# Orlando Ophthalmology Surgery Center Authorization for Surgical Procedure Descemet's Stripping Automated Endothelial Keratoplasty (DSAEK)

Patient Name	Surgeon	
Proposed Procedure: Descemet's Stripping Automated Endothelial I	Keratoplasty	eye

You have a condition that has affected your cornea (the front part of your eye). Your doctor has determined that you need a corneal transplant and that you are a good candidate for the Descemet's Stripping Automated Endothelial Keratoplasty (DSAEK) technique of corneal transplantation. This technique is a form of "endothelial keratoplasty" and is used instead of the full thickness traditional method called "penetrating keratoplasty" (PK).

### Indication

1. You have been advised that DSAEK would be a reasonable procedure for your treatment because only one part of your cornea is not working properly. The endothelial layer of your cornea is failing and is causing your cornea to become swollen. The endothelium is the layer of cells on the inside surface of your cornea. In the past, the only way to replace that layer of cells was with a full thickness corneal transplant. (PK)

A split thickness transplant of this inner layer is called an "endothelial keratoplasty". The DSAEK technique would remove (or "strip") only the diseased portion of your cornea (like "stripping" wallpaper off of a wall) and then use a lamellar transplant of donor tissue to replace only the diseased tissue while leaving the rest of your cornea intact. In addition, a smaller incision will be used compared to a traditional PK. The post-operative care after DSAEK surgery is nearly identical to those of patients that have had traditional PK surgery but they are usually fewer in number and sutures do not need to be removed at office visits as in traditional full-thickness PK procedures.

### 2. ADVANTAGES AND DISADVANTAGES OF TRADITIONAL TECHNIQUE

Standard corneal transplant surgery consists of removing the entire cloudy cornea and replacing it with a full thickness donor cornea, thereby replacing all three layers of the cornea.

Ophthalmic researchers and surgeons have long recognized that for many patients needing a corneal transplant, only the diseased or missing endothelial cells needed to be replaced, as the stroma and epithelial layers were otherwise normal. With DSAEK, a thin button of donor tissue containing only the endothelial cell layer is inserted onto the back surface of the patient's cornea. The surgery itself takes less time, involves a smaller surgical incision, requires far fewer sutures, heals faster and more reliably, and the vision returns faster.

The advantage of the traditional corneal transplant operation is the long and successful track record that we have with it. There is a 90% success rate. The rate of rejection is only about 8%. The disadvantages of the traditional corneal transplant operation are the time involved in performing the actual operation, the difficulties in suturing the new cornea in place, and occasional problems with the sutures which can

come loose, cause infections, or cause astigmatism (an irregular corneal shape). The astigmatism after traditional corneal transplant surgery can be so significant that eyeglasses alone won't give adequate vision and some patients ultimately require contact lenses or additional surgery to reduce or eliminate the astigmatism. Because the wound is a full 360 degrees, and the sutures used are finer than human hair, the corneal transplant wound is always very delicate and at risk to rupture or break open from mild or incidental trauma, even several years after the surgery. The visual recovery can take 6 to 12 months.

## 3. ADVANTAGES AND DISADVANTAGES OF DSAEK TECHNIQUE

There are several significant advantages to the DSAEK operation compared to the standard corneal transplant operation. The operation is faster. The wound is smaller, more stable and less likely to break open from inadvertent trauma. Because the wound is smaller and requires far fewer sutures, there is very little postoperative astigmatism which can delay the visual recovery. The maximum return in vision takes only about 3 to 4 months following DSAEK. Since only the thin inner layer of the cornea is replaced, over 90% of the patient's own cornea remains behind contributing to greater structural integrity and a reduced incidence of rejection.

Some patients with corneal scarring or other conditions are not suitable candidates for DSAEK. There are risks involved with the DSAEK operation. There is a risk of the thin button of endothelium becoming displaced within the first few days or weeks after surgery and requiring a return trip to the operating room to reposition it. If the DSAEK operation fails, the operation can be repeated with another button of donor endothelium. If the DSAEK fails, either after one or multiple attempts, a traditional corneal transplant operation can be performed.

### RISKS AND COMPLICATIONS OF DSAEK CORNEAL TRANSPLANT SURGERY

The general risks of the DSAEK that are similar to the traditional corneal transplant operation include the risk of hemorrhage in the eye, infection, swelling of the retina causing temporary or permanent blurring of vision, a retinal detachment, glaucoma or high pressure in the eye, rejection of the transplanted tissue, chronic inflammation, double vision, a droopy eyelid, loss of corneal clarity, poor vision, total loss of vision, or even loss of the eye. Rarely, the transmission of infectious diseases can occur such as Hepatitis, AIDS, and syphilis, although the corneal donor is routinely tested for these diseases before the tissue is approved and released for transplantation.

I understand that there may be other unexpected risks or complications that can occur that were not listed in the consent form or discussed by the doctor. I also understand that during the course of the proposed operation unforeseen conditions may be revealed that require the performance of additional procedures, and I authorize such procedures to be performed. I further acknowledge that no guarantees or promises have been made to me concerning the results of any procedure or treatment.

# 4. COMPLICATIONS OF LOCAL ANESTHESIA INJECTION:

Complications of local anesthesia injections around the eye include perforation of the eyeball; bleeding behind the eye; destruction of the optic nerve; interference with circulation of the retina; possible drooping of the eyelid; double vision; permanent loss of vision; respiratory depression or arrest; hypotension; and in rare cases, coma and death.

## 5. ADDITIONAL UNFORESEEN CONDITIONS OF SURGERY IN GENERAL:

Just as there are benefits to the procedure(s), I also understand that medical and surgical procedures involve risks. These risks include, but are not limited to allergic reactions, bleeding, blood clots, infections, adverse side effects of drugs, or even loss of bodily function or life as well as the transmission of infectious disease, including hepatitis and Acquired Immune Deficiency Syndrome (AIDS).

- 6. The nature and purpose of the operation and anesthesia, possible alternative methods of treatment, the risk(s) involved, and the possibility of complications listed above have been fully explained to me by physician. I acknowledge that no guarantee or assurance has been made as to the results that may be obtained.
- 7. I hereby authorize the above named surgeon and whomever he/she may designate as his/her assistants, to perform upon me (the above named patient) the above specified operation or procedure and if any unforeseen condition arises in the course of the operation, which in the judgment of the attending physician or the surgeon in charge calls for procedure(s) or operation(s) in addition to or different from those now contemplated. I further request and authorize him or her to do whatever he/she deems advisable.
- 8. If any unforeseen medical condition should arise while I am at the Surgery Center, I hereby authorize treatment including, but not limited to evaluation, consultation and transfer to another level of care.
- 9. I consent to the administration of medications, blood or blood products and other substances and the use of x-ray and other procedures deemed appropriate by the physician(s) or surgeon(s) in charge of me in the exercise of his or her judgment.
- 10. I consent to the examination, use or disposal by my physician or surgeon or an appointed physician or surgeon of the Orlando Ophthalmology Surgery Center, of any organs, tissues, fluids, or parts removed from the body.
- 11. I consent to the taking and publication of any photographs or videotaping in the course of this operation for medical, scientific or educational purposes. Photographs may include appropriate portions of the body, provided no identity by the pictures or by descriptive text accompany them. Video tapes are property of the physician. Photographs will be incorporated in the medical record.
- 12. I consent to the admittance of observers in the operating room for the purpose of advancing medical education.
- 13. I authorize the release of any medical information necessary to process the claim.
- 14. I authorize payment of medical benefits to Orlando Ophthalmology Surgery Center for services described above.

#### I CERTIFY THAT I HAVE READ OR HAVE HAD READ TO ME AND FULLY UNDERSTAND THE ABOVE CONSENT FOR SURGICAL AND/OR DIAGNOSTIC PROCEDURES, THAT THE EXPLANATIONS THEREIN REFERRED TO WERE MADE, AND THAT ALL BLANKS OR STATEMENTS REQUIRING INSERTION OR COMPLETION WERE FILLED IN AND INAPPLICABLE PARAGRAPHS, IF ANY, WERE STRICKEN BEFORE I SIGNED.

Signature of Patient	Date	Time		
When Patient is a minor or incompetent to give consent:   Patient is a minor years of age or is unable to sign because				
Signature of person authorized to give consent for Patient:				
Relationship to Patient	Date	Time		
WITNESS:	Date	Time		
Translator/Interpreter (Print Name, Address and Phone Number)				

#### PHYSICIAN'S AFFIRMATION OF CONSENT

I certify that I have informed the patient or his/her representative of the nature of this procedure, alternative methods thereto, including non-treatment, and the risks associated therewith.

Physician's Signature	M.D.	Date
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