

What do the recent technological advancements for femto cataract surgery mean?

What you need to know if you are considering the LenSx Laser for your practice

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Innovations in femtosecond technology

by Robert Cionni, MD

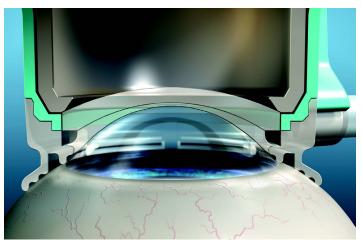
Surgical outcomes of laser cataract surgery have improved significantly with the latest technology and development of modified techniques. I have been using the LenSx Laser (Alcon, Fort Worth, Texas) since February 2011.

In a study of 3,355 consecutive cataract/refractive lens exchange procedures performed with the LenSx Laser between April 2012 and October 2014, a break in the capsule rim was identified in 7 (0.21%) eyes.¹ This occurred during phacoemulsification in 6 eyes and during irrigation/aspiration in 1 eye. The tear extended to the posterior capsule in 2 eyes, and 1 of these eyes required anterior vitrectomy. Sulcus IOL implantation was safely performed in both cases. In 2 cases, the tear extended to the equator without posterior capsule involvement or vitreous loss, and in-the-bag IOL implantation was successfully performed with the haptics aligned away from the laser. All tears were observed after phacoemulsification or cortical removal in cases with no predisposing conditions recorded.

In my practice, for routine cases, capsular tear rates are less than 1% in femtosecond cases compared with 2% to 3% for manual cases. With a femtosecond-made capsulotomy, I know the anterior capsular opening will be centered and about 5.2 mm every time. With a manual technique, I may think I'm tearing a 5.5-mm capsulotomy, but by the time I'm done, the capsulotomy may actually be a little larger or a little smaller and not perfectly centered. I think we get tears in manual cases because we nick an edge with the phaco tip or with a second instrument as we are a little less certain of the size of the opening and exactly where those edges are.

In the manual cases, I use an optical zone marker to make an indentation on the corneal epithelium before I do my manual capsulotomy. Due to the effect of corneal magnification, if I stay inside that ring, I usually end up with about a 5.25mm capsulotomy, but it can still vary depending on chamber depth and corneal curvature. It can also vary because I have to do it manually. I've performed a lot of cataract surgery, and I typically achieve a fairly round, nicely sized capsulotomy. However, it's not every time. With the laser, it's every time.

The Variable Beam Profile is unique to the LenSx Laser. Most lasers were designed either for cornea work or for capsule work, meaning that the laser beams are oriented or focused in such a way as to work deeper in the eye or, alternatively, more anteriorly on the surface of the eye. The innovation in the LenSx Laser is that it has a variable beam, such that when it's working at the corneal surface, it focuses differently, from different angles, than when it's focusing deeper. So it behaves

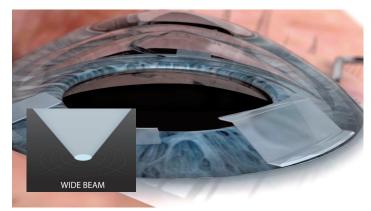


Using proprietary hydrogel technology, the SoftFit Patient Interface conforms to the patient's natural corneal curvature for precise docking.

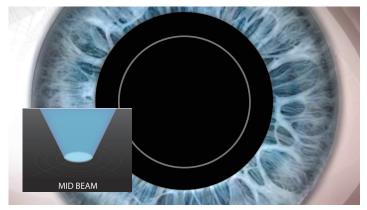
both like a laser that was made to work on the lens and like a laser that was made to work on the cornea. The LenSx Laser creates beautiful capsulotomy incisions, beautiful lens chop incisions, and beautiful corneal incisions.

A recent study has found that this procedure is efficient and less damaging than manual procedures.² The study included 60 eyes of 60 patients who underwent clear corneal incision cataract surgery; in 30 eyes, the incision was performed with the LenSx Laser, and in 30 eyes, the incision was performed manually. In the eyes in the LenSx Laser group, there was less central endothelial cell loss, less increase in corneal thickness at the incision site, and better tunnel morphology than in eyes in the manual group.

Combined with the Variable Beam Profile, the SoftFit Patient Interface helps the precision of the platform by providing fixation with very minimal corneal distortion. The SoftFit Patient Interface incorporates a soft hydrogel lens in the interface so that the interface conforms to the cornea, thereby markedly minimizing the risk of corneal folds and reducing the scattering of that energy. The result is a smooth and complete capsulotomy nearly all of the time with a much lower risk of having tags or rough edges. It also holds the eye with an appropriate amount of vacuum to prevent eye movements that can lead to misguided energy delivery as can be seen more frequently in other laser platforms that don't fixate the eye.



The wide beam is designed for corneal accuracy



The mid beam puts focus on the capsule.



The narrow beam is intended for effective lens fragmentation.

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The innovation in the LenSx Laser is that it has a variable beam, such that when it's working at the corneal surface, it focuses differently, from different angles, than when it's focusing deeper. So it behaves both like a laser that was made to work on the lens and like a laser that was made to work on the cornea.

The LenSx Laser is helpful in patients with intumescent white cataracts. The anterior chamber is fully inflated. As the surgeon performs the capsulotomy, pressure in the anterior chamber is maintained, and this helps prevent the tear from running out to the periphery, which is common in these cases when the capsulotomy is performed manually.

The fact that the chamber remains pressurized and the fact that the capsulotomy occurs for 360 degrees almost instantaneously help decrease the risk of having a radial tear.

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Femtosecond laser-assisted cataract surgery offers benefits for surgeons, patients

by Kerry Solomon, MD

Femtosecond laser-assisted cataract surgery with the LenSx Laser (Alcon, Fort Worth, Texas) offers advantages over manual cataract surgery.

Innovative high-definition visualization

One of the benefits of the LenSx Laser over manual cataract surgery is optimal visualization, and both visualization and docking are quite easy. I can visualize every aspect of the procedure from beginning to end, which is a big advantage. Additionally, the LenSx Laser allows for quick centration.

Another feature is the proprietary OCT technology, which is able to image down to a depth of 8.5 mm in a single image, without having to stitch multiple images together. It has high-definition imaging where the entire anterior segment is in clear view. It also has a zoom feature, which is helpful when finalizing the laser's surgical plan for capsulotomy and incisions. It helps maximize dialing in the precision of the laser treatments to a high degree and the precision of the surgical outcome.

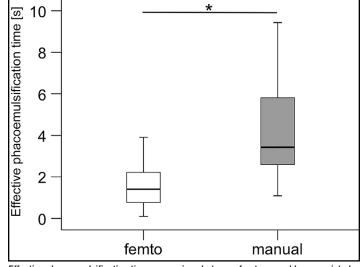
Reduced procedure time

The timeliness of the scanning and imaging process is also important to help minimize suction time for the patient during the procedure. Once a patient is docked, the surgeon presses a button on the joystick, and the imaging, scanning, and auto-centration process occurs in seconds. The level of speed of this part of the process as well as the level of speed of the total laser treatment time and total procedure time is unique to the LenSx Laser. Typically, total procedure suction time is less than 2 minutes, and laser treatment time for all incisions, capsulotomy, and fragmentation is typically less than 30 seconds in total.

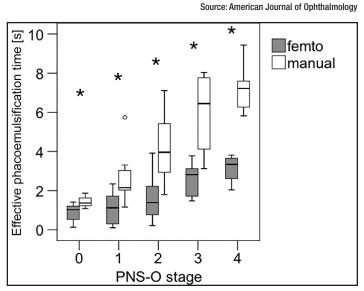
A recent study conducted in Germany found that femtosecond laser-assisted cataract surgery with the LenSx Laser allows a significant reduction in effective phacoemulsification time, which correlates positively with the preoperative lens opacity.¹ The study included 150 eyes of 86 patients with senile cataract: 88 eyes underwent femtosecond laser-assisted surgery and 62 eyes underwent complete cataract removal performed with phacoemulsification only. Postoperative Pentacam (Oculus, Arlington, Wash.) nucleus staging showed no significant differences between the groups. Overall mean effective phacoemulsification time was 1.58±1.02 seconds in the femtosecond group compared to 4.17±2.06 seconds in the phaco group. Additionally, endothelial cell loss was significantly lower in the femtosecond group.

Preserving the cornea

The LenSx Laser procedure also has advantages for the cornea compared to manual cataract surgery. It offers excellent



Effective phacoemulsification time comparison between femtosecond laser-assisted cataract surgery and manual surgery. Significant reduction in time in the femto (femtosecond laser-assisted cataract surgery) group (* = significant difference between groups; P=0.001).



Mean effective phacoemulsification time in PNS-0 (Pentacam automated nucleus staging; ordinal scale) stages (* = significant difference between groups: manual surgery [manual] and femtosecond laser-assisted surgery [femto]; *P*<0.01). Source: American Journal of Ophthalmology

precision for all incisions and arcuate incisions that can be left open or closed. There is less endothelial cell loss, less corneal edema, and clearer corneas the day after surgery.² A study conducted in Italy found that the femtosecond laser cataract procedure was efficient and less damaging than manual cataract surgery, as was demonstrated by lower central endothelial

For important product information, please see page 8.



With multiple fragmentation patterns and combinations available, the LenSx Laser provides greater flexibility to fit more patient anatomies and surgeon preferences.

cell loss, lower increase of corneal thickness at the incision site, and better tunnel morphology compared to the manual technique.² The study included 60 eyes: 30 that underwent femtosecond laser clear corneal incisions and 30 that underwent manual clear corneal incisions. Central endothelial cell count was significantly higher in the femtosecond laser group compared to the manual group at 7 and 30 days postoperatively. Total phaco time was significantly lower in the femtosecond laser group.

The LenSx Laser also offers multiple lens fragmentation pattern options. I use a grid pattern, which is composed of tiny cubes. The surgeon can determine the exact size of the cube shapes, and I have gotten used to cube shapes around 275 μ m to 300 μ m. I find that this size cube will go down the lumen of the phaco port without needing much energy. The femtosecond laser is prechopping the lens into these tiny cubes, but I focus the energy more on the densest part of the cataract, the central 4–4.5 mm. I do not put as much energy outside of this area; I haven't found it to be necessary. The LenSx Laser reduces the need for phaco energy and femto energy, and it simplifies the entire procedure. It decreases procedure time, and I am consistently in the low single digits with CDE power.

In my practice, I have two OR setups, and the laser is in a separate third room. I find this to be very efficient, as I rotate between the rooms with typically no downtime between patients.

Refractive outcomes

Laser refractive cataract surgery with a femtosecond laser has been shown to improve predictability of IOL power calculation over conventional phacoemulsification surgery.³ A recent study prospectively evaluated 77 eyes from 77 patients who underwent laser refractive cataract surgery and 57 eyes from 57 patients who underwent conventional cataract surgery. No significant differences were found between the groups with regard to age, axial length, keratometry, and preoperative corrected visual acuity. At least 6 weeks after surgery, mean absolute error was significantly lower in the LenSx Laser group than in the conventional group. The difference was the greatest in short (axial length <22.0 mm) and long (axial length >26.0 mm) eyes.

Additionally, a separate study found that a continuous curvilinear capsulorhexis created with the LenSx Laser resulted in a more stable refractive result and less IOL tilt and decentration than a manual continuous curvilinear capsulorhexis.⁴ In this prospective, randomized study, 20 eyes had a continuous curvilinear capsulorhexis created by the LenSx Laser, while 25 eyes had a continuous curvilinear capsulorhexis created manually. The study found that horizontal and vertical tilt were

significantly higher in the manual continuous curvilinear capsulorhexis group, and lenses implanted after manual continuous curvilinear capsulorhexis had greater horizontal and total decentration. The researchers noted significant differences in the homogeneity of dichotomized IOL vertical tilt and both horizontal and total decentration distribution. Total IOL decentration was found to have a significant correlation with changes in manifest refraction values between 1 month and 1 year after surgery, and a significant correlation was observed between IOL vertical tilt and corrected distance visual acuity.

Difficult cases

The LenSx Laser is especially beneficial in difficult cases. I have used it on a few eyes with anterior lenticonus, and it has worked very well. Additionally, I have used it on a couple of eyes with posterior lenticonus, and that has worked out great. It has also been terrific in treating eyes with traumatic cataract where we have had ruptured anterior lens capsules and white mature cataracts for the capsulotomy. These are the types of challenging cases where I think the LenSx Laser has really helped. In virtually all of those cases, it wasn't done from a refractive standpoint but what we felt was in the best interest of the patient.

I have been thrilled with its consistency and reproducibility, and I think it has been wonderful overall.

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Advances to the LenSx Laser improve efficiency in the office

by Stephen Lane, MD

After conquering the learning curve, the LenSx Laser (Alcon, Fort Worth, Texas) can improve time efficiency and patient flow in your office. How to best incorporate this technology will vary a bit from practice to practice. Optimally, each practice should attempt to disrupt the flow that has worked well in the past as little as possible. The amount of flow change and possible disruption that takes place will depend on two factors: whether you operate out of one room or two and where you plan to place the laser.

In my practice, because we only have one operating room, we found that it was much more efficient to place the laser outside the operating room in a clean, adjacent room, so that there is very little travel time from the LenSx Laser room to the operating room. Before we had the LenSx Laser, we had a system where we always had the next patient ready to go so that one patient was essentially being wheeled out of the operating room as the next one was being wheeled in. It was a very efficient system; however, the LenSx Laser has some operating time involved with it, so we had to make some adjustments.

We have been able to overcome the flow challenges by having staff prepare a LenSx Laser case at the same time that another patient is being brought into the operating suite. In other words, our office staggers LenSx Laser cases with non-LenSx Laser cases so that the operating room is always full, just as it was before we had the laser. For example, I will finish with a case in the operating room and go directly to the LenSx Laser room where a patient is already prepped and underneath the laser. While I am performing the LenSx Laser procedure, another patient is being wheeled into the operating room and is being prepped and draped. When the LenSx Laser procedure is completed, the second patient is in the operating room waiting for me to operate. The just-completed LenSx Laser patient is put into a holding bay and will be the next patient to go into the operating room. This makes our ASC extremely efficient.

A major advantage of the LenSx Laser platform is that there is no fixed bed. The patient can stay on the same operating bed for the laser portion of the procedure as well as for the intraocular portion of the procedure that takes place in the operating room. The patient never has to leave the bed and can be easily moved/wheeled from one location to another, optimizing the type of flow pattern described above.

With regard to the procedure itself, the LenSx Laser is quite easy to use. The screen is very intuitive in terms of the sequence of steps from the beginning to the end of the procedure. Surgeons use a combination of a touch screen or a trackball. For those surgeons who like to do everything themselves, they can manipulate the laser and go through the steps by manipulating the trackball. However, if they prefer to have an assistant perform the steps, the assistant can do so by using the touch screen and verbal instructions from the surgeon.

Additionally, the graphic user interface (GUI) moves the surgeon through the entire planning and execution process. The surgical plan automatically comes up on the screen so that the surgeon can double-check it with other information he or she may have written down or on another computer.

Another benefit of the system is autocentration. For example, the surgeon can choose whether the capsulorhexis will be centered over the dilated pupil or centered on the line of sight. The system makes these kinds of choices available, and it autocenters the rhexis based on the surgeon's preference. When paired with Verion, the LenSx Laser can do autocentration of all laser treatments based on the preoperative undilated pupil.

Automation of the femtosecond laser gives surgeons an edge in terms of being able to predictably, confidently, and precisely perform the various initial steps of the procedure. This provides the consistency to help ensure a successful procedure.

Additionally, the cases that I perform with the LenSx Laser are truly less stressful to me than the cases that I perform manually from beginning to end. The incisions are uniform with the femtosecond laser compared to some variability that I have when I create incisions myself with either a diamond or a metal knife. As I mentioned previously, surgeons can make the capsulorhexis perfectly round, place it exactly where they want it, and make it exactly the size they want it every time. Many surgeons are excellent at making a capsulorhexis, but no surgeon can make them exactly the same, of the desired size and in the desired location time after time.

A recent study has found that a continuous curvilinear capsulorhexis created with a femtosecond laser results in a more stable refractive result and less IOL tilt and decentration than a manual continuous curvilinear capsulorhexis.¹ In this prospective, randomized study, a laser continuous curvilinear capsulorhexis was performed in 20 eyes, and a manual continuous curvilinear capsulorhexis was performed in 25 eyes. Horizontal and vertical tilt were statistically significantly higher in the manual group, and lenses implanted after manual continuous curvilinear capsulorhexis showed greater horizontal and total decentration.

Finally, the LenSx Laser gives us the ability to perform the lens chop, which makes removal of the lens easier. The



The LenSx Laser shown with the Verion Digital Marker

"prechopped" nucleus is easier to fragment and easier to segment, and it uses less energy and time than if it were done manually.

As we gain more experience with the LenSx Laser, we are coming to realize its utility in complicated and difficult cases. I recently saw a patient who had a dislocated, cataractous lens resulting from a traumatic injury. The LenSx Laser allowed me to perform a capsulorhexis much more easily than I would have been able to do manually. Being able to perform the capsulorhexis exactly in the portion of the lens that I wanted and to make it exactly the size that I wanted allowed me to use capsular retraction hooks more effectively and without the concern of these tearing out. It was done more easily and accurately with the femtosecond laser.

Similarly, I used the LenSx Laser in another case where the patient had an intumescent, white lens that clinically appeared to have significant intralenticular pressure. I was concerned that this case could be complicated, producing an Argentinian flag sign. This phenomenon is well-known and is a concern because of the high intralenticular pressure. When the capsule is punctured after having applied trypan blue to enhance capsular visibility (even in the presence of viscoelastic and a pressurized chamber), the capsule can tear out, creating a central white band (the white lens) with a blue band on either side resembling the Argentina flag. This is not a concern with a femtosecond laser, however. A perfect capsulorhexis can be performed without having it tear out because the pressure inside the eye is maintained and constant. This significantly improves the safety margin in these type of cases.

Recent advancements have made femtosecond laser technology even more exciting. When you think about it, phacoemulsification has been around for 30 or 40 years. Femtosecond laser technology has only been around for 4 or 5 years, and it is amazing that it can perform the steps of the procedure more precisely than manual techniques.

Most surgeons who perform these steps manually believe that they can be better, more consistent, more accurate, more precise, and more reliable with femtosecond technology. Why isn't everyone using it? A big question is the economics of the technology. We are finding that this can be overcome and that discussing the use of the femtosecond laser with patients is not as difficult as we once thought.

We continue to see remarkable improvements in the upgrades of the instruments. There have been numerous upgrades to the current LenSx Laser system since its inception, and each one has made a powerful impact on the improvement of the procedure. I expect that this technology will continue to evolve and as a result provide the opportunity to enhance our practices and our patient outcomes.

Reference

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Product information

LenSx® Laser

Caution: United States Federal Law restricts this device to sale and use by or on the order of a physician or licensed eyecare practitioner.

Indication:

Cataract Surgery Indication

The LenSx[®] Laser is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, phacofragmentation, and the creation of single plane and multi-plane arc cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure.

Corneal Flap Indication

The LenSx[®] Laser is indicated for use in the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.

Restrictions:

- Patients must be able to lie flat and motionless in a supine position.
- · Patients must be able to understand and give an informed consent.
- · Patients must be able to tolerate local or topical anesthesia.
- Patients with elevated IOP should use topical steroids only under close medical supervision.

Contraindications:

Cataract Surgery Contraindications

- Corneal disease that precludes applanation of the cornea or transmission of laser light at 1030 nm wavelength
- Descemetocele with impending corneal rupture
- Presence of blood or other material in the anterior chamber
- Poorly dilating pupil, such that the iris is not peripheral to the intended diameter
- for the capsulotomy
- Conditions that would cause inadequate clearance between the intended capsulotomy depth and the endothelium (applicable to capsulotomy only)
- Previous corneal incisions that might provide a potential space into which the gas produced by the procedure can escape
- Corneal thickness requirements that are beyond the range of the system
- Corneal opacity that would interfere with the laser beam
- Hypotony, glaucoma* or the presence of a corneal implant
- Residual, recurrent, active ocular or eyelid disease, including any corneal abnormality (for example, recurrent corneal erosion, severe basement membrane disease)
- History of lens or zonular instability
- Any contraindication to cataract or keratoplasty
- This device is not intended for use in pediatric surgery.

*Glaucoma is not a contraindication when these procedures are performed using the LenSx® Laser SoftFitTM Patient Interface Accessory

Corneal Flap Contraindications

- Corneal lesions
- Corneal edema
- Hypotony
- Glaucoma
 - Existing corneal implant
 - KeratoconusThis device is not intended for use in pediatric surgery.
 - Warnings:

The LenSx[®] Laser System should only be operated by a physician trained in its use.

The LenSx® Laser delivery system employs one sterile disposable Patient Interface consisting of an applanation lens and suction ring. The Patient Interface is intended for single use only. The disposables used in conjunction with ALCON® instrument products constitute a complete surgical system. Use of disposables other than those manufactured by Alcon may affect system performance and create potential hazards.

The physician should base patient selection criteria on professional experience, published literature, and educational courses. Adult patients should be scheduled to undergo cataract extraction.

Precautions:

- Do not use cell phones or pagers of any kind in the same room as the LenSx® Laser.
- Discard used Patient Interfaces as medical waste.

Complications:

Cataract Surgery AEs/Complications

- Capsulotomy, phacofragmentation, or cut or incision decentration
- Incomplete or interrupted capsulotomy, fragmentation, or corneal incision procedure
- Capsular tearCorneal abrasion or defect
- Corneal abrasion or deter
 Pain
- Infection
- Bleeding
- Damage to intraocular structures
- Anterior chamber fluid leakage, anterior chamber collapse
- · Elevated pressure to the eye

Corneal Flap AEs/Complications

- Corneal edema
- Corneal pain
- Epithelial in-growth
- Epithelial defect
- Infection
- Flap decentration
 Incomplete flap creation
- Flap tearing or incomplete lift-off
- Free cap

Attention: Refer to the LenSx[®] Laser Operator's Manual for a complete listing of indications, warnings and precautions.

VERION[™] Image Guided System

VERION[™] Reference Unit and VERION[™] Digital Marker

Caution: Federal (U.S.) law restricts this device to sale by, or on the order of, a physician.

Intended Uses: The VERION[™] Reference Unit is a preoperative measurement device that captures and utilizes a high-resolution reference image of a patient's eye. In addition, the VERION[™] Reference Unit provides preoperative surgical planning functions to assist the surgeon with planning cataract surgical procedures. The VERION[™] Reference Unit also supports the export of the reference image, preoperative measurement data, and surgical plans for use with the VERION[™] Digital Marker and other compatible devices through the use of a USB memory stick. The VERION[™] Digital Marker links to compatible surgical microscopes to display concurrently the reference and microscope images, allowing the surgeon to account for lateral and rotational eye movements. In addition, details from the VERION[™] Reference Unit surgical plan can be overlaid on a computer screen or the physician's microscope view.

Contraindications: The following conditions may affect the accuracy of surgical plans prepared with the VERION™ Reference Unit: a pseudophakic eye, eye fixation problems, a non-intact cornea, or an irregular cornea. In addition, patients should refrain from wearing contact lenses during the reference measurement as this may interfere with the accuracy of the measurements. The following conditions may affect the proper functioning of the VERION™ Digital Marker: changes in a patient's eye between

preoperative measurement and surgery, an irregular elliptic limbus (e.g., due to eye fixation during surgery, and bleeding or bloated conjunctiva due to anesthesia). In addition, the use of eye drops that constrict sclera vessels before or during surgery should be avoided.

Warnings: Only properly trained personnel should operate the VERION[™] Reference Unit and VERION[™] Digital Marker. Use only the provided medical power supplies and data communication cable. Power supplies for the VERION[™] Reference Unit and the VERION[™] Digital Marker must be uninterruptible. Do not use these devices in combination with an extension cord. Do not cover any of the component devices while turned on. The VERION[™] Reference Unit uses infrared light. Unless necessary, medical personnel and patients should avoid direct eye exposure to the emitted or reflected beam.

Precautions: To ensure the accuracy of VERION[™] Reference Unit measurements, device calibration and the reference measurement should be conducted in dimmed ambient light conditions. Only use the VERION[™] Digital Marker in conjunction with compatible surgical microscopes.

Attention: Refer to the user manuals for the VERION[™] Reference Unit and the VERION[™] Digital Marker for a complete description of proper use and maintenance of these devices, as well as a complete list of contraindications, warnings and precautions.

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