Endophotocoagulation Probes: Maximizing Product Safety, Efficiency, and Quality via a System-Level Approach to Design, Manufacture, Test, and Calibration

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Microincision vitrectomy surgery (MIVS) has been an important innovation in retinal surgery. The advantages of MIVS include faster, sutureless surgery, with less trauma, inflammation, and patient discomfort; more rapid visual rehabilitation; and better preservation of filtering blebs in glaucoma patients[1,2].

Although these advantages have been known for some time, the move to 25 gauge or 23 gauge surgery was initially limited by instrument availability and performance and availability. Today, however, such small gauge instruments are approaching the full functionality of 20 gauge instrumentation, making the surgical transition to MIVS more compelling[3].

In the midst of this transition, it is easy to overlook the corresponding new demands on the probes through which laser treatments are delivered. The primary requirement for these single-use devices is that they provide a safe means to deliver laser light to the retina. Probes must function well in gas or fluid media and produce uniform, consistent lesions. They must also adapt to the challenges of fitting through smaller diameter cannulae without compromising reliability, laser delivery, or secondary functions such as illumination.

When using the IRIDEX EndoProbe®, surgeons can direct their attention to other aspects of the surgical procedure, confident that the probe itself is of superior quality and designed to produce safe, consistent results.

The EndoProbe is available in a wide variety of configurations. Surgeons may select straight, angled, active or passive aspirating, illuminating, or adjustable and intuitive probes, according to personal preference and surgical need. The newest, stepped-angled probes have a gentle, tapering arc designed specifically for small gauge surgery and are also available with illumination as an option.

The Ultimate Calibration: Device Recognition
IRIDEX laser consoles are calibrated to international laser standards using IRIDEX probes and devices. The proper function of every EndoProbe is verified on an IRIDEX laser, not just once but multiple times during the manufacturing and testing process.

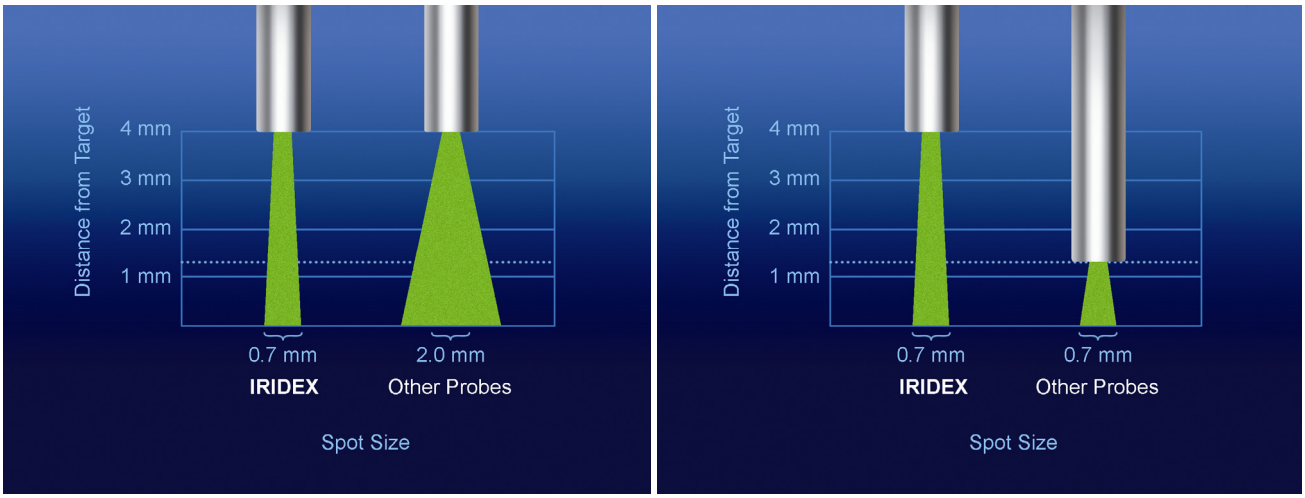
Every EndoProbe model and IRIDEX laser photocoagulator is designed to work together as a system in a number of ways that perhaps are not immediately obvious to the user. The laser console and probe communicate with each other via an electrical circuit that is automatically completed whenever the device is connected. Information sent to the console is derived from empirical data compiled from fiber size, transmission losses, beam divergence and downstream optics (if any) for every type of delivery device. The laser then uses that unique information to produce the requested output power at the tip of the EndoProbe. If the laser is set at 500 mW, for example, the user expects, quite properly, output of 500 mW. Working together, the IRIDEX console and EndoProbe realize that expectation.

The probe circuit can also provide the laser with a complex set of instructions and assumptions: type and diameter of fiber used; polishing and manufacturing techniques; transmission characteristics; and other factors that can affect laser output. Using an IRIDEX EndoProbe ensures all these factors are conveyed. Use of an adapter or 3rd party delivery devices removes this level of detail and may not perform in a manner identical to genuine IRIDEX devices. The system may recognize another supplier's device having a similar resistor, for example, but recognition alone does not ensure equivalent performance.

Poor calibration increases the uncertainty in power output, reduces repeatability, and contributes greatly to probe-to-probe performance variation. Inconsisent performance of surgical tools can compromise surgeon confidence, extend the time required for surgery, and lengthen surgeons' learning curves. When using an IRIDEX laser, the only way to ensure the highest quality and achieve accurate calibration of the system is to use genuine IRIDEX EndoProbe or delivery device.

Quality Manufacturing and Design
Each IRIDEX EndoProbe has been carefully designed with great attention to detail so that the surgeon does not have to worry about probe performance or consistency from case to case. Each probe incorporates the highest quality components to maximize the surgical result.

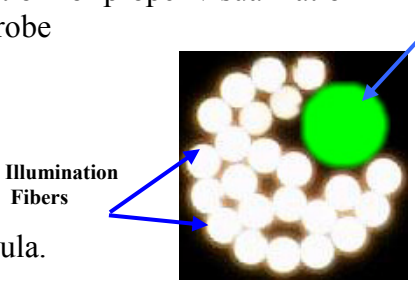
High-grade glass fibers
Most importantly, IRIDEX probes use highest-grade glass fibers to ensure optimal laser energy throughput and efficiency. They are designed to have a narrow cone angle, meaning that the angular divergence of the laser beam from the probe aperture is consistently low when compared with probes from other manufacturers.



Cone angle dictates the spot size at a given working distance. High-grade glass fiber yields a narrow cone angle (left probe, both images) allowing work from the retina at greater distances. Lower grade fibers (right probe, both images) shows how much closer to the retina the probe needs to be to provide the same spot size as an IRIDEX probe.

The laser energy emitted from an IRIDEX probe is delivered in a tighter, smaller diameter, allowing the surgeon to position the probe farther from the retina. Such a probe improves patient safety and minimizes changes in tissue irradiance and associated endpoint appearance with inevitable variations in probe-retina distances. This is a very significant characteristic when considering a procedure that often delivers hundreds of discrete laser spots to retinal targets from a handheld device. Other probes need to be much closer to the target tissue to deliver a similar narrowly-focused spot.

When using illuminated probes, the need for a narrow cone angle of laser delivery must be balanced with the desire for a wide area of illumination for proper visualization of the peripheral retina. The IRIDEX illuminated probe design surrounds the laser fiber optic with many illumination fibers, numbering to over 70 fibers depending on the gauge being used.These light bundles achieve a wide area of illumination even through a small-diameter cannula.



Example of a fiber bundle used in the 27gauge (0.361mm) distal tip of a 25-27ga Stepped BriteLight EndoProbe.

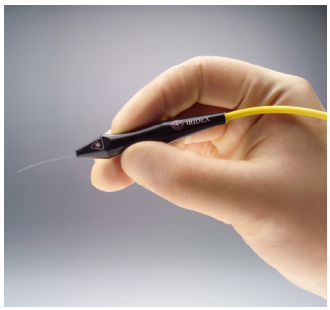
The bayonet-style probe is one approach IRIDEX uses for illumination with 20 gauge surgery. By combining recessed light fibers with a laser fiber in the forward position, it is possible to achieve a narrow laser cone angle with wide illumination.

Advancements in technology allow MIVS to utilize illuminating laser probes. Due to the size restrictions of finer gauge surgery, bayonet probes are too fragile, thus new technology and improved illumination fibers are utilized where they are both flush with the probe needle. These offer the same narrow cone angle for the laser fiber, but wider cone angles for illumination fibers to improve visualization. By keeping the laser fiber and illumination fibers flush, the safety profile of the device is improved and the opportunity for breakage is reduced.

Mode quality

The goal with any probe is to achieve a high-quality, homogeneous laser mode—the delivery of a uniform spot through the laser fiber. Ideally, one would like to see a perfectly circular lesion, with no hot or cold spots or other regions of optical nonuniformity.. This is another area where the quality of the glass fiber and the preparation of its endfaces make an appreciable difference. As a result of both the fiber quality and the proprietary manufacturing processes, IRIDEX probes have superior beam profile quality, resulting in consistent and reproducible burns.

Ergonomic design



Although a laser probe is a disposable device, it is still a surgical instrument and as such should feel like one. IRIDEX probes are designed with an ergonomic handle shaped to fit comfortably in the surgeon's hand. They are made from machined aluminum, rather than plastic, so the probes have the heft and feel of a reliable, quality surgical instrument. Finally, the handpiece incorporates a machined bevel feature to aid in its precise orientation, giving tactile feedback regarding the angle and direction of the probe needle. As the surgeon rotates and manipulates the probe, the feature always serves as a ready tactile indicator of the needle position.

Quality control testing

Unlike many single-use instruments, IRIDEX probes undergo rigorous testing during the manufacturing process. Calibration and energy output are thoroughly tested prior to final packaging and sterilization—and not on a random basis, but for *each* probe. This virtually eliminates probe-to-probe variances and ensures consistent performance from one probe to the next. This process and attention to detail helps to ensure errors are caught before shipping, reducing wasted time in the operating room and administrative hassles afterward. IRIDEX is proud to have reported probe failure rates of much less than 1%.

Summary

As with other instrumentation, small gauge surgery presents numerous challenges which also apply in the design of endophotocoagulation probes. IRIDEX has set the standard for probe technology, meeting surgical needs for small-gauge probes that consistently and accurately deliver laser treatment at a safe distance from the retina, without sacrificing illumination.

IRIDEX offers probe models for every surgical application and preference. EndoProbe models have an ergonomic feel for precision handling. Surgeons can be assured that they are manufactured from the highest quality components designed and validated to meet rigorous manufacturing standards. In combination with an IRIDEX laser, the IRIDEX EndoProbe sets the benchmark for laser probe performance and consistent surgical results.

References:

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3. Rizzo S, Genovesi-Ebert F, Murri S, et al. 25-gauge, sutureless vitrectomy and standard 20-gauge pars plana vitrectomy in idiopathic epiretinal membrane surgery: A comparative pilot study. Graefe's Arch Clin Exp Ophthalmol 2006;244:472-9.