ISBCS Implementation Manual

Developed by the BICAT-NL Implementation Project

Implementation Manual for Immediate Sequential Bilateral Cataract Surgery (ISBCS)

Developed by BICAT-NL Implementation Project

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We are grateful for the support of many colleagues, subject matter experts and industry partner organizations that have contributed to the development of this manual.

Their time and expertise has been invaluable towards improving the quality and impact of this resource.

Implementation Manual for Immediate Sequential Bilateral Cataract Surgery (ISBCS)

This manual has been created as part of the BICAT-NL Implementation Project – a project funded by ZonMw under the “Implementation of knowledge and innovations for appropriate care” program.

This project is aimed at facilitating sustainable implementation of ISBCS across healthcare organizations in the Netherlands.

Based on the results of the BICAT-NL Study as well as the experiences and knowledge of healthcare institutions already performing ISBCS, this project group has compiled an implementation manual outlining the points for attention for successful implementation of ISBCS in a healthcare institution.

The key aims of this manual:

1. To outline the points of attention for successful implementation of ISBCS in a healthcare institution
2. Share good practice for ISBCS underpinned by evidence and professional guidance
3. Describe and provide a practical toolkit to facilitate the required adjustments in logistics and production processes for ISBCS in line with international and national guidelines. In particular, providing detailed guidance for adhering to the strict separation of aseptic procedures for each eye.
4. Support the progress towards optimal implementation of ISBCS in Dutch healthcare.

We invite you to use this manual and the accompanying toolkit to develop a strategy for your own organisation.

We greatly value your feedback as we continue to update this manual. Please send any suggestions for improvement to bicat.implementatie@mumc.nl

Implementation Manual for Immediate Sequential Bilateral Cataract Surgery (ISBCS)

We encourage you to use this document as a guide.

It provides a comprehensive view of steps to be considered before, during and after implementation. It shares a practical guide and tools that you may tailor for your own organization to support your journey to successful implementation.

This manual summarizes professional, safety, and regulatory recommendations so that these can be considered from the start of the implementation. It provides a range of recommendations and practical advice, for different professionals at different points in the implementation journey. Some sections may be more relevant to you than others.

To get the best out of this toolkit, tailor how you navigate through it using its interactive function. You can select:

- your starting point
- the pathway directly relevant to your role
- a specific or immediate area of interest or
- a key challenge with advice from other practices on how they have overcome it

There is no one size fits all method, each healthcare institution will need to develop their own personalized implementation approach to enable ISBCS to work successfully in their own setting.

Disclaimer:

The information in this manual has been compiled with great care.

However, we cannot guarantee the completeness, accuracy, timeliness or suitability of the information provided in this manual.

We accept no liability for any damage, direct or indirect, arising from the use of this manual.

About this manual

Interactive Functions

Implementation Manual for Immediate Sequential Bilateral Cataract Surgery (ISBCS)

This manual has been designed with interactive functions which will allow you to navigate through the manual easily. Below is a summary of the different functions you will see throughout the manual

Grey Boxes

Selecting these boxes moves you to different sections in the Implementation Manual

iSBCS Guidelines

Blue icons

These are navigation arrows and move you forward and back through the pages of the Implementation Manual, or to return home to the contents page.

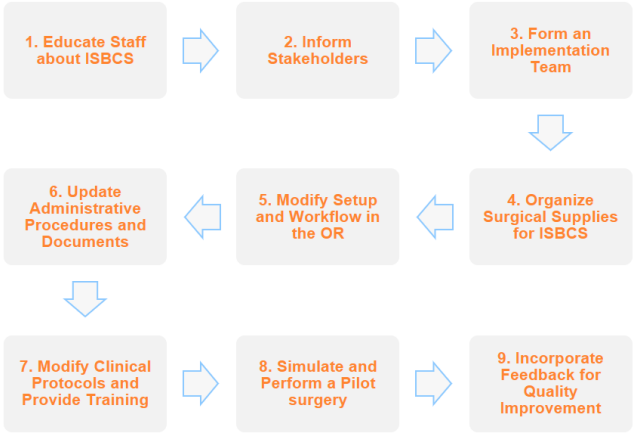
Orange boxes

These are links to webpages or documents which are external to the manual. You will need to be connected to the internet for these to work.

Download SOP: ISBCS Procedure

Interactive navigation

Click on a grey box within the interactive implementation guide to take you to the relevant chapter or tool in this manual. Once you have finished, you may use the toolbar on the left hand side to return to the Implementation Guide in order to choose the next step.



Implementation Manual for Immediate Sequential Bilateral Cataract Surgery (ISBCS)

If you have registered to participate in the BICAT-NL Implementation Project, you will receive periodic contact from our project group to monitor your progress. Further guidance to evaluate and adjust implementation activities may be provided when required.

Webinars will also be held for participating healthcare institutions to exchange experiences and obstacles during the implementation process.

Click here to register as a participant in the BICAT-NL Implementation Project.

Contents

Introduction

An estimated 180,000 cataract operations are performed annually in the Netherlands.[1]

It is known from the literature that 71% of cataract patients are eligible for cataract surgery on both eyes (more than 74,000 patients per year).[2]

The experiences in the MUMC+ and Zuyderland Medical Center (where ISBCS has been implemented as standard treatment) show that approximately 46% of these are suitable for ISBCS. Nationally, this concerns more than 34,000 patients per year.

Although a number of clinics have already switched to ISBCS during the COVID pandemic, data from Cataract Quality Registry shows that the percentage of ISBCS treatments performed in the Netherlands in 2022 was only 2.7% of the total number of patients that had bilateral cataract surgery.[3]

However, increasing evidence supports ISBCS as an effective alternative to DSBCS in terms of clinical outline measures, quality of life, patient satisfaction and cost-effectiveness.[4, 5] Furthermore, taking into consideration that ISBCS has now been included in the national Cataract guideline as a recommendation for suitable patients,[6] and increasing interest in ISBCS from ophthalmologists and patients, a paradigm shift towards large-scale adoption of ISBCS is underway.

Benefits of Immediate Sequential Bilateral Cataract Surgery - Summary

For the patient: [4, 5, 7-9]

- Accelerated visual recovery without visual imbalance, quicker restoration of binocular vision
- Less discomfort between surgeries
- Better patient quality of life, able to resume tasks such as driving and work sooner
- Less risk of falls for elderly patients
- Obtain spectacle adjustment post-surgery sooner
- One surgery admission and fewer hospital visits
- More convenient for patient and/or caregivers
- Reduced psychological burden of one surgery vs two
- Reduced transportation costs
- Simplification of post-operative drop regime
- Reduced need for home care or assistance accompanying hospital visit
- Less burden on family/assistance

Benefits of Immediate Sequential Bilateral Cataract Surgery – Summary (continued)

For the surgeon and organization: [2, 4, 10, 11]

- Reduce surgery waiting lists
- Increased efficiency of surgical logistics and patient flow
- Increased availability in outpatient clinic due to reduced number of hospital, outpatient clinic and pharmacy visits (on operating day and post-operative visit)
- Ability to offer ISBCS to patients
- Reduced hospital administration due to reduced number of patient visits
- Fewer patients in pre-operative processing, fewer patients in and out of day center and operating theatre

For society: [2, 4, 12, 13]

- Potential cost savings and improvement in healthcare efficiency
- Reduced surgery waiting lists
- Lowered costs associated with reduced day-care admissions, fewer outpatient visits, decreased travel expenses, decreased reliance on home care and informal care, and reduced productivity loss.
- ISBCS led to societal cost savings of €403 (US$507), with potential annual savings of €27.4 million (US$34.5 million) in the Netherlands alone. [4]
- Potential reduced CO^2 emission due to less transportation of patients

Concerns regarding Immediate Sequential Bilateral Cataract Surgery

Bilateral Endophthalmitis

The fear of endophthalmitis, particularly in both eyes, is one of the main reasons for the hesitation to perform ISBCS.[14, 15]

However, incidence rates of endophthalmitis have decreased significantly over the years with widespread use of intraocular antibiotics [16, 17] and the calculated risk of bilateral endophthalmitis is extremely low (one in 70 million cases). [5, 18, 19] Reported cases of bilateral endophthalmitis in ISBCS can be attributed to faults in aseptic procedures and non-adherence to international principles for ISBCS.

To mitigate the risk of bilateral endophthalmitis, general principles have been established by the International Society of Bilateral Cataract Surgeons (iSBCS). This international society was established to ‘promote education, mutual co-operation and progress in simultaneous bilateral cataract surgery’ by surgeons with significant experience in ISBCS, and in 2009 published the “iSBCS General Principles for Excellence in ISBCS”. [20] This document provides clear guiding principles for the practice of ISBCS.

These guidelines recommend the management of relevant ocular or periocular diseases and emphasize the importance of complete aseptic separation between the surgeries of the first and second eyes. This entails ensuring that no items that have come into contact with the first eye are used during the second eye surgery. Instruments used for each eye must undergo thorough and separate sterilization cycles, preventing any cross-contamination of instruments, drugs, or devices.

Furthermore, for the right and left eye, it is advisable to utilize Ophthalmic Visco-elastic Devices (OVDs), products and surgical supplies from different manufacturers or lot numbers, whenever feasible and reasonable, to mitigate the risk of bilateral infection and toxic anterior segment syndrome. Separate sterile routines and preparations of the operative field should be performed for the first and second eyes. Additionally, it is strongly recommended to administer intracameral antibiotics at the conclusion of the surgery. In the event of a complication occurring in the first eye, it must be resolved before proceeding with the surgery on the second eye, and consideration should be given to deferring the second eye surgery if necessary.

Concerns regarding Immediate Sequential Bilateral Cataract Surgery

Refractive Surprise

Another concern regarding ISBCS is the risk of refractive surprise.

Whilst some studies (and hence surgeons) set forth that in case of delayed sequential bilateral cataract surgery, the refractive outcomes of the first eye can be used to further optimize the prediction accuracy of the second eye, other studies show no improvement in prediction accuracy for the second eye when using first eye outcomes.[21]

The landmark BICAT-NL Study showed that ISBCS was non-inferior to DSBCS regarding post-operative refractive outcomes within 1.0 D and 0.5 D of target refraction and visual acuity.[4] This is consistent with previous randomized controlled trials,[22] and on par with the proportions of target refractions reported by European Registry of Quality Outcomes for Cataract and Refractive Surgery database.[23]

Better refractive outcomes can be achieved from the use of a modern intraocular lens power calculation formula (such as the Barrett Universal II formula) and the exclusion of patients with aberrant axial lengths. Further improvements in intraocular lens calculation methods could further mitigate the risk of refractive surprise.

Other post-operative complications

Apart from endophthalmitis and refractive surprise, the risk of other complications (both intra-operative and post-operative) was found to not be significantly different for ISBCS compared with DSBCS. [4, 22, 24]

In general, during surgery it is recommended that the surgeon only continues with ISBCS if any intra-operative complication in the first eye is resolved before continuing with the second eye, and patient safety and benefit are paramount factors in deciding whether to proceed.[20]

In the case of post-operative complications such as macular oedema and corneal decompensation, both conditions would not commonly be identified in the window of time prior to surgery of the second eye in many DSBCS procedure. Cystoid macular edema and corneal edema are treatable either by drops, injections, or surgery. Careful selection of patients for ISBCS minimizes these risks.

Concerns regarding Immediate Sequential Bilateral Cataract Surgery

Conclusion:

Implementation of ISBCS will lead to a change in the organization of cataract surgery care.

Recently available evidence shows that ISBCS is an effective alternative to DSBCS in terms of clinical outline measures, quality of life, patient satisfaction and cost-effectiveness, provided that patients are selected carefully and safety guidelines are strictly followed.

Furthermore, by reducing the number of patient visits, implementing ISBCS will lead to a positive impact on reducing long waiting lists within ophthalmology, ensuring more efficient use of resources in the Dutch health system.

Further Reading – Publication Pack and Course Material

Please refer to the ISBCS Publication Pack which includes relevant publications and course material to provide a comprehensive snapshot of the evidence supporting ISBCS. We also recommend this webinar on simultaneous bilateral cataract surgery

Click here to access the ISBCS Publication Pack

Acknowledgements: this chapter has been adapted from the article:
[25] Spekreijse, L.S. and R. Nuijts, An update on immediate sequential bilateral cataract surgery. Curr Opin Ophthalmol, 2023. 34(1): p. 21-26

Key Principles for Change Management

Communicate a clear story for change to engage others in understanding the aims and benefits.

Allow plenty of time for discussion with staff analyze the current patient journey and how the workflow redesign should translate to your setting, create opportunity to share ideas, concerns and assess readiness. Co-design the change process.

Map out your logic model - what effects do you anticipate for all involved? What might be the unintended consequences? It is important to factor in monitoring adverse consequences just as much as the benefits.

Build a team of implementation leaders to provide leadership, support champions and work with stakeholders e.g. suppliers, staff and patients to establish the new status quo, watching out for signs of backsliding.

Visualise your workflow, map the patient journey and administrative process with an understanding of your demand, activity and capacity to ensure the design does not increase workload or deliver a poor experience.

Identify and address barriers to change – there may be cultural or structural elements that need to be addressed.

Practice then pilot - do a practice run with all staff followed by a pilot case.

Maintain momentum - have regular team meetings initially to keep staff motivated and share positive feedback. It is helpful to facilitate feedback and the generation of new ideas, sharing comments and impact statements from staff and patients to drive a continuous cycle of improvement.

Principles adapted from:
[26] Campbell, R.J., Change management in health care. Health Care Manag (Frederick), 2008. 27(1): p. 23-39.

Preparing for Change

- Why Change?
- Who Will Be the Leaders?
- What Changes are Needed?
- What is the Goal?
- How Long Will it Take?

Preparing for Change – Who Will Be the Leaders?

Appoint Implementation Leaders or Champions

To maximize success, internal implementation leaders must be appointed. Implementation leaders are the drivers of change – they must be committed to the task, understand the required changes and have influence to enact change within the healthcare institution.

A multidisciplinary team of implementation leaders may include:

- Ophthalmologist(s)
- Clinical or Administrative Leaders (e.g. Ophthalmology Nurse, Clinic Manager)
- Representative from pharmacy and/or suppliers
- Representative from Central Sterilization Department/Provider

Preparing for Change – What Changes are Needed?

Culture Change

Implementation leaders must engage with all relevant team members involved in the implementation to drive a change of attitudes and perspectives:

- Provide education to ensure all relevant members in organization understand the rationale and benefits of ISBCS
- Obtain approval for implementation from management
- Ensure motivation from team to implement new processes
- Evaluate if there is a demand for ISBCS for your patients

Structural Change

Implementation leaders must identify what environmental or structural resources and processes need to change, including:

- Administrative setup including patient records and planning of surgery date and appointments
- Procurement of supplies for ISBCS from different batch numbers and sterilization cycles for each eye
- Logistics, storage and stock control for medical devices and intraocular pharmaceuticals
- Workflow and adjustment of processes in the operating theater in line with strict separation of aseptic procedures
- Workflow of the patient (before, during and after surgery)

Preparing for Change – What is the Goal? How long will it take?

What is the goal?

Identify and establish outcomes of ISBCS for your organization.

For example;

- Start date for pilot ISBCS surgery
- Current numbers of ISBCS per month
- Achievable target of ISBCS per month

How long will it take?

Establish a realistic time frame for change, based on the degree of structural and cultural change required within your organization.

This timeline should be developed with the implementation team, as well as scheduled meetings to monitor progress.

Organizational Readiness for Change Assessment (ORCA)

The ORCA Questionnaire is a validated survey designed to assess the extent of which your organization is ready for change.

It is used to understand the perspectives of members in your organization regarding the new implementation of ISBCS, and identify potential barriers.

We recommend providing this survey to team members in your organization at all levels to get a complete picture.

This questionnaire provides an environmental scan of your institution and its members to gauge internal readiness for implementation. It will help you to identify facilitating factors and barriers, in order to understand if there are specific actions to move to the next step of implementation.

To request a template of the ORCA Questionnaire, contact us via

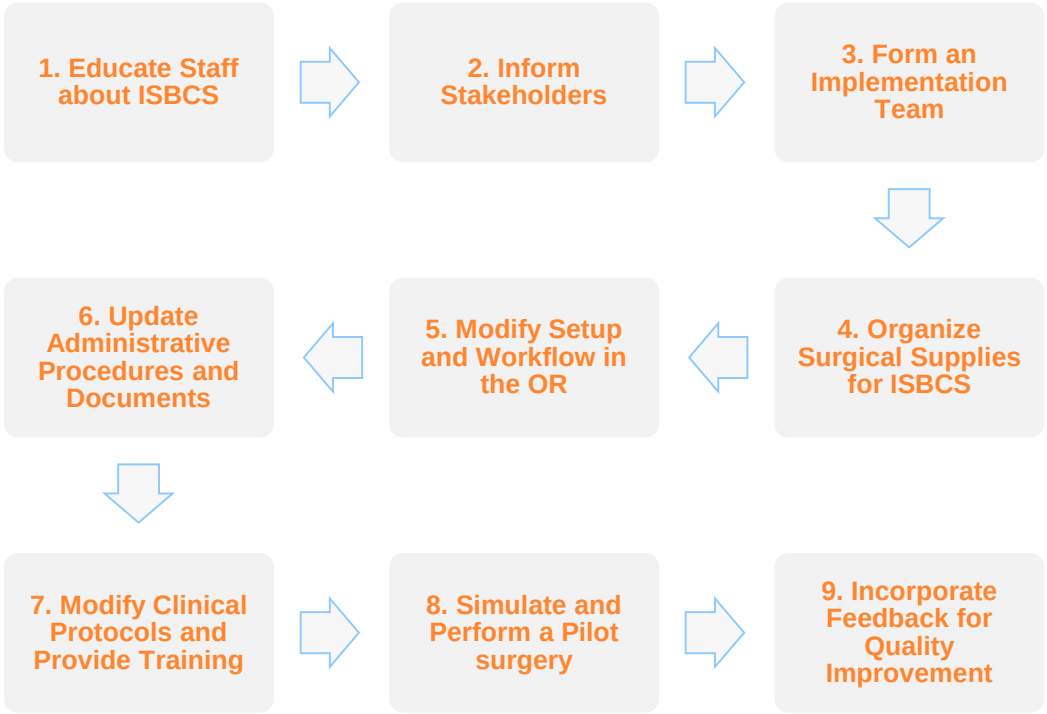
bicat.implementatie@mumc.nl

Checkpoint: ISBCS Preparation Checklist

Use this checklist to identify important starting points to prepare for implementation of ISBCS in your organization

- [ ] Ophthalmic surgeon(s) skilled and motivated for ISBCS
- [ ] Clinical, Surgical and Administrative Staff skilled and motivated for ISBCS
- [ ] Approval from senior leadership/management in your organization to implement ISBCS
- [ ] Implementation Leaders appointed
- [ ] iSBCS General Principles (2009) and National Cataract Guidelines (2021) are read and understood
- [ ] Enquire with suppliers regarding availability of surgical packs from separate batches for right and left eye
- [ ] Confirm commitment from the Central Sterilization department/provider and hospital pharmacy to comply with iSCBS Guidelines
- [ ] Appropriate physical space in the organization for surgical preparation and stock control

Implementing ISBCS: 9 Steps to Success



Implementing ISBCS: 9 Steps to Success (Step 1 to 3)

	Action:	See Toolkit:
1	Educate all relevant staff members on the principles and benefits of ISBCS. • Provide informational sessions to ensure understanding. • Share educational materials and resources.	Publication Pack
2	Establish a communication plan to inform stakeholders about the upcoming changes. • Communicate the goals, benefits, and proposed timeline of ISBCS implementation. • Address concerns and provide channels for feedback.	Communication Plan
3	Create an implementation team and timeline with specific milestones and deadlines. • Appoint implementation leader(s). • Break down the implementation process into manageable phases. Assign responsibilities and monitor progress.	Preparing for Change

Implementing ISBCS: 9 Steps to Success (Step 4 & 5)

	Action:	See Toolkit:
4	Collaborate with suppliers and central sterilization department to ensure sufficient and consistent supply of surgical equipment and pharmaceuticals from separate batch numbers. • Ensure strict adherence to ISBCS guidelines (2009). • Coordinate with vendors and suppliers to meet the demand. • Establish procedures for inventory management and reordering.	Logistics and Organization SOP: Materials iSBCS Guidelines
5	Assess and modify the physical layout of the surgical area, if required. • Ensure proper space allocation for pre-operative and post-operative activities, with strict adherence to ISBCS guidelines. • Review workflow of operating room and surgical setup.	Logistics and Organization Intra-operative Protocols Patient Flow ISBCS SOP: ISBCS SOP: Materials

Implementing ISBCS: 9 Steps to Success (Step 6 & 7)

	Action:	See Toolkit:
6	Ensure proper documentation and consent procedures are in place for ISBCS. • Review and update consent forms and patient information. • Review and update administrative protocols. • Train staff on the new procedures and requirements.	Administrative Tips Patient Education and Information
7	Develop new protocols and provide training to relevant clinical and surgical staff. • Adjust pre-operative, intra-operative and post-operative protocols, ensuring strict adherence to ISBCS guidelines. • Identify training needs and provide appropriate training sessions.	Patient Selection Pre-operative Protocols Intra-Operative Protocols SOP: ISBCS Post-Operative Protocols Patient Flow ISBCS iSBCS Guidelines

Implementing ISBCS: 9 Steps to Success (Step 8 & 9)

	Action:	See Toolkit:
8	Conduct mock scenarios followed by pilot tests. • Simulate mock ISBCS procedures to assess the workflow and identify potential challenges and areas that requirement improvement. • Use feedback from simulations to make necessary adjustments. • Plan and perform a pilot surgery and use feedback to make necessary adjustments.	Pilot Checklist
9	Establish a system for continuous evaluation and quality improvement. • Incorporate feedback from staff and patients. • Implement regular performance evaluations and data analysis.	

Toolkit Library Quick Access Page

Click on the buttons below to access Implementation Tools

GENERAL

- iSBCS Guidelines
- Administrative Tips
- Template: Communication Plan
- Patient Selection
- Patient Information
- Pilot Checklist

CLINICAL

- Patient Flow in ISBCS
- Pre-operative Protocols
- Intra-operative Protocols
- Sample SOP: ISBCS
- Post-operative Protocols

LOGISTICS

- Logistics and Organization
- Sample SOP: OR Materials and Setup
- Template: ISBCS Traceability Form

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iSBCS Guidelines: iSBCS General Principles for Excellence in ISBCS

iSBCS General Principles for Excellence in ISBCS2009

This document was reviewed and approved by the membership at the 2nd annual meeting of iSBCS, Sept. 14, 2009.

General Principles Committee 2008-9: Steve Arshinoff MD FRCSC, Toronto, Canada
Charles Claoué MD FRCS, FRCOphth, FEBO, London, UK Bjorn Johansson MD, PhD, Linkoping, Sweden.

The committee would like to thank the membership of iSBCS for their constructive input into this document: Drs David & Miguel Perez Silguero, FJ Goas Jglesias de Ussel, & Ramon Henriques de la Fe, all of the Canary Islands, Spain, & others.

1. Cataract or refractive lens surgery should be indicated in both eyes.
2. Any concomitant relevant ocular or periocular disease should be managed.
3. The complexity of the proposed ISBCS procedure should be easily within the competence of the surgeon.
4. The patient should provide suitable informed consent for ISBCS, being free to choose ISBCS or DSBCS.
5. The risk for Right – Left eye errors should be minimized by listing all surgical parameters (selected IOL, astigmatism, etc.) for both eyes on a board visible to all in the operating room (OR), at the beginning of each ISBCS case. The WHO operative checklists should also be used if possible.[1]
6. Intraocular lens power errors are minimized by having OR personnel familiar with the calculation methods used. The original patient charts should be available in the OR, and everybody passing the IOL to the surgical table should confirm the IOL choice. ISBCS nursing staff should be specifically trained and experienced.
7. Complete aseptic separation of the first and second eye surgeries is mandatory to minimize the risk of postoperative bilateral simultaneous endophthalmitis (BSE).
   a. Nothing in physical contact with the 1st eye surgery should be used for the 2nd.
   b. The separate instrument trays for the two eyes should go though complete and separate sterilization cycles with indicators.
   c. There should be no cross-over of instruments, drugs or devices between the two trays for the two eyes at any time before or during the surgery of either eye.
   d. Different OVDs, and different manufacturers or lots of surgical supplies should be used, whenever reasonable (where the device or drug type has ever been found to be causative of endophthalmitis of toxic anterior segment syndrome) and possible (if different lots or manufacturers are available) for the Right and Left eyes.
   e. Nothing should be changed with respect to suppliers or devices used in surgery without a thorough review by the entire surgical team, to assure the safety of proposed changes.
   f. Before the operation of the second eye, the surgeon and nurse shall use acceptable sterile routines of at least re-gloving after independent preparation of the second eye's operative field.
   g. Intracameral antibiotics have been shown to dramatically reduce the risk of post-operative endophthalmitis. Their use is strongly recommended for ISBCS.
8. Any complication with the first eye surgery must be resolved before proceeding. Patient safety and benefit is paramount in deciding to proceed to the 2nd eye.
9. ISBCS patients should not be patched. Post-operative topical drops are most effective immediately postoperatively and should be begun immediately post-op, in high doses, which can be tapered after the first few days. Other ophthalmic medications (e.g. for glaucoma) should be continued uninterrupted.
10. ISBCS surgeons should routinely review their cases and the international literature to be sure that they are experiencing no more than acceptable levels of surgical and post-operative complications. Membership in the *International Society of Bilateral Cataract Surgeons* (www.iSBCS.org) is highly recommended to keep abreast of the latest ISBCS information.

To download these Guidelines, click on the button below.

Internet connection is required

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Stakeholder Communication Plan: Template

To download a copy of this template, click on the button below.
Internet connection is required

Download Communication Plan

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Stakeholder Communication Plan

Proposal: *Implement ISBCS at*	**Start Date:**	**Completion Date:**
Implementation Leader(s):		
Objective:		

Stakeholder	Communication Objective	Communication Method	Frequency	Activities / Responsibilities	Feedback via
E.g. Head of Department	*Project Approval Project Updates*	*F2F Meeting Online Meeting*	*Quarterly*	*Approve implementation activities and financing Review Status*	*Email*
E.g. Hospital Pharmacy	*Establish pharmaceutical supplies for ISBCS*	*Phone Call Email*	*As needed*	*Form supply agreement Logistical arrangements*	*Email*

Patient Selection – Is a patient suitable for ISBCS?

Appropriate patient selection is the first step in successful ISBCS.

First and foremost, **all patients that are eligible for ISBCS must be given the choice to choose ISBCS or DSBCS.** Please refer to the relevant section in the National Cataract Guidelines (click here).

When considering if a patient is suitable for ISBCS, consider the following criteria:

Patients are eligible for ISBCS with the following indications:

- suffer from bilateral cataract
- have an indication for bilateral cataract surgery using standard phacoemulsification technique
- bilateral cataract surgery is expected to be uncomplicated

The following factors may influence suitability for ISBCS over DSBCS:

- patients with concerns about ability of themselves and/or their care providers to attend surgery and post-operative visits
- elderly patients with high refractive errors; ISBCS reduces fall risk from refractive anisometropia following unilateral surgery
- patients required to travel long distances to attend appointments
- medical co-morbidities requiring a general anaesthetic for cataract surgery (e.g. dementia, psychiatric illness, developmental delay)

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Patient Selection – Is a patient suitable for ISBCS? (continued)

Patients are in general NOT suitable for ISBCS with the following contra-indications:

- Age < 18 years
- Patient uncertainty or insufficient understanding of intra-operative risks and post-operative requirements
- Unilateral cataract
- Non-routine cataract surgery (e.g., cataract surgery combined with another ocular procedure)
- Cognitive or behavioural conditions that might interfere with surgery
- Conditions that increase the risk of endophthalmitis, such as:
    - Current ocular, adnexal, or periocular infections (e.g., untreated blepharitis)
    - Immune-compromised (e.g., systemic corticosteroid use, leukaemia)
    - Iodine allergy
- Factors that increase the risk of refractive surprise:
    - Abnormal axial lengths (< 21 mm or > 27 mm) or a difference between both eyes of > 1.5 mm
    - Abnormal keratometry readings
    - Previous refractive surgery
    - Myopia with posterior staphylomas
- Conditions that increase the risk of corneal edema (e.g., Fuchs' endothelial dystrophy, corneal guttata)
- Factors that increase the risk of complicated surgery:
    - Previous ocular surgery, perforating or blunt eye trauma
    - Eye, adnexal, or anatomical abnormalities (including pseudoexfoliation syndrome)
    - Lens subluxation or iridodonesis
    - Cataract nigrans, posterior polar cataract
    - Floppy Iris Syndrome
- Sight-threatening comorbidity
- Glaucoma or intraocular pressure of > 24 mmHg
- Uveitis
- Diabetes mellitus with diabetic retinopathy and macular edema
- Other significant retinal pathology

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Patient Selection – Key Points

Appropriate patient selection is the first step in successful ISBCS. Below is a summary of the key points from this chapter:

Key Points for Patient Selection for ISBCS

- A patient with bilateral cataracts requiring surgery for visual improvement is the primary indication for ISBCS
- Each eye should be expected to be a routine phacoemulsification and IOL implantation procedure i.e. there is no significant unilateral or bilateral ocular co-pathology and the cataract surgery is not combined with another procedure e.g. MIGS.
- The patient has been fully informed about and consents to the option of immediate sequential bilateral cataract surgery (ISBCS) and the alternative being the standard practice of the delayed sequential bilateral cataract surgery (DSBCS), i.e. the second eye surgery being performed on a different day.

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Administrative Tips for ISBCS

In order to implement ISBCS in your organization, certain administrative protocols need to be adjusted, including surgical and appointment planning as well as patient records. This will vary according to your organization.

Below are some general administrative tips to help with this process: :

In Patient Records

- Clear note that patient is undergoing bilateral surgery (e.g. cataract surgery ODS)
- Informed consent noted in patient dossier
- Allocated space on record for pre-operative and post-operative visual outcomes for both eyes
- Adjustment to forms to include ‘’ODS’’ may be required

Surgery Schedule / Timing

- Appointed duration of surgery time for ISBCS will need to be adjusted by the surgical team in your organization, and will vary according to the scheduling of the operating theatre in your organization.
- More efficiency in the surgery schedule with ISBCS may be achieved due to time saved from moving patients in and out from the operating room.
- It is helpful monitor the timing of surgery after your team has become well-practiced in the logistics and surgical workflow for ISBCS

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Administrative Tips for ISBCS (continued)

Surgical Files and Planning

- Even though surgeries are done on the same day, the right and left eye surgeries should still be recorded as two separate surgeries on the surgical files. This is to reflect two separate procedures (just immediately sequential)
- The purpose of this is to maintain separate procedures of each eye. This allows for a surgical time-out in between the first and second eye to cross check the IOL parameters for the second eye, and also to re-plan the second eye if there is a complication with the first.
- This administrative separation also allows for separate surgical materials to be allocated for each eye (i.e. surgical equipment, IOLs, and pharmaceutical products) and for these to be recorded appropriately.
- See the next page for an example of how ISBCS is ordered at MUMC+ Ophthalmology (Dutch only)

Post-operative Administration

- Arrange post-operative care appointments at the frequency as per standard care, both eyes will be examined together.
- During triage, patients that have undergone ISBCS should be clearly indicated on file and be noted to have a lower threshold of symptoms/complaints to be considered for review

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Administrative Tips for ISBCS (continued)

See below for an example of the surgical order for ISBCS at MUMC+ Ophthalmology (Dutch only)

OK order unilateraal / bilateraal		
Unilateraal	**2 separate orders niet gekoppeld**	**2 opnames**
Bilateraal	**2 separate orders wel gekoppeld**	**1 opname**

OK order opmerkingenveld bilaterale cataract:

TOP: CAT 1-4; Bilateraal in 1 sessie: ja
Behandelplan (kopieren naar OK-order); akkoord: dr.
Phaco OD1+ (IOL) 0.0 D; goal = anders, namelijk
Phaco OS2+ (IOL) 0.0 D; goal = anders, namelijk
Bilateraal opereren in 1 sessie: ja (informed consent)
Operateur:
Verdoving:
Contra-indicaties lorazepam (bijv. allergie voor benzodiazepines, neuromusculaire aandoeningen en obesitas met BMI > 32)? :
Overige voorzorgsmaatregelen:

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Pre-operative Protocols

Whilst the pre-operative protocols between ISBCS and DSBCS are very similar, there are a number of adjustments before surgery that must be made to ensure no confusion occurs amongst the surgical staff in the process of performing **two, immediately sequential but separate cataract surgeries** on the same patient.

Specific changes will vary according to your organization. Below are some general pre-operative adjustments that should be noted:

Pre-operative Adjustments for ISBCS

- Always have a defined order of surgery (e.g. right eye first, then left eye) regardless of visual acuity or cataract severity. This it to maintain strict adherence of protocol and avoid human error such as mix-ups or IOL swaps.
- Always have 2 separate operations; also make sure that you prepare the intra-ocular lens separately for each eye, so that it is clear which lens belongs to which eye.
- Mark all materials and agree what the indicators for right and left eye are, so that this is clear and visible for all team members (for more information, see Chapter: ‘Organization and Logistics’ in this toolkit).
- Anesthetize (topically, sub-tenon is not possible in ISBCS) only the first eye at the pre-operative check point. The second eye is only anesthetized when the second surgery will commence.
- Adjust existing protocols such as pre-operative safety checklists and time-outs to incorporate the assessment and preparation of both eyes (e.g. adding ‘ODS’ or having a colour-coded stickers or forms).
- Confirm that there are no signs of eye infection or contraindication to surgery (as per standard pre-operative precautions for DSBCS).

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Intra-operative Protocols

Intra-operative Considerations for the Ophthalmic Surgeon in ISBCS

ISBCS is to be performed by an experienced cataract surgeon during a single operating session using a phacoemulsification technique. ISBCS should be performed in strict accordance with the *"iSBCS General Principles for Excellence in ISBCS 2009"* (source: www.iSBCS.org). The considerations are further explained in detail below:

- The complexity of the surgery for each independent eye should be within the ophthalmic surgeons skill and experience, and all assistants and staff should have experience with cataract surgery.
- The surgical technique should be one that is routinely performed by the surgeon, no difference is indicated as the procedure for standard cataract procedure using phacoemulsification technique.
- In order to minimize the risk of mixing up left and right eyes, all surgical parameters (IOL, astigmatism, etc.) for both eyes will be listed on a board that is visible to all operating room (OR) staff.
- All OR staff needs to be familiar with IOL calculation methods and original patient charts need to be available in the OR. All OR staff handling IOLs need to confirm the IOL choice. Nursing staff will receive specific training.
- Decide on a defined order of surgery in your organization for every ISBCS procedure (e.g. right eye first, then left eye) regardless of visual acuity or cataract severity. This is to maintain strict adherence of protocol and avoid human error such as mix-ups or IOL swaps.
- A separate time out must be performed before each surgery.

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iSBCS Guidelines

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Intra-operative Protocols

Intra-operative Considerations for the Ophthalmic Surgeon in ISBCS (continued)

- Extra attention must be paid to treating each eye as **completely separate aseptic procedures** to minimize the risk of bilateral endophthalmitis:
    - Nothing that comes in physical contact with the first eye is allowed to be used for the second eye.
    - The two instrument trays used for both eyes need to go through complete and **separate sterilization cycles** (this includes the phacoemulsification hand pieces).
    - There should be no cross-over of instruments, drugs, or devices between the two instrument trays at any time before or during the surgery.
    - Ophthalmic Viscosurgical Devices (OVDs), pharmaceutical products and surgical supplies from **different production lot numbers** must be used for each eye when reasonable and possible. This includes disposable instruments, balanced salt solution and perioperative drugs used during and after surgery.
    - Nothing should be changed with respect to suppliers or devices used during surgery without a thorough review by the entire surgical team to assure safety.
    - Between surgery of the first and second eye the surgeon and assistants will rescrub. In some cases it may be suitable to have a different scrub nurse for the second eye surgery.
    - Between surgery of the first and second eye the patient needs to be re-prepped and re-draped as per a separate procedure.
    - Intracameral antibiotics must be administered in both eyes.

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Intra-operative Protocols

Intra-operative Considerations for the Ophthalmic Surgeon in ISBCS (continued)

- Complications that arise during surgery of the first eye must be resolved before proceeding with the second eye. Postponement of second-eye surgery should be considered as directed by the surgeon. If there is any significant intra-operative complication (including but not limited to posterior capsule tear, vitreous loss or zonular dialysis) or a complication that increases the risk of endophthalmitis of other adverse outcome, the second eye surgery must be deferred.
- The operating microscope sterile handle covers must be changed between eyes and be from separate sterilization batches.
- The used operating theatre trolley and all instruments, microscope covers etc. from the first surgery must be removed from the operating room before a sterile field is setup for the second eye surgery.
- Patients' eyes will not be patched as usual post-operatively, instead they may receive transparent plastic eye shields. If post-operative topical antibiotics and anti-inflammatory drugs are to be used, they will be commenced immediately after surgery
- Other ophthalmic medications should be continued uninterrupted.

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For further reading, please refer to the following publications:
[27] Arshinoff, S.A. and S. Odorcic, Same-day sequential cataract surgery. Curr Opin Ophthalmol, 2009. ***20****(1): p. 3-12.*
[28] Sandhu, S., et al., Immediately sequential bilateral cataract surgery (ISBCS) adapted protocol during COVID-19. Can J Ophthalmol, 2023. ***58****(3): p. 171-178.*

Intra-operative Protocols

Intra-operative Considerations for the Ophthalmic Surgeon in ISBCS (continued)

Summary of General Principles for ISBCS

- Bilateral indication for cataract surgery
- Relevant ocular or periocular disease must be controlled
- Case complexity well within surgeon's competences
- Patient retains choice between ISBCS and DSBCS
- Attention to preventing OD/OS mix-ups and lens power errors
- Complete separation of sterility between OD/OS
- Any complication in the first eye must be resolved before operating on second eye and consideration of postponing second eye at surgeons' discretion
- Intracameral antibiotics administered in all cases and post-operative medication administered immediately
- Surgeons must review their own cases and keep abreast of literature, compare ratio of own complications to literature-reported complications

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Intra-operative Protocols

Ophthalmology Residents and ISBCS

The decision to allow Ophthalmology residents and fellows to be involved in ISBCS should be based on the policy within your organization, taking into consideration factors such as patient consent, resident skill level, and complexity of the cases. Resident involvement and teaching may be improved with ISBCS. By observing the surgery on the first eye, the resident may be better equipped to immediately use that surgical experience to help guide surgical steps on the contralateral eye, as both eyes may behave similarly in the same patient.

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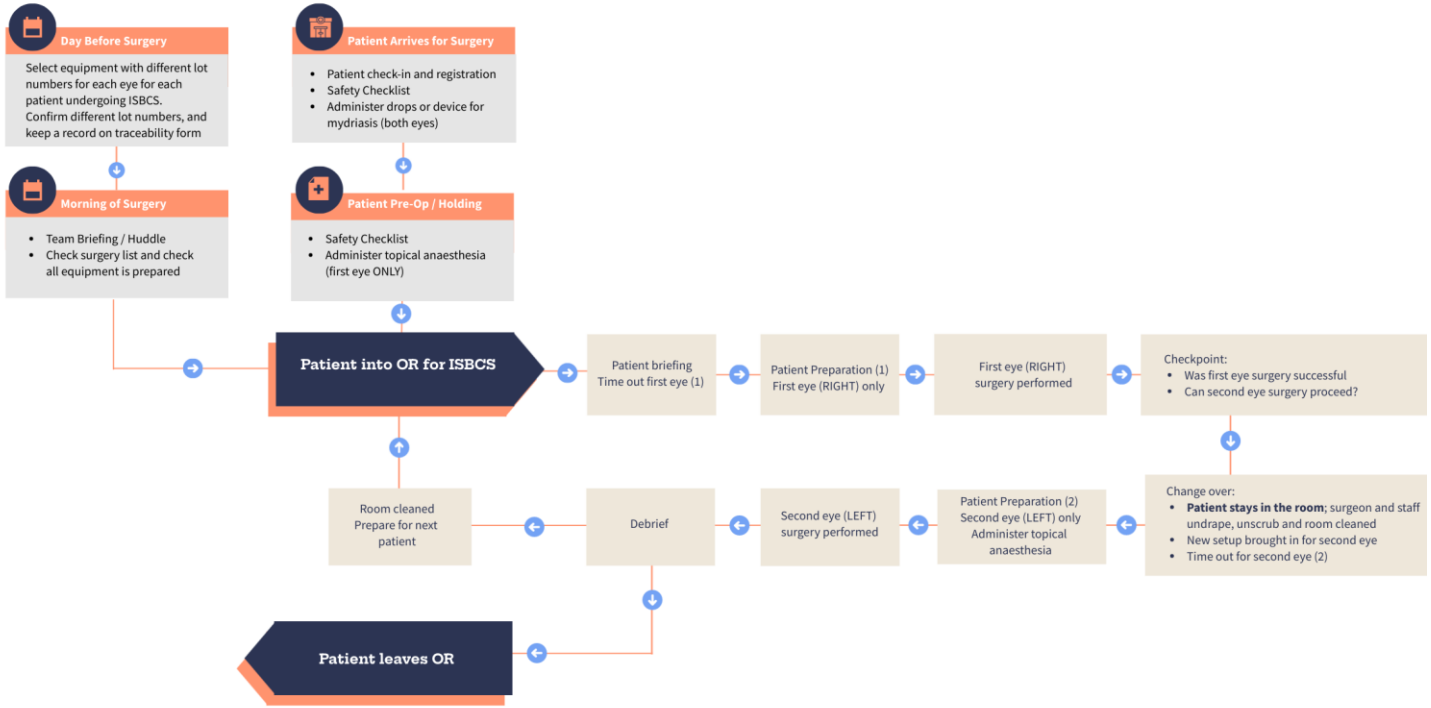
Patient Flow ISBCS

Below is an example of the patient and operating room workflow at MUMC+ during ISBCS



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Download SOP: ISBCS Procedure

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Sample Standard Operating Procedure (SOP): ISBCS

Standard Operating Procedure (SOP)
ISBCS : OK procedure

Document Coordinator:	
Author :	
Version :	

1. Goal

The purpose of this Standard Operating Procedure (SOP) is to provide a guideline for surgical staff involved in bilateral cataract operations (surgeons, assistants , etc.). This guideline is based on the international guideline for 'Immediately Sequential Bilateral Cataract Surgery' (ISBCS): *' iSBCS General Principles for Excellence in ISBCS 2009".*

2.Standard Operating Procedure (SOP)

FIRST EYE

Before surgery on the first eye

1. Surgical parameters (eg. IOLmaster) of both eyes should be displayed and visible at all times for all OR staff .
2. Surgical table must have the surgical supplies set up and ready for the first eye according to the 'SOP: Materials and Setup'.
3. The IOL for the first eye is checked and laid out
4. Patient is prepared and set up for surgery of the first eye.

During surgery of the first eye

1. A regular phaco-emulsification and cataract extraction is executed
2. At the end of the operation intracameral antibiotics are injected

After surgery on the first eye

1. Postponing the operation of second eye is considered (by the surgeon) in case of complications with the first surgery
2. Antibiotic and anti-inflammatory drops are instilled in the operated (first) eye is. The first eye is then temporary covered with a (transparent) cap or bandage.
3. All materials in physical contact with the patient during the surgery of the first eye is removed, and will not be used in any contact during operation of the second eye.
4. Surgeon and assistant de-scrub.

SECOND EYE (immediately after eye 1)

The surgery of the second eye is considered a completely new surgery. It is advised to hold a short lens timeout to confirm the IOL lens power for the second eye.

Before surgery on the second eye

1. Patient is prepared and iodized
2. The IOL for the second eye is checked and laid out.
3. Surgical table must have the surgical supplies set up and ready for the second according to the 'SOP: Materials and Setup'.
4. ***All materials for the second eye must be from a different lot number to those used in the first eye*** (noted in the Traceability form). This must be prepared in advance by the surgical staff before surgery takes place.
5. Surgeon and assistant wear new sterile surgical gown and new sterile gloves.

During surgery on the second eye

1. A regular phaco-emulsification and cataract extraction is executed
2. At the end of the operation intracameral antibiotics are injected

After surgery on the second eye

1. Antibiotic and anti-inflammatory drops are instilled in the second eye
2. Both eyes are temporary covered with a transparent caps (NOT bandages)

Logistics and Organization for ISBCS - Introduction

Since immediately sequential bilateral cataract surgery (ISBCS) does not involve a new surgical technique or treatment, a significant implementation barrier is related to the logistics and organization of surgical materials within the healthcare facility. Designing this can present as a major challenge for hospital organizations and suppliers. This chapter provides a detailed suggested approach to overcome this hurdle. However, each healthcare institution may need to develop a tailored strategy based on local factors. The most important principle is to ensure that the conditions of the International Society of Bilateral Cataract Surgeons (iSBCS), meaning that ISBCS must be set up in such a way that a strict separation of aseptic procedures between the two eyes can be guaranteed.

General Principles for Aseptic Separation

- No crossover of instruments, medication or devices - the surgeon and surgical team must NOT use anything that is in physical contact with the first eye for the second eye
- Instruments for both eyes must go through separate sterilization cycles with indicators
- Visco-elastics and surgical supplies from different batch numbers or suppliers must be used for each eye where reasonable and possible, due to risk of endopthalmitis and Toxic Anterior Segment Syndrome (TASS)
- Any change in routine/procedure must be discussed and known by the entire surgical team
- During surgery a new preparation of sterile field is created per eye
- Strong recommendation for standard use of intracameral antibiotics

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Logistics and Organization for ISBCS – Supplier Capability

ISBCS must be performed in strict accordance with the “iSBCS General Principles for Excellence in ISBCS 2009” (source: www.iSBCS.org). This document states the following:

- *Both eyes will be treated as completely separate aseptic procedures to minimize the risk of bilateral endophthalmitis*
- *Different Ophthalmic Viscosurgical Devices (OVDs), and different manufacturers or production lot numbers of surgical supplies will be used for each eye when reasonable and possible.*
- *The two instrument trays used for both eyes need to go through complete and separate sterilization cycles.*
- *Intracameral antibiotics will be administered in both eyes.*

These guidelines must be adhered to by any healthcare organization implementing ISBCS, in order to minimize the risk of bilateral endophthalmitis and toxic anterior segment syndrome (TASS). Therefore, healthcare organizations will need to procure all products routinely used in cataract surgery in line with these guidelines.

To proceed, the first step is to determine whether your suppliers are able to provide sufficient and consistent supply of surgical equipment and pharmaceutical products in compliance with the above requirements. The BICAT-NL Implementation Project Group is actively in discussion with key industry stakeholders to encourage facilitation and commitment from suppliers to meet these needs. This includes the Nefemed group, an interest group representing producers, importers, and traders of medical devices.

In your discussions with your suppliers, you may present the following questions to them for consideration:

1. Is your company able to supply two batches of the same product from different production lot numbers on demand? (i.e. custom packs, medical devices including OVDs and pharmacueticals)
2. What is your opinion on dividing products for ISBCS? Is your company able to modify packaging to distinguish between products for right and left eye? (e.g. colour coding or different labels)
3. What is the average lead time to receive an order involving two separate batches of the same product?
4. What effect will this have on cost price of these products to us as the customer?

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Logistics and Organization for ISBCS – Logistical Adjustments

The next step is to implement the following adjustments in collaboration and agreement with the respective departments or suppliers:

Central Sterilization Department or Supplier:

A working arrangement must be made with your Central Sterilization Department or supplier. The ophthalmic instrument sets must be distributed amongst multiple cycles, in order to avoid being sterilised in the same autoclave cycle to minimise risk of TASS.

Request for labelling or numbering of the surgical sets based on the autoclave cycle (see: Figure 1). If your organization operates with an internal sterilization department, this should be fairly straightforward to arrange. Adjustments can be made when sets are scanned and the name can be digitally adjusted (see photo). This may not possible if the Sterilization Department does not have multiple autoclave machines, or if your surgical equipment is sterilized externally (from an outside provider). In this instance an alternative solution may be to use a colored sticker to distinguish between cycles; provided this is approved by the sterilization team and is compliant with sterilization regulations.

When the surgical sets have been sterilized and clearly labelled from different cycles, then the equipment can be allocated to be used for right and left eye surgeries, so that no two instruments trays from the same cycle are used on both eyes on the same day.

Figure 1: Numbered labels indicating different sterilisation cycles

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Logistics and Organization for ISBCS – Logistical Adjustments

Industry Suppliers

It is wise to approach different suppliers to investigate supplier capability to facilitate ISBCS.

In the case of surgical custom packs, suppliers may be able to provide different custom packs for right and left eye (e.g. in different colored packaging or with R/L labels, see: Figure 2). Also make sure that the custom packs are delivered as complete as possible, to minimize waste of disposables.

Suppliers must agree to provide different batch numbers of the same product on each delivery. Sourcing as many products from one supplier will simplify and shorten ordering lines, and make it easier monitor stock levels. However, if one supplier cannot provide different batch numbers of the same product, it is possible to consider ordering similar products from different suppliers for each eye, hence ensuring a difference between products for each eye.

Many organizations order their OVDs and irrigating fluid through their hospital pharmacy. However, occasionally it may be more suitable to order these directly through an external supplier. This provides direct procurement of two batches and faster management of stock control. This may require some negotiations between various departments or stakeholders in your organization.

Tip: It is important to note that supply chain availability and manufacturing time are potential limiting factors when ordering custom packs from different lot numbers. It is advisable to factor in this lead time when re-stocking for bilateral cataract surgery.

Figure 2: Different coloured custom packs for right and left

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Logistics and Organization for ISBCS – Logistical Adjustments

Pharmacy

It must be agreed with the pharmacy that they agree to provide two different types of batch / lot numbers for the medications used in cataract surgery, in order to comply with the recommendations outlined by the iSBCS guidelines.

In some cases, this can be a major challenge. The pharmacy (whether internal or external) may not always have the capacity, resources or time to arrange this. Medications that must be arranged through the pharmacy include:

- Adrenaline
- Intracameral antibiotics
- NaCl 0.9%

Some organizations may also source OVDs and irrigating fluid through the pharmacy.

Tip: Be creative! Discuss with your implementation team to come up with a solution.

In the case that the pharmacy is unable to provide two batch numbers of the same product or item, one approach is to consider purchasing from a new supplier based on availability. Alternatively, it also may be possible to overcome this hurdle with some creative solutions to obtain two different lot numbers of the same or similar product. Below are some examples of how other organizations have achieved this:

Item Needed	Proposed solution if two batch numbers are unavailable
NaCl 0.9% in 10cc	Source a different tube size or packaging for the second eye (e.g. NaCl 0.9% in 20cc)
Adrenaline 1mg/mL	Source another concentration of adrenaline; possibly adrenaline 1mg/10mL and adjust dosage
Intracameral antibiotics	Use antibiotics purchased from different suppliers for each eye
BSS+	Use BSS+ for one eye and BSS for the other, or purchase products from different manufacturers
OVDs	Use different OVD brands for each eye. (E.g. Provisc in one, Healon in the other)

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Logistics and Organization for ISBCS

Storage and Organization of Materials

Once procurement of supplies has been arranged, you may start setting up the OR and training the team. Do not forget to inform the logistics staff about the preparation of the OR for bilateral surgery.

Ensure there is appropriate physical space in your organization for adequate supply and storage of supplies for right and left eye.

Always mark all articles, to make the difference between ‘Left’ and ‘Right’ visible on each item, shelf and/or cupboards, and all throughout the operating room.

Create space in the storage room to store the custom packs and surgical sets in separate sections for left and right eye (Figure 3).

Figure 3: Dedicated shelving space for materials, labelled and sorted into right and left

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Logistics and Organization for ISBCS

Storage and Organization of Materials

Create a bilateral OR cart to store the medications and pharmaceutical products. The advantage of a separate cart is that the separation of batch/lot numbers between the right and left eye is created in advance. (Figure 4 and 5).

Create a separate place in the refrigerator for the OVDs with allocated space for products for right and left eye (Figure 6). This also allows a clear overview of the stock levels to identify when re-ordering is necessary.

Figure 6: Separation of products for right and left eye in the refrigerator

Figure 4: Storage cart with separation of products

Figure 5: Pharmacuetical products stored and labelled Right / Left

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Logistics and Organization for ISBCS

Storage and Organization of Materials

Mark all products/materials with 2 different colored stickers (Figure 7), and make agreements with the team so that the markings for left and right eye are clear and known by all surgical staff.

With clear and visible labelling of products and equipment, the logistical preparation required for ISBCS is streamlined. This organization maintains the separation of lot/batch numbers for products used in ISBCS, and reduces the risk of errors in urgent scenarios or during shift changes. For example, if an extra product is needed during surgery, this can be quickly and accurately obtained without having to check batch numbers.

Clear labelling and storage also ensures that supply levels are easily visible for all surgical staff, so that it can be noted when restocking is needed.

Please note that the team must be well instructed and trained on the new organization system.

Discuss with your implementation team what type of organization system will work best for your storage space, logistics team and surgical workflow

Figure 7: Colored stickers and Left / Right labels for marking all products and shelves for ISBCS

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Logistics and Organization for ISBCS

Surgical Equipment and Materials Set up for ISBCS

On the day before an OR program with scheduled ISBCS, the logistics employee or surgical staff employee who sets out the surgical equipment must set up the required surgical materials in a clear manner. All surgical sets, custom packs and materials are properly marked, allocated to right and left eye and prepared in a way that is clearly visible (See Figure 8 and 9).

Create a form where all batch numbers can be noted for each patient (see ‘Traceability Form’). This form can already be completed by the logistics team ahead of time (e.g. the day before ISBCS procedures are scheduled). This avoids extra administrative workload for the surgical staff during the time surgeries are taking place. The traceability forms can already be filled in and placed with the items, so that they are easy to find for the OR staff.

Figure 8 & Figure 9: Surgical materials prepared in advance in preparation for surgery the next day

Go to: ISBCS Traceability Form

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Logistics and Organization for ISBCS

Surgical Equipment and Materials Set up for ISBCS

Consumable products in the operating room must also be set-up in a way that is made very clearly visible (Figure 10).

If you have an OR program with both DSBCS (unilateral) and ISBCS (bilateral) procedures, it may help to use a small table that you set up specifically for ISBCS. This avoids confusion among the OR staff, or errors in using up materials that are allocated for ISBCS procedures.

Discuss with your implementation team what type of organization system will work best for your storage space, logistics team and surgical workflow.

Tip: Provide a safe working environment that allows for feedback where necessary.

Tip: Provide a comprehensive team briefing in the morning when ISBCS is scheduled, so that everyone is reminded of the changes that have been implemented.

Figure 10: Consumable products organised in the OR clearly separated as right and left for each ISBCS procedure.

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Sample Standard Operating Procedure (SOP): OR Materials and Setup

Standard Operating Procedure (SOP)

ISBCS : OR materials – Procurement and Setup

Document Coordinator:	
Author :	
Version :	

1. Goal

The purpose of this Standard Operating Procedure (SOP) is to provide a guideline for surgical staff outlining the procurement, storage and set up of surgical equipment and materials before bilateral cataract surgery (Immediate Sequential Bilateral Cataract surgery; ISBCS) takes place .

2. Procedure

2.1 Procurement and storage of products

1. In the case of ISBCS there are additional requirements regarding the procurement of intra-ocular products , namely :

   - Antibiotic
   - Viscoelastic
   - Adrenaline 1mg/ml ampoule
   - NaCl 0.9% (for antibiotic solution)
   - BSS bags
   - Custom packs

   ➔ *These products must be provided from different production batch numbers. If delivery of different batch numbers (lot numbers) is not possible , the products can be sourced from different brands or providers.*

   - Reusable phacosets

   ➔ This product must be delivered from different autoclaves (sterilization cycles). On the phacoset label an autoclave number is added to clearly identify set from different cycles for right and left eye. This is a mandatory procedure.

2. [Staff member] will **place** the **order of several batches** made in accordance with the pharmacy agreements with the supplier .

   Example :

   Aprokam :

   - Agreements with [Supplier]
   - Mode order :
     - order from the pharmacy post to [email]
     - Contact person from supplier (also put in CC): [name , details]]
   - During order explicitly mention :
     "Aprokam order for . bilateral cataract procedures" :
     - "xx" boxes (à 10 loose pieces per box) Aprokam batch 1
     - "xx" boxes (à 10 loose pieces per box) Aprokam batch 2

3. **Storage locations :** Materials are to be stored in the storage areas / refrigerator with designated sections or shelves divided into right and left. All products are to be divided from different batch numbers for right and left, and clearly marked with labelling or stickers. .

2.2 Setup of materials for ISBCS

1. Take 1 **Custom Pak** for left eye (green) and 1 Custompak for right eye (blue) from the pantry.
   → *Note batch number on registration form*
2. Take 1 reusable **phacoset** (large or small) with one of the autoclave numbers 1 to 4 for one eye, and take a phacoset **from a different autoclave number** for the other eye .
   → *Note autoclave number on registration form*
3. Take 1 **BSS bag** (with batch number 'X') for one eye , and take **one other batch number** BSS bag for the other eye .
   → *Note batch number on registration form*
4. Repeat point 3 for : Antibiotic , OVD (Provisc , Viscoat), Adrenaline, NaCl 0.9%
   →*Note batch numbers on registration form*
5. Other materials can be prepared in accordance with standard / regular procedure

ISBCS Traceability Form: Template

For traceability, auditing and patient safety, the operating records should list the batch numbers and sterilization cycle details of all instruments, devices and perioperative drugs used for each eye.

Use a Traceability Form to record different batch numbers for right and left eyes for accurate record keeping on the patient's file. This form is used when preparing the surgical equipment the day before scheduled ISBCS, and remains with the patient file after the surgery is completed.

To download a copy of this template, click on the button below.
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Download ISBCS Traceability Form

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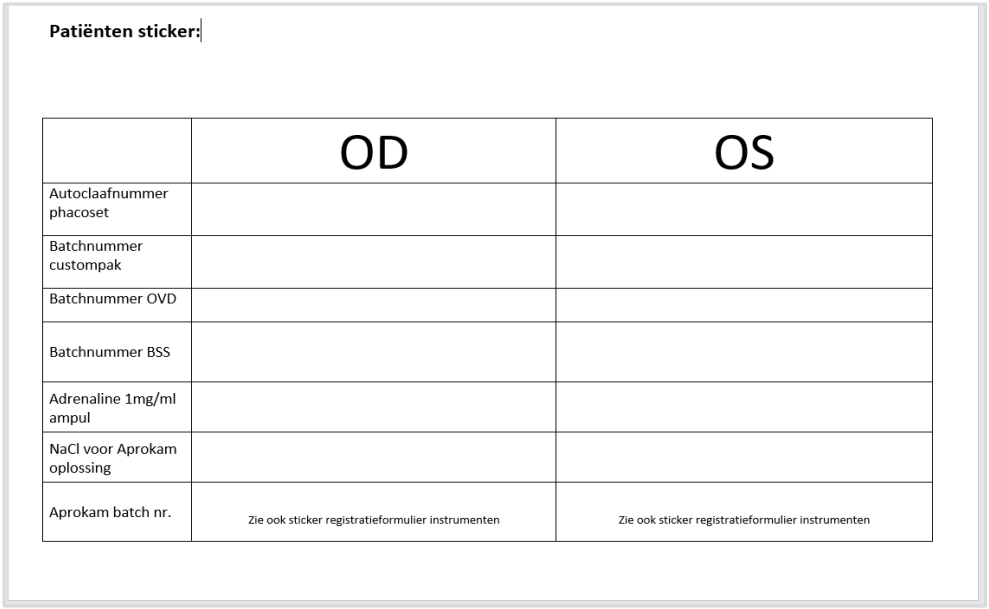

Patiënten sticker:

	OD	OS
Autoclaafnummer phacoset		
Batchnummer custompak		
Batchnummer OVD		
Batchnummer BSS		
Adrenaline 1mg/ml ampul		
NaCl voor Aprokam oplossing		
Aprokam batch nr.	Zie ook sticker registratieformulier instrumenten	Zie ook sticker registratieformulier instrumenten

Post-operative Protocols

Post-operative patient care will vary between surgeons, however similar post-operative principles apply to ISBCS as per DSBCS. Specific changes will vary according to your organization. The following considerations highlight points of attention that apply to ISBCS:

Post-operative Adjustments for ISBCS

- No patches are used following surgery. Instead, transparent shields are used immediately after surgery and during the first day to protect the eye and continued in the evenings for the first week. Some surgeons skip this altogether.
- Post-operative drops follow the regimen of DSBCS, but with both eyes on the same schedule. Drops should be commenced immediately after surgery.
- Patients are recommended to get a different set of bottles for each eye. These should be clearly labelled.
- Arrange frequency of post-operative care appointments as per standard care, both eyes will be examined together.
- Patients must be monitored closely for post-operative complications, particularly endophthalmitis, TASS and macular oedema.
- Clear post-operative instructions must be given to the patient including a 24-hour contact to a health care professional in the case of any emergency queries.
- Triage teams and clinical staff should be made aware that patients that have undergone ISBCS should be seen with a lower threshold of symptoms/complaints.
- Post-operative complications should be reported appropriately. All significant post-operative complications or unexpected patient contact or attendances must be fed back to the operating surgeon.
- There must be a separate, mandatory patient safety reporting system in place for the reporting of confirmed or suspected endophthalmitis cases.

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Post-Operative Protocols – Sample

See below an example of the post-operative patient leaflet provided at MUMC+

Universiteitskliniek voor Oogheelkunde
Maastricht Universitair Medisch Centrum
P. Debyelaan 25
6202 AZ Maastricht
043-3876800

Nazorg bij een staaroperatie

Inleiding
Wanneer u de Universiteitskliniek voor Oogheelkunde na een staaroperatie verlaat, is het uitermate belangrijk dat u zich aan een aantal (leef)regels houdt. U kunt daarmee het herstel bespoedigen en voorkomen dat problemen ontstaan. Leest u daarom deze folder aandachtig door.

Algemeen
- Bij matige pijnklachten direct na de operatie kunt u een paracetamol innemen.
- In principe vindt de dag na de operatie een telefonische controle plaats.
- Soms vindt de oogarts het raadzaam om op de eerste dag een normale controle te verrichten. In dat geval krijgt u daarvoor een afspraak mee.
- De ochtend na de operatie mag u zelf het oogverband verwijderen; het plastic kapje dient u echter te bewaren!
- Telkens als u plat gaat liggen, dus bijvoorbeeld als u gaat slapen, moet u het plastic kapje voor het oog aanbrengen, zodat u niet in het oog kunt wrijven. Dit doet u 7 dagen.
- Het oog kan de eerste dagen wat rood en gevoelig zijn en het zien is meestal nog niet optimaal. U hoeft zich hierover geen zorgen te maken.
- Bij hevige pijn of hoofdpijn a.u.b. direct contact opnemen met ons (zie hieronder voor de contactgegevens).

U dient de dag na de operatie te beginnen met druppelen volgens het schema:
1e week: Nevanac 1 x daags 1 druppel en Dexa-pos 4 x daags 1 druppel
2e week: Nevanac 1 x daags 1 druppel en Dexa-pos 3 x daags 1 druppel
3e week: Nevanac 1 x daags 1 druppel en Dexa-pos 2 x daags 1 druppel
4e week: Nevanac 1 x daags 1 druppel en Dexa-pos 1 x daags 1 druppel ; daarna stoppen

- Gebruik de voorgeschreven druppelflesjes en houd u aan de voorgeschreven dosering.
- Was uw handen goed voordat u met druppelen begint.
- Na elke druppel moet u 1 à 2 minuten wachten voordat u weer druppelt.
- De volgorde waarin u de verschillende soorten oogdruppels gebruikt, is niet van belang.
- Bij het druppelen dient u het onderste ooglid naar beneden te trekken en niet het bovenste ooglid naar boven. Probeer niet te knijpen. U kunt ook eventueel vragen of uw partner of iemand anders u wilt indruppelen.
- Mocht u aan twee ogen tegelijk geopereerd zijn, gebruik dan niet voor beide ogen dezelfde oogdruppel flesjes maar voor elk oog aparte flesjes (zet er eventueel 'links' en 'rechts' op) .

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Patient Education and Informed Consent

As with all procedures, informed consent of the patient must always be clearly documented in the patient file.

In the case of ISBCS, the patient must always be presented with the choice of ISBCS or DSBCS. The patient must also be presented with the standard information and risks that apply to cataract surgery (as per DSBCS).

The table below highlights key points that apply in the case of ISBCS:

Key Points for Patient Education and Informed Consent for ISBCS
• The patient has been fully informed about and consents to the option of immediate sequential bilateral cataract surgery (ISBCS) and the alternative being the standard practice of the delayed sequential bilateral cataract surgery (DSBCS), i.e. the second eye surgery being performed on a different day. • The patient is informed of the comparative risks of ISBCS vs DSBCS • The patient understands that the surgeon may delay surgery on the second eye if a complication arises with the first eye. • The risk of bilateral post-operative endophthalmitis has been discussed. • Preference of intra-ocular lens options (e.g. monofocal, toric, EDOF, multifocal) and refractive target for **each eye** has been clearly discussed.

For further resources regarding patient information visit our BICAT-NL Website

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ISBCS Pilot Checklist

Use this checklist to cross check that all your preparations are complete before conducting a pilot ISBCS procedure:

- [ ] Source consumable and pharmaceutical products from different batch numbers for right and left eye
- [ ] Source surgical custom packs and materials from different batch numbers for right and left eye
- [ ] Source surgical equipment that has been sterilized from different autoclave cycles (and clearly marked) for right and left eye
- [ ] Establish a system for inventory management of supplies for right and left eye
- [ ] Adjust intra-operative protocols in accordance with iSBCS guidelines
- [ ] Adjust workflow in the operating room and surgical setup to ensure aseptic separation of right and left eye in accordance with iSBCS guidelines
- [ ] Adjust pre-operative and post-operative protocols Review and update administrative protocols
- [ ] Review and update consent forms and patient information
- [ ] Ensure all staff are trained on new procedures and requirements
- [ ] Assign surgical team to participate in pilot surgery
- [ ] Simulate a mock ISBCS procedure from beginning to end
- [ ] Allocate a patient and date for pilot surgery

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