INDICATIONS
The iFS® Femtosecond Laser is an ophthalmic surgical laser indicated for use in patients undergoing surgery or treatment requiring initial lamellar resection of the cornea, in treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments, in treatment requiring arcuate cuts/incisions in the cornea, penetrating and/or intrastromal. In lamellar IEK and corneal harvesting; in the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea, in the creation of a lamellar cut/resection of the cornea for lamellar IEK and for the creation of a penetrating cut/incision for penetrating IEK, in treatment requiring the creation of corneal channels for placement/insertion of a corneal inlay device.
PROVEN TECHNOLOGY

Built from a legacy of market leading and innovative IntraLase® Technology utilized in over 8 million procedures with more than 300 scientific citations, giving you confidence when treating patients

PROVEN RESULTS

Rooted in a solid foundation of precision and performance, helping to maximize patient outcomes

PROVEN VERSATILITY

Modular and upgradeable for multiple applications, giving you more surgical options

“All around, the iFS® Laser is just a very solid instrument that does exactly what it’s supposed to do.”

—JOHN VUKICH, MD
GOING WELL BEYOND LASIK FLAPS

Fully individualized, precise incisions for your ophthalmic procedures utilizing a single laser system

- LASIK flaps
- *IntraLase*-Enabled Keratoplasty (IEK) incisions
- Laser Cataract: Arcuate incisions and clear corneal and paracentesis incisions
- Corneal channel
- Intracorneal ring segments

The ideal choice for your subspecialty

- Refractive surgery
- Corneal surgery
- Cataract surgery
- Presbyopia surgery
LASIK FLAPS

State-of-the-art customization capabilities for flap surgical precision:

- Inverted bevel-in side cut up to 150°
  - Increased flap stability and strength post-operatively\(^1\)*
  - Fewer signs and symptoms of dry eye than with 30° side cut\(^2\)
  - Results in less strain on the cornea with little biomechanical change\(^3,4\)
- Thin, uniform (planar) flaps

Inverted bevel-in side cut, customizable to 150°, promotes flap replacement, positioning and adhesion for optimal biomechanical stability of the post-LASIK cornea\(^*\).

*Based on rabbit study
LASIK FLAPS

Elliptical flap option maximizes stromal bed exposure for full delivery of excimer ablation

- Elliptical flap option results in better flap alignment\textsuperscript{5,6}
- Follows the natural contour of the cornea, preserving the vital lamellar fibers during flap creation\textsuperscript{5,6}

Elliptical flap option available only with the iFS\textsuperscript{®} Laser\textsuperscript{*}.

Standard round flap.

\textsuperscript{*}Not available on IntraLase\textsuperscript{®} FS Systems
LASIK FLAPS

Low energy setting, tight spot, and line separation:

- Results in smooth stromal beds for easier flap lift
- Helps minimize inflammatory tissue reaction
- Fast flap creation

Images of the iFS® Laser are provided by Melvin A. Sarayba, MD
Precision-designed corneal incisions with advanced edge profiles

- Precisely shaped edges in multiple configurations (Mushroom, Zig-Zag, Christmas Tree, Top Hat)\textsuperscript{9}

\begin{itemize}
  \item Reproducible grafting of donor and host cornea\textsuperscript{9,10}
    \begin{itemize}
      \item Benefits of improved tissue alignment
        \begin{itemize}
          \item Shaped incisions may be stronger and more stable\textsuperscript{9,10}
          \item Utilizing incisions with multiplanar pattern configuration ensures a snug fit that may require less suture tension\textsuperscript{9,10}
        \end{itemize}
    \end{itemize}
\end{itemize}

OCT image of \textit{iFS}\textsuperscript{\textregistered} Laser-created zig-zag pattern performed on the cornea.

SEM image showing the precisely shaped angled edge.

OCT image showing multiplanar pattern configuration to ensure a snug fit.
CATARACT INCISIONS

Full customization of all laser parameters for greater surgical precision

Intrastromal and penetrating arcuate incisions

- Complete control of angles, placement, and orientations with micron-level accuracy unmatched by manual blades
- Single or paired arc shaped incisions with smooth edges

Light microscopy of human cadaver eye showing a single intrastromal arcuate incision created with the iFS® Laser.

OCT showing a paired set of intrastromal arcuate incisions created with the iFS® Laser.

SEM images showing very regular, arc-shaped penetrating arcuate incision with the iFS® Laser. Note: sharply cut epithelium and Bowman’s layer.

SEM image showing irregular arc pattern created with a manual blade.
CATARACT INCISIONS

Precision designed cataract incisions

• Creation of multiplanar clear corneal and planar paracentesis incisions

• Incisions have a precise construction with clear defined planes\textsuperscript{12}

• Provides flexibility, allowing you to create incisions in your surgical suite and then move patient to the operating facility

\textbf{OCT side view image of the cornea after creation of a triplanar clear corneal incision. Note: incisions have a precise construction, with clear, defined planes.}

\textbf{OCT image of 1-day post-surgical clear corneal incision.}
CORNEAL CHANNEL CREATION

The *iFS®* Laser intuitive user interface for precise inlay channel creation

- Advanced graphical user interface provides you with full control of the inlay channel settings
- Parameter adjustments and patient data entry can be conveniently performed onscreen

### Multiple parameter setting options

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Channel width</td>
<td>Superior to inferior size the channel: 3.6 mm—4.7 mm</td>
</tr>
<tr>
<td>Channel offset</td>
<td>Distance between surgical field center and channel reference axis: 0.0 mm—2.8 mm</td>
</tr>
<tr>
<td>Channel depth</td>
<td>Stromal depth of channel: 100-400 microns</td>
</tr>
<tr>
<td>Side cut radius</td>
<td>Distance between the channel reference axis and entry side cut: 3.7 mm—7.6 mm</td>
</tr>
<tr>
<td>Side cut angle</td>
<td>Angle from channel to epithelial surface: 30°—90°</td>
</tr>
</tbody>
</table>

Note: An offset dock may be required for performing a corneal channel. The corneal channel is created in the temporal position and cannot be modified.

Treatment parameter modifications are allowed up to the point of treatment initiation.
More precise control in intracorneal ring segments (ICRS)

- Greater channel depth control and accuracy than mechanical instruments
- A better match with various ring segment dimensions
COMMitted To Your Practice Success

Sharing expertise and support from the proven leader

Business Development

- In person and online education-practice-building tools and patient marketing initiatives
- Diagnosis and solutions to elevate practice performance

Application Support

- On-site surgeon and technician training and support to help improve outcomes by maximizing team skills
- Highly skilled application support team and renowned medical monitors—ongoing clinical consultation and analysis to enhance patient outcomes

Field Service Support

- Multiple service plans to meet your practice needs—so you can be confident in your system’s performance
- 10-time recipient of the Omega Management Group’s Annual NorthFace Scoreboard Award for consistently exceeding customer expectations
IMPORTANT SAFETY INFORMATION:

CONTRAINDICATIONS
Lamellar resection for the creation of a corneal flap is contraindicated in the presence of corneal edema, corneal lesions, hypotony, glaucoma, existing corneal implant, or keratoconus. IEK procedures and arcuate incisions are contraindicated in the presence of any corneal opacity adequately dense to obscure visualization of the iris, descemetocoele with impending corneal rupture, previous corneal incisions that might provide a potential space into which the gas produced by the procedure can escape, or corneal thickness requirements that are beyond the range of the system. Creation of corneal channels for placement/insertion of a corneal inlay device are contraindicated in the presence of any corneal opacity adequately dense to obscure visualization of the iris, descemetocoele with impending corneal rupture, 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, any previous incisional refractive corneal procedure, e.g. radial keratotomy, significant corneal neovascularization in the limbal area for a planned incision, previous history of corneal Herpes Simplex Keratitis, previous corneal transplant, any cataract, corneal edema, corneal lesions, hypotony, existing corneal implant, keratoconus or subjects with severe corneal thinning less than 450 microns.

PRECAUTIONS
A high level of surgical skill is required for these lasers. A surgeon should have successfully completed one or more training courses before attempting to create a corneal resection. The use of the iFS® Laser for IEK procedures or for arcuate incisions is not recommended for patients with severe corneal thinning, preexisting glaucoma, a history of steroid-responsive rise in intraocular pressure, preoperative intraocular pressure greater than 21 mm Hg in the operative eye, more than 1200 µm corneal thickness at the 9 mm peripheral zone, active intraocular inflammation, or active ocular infection or keratoconus. The use of the iFS® laser for creation of corneal channels for placement of a corneal inlay device is not recommended for patients with preexisting glaucoma, a history of steroid-responsive rise in intraocular pressure, preoperative intraocular pressure greater than 21 mm Hg in the operative eye, more than 1200 µm corneal thickness at the 9 mm peripheral zone, active intraocular inflammation, or active ocular infection or keratoconus.
IMPORTANT SAFETY INFORMATION (CONTINUED):

ADVERSE EVENTS
Possible complications resulting from LASIK flap creation include corneal edema/inflammation, corneal pain, epithelial ingrowth, epithelial defect, infection, photophobia, flap decentration, incomplete flap creation, flap tearing or incomplete lift-off, free cap, inflammation (e.g., diffuse lamellar keratitis, corneal infiltrates, or iritis), thin or thick flaps, or flap striae. Transient light sensitivity syndrome (TLSS) and peripheral light spectrum (PLS) have been sporadically reported and may occur following LASIK flap creation. TLSS is characterized by symptoms of mild to severe light sensitivity that manifests between 2 and 6 weeks postoperatively. Patients experience no decrease in uncorrected or best spectacle-corrected visual acuity. The incidence of this sensitivity is observed in approximately 1% of patients who undergo flap creation with either laser. Patients respond to the use of hourly topical steroids and most report improvement within 1 week of treatment. PLS is a temporary phenomenon whereby patients report the perception of a spoke-like spectrum of light in the periphery of their vision. PLS has no clinical examination findings and no effect on visual acuity; however, the potential diffractive effects may be bothersome to some patients. Reported in only 0.03% of cases, the onset of symptoms occurs during the immediate postoperative period, and typically resolves within 3 months but may be slightly persistent in rare cases. The visual impact of PLS is clinically inconsequential for the vast majority of patients. Arcuate incision complications include corneal edema/inflammation, corneal pain, epithelial ingrowth, epithelial defect, infection, photophobia or corneal endothelium perforation. Creation of corneal channel for placement of a corneal inlay device complications include corneal edema, corneal pain, epithelial ingrowth, epithelial defect, infection, implant de-centration, incomplete inlay channel creation, corneal tearing or incomplete inlay channel dissection, photophobia, corneal inflammation, such as diffuse lamellar keratitis (DLK), corneal infiltrates, and iritis, and inlay channel bleeding.

WARNINGS
Check all treatment parameters for accuracy. The posterior depth should be programmed at least 125 microns above the corneal endothelium. Use of these laser systems allows laser surgical incisions up to 1200 µm deep. Setting the posterior depth too deep could result in injury to other ocular structures. Use caution when setting cut position and cut angle to avoid overlapping arcuate incisions. The applanation lens...
IMPORTANT SAFETY INFORMATION (CONTINUED):

becomes etched by the laser during the side-cut procedures and must not be reused. Laser light will not effectively permeate an etched lens, and the precision of the laser will be altered. Patient interface disposables should not be reused or resterilized.

CAUTION

U.S. Federal law restricts this device to sale, distribution, and use by or on the order of a physician or other licensed eye care practitioner who has been trained in the calibration and operation of this device.

REFERENCES

6. Probst LE. The next horizon in creating the LASIK flap. CRST. July 2012.