



655 Beach Street
San Francisco CA 94109-1336
P.O. Box 880610
San Francisco CA 94188-0610

Phone: (800) 562-6642, ext. 639
Fax: (415) 771-7087
Email: omic@omic.com
Web site: www.omic.com

OMIC requires special underwriting review of physicians requesting coverage for the performance of refractive surgical procedures. **Coverage is not included under the policy until and unless approved and specifically endorsed.**

TRAINING AND EXPERIENCE

1 **A.** What training did you receive specific to the performance of intrastromal corneal ring segments?
Attach a copy of your certificate of completion of training.

Course Title	_____	_____	_____
Dates	_____	_____	_____
Location	_____	_____	_____
Sponsor	_____	_____	_____
Instructor	_____	_____	_____

B. Have you also reviewed the KeraVision physician training manual? Yes No

2 During your training, how many cases did you:

	Observe?	Assist?	Perform?
A. Live	_____	_____	_____
B. Animal	_____	_____	_____
C. Human Cadaver	_____	_____	_____

3 How many "Intacs" procedures have you performed as primary surgeon (rough estimates are acceptable):

A. Since completion of your training?	_____
B. In the past 12 months?	_____
C. Anticipated for the next 12 months?	_____

4 If you have no experience as primary surgeon for "Intacs," do you intend to be proctored for your first several cases? Yes No

PATIENT SELECTION

5 Who conducts the preoperative evaluations? (Check all that apply.)

- Surgeon Surgeon's non-physician staff Surgery center staff Referring optometrist

6 Patients must meet the following eligibility criteria:

- Patients can have no more than 1.0 diopter of **astigmatism**.
- Patients must have at least 1.0 diopter and no more than 3.00 diopters of **myopia**.

NOTE: These requirements do not apply to keratoconus patients. See item 7 below.

7 Do you intend to perform this procedure on keratoconus patients? Yes No

The FDA has granted a Humanitarian Device Exemption (HDE) for treatment of keratoconus with Intacs. Under the HDE, IRB review and approval is required. An IRB has been established through IntegReview, Inc. for this purpose. (Please contact IntegReview for details.) Alternatively, physicians may establish their own IRB.

Although OMIC strongly recommends that treatment of keratoconus with Intacs be performed under the HDE, coverage is also available through OMIC for off-label procedures. If treatment of keratconus is performed as an off-label use of the ring segments, patients must be informed of and understand the off-label nature of the procedure and the discussion must be clearly documented in the patient's medical records and consent form.

To qualify for the treatment of keratoconus, patients must meet the following eligibility criteria:

- Patients must be contact-lens intolerant.
- Patients must have clear central corneas or only minimal central scarring. (Patients with central scarring must be advised of the risks and/or side effects they may experience as a result of their scarring.)
- Patients must have corneal thickness of 450 microns or more at the sides of the segments.
- Patients must have only PKP as an option to improve vision.

In addition, keratoconus patients must be informed that the procedure is likely to only temporize the progression of the cone and that the patient may need a PKP for definitive therapy. This must be documented in the consent form and medical records.

INFORMED CONSENT

8 The patient must be provided with a copy of the **KeraVision patient information booklet**.

9 The informed consent document must be procedure-specific and adequately address the indications, alternatives, benefits, risks, and complications. OMIC and KeraVision have jointly developed a sample **consent form** for "Intacs." A copy is attached for your convenience. If you will use a consent document other than OMIC's sample consent, please carefully review your consent form to ensure that it is equivalent.

Which consent form will you will use? OMIC's Another equivalent form

OPERATIVE PROCEDURES

10 Where do you perform this procedure? (Please check all that apply.)

- Your office Local physician-owned ASC Commercial surgery center Academic facility

11 Do you perform this procedure in any states/counties other than the county and state of your primary practice location? Yes No

If yes, please indicate which state(s)/county(ies), how frequently you travel to that location, and for what duration:

12 There must be a **minimum interval** of one week **between primary procedures**, and OMIC recommends a minimum interval of one month.

Once a physician has performed 5 Intacs cases with results satisfactory to both the patient and the surgeon, coverage for a shorter interval, including bilateral simultaneous Intacs, may be granted. Separate provisions, including underwriting review and approval, apply. (See attached request form.)

Do you intend to perform bilateral simultaneous Intacs? Yes No

POSTOPERATIVE CARE

13 Do you co-manage? Yes No

If yes, refer to OMIC's postoperative care guidelines.

ADVERTISING

14 Do you advertise your availability to perform this procedure? Yes No

Advertisements must comply with state law and FDA- and FTC-mandated guidelines. Ads and other patient information materials must not be misleading and must not make statements that guarantee results or cause unrealistic expectations. Similarly, satisfaction guarantees, warranties, and similar contracts are not permitted. Please refer to the attached **Review of Advertisement for Medical Services** form so that you may evaluate and monitor your compliance with OMIC's underwriting requirements with respect to advertising.

"I have read and hereby agree to comply with OMIC's underwriting requirements specific to intrastromal corneal ring segments ("Intacs") and with OMIC's standard refractive surgery requirements. I also agree to notify OMIC prior to implementing any intended changes to my responses above. **I understand that failure to comply with OMIC's underwriting requirements or to notify OMIC promptly of changes in my protocol may result in uninsured risk or termination of coverage.**"

Applicant's Signature (Please do not use signature stamp.)

Date

Applicant's Name (Please type or print.)