

LICENCE CONDITIONS FOR ACUTE HOSPITAL SERVICE AND AMBULATORY SURGICAL CENTRE SERVICE LICENSEES PROVIDING CATARACT SURGERY

IMPOSED UNDER SECTION 13(1) OF THE HEALTHCARE SERVICES ACT 2020

1 Application

- 1.1. These licence conditions (“**LCs**”) apply to all persons that have been licensed under the Healthcare Services Act 2020 (the “**HCSA**”) to provide one or more of the following services (such persons referred to as “**Licensees**”), and provides cataract surgery as part of their services:
 - (a) an acute hospital service (“**AHS**”); and
 - (b) an ambulatory surgical centre service (“**ASCS**”).
- 1.2. For avoidance of doubt, the defined terms as used in these LCs shall have the meaning ascribed to them in the HCSA and any Regulations made thereunder, unless otherwise stated.
- 1.3. A breach of these LCs may result in regulatory action being taken against Licensees under section 20 of the HCSA, including but not limited to:
 - (a) suspension or revocation of the Licensee’s AHS and / or ASCS licence;
 - (b) shortening the term of the Licensee’s AHS and / or ASCS licence (where applicable);
 - (c) a direction requiring the Licensee to rectify the contravention, or prevent a recurrence of the contravention; and/or
 - (d) a direction requiring the Licensee to pay a financial penalty.
- 1.4. These LCs do not override the healthcare professionals’ duty to make clinical decisions that are in the best interests of each patient with their valid consent.
- 1.5. For avoidance of doubt, the requirements in these LCs are without prejudice, and in addition to the requirements imposed under the HCSA as well as any Regulations and other applicable licensing conditions, directions, and codes of practice made thereunder.

2 Definitions

- 2.1 “**Complicated cataract surgeries**” refers to cataract surgeries that are performed on patients who have a higher risk of complications intra-operatively

or post-operatively,¹ or have uncontrolled co-morbidities, past/existing eye conditions and/or previous eye surgeries.

3 Specific Restrictions

- 3.1 The Licensee shall only perform complicated cataract surgeries in an operating theatre located within the licensed premises of an AHS or in a tertiary eye specialist centre².

4 Education and Training

- 4.1 The Licensee shall ensure that same-day bilateral cataract surgery may only be performed by competent surgeons with proven track records and employed by the Licensee.

- 4.2 “Competent surgeons with proven track records” in paragraph 4.1 above refers to surgeons who:

- (a) are certified by the Specialists Accreditation Board;
- (b) are accredited by the licensee of an AHS or ASCS to perform cataract surgery;
- (c) have adhered to the requirements stipulated in these LCs;
- (d) are familiar with using surgical equipment designed for cataract surgery; and
- (e) have kept an on-going audit/record of his/her previous cataract surgery results.

5 Patient Management

Selection and Assessment

- 5.1 The Licensee shall only provide cataract surgery for the second eye after the first eye has fully recovered. The Licensee shall not provide same-day bilateral cataract surgeries to patients, save for the following exceptions³:

- (a) The patient is diagnosed with bilateral hypermature cataracts with impending glaucoma;

¹ Intra-operative complications may include (but not limited to) suprachoroidal haemorrhage, loss of capsular support, vitreous presentation, and dropped lens fragments. Post-operative complications may include inflammation, glaucoma, corneal edema, intraocular lens subluxation, retinal edema, retinal tears, and endophthalmitis. Some pre-existing conditions which may put patients at higher risks are tight palpebral aperture, shallow anterior chamber, poorly dilated pupils, previous traumatic eye injury, cornea opacities, zonulysis, dense cataract, posterior polar cataract, and glaucomatous eye. Systematically, patients who are uncooperative under local anaesthesia or who are on oral medications for prostate enlargement (e.g. Flomax) which is known to cause intra-operative floppy iris can make surgery more challenging.

² Tertiary eye specialist centre refers to any of the following:

- (a) Singapore National Eye Centre;
- (b) Specialist Eye Ambulatory Surgical Centres located within acute hospitals.

³ Other reasons such as anxiety and fear of surgery cannot be sufficiently justified to permit the conduct of same-day bilateral cataract surgeries.

- (b) The patient is mentally compromised and requires general anaesthesia for the cataract surgery(ies);
- (c) The patient is diagnosed with bilateral congenital cataracts; and
- (d) The cataract surgery is performed for refractive enhancement rather than primarily visual restoration.

Patient Preparation (including consent)

5.2 The Licensee shall ensure that patients intending to undergo same-day bilateral cataract surgery must be informed, at the minimum, of the following consequences and implications of same-day bilateral cataract surgery before performing such surgery:

- (a) Bilateral post-operative endophthalmitis, which is devastating and potentially blinding if it occurs in both eyes;
- (b) Loss of opportunity to refine the target refraction in the second eye, with both eyes having refractive surprises; and
- (c) In the event of slower visual recovery, a longer period of immobility can be expected, with an increased risk of fall.

5.3 The Licensee shall ensure that patients intending to undergo same-day bilateral cataract surgery understand and accept the consequences and implications listed in Paragraph 5.2 above before performing such surgery.

5.4 The Licensee shall ensure that for same-day bilateral cataract surgery, the surgery for each eye must be treated as a completely separate procedure to mitigate surgical infection risks, i.e. staff have to re-scrub, change drapes and use new sets of fluid bottles, tubing and instruments.

6 Facilities, Equipment and Devices

6.1 The Licensee shall ensure that the HEPA⁴ air filtration system (regardless of whether it is portable or built-in) used in the operating theatre can deliver **at least 15 air exchanges per hour** and must be capable of maintaining a clean environment necessary for the surgical procedures to be carried out.

6.2 The Licensee shall ensure that the HEPA air filtration system is serviced regularly according to the manufacturer's recommendation. In addition, the Licensee shall conduct regular assessments of the operating theatre's air quality, in accordance with the recommendations of the manufacturer or an appropriate expert.

⁴ Should be "True" HEPA air filtration systems, i.e. the HEPA filter should be capable of removing 99.97% of all airborne particles as small as 0.3 micrometre.