Corneal Refractive Surgery

Standards & Guidelines

September 2012 v8
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1.0 Introduction

This document addresses privileges and standards for Corneal Refractive Surgery, and is intended to supplement the College’s standards for Non-Hospital Surgical Facilities for facilities performing other procedures. In this document:

- “shall” is used when a section is a requirement for accreditation;
- “should” is used when a section is recommended; and
- “may” is used when a section is discretionary.

The College requires all accredited medical facilities to have a Medical Director (i.e. a practitioner who is registered with the Alberta College of Physicians & Surgeons) who is accountable for the practice of medicine within the facility.

Alberta’s Health Professions Act provides for the accreditation of medical services in non-hospital facilities by the College of Physicians and Surgeons of Alberta. Section 8.1 in Schedule 21 of the Act states:

8.1(1) A regulated member shall not provide a prescribed health service, or cause a prescribed health service to be provided, in a facility unless the facility is an accredited medical facility or a facility referred to in subsection (2).

(2) Subsection (1) does not apply with respect to a prescribed health service provided in

(a) an approved hospital within the meaning of the Hospitals Act,

(b) a hospital operated by the Government of Canada,

(c) a health care facility operated by the Government of Canada or the Government of Alberta,

(d) a hospital, clinic or centre operated by a regional health authority under the Regional Health Authorities Act,

(e) a facility within the meaning of the Mental Health Act or an accredited health centre established for the purpose of section 49(b) of the Mental Health Act, or

(f) a facility that is prescribed in the regulations.

Non-Hospital Surgical Facility services are one of many health services for which the College requires accreditation. A complete list of prescribed health services is contained in the College’s by-laws and available on the College’s website.

The Advisory Committee on Non-Hospital Surgical Facilities is a standing committee of the College of Physicians and Surgeons of Alberta (hereinafter referred to as The College) which advises the Medical Facility Accreditation Committee (MFAC) of the College with respect to all matters pertaining to non-hospital surgical facilities.
The Committee considers all issues related to the provision of surgical and anesthesia services within these facilities that may include but are not restricted to the following:

1. Develop and maintain evidence based standards and guidelines for anaesthetic and surgical care in NHSFs;
2. Assess and audit the medical practices in NHSFs to ensure that medical services provide safe and effective patient care;
3. Provide advice to promote safe and effective practices in NHSFs;
4. Assess physicians’ qualifications for privileges in NHSFs;
5. Assess and audit of business practices in NHSFs to the extent necessary to ensure compliance with relevant College by-laws.
2.0 Administrative

2.1 Applications for accreditation of new facilities shall be made to the College of Physicians and Surgeons of Alberta.

2.2 The Standard of Practice #20 – Direction and Control of Medical Practice as established by the Council of the College are applicable. (Those principles define the practice of medicine and outline the responsibility of physicians for aspects of practice other than the direct care of patients.) The Medical Director’s responsibilities include:

2.2.1 The qualifications and supervision of all staff who participate in patient care;
2.2.2 The safety and quality of medical equipment used in the facility;
2.2.3 The access to and confidentiality of medical records; and
2.2.4 The propriety and accuracy of all claims for payment made by the facility for medical services provided in the facility but not for claims for payment made by individual members of the medical staff.

2.3 Accreditation involves:

2.3.1 Completion of a pre-assessment data verification form;
2.3.2 An on-site assessment by one or more physicians (with expertise in the appropriate area of medical practice) designated by the College;
2.3.3 A review of all applications for privileges at the facility; and
2.3.4 Review of the facility's compliance with the College's standards.

2.4 "Full Accreditation" is granted to those facilities with no identified deficiencies.

2.5 “Provisional Accreditation” may be granted for a 30-day period to those facilities with minor deficiencies to allow for their correction. A written response to each deficiency is required. A follow-up assessment may be required at the sole discretion of the College. “Full Accreditation” will be granted when responses to deficiencies have been corrected to the satisfaction of the College.

2.6 General accreditation issues

2.6.1 Requirements shall be met before accreditation will be granted or renewed by the College.
2.6.2 The College may revoke accreditation if practice in the facility is considered unsafe.
2.6.3 A "Certificate of Accreditation" will be issued by the College of Physicians and Surgeons of Alberta to all facilities with full accreditation.
2.6.4 Accreditation is limited to 4 years from the last date of approval unless extended by the College and may be renewed through a process of re-accreditation which will follow the same steps as those for accreditation.
2.6.5 Payment to the College for the cost of the assessment is the responsibility of the Medical Director of the facility.
2.6.6 “Spot” assessments conducted without prior notice may also be conducted. These are at no cost to the facility.
2.6.7 A record of each facility will be kept on file at the College of Physicians and Surgeons of Alberta.

2.6.8 The College shall be advised of:

1. Any change of ownership of the medical practice or Medical Director of the facility;
2. Any major structural changes to patient care areas; or
3. Any major change in types of procedures or practices.

2.6.9 Each facility is required to pay an annual fee, set by Council, for the administration of the accreditation program.
3.0 Personnel

3.1 Medical Director

3.1.1 Qualifications

The Medical Director of each Corneal Refractive Surgery facility shall be a physician licensed to practice medicine in Alberta.

3.1.2 Duties

1. The Medical Director shall personally ensure the following:

   a. The safe and effective care of patients in the facility;
   b. That appropriate and up-to-date policy and procedures manuals are in place;
   c. That the duties and responsibilities of all personnel are written and understood;
   d. That applications for privileges in refractive surgery in the facility and changes to these privileges are approved by the College;
   e. That sufficient numbers of appropriately trained personnel are present during procedures;
   f. That procedures and equipment are appropriate and safe; and
   g. That policies and procedures are in place for the emergency transfer of patients to hospital;
   h. That complete and accurate confidential patient records and documentation relating to the operation of the facility and procedures performed are kept;
   i. That an adequate quality assurance program, including the monitoring of infection & medical complication rates, is in place; and
   j. That documentation and fees required by the College are submitted as required.

3.1.3 Applications for privileges

1. A surgeon seeking privilege in an NHSF or a Corneal Refractive Surgery facility approved by Council shall apply in writing to the Medical Director of the facility

2. The Medical Director shall forward a copy of all applications for privileges, including those of the Medical Director, to the College together with his/her assessment of the suitability of the applicant and the privileges requested.

   NOTE: Applications for privileges for the Medical Director must include two letters of reference attesting to competence for the procedures requested.

3. The Advisory Committee designated by the Council shall consider all applications and make recommendations as to privileges.

4. Interim recommendations may be made by the Registrar, to be amended or confirmed at the next meeting of the Advisory Committee designated by Council.

5. The decision of the Advisory Committee will be sent to the physician applying for privileges and to the Medical Director.

6. Appeals of the Committee's decision shall be made in the first instance to the Registrar, who may refer it back to the Committee for reconsideration.

7. A further appeal may be made to Council if necessary.
8. It may be considered unbecoming conduct for a medical practitioner to perform a procedure in an NHSF or a Corneal Refractive Surgery facility for which privileges have not been recommended by the College where approval is required.

9. The Medical Director shall maintain an up-to-date list of all privileges approved for each physician in the facility and a file with all applications and reapplications for privileges for assessment by the College upon request.

10. Applications for additional privileges of a different type than currently held in the facility by the physician shall be sent by the Medical Director to the College for review by its Advisory Committee.

3.1.4 Application for renewal of privileges

1. On an annual basis, physicians shall provide to the Medical Director a copy of the regional health authorities’ confirmation of privilege renewal in the region.

2. Physicians that do not hold regional privileges shall make re-application to the Medical Director annually and include:
   a. The approximate number of corneal refractive surgery procedures performed during the previous year;
   b. Any changes to privileges in this or other health care facilities during the previous year;
   c. A summary of CME and any performance reviews undertaken during the previous year;
   d. The outcome of discipline for professional conduct or competence during the previous year by any professional body; and
   e. Any other matters which may affect a physician’s competence or performance.

3. The Medical Director shall also personally keep on file a confirmation of re-application form for annual regional health authority privileges renewal or as in 3.1.4.2 if the Medical Director does not hold regional privileges.

4. The Medical Director shall advise the College of Physicians and Surgeons of Alberta of any information contained in a re-application for privileges which, in his/her opinion, could adversely affect a decision to continue privileges.

3.2 Corneal Refractive Surgeons – Qualifications

3.2.1 Surgeons who perform Corneal Refractive Surgery in an NHSF or in a Corneal Refractive Surgery facility shall:

1. Be registered in Alberta as a physician and be recognized by the Council as a specialist in ophthalmology, and

2. Have successfully completed supervised training and an evaluation of his or her skills in those procedures satisfactory to the College*; and

3. Show evidence of successful completion of training in the procedure and operation of the instrumentation specific to the procedure; and

4. Show evidence of successful completion of training in the calibration and programming of any laser used in the procedure; and
5. Maintain competence through continuing education in the procedures performed.

[*Suggested Training: For PRK and LASEK, a minimum of ten (10) patients under supervision may be necessary; For LASIK and Corneal Ring-Segment Implants, a minimum of twenty-five (25) patients under supervision may be necessary.]

3.3 Assisting Personnel – Qualifications

3.3.1 Personnel assisting the Corneal Refractive surgeon shall have documented training or experience with aseptic technique and with any of the following, if performed:

1. Sterilization of instruments; and
2. Assembly, calibration, programming and/or operation of equipment.

(Documentation may include documentation of training and assessment by the current employer, or letters of reference from former employers, or certificates of completion of training from equipment vendors or other agencies.)
4.0 Facility

4.1 Operating Room and Instrumentation

4.1.1 Design specifications shall comply with the laser manufacturer’s recommendations where applicable.

4.1.2 The temperature and humidity in the facility shall be documented on days corneal refractive procedures are performed.

4.1.3 It is recommended that the facility maintains a consistent temperature and humidity.

4.2 Infection Prevention and Control

4.2.1 Preventive measures shall include:

1. documentation of technique for cleaning and sterilization of equipment;
2. disposal of single patient-use instruments and components;
3. hand washing between cases;
4. use of talc-free sterile gloves when handling sterile instruments and tissues;
5. use of aseptic technique during surgery; and
6. use of “clean” operating room attire.
   [Operating room attire should be changed daily, or between patients if stained with blood or other body fluids. It is recommended they be professionally cleaned in hot water and enzymatic detergents. Clothing worn outside the facility, “street clothes,” are not appropriate wear in the operating room.]
7. surgical masks should be worn by the surgeon and any staff within one meter of a surgical or sterile field.

4.2.2 There shall be a designated area for soiled supplies. This area shall be physically separated from patient care areas and from areas housing clean and sterile supplies.

4.2.3 The soiled area should have:

1. Adequate counter space to receive soiled supplies.
2. A double utility sink to rinse and clean soiled items.
3. A flushing device for the disposal of body fluid wastes.
4. An adequate facility to hand wash. (The dirty utility sink is not appropriate.)

4.2.4 Personnel working in the soiled area shall have proper protective apparel for their personal protection, shall be properly trained, and should have hepatitis B immunization.

4.2.5 The clean area shall have adequate counter space for receiving washed equipment for storage or wrapping.

4.2.6 There should be written policies and procedures for reprocessing specialized equipment.

4.2.7 There should be written policies and procedures for the operation and maintenance of the sterilizers.

4.2.8 Routine preventive maintenance shall be performed on the sterilizer. This shall be documented.

4.2.9 Daily preventive maintenance of steam sterilizers shall include drainage of the distilled water reservoir for the sterilizer.
4.2.10 There shall be a method to check the sterilization parameters of the equipment (i.e. temperature reached, time, etc.).

4.2.11 There shall be appropriate monitoring of the sterilizers with:

1. Chemical indicators with each load; and
2. Biological indicators each day the sterilizer is used or with every load if sterilizing implantable devices. This is in conjunction with a recall method for loads where a biological monitor is positive (i.e. date and batch number clearly labeled on the package).

4.2.12 Personnel operating the sterilizers shall be properly trained.

4.2.13 An approved method of sterilization shall be used.

4.2.14 Clean and sterile supplies shall be stored in an area protected from dust and moisture, with access limited to authorized individuals.

4.2.15 Sterile supplies shall be clearly marked.

4.2.16 Supplies shall be stored off the floor.

4.2.17 Outside shipping cartons shall not be kept in the clean supply area. De-boxing of the cartons shall not be carried out in the clean area or in the patient care areas.

4.2.18 There shall be no re-use of critical or semi-critical medical equipment labeled as single-use by the manufacturer.

4.3 Housekeeping and Waste Management

4.3.1 The premises shall be kept neat, clean and free of waste material.

4.3.2 Handling of waste material shall comply with the Regional waste handling requirements.

4.3.3 Specifically trained housekeeping personnel should maintain an established housekeeping routine.

4.3.4 Personnel shall adhere to a written protocol for cleaning each operating room:

1. Between cases
2. At the end of the day
3. Weekly
4. Monthly

4.3.5 Wet mopping shall be used. Dry dusting and dry mopping are not acceptable.

4.3.6 Provisions shall be made for proper laundering of linen and washable goods.

4.3.7 Soiled linen shall be placed in containers and handled as little as possible.

4.3.8 Protective garments (e.g. leather gowns and leather gloves) should be worn to sort soiled linen if necessary.

4.3.9 All patient care linen shall be removed from the operating room after each use.

4.3.10 Clean linen shall be covered and stored away from soiled linen.
4.3.11 Garbage shall be collected, contained, stored, and disposed so as to prevent disease transmission.

4.3.12 Sharps shall be disposed in clearly labeled puncture resistant containers, and transported and disposed of according to the local regulations.

4.3.13 Sharps containers shall not be over-filled, and one container shall never be emptied into another.

4.3.14 Food and beverages consumed in personnel lounges shall be disposed of or stored away daily, and the area cleaned to prevent rodent and insect infestations.

4.4 Safety Procedures

4.4.1 Operating room gases and hazards

1. Laser safety instruction shall be documented for all personnel working in the operating room if lasers are used.

2. Toxic gases used by lasers shall be contained in a manner that is certified by the manufacturer as fail-safe, or shall be connected for emergency venting outside of the building in a manner so as not to pose a hazard to other building occupants or to the community.

3. There shall be a documented procedure for responding to fluorine or other toxic gas leaks.

4. Laser surgical masks capable of filtering viral particles are recommended for surgeons and others in close proximity to the surgical field.

5. There shall be a documented procedure for appropriate disposal of biohazardous waste.

4.4.2 Patients

1. Peri-operative vital signs shall be monitored when indicated.

2. Epinephrine for subcutaneous administration shall be available for anaphylactic reactions.

3. Procedures shall be written for the facility’s response to:
   a. syncope
   b. seizure
   c. anaphylaxis

4. At a minimum, one member of the staff in the facility or the surgeon must be currently certified in CPR.

4.4.3 General Facility

1. Mock drills to prepare employees for emergency situations such as cardiac arrest, shall be conducted at least every six months. The type of drill and employee attendance shall be documented.
2. The facility shall have plans for emergencies such as:

1. Fire
2. Power Loss
3. Equipment Failure
4. Cardiopulmonary Arrest
5. Emergency Transfer to Hospital

3. There should be documented evidence that all personnel, including medical personnel, are familiar with emergency plans.

4. Smoking shall be prohibited in the patient care, sterile, and preparation areas of the facility.
5.0 Patient Selection and Care

5.1 The clinical record of patients undergoing Corneal Refractive Surgery in the facility shall include documentation of:

5.1.1 A pre-operative evaluation by an ophthalmologist or optometrist registered in Alberta, which includes the following determinations:

1. absence of contraindications due to systemic and ocular disease;
2. refractive stability over time and especially after rigid contact lens removal; and
3. corneal topography, pachymetry and complete slit lamp and dilated fundoscopic examination;

5.1.2 An opportunity for individualized discussion between the patient and the surgeon of the risks, benefits and alternatives to refractive surgery prior to the procedure;

5.1.3 A signed consent for the procedure/anesthetic that is part of the patient's clinical record.

5.1.4 Confirmation of the refractive error and a slit-lamp examination by the surgeon.

5.2 Patients shall receive written instructions as to their responsibilities prior to and after surgery.
6.0 Post-Operative Care

6.1 Patients shall be given discharge instructions verbally and in writing including an after-hours emergency telephone number giving them access to the operating surgeon or designated healthcare professional.

6.2 Discharge instructions shall include calling the facility if they are admitted to hospital within 30 days.

6.3 The operating surgeon or designated healthcare professional shall be available in a timely manner for assessment and follow-up as needed in the post-operative period.

6.4 The operating surgeon shall ensure that the healthcare provider designated to provide post-operative follow-up care is appropriately trained and qualified to provide the care required.
7.0 Quality Assurance

7.1 The quality assurance program in a facility where Corneal Refractive Surgery is performed shall record and monitor the following in regard to Corneal Refractive Surgery procedures in the facility:

7.1.1 The rate of unplanned secondary procedures (enhancements);
7.1.2 Adverse events and complications including all surgery related post-operative infection; and
7.1.3 Patient satisfaction.
7.1.4 There shall be a documented policy and procedure in place for handling patient concerns/complaints.
7.1.5 The Medical Director shall ensure that the process for lodging concerns is readily available and apparent to patients and the public.
8.0 Notification to the College

8.1 Incident Reports

NOTE: Incident defined as untoward, undesirable and usually unanticipated events or outcomes that caused harm or risk of harm to a patient, employee or visitor in the facility. An incident may or may not be a result of a deviation from the normal process of care.

8.1.1 There shall be an internal process to document and investigate incidents. An incident report shall be completed which includes the following:

1. Name, age, and sex of the person involved in the incident.
2. Name of witness(es) to the incident.
3. Date and type of procedure (if applicable).
4. Date and time of the incident.
5. Nature of the incident and treatment rendered.
6. Analysis of reasons for the incident.
7. Outcome.

8.1.2 There shall be a process to document corrective action taken if applicable.

8.1.3 A copy of all incident reports shall be kept in a separate file.

8.1.4 All incident reports shall be reviewed at least annually by the Medical Director.

8.2 Reportable Incidents

(Reportable incidents, as defined below, are also known as “significant mishaps” in the Health Care Protection Regulations of Alberta.)

8.2.1 Medical Examiner

1. In the event of a death within the facility, the Medical Examiner shall be notified prior to moving the body or removal of any lines or tubes from the body.

8.2.2 Registrar - College of Physicians and Surgeons of Alberta

1. The Medical Director shall notify the College of Physicians and Surgeons of Alberta (Quality of Care Department) within one working day after the discovery of any reportable incident, including:

   a. Deaths within the facility or within 10 days of the procedure.
   b. Transfers from the facility to a hospital regardless of whether or not the patient was admitted.
   c. Unexpected admission to hospital within 30 days of a procedure or anesthetic performed in the facility (See also discharge instructions to patients).

   NOTE: When notified of an unexpected admission of a patient to hospital within 10 days of the procedure in the NHSF, the Registrar may determine that written notification is not required when the reason given for admission to hospital is not related to the services provided in the facility.
   d. Clusters of infections among patients treated in the facility.
   e. Any procedure performed on the wrong patient, site or side.
2. Within **two weeks** of notification, the following shall be submitted to the College:

   - Completed reportable incident form signed by the Medical Director
   - Copy of the facility clinical record
   - Narrative summary describing the incident by the most involved physician

3. The Registrar will review the circumstances with the Medical Director and may consult with other practitioners to determine the risk of harm to patients. If necessary, the Registrar may suspend the accreditation of any facility on a suspicion of continuing risk. An investigation of the facility will then be initiated as soon as is reasonably possible.
9.0 Retention of Records

9.1 Notwithstanding the College’s requirement that clinical records be retained for a minimum of ten years (or two years past the age of majority, whichever is longer), it is recommended that the following information be retained indefinitely for each patient:

9.1.1 Pre- and post-operative corneal curvature measurements

9.1.2 Refraction measurements pre-operatively and when stable (approximately 12 months post-operatively).

9.2 The facility shall provide a copy of the above measurements to each patient with instructions to retain it for future reference.
10.0 Procedure Manuals

10.1 Procedure Manuals are recommended for all major procedures which are performed in the facility or may be performed in an emergency. The following are guidelines provided to NHSFs.

10.1.1 Current procedure manual(s) should be readily available in the appropriate work area.

10.1.2 If the manual is separated into several work areas, one master manual should be maintained in a central location in the facility. Repetitive routines, such as cleaning protocols, should be summarized and posted on walls in actual work areas to assist with compliance.

10.1.3 The Medical Director or a designated member of personnel should ensure that manuals are current and accurate.

10.1.4 Each manual should contain a table of contents identifying a complete list of procedures and processes that are provided, as well as support processes, equipment requirements and related routines in the facility.

10.1.5 All physicians involved with the procedures should have knowledge of the written procedures and should be involved in changes to the procedures each provides.

10.1.6 Related information should be consolidated in one section.

10.1.7 All procedures shall be signed by the Medical Director or appropriate designate as developed.

10.1.8 A process for review and signature by the Medical Director or appropriate designate shall occur at least every 4 years.

10.1.9 The list of procedures shall be those approved for the facility.

10.1.10 A process to assess compliance with procedures should be in place.

10.1.11 Vendor manuals should be attached/located with or near each piece of equipment. Complex equipment should have quick reference summaries attached, e.g. microkeratomes.

10.1.12 All personnel shall be orientated, upon hiring, to the procedure manuals. The extent of a step-by-step orientation of new personnel to each procedure will depend on the specific role of the new member, the risk of injury or damage and implications of non-compliance.

10.1.13 Each member of the personnel should be responsible for updating or informing the appropriate person of a need to update procedures which they perform that may be inaccurate or outdated.

10.1.14 A communication process should be established to inform the necessary personnel of changes in procedures, updates and new procedures.

10.1.15 Where significant changes to a procedure manual are made, the administrative area shall keep a file of the previous procedure, for legal reasons.
10.1.15  A standard format should be developed and used for all procedures. It should include, but is not limited to: (sample format - Appendix C):

1. Name of procedure
2. Principle/purpose of procedure
3. Patient preparation
4. Equipment/supplies needed
5. Equipment calibration steps and trouble shooting if applicable
6. Special equipment cleaning/sterilizing
7. Steps of procedure in sequential order
8. Utilization of pictures and diagrams where helpful
9. Rationale for steps in procedure included where helpful
10. Limitations/potential complications
11. Special safety precautions
12. Reference sources e.g. CSA documents, Provincial/National Standards, Vendor reference source
13. Comments section for special notes
14. Date procedure was established
15. Last date of review/revision
16. Source of approval (responsible person) - with actual signature

10.1.16. The topics of Procedure Manuals should include, but are not limited to:

1. Aseptic Practices:
   a. Processing, handling, storage and control sterile goods
   b. Traffic restrictions
   c. Washing, storage, folding, reprocessing of fabrics for the operating room
   d. Packaging materials

2. Infection Prevention:
   a. Cleaning procedures - instruments, furniture, materials, devices
   b. Containment of soiled materials
   c. Hand washing
   d. Hand scrubbing protocols
   e. Handling of infectious wastes (blood/body fluids)
   f. Handling of known infected/contagious patients

3. Housekeeping (in the operating room) between cases, daily, weekly, and monthly:
   a. Restriction of infected/contagious personnel
   b. Universal precautions
   c. Protective devices/equipment
   d. Soap/detergent/antiseptic use and dispensing (including approved agents)
   e. Transport of soiled materials

4. Cardiopulmonary Arrest:
   a. Management of
5. Dress Code:
   a. Identification of personnel
   b. Operating room dress code
   c. Dress code in non-operating room areas
   d. Protective clothing

6. Emergency Patient Transfer:
   a. Process to be followed
11.0 Laser Registration

11.1 The Radiation Protection Act and Regulations shall apply.

11.2 All class IIIb and IV laser equipment as defined in the Radiation Protection Act and Regulations, shall be registered for use in Alberta with the College of Physicians and Surgeons of Alberta.
12.0 Additional Safety

12.1 Electrical

12.1.1 Electrical safety shall meet or exceed the standards as outlined in the following:

- CSA C22.1-94: Canadian Electrical Code, 17th edition and Alberta Regulation 239/95 Special Addition
- CAN/CSA 3-232.2: Electrical Safety in Patient Care Areas
- CAN/CSA 3-232.4: Essential Electrical Systems for Hospitals

12.1.2 A copy of these standards may be obtained from:

Canadian Standards Association
1707 94 Street
Edmonton AB T6N 1E6
Phone: 1-800-463-6727
Fax: (780) 435-0998

12.2 Fire

12.2.1 Fire safety shall meet or exceed the standards as outlined in the Alberta Fire Code. A copy of the Code may be obtained from:

Learning Resources Centre
12360 142 Street
Edmonton AB T5L 4X9
Phone: (780) 427-2767
Fax: (780) 422-9750
## Appendix C - Procedure Manual - Sample Format

### Facility Name

<table>
<thead>
<tr>
<th>Date of Original Procedure:</th>
<th>Procedure No:</th>
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<table>
<thead>
<tr>
<th>Last Review / Revision Date:</th>
<th>Page</th>
<th>of</th>
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<th>Next Review Date:</th>
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<th>Source:</th>
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<tr>
<th>Medical Director / Designate Signature</th>
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### Procedure

**General Description:**

**Patient Preparation:**

**Procedure Steps:**

<table>
<thead>
<tr>
<th>Procedure Steps</th>
<th>Rationale</th>
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<tbody>
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<td>4.</td>
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<tr>
<td>5.</td>
<td></td>
</tr>
</tbody>
</table>

**Equipment:** (Procedure to setup, calibrate, recording required)

**Precautions/Safety Measures:**

**Comments/Diagrams:**

**Specific Surgeon Needs:**

**References:**