Health & Family Welfare under Medical Device Rules 2017 having CDSCO Approval are attached herewith in this link: Click Here or Follow this link: -

https://drive.google.com/file/d/1dJquIpu5IeFQGglu9bES9OqRfB4PIfHW/view?usp=sharing

5Things to keep in mind after purchase:

Check Back-side of the Device and parameters:
Always check backside of the system, whether everything is same as its mentioned in brochure or not. Check the serial number of device and its similarity on machine, the brochure and the bill. Always check calibration report before using device and confirm the energy what is shown on screen is delivered.. discuss the various parameters of laser machine with guidelines given by company. Check that parameters suits to skin of colour and then start to use machine.

Maintenance and Safety:
Regular maintenance and safety checks of the laser device are essential to ensure its proper functioning and prevent accidents. Dermatologists should establish maintenance protocols and adhere to them. Every system on the earth or any medical speciality Periodic servicing is must, these are energy-based device, wear and tear are mandatory, so no compromising in regular service and maintenance.

Patient Informed Consent:
Dermatologists should obtain informed and written consent from patients before performing any laser treatments. Patients should be informed about potential risks, benefits, and alternatives. Ask distributor, if they have pre-printed consent of that device where you can add name of clinic/hospital and make it available for your patients.

Record Keeping:
Maintain accurate records of all laser treatments, including patient information, treatment parameters, and outcomes, as required by regulatory authorities. This will help you in evaluating and deciding best suitable parameters for your patients.

Continual Education:
Stay updated on the latest advancements, research, and safety guidelines related to dermatological laser treatments through ongoing education and professional development.

By using this checklist, you acknowledge that IADVL is not liable, and force for any decisions made by dermatologists or their staff regarding

the purchase or use of medical laser devices. The responsibility for ensuring the safety, efficacy, and compliance of laser treatments rests solely with the dermatologist and their practice**. These are guidelines and not a legal document.** Please consult with legal and regulatory experts to ensure full compliance with all relevant laws and guidelines before purchasing and using a medical laser device.

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