

INFORMED CONSENT FOR CATARACT SURGERY USING THE FEMTOSECOND LASER WITH THE IMPLANTATION OF AN INTRAOCULAR LENS

INTRODUCTION

THIS INFORMATION IS GIVEN TO YOU SO THAT YOU CAN MAKE AN INFORMED DECISION ABOUT HAVING EYE SURGERY. TAKE AS MUCH TIME AS YOU WISH TO MAKE YOUR DECISION ABOUT SIGNING THIS INFORMED CONSENT. YOU HAVE THE RIGHT TO ASK QUESTIONS ABOUT ANY PROCEDURE BEFORE AGREEING TO HAVE THE OPERATION.

EXCEPT FOR UNUSUAL PROBLEMS, A CATARACT OPERATION IS INDICATED ONLY WHEN YOU CANNOT FUNCTION ADEQUATELY DUE TO POOR SIGHT PRODUCED BY THE CATARACT. THE NATURAL LENS WITHIN YOUR OWN EYE EVEN WITH A SLIGHT CATARACT, ALTHOUGH NOT PERFECT, HAS SOME DISTINCT ADVANTAGES OVER ANY MAN MADE LENS.

AFTER DR. RUBMAN HAS TOLD YOU THAT YOU HAVE A CATARACT, YOU AND DR. RUBMAN ARE THE ONLY ONES WHO CAN DETERMINE IF OR WHEN YOU SHOULD HAVE A CATARACT OPERATION BASED ON YOUR OWN VISUAL NEEDS AND MEDICAL CONSIDERATIONS, UNLESS YOU HAVE AN UNUSUAL CATARACT THAT MAY NEED IMMEDIATE SURGERY.

DR. RUBMAN PERFORMS CATARACT SURGERY IN TWO PARTS: THE FIRST UTILIZES THE FEMTOSECOND LASER AND THE SECOND PART IS PERFORMED IN THE OPERATING ROOM.

LASER-ASSISTED CATARACT SURGERY IS PERFORMED AT THE NEW YORK EYE & EAR INFIRMARY OF MT. SINAI USING THE OPTIMEDICA CATALYS FEMTOSECOND LASER, A SOLID STATE FDA APPROVED MEDICAL DEVICE THAT UTILIZES A "FLYING SPOT" TO PERFORM A VARIETY OF COMPUTER CONTROLLED SURGICAL MANEUVERS. THE CATALYS IS CONSIDERED TO HAVE THE MOST ADVANCED TECHNOLOGY CURRENTLY AVAILABLE. LASER-ASSISTED CATARACT SURGERY IS DESIGNED TO PROVIDE A CUSTOMIZED, PRECISE AND GENTLE APPROACH TO THE FIRST PHASE OF CATARACT SURGERY: THE PREPARATION OF AN EXTREMELY ACCURATELY CENTERED CIRCULAR OPENING TO THE ANTERIOR CAPSULE, THE CAPSULORHEXIS. NEXT A DIVISION OF THE CATARACT INTO 4, 6 OR 8 SECTORS OCCURS (THE HARDER THE CATARACT, THE MORE SEGMENTS ARE CREATED), FOLLOWED BY A LASER SOFTENING OF THESE FRAGMENTS. BECAUSE THE CATARACT IS SECTIONED AND SOFTENED, THE ACTUAL REMOVAL OF THIS MATERIAL IN THE OPERATING ROOM IS SAFER, REQUIRING LESS PHACOEMULSIFICATION (ULTRASOUND ENERGY) TO REMOVE THESE PIECES. THIS RESULTS IN A REDUCTION OF INFLAMMATION TO THE EYE AND A MORE RAPID RECOVERY. ADDITIONALLY, IN THE LAST FEW SECONDS OF THE FEMTOSECOND PROCEDURE, ONE OR TWO ARCUATE INCISIONS ARE MADE WITHIN THE CORNEA (INTRASTROMALLY) IN THE STEEPEST CURVATURE OF THE CORNEA TO REDUCE OR ELIMINATE CORNEAL ASTIGMATISM.

LASER-ASSISTED CATARACT SURGERY IS BEGUN BY YOUR LYING ON THE CATALYS SURGICAL BED AND HAVING YOUR HEAD SECURELY IMMOBILIZED. TOPICAL ANESTHETIC DROPS ARE THEN PLACED IN THE EYE TO BE OPERATED. A LID SPECULUM IS USED, AND A VACUUM SUCTION CONE IS THEN PLACED IN THE EYE AND THE VACUUM ACTIVATED. SALINE IS PLACED IN THE VACUUM

CONE AND THE SURGICAL BED IS POSITIONED UNDER THE CATALYS LASER. THE CONE IS THEN ALIGNED WITH THE OPTICS OF THE LASER AND SECURED IN PLACE. THE EYE IS SCANNED BY THE OCT 3-D IMAGING SYSTEM AND THE LASER IS THEN ACTIVATED. THE ACTUAL LASERING WILL TAKE NO MORE THAN 2 MINUTES, AFTER WHICH YOU ARE DECOUPLED FROM THE LASER AND THE SUCTION CONE IS REMOVED.

THE CRITICAL REQUIREMENTS TO UNDERGO THIS TREATMENT ARE THE ABILITY TO LIE FLAT AND TO REMAIN STILL. IT IS POSSIBLE BUT RARE THAT THE CONTEMPLATED PROCEDURE WILL NOT BE ABLE TO BE UNDERTAKEN. SINCE THE SUCTION CONE IS ATTACHED WITH MINIMAL VACUUM, IT IS POSSIBLE TO BREAK THE SUCTION AND DEACTIVATE THE LASER, WITH THE RESULT THAT THE LASER PORTION OF THE SURGERY CANNOT BE COMPLETED. AN ADEQUATE PUPIL DILATION IS ALSO REQUIRED. IF FOR SOME REASON THE PUPIL FAILS TO DILATE PROPERLY OR THE PUPIL CONSTRICTS PRIOR TO THE PROCEDURE, THE LASER SURGERY WILL NOT BE ABLE TO PROCEED.

FOLLOWING THE LASER PORTION OF THE SURGERY, YOU WILL BE MOVED TO THE OPERATING ROOM. YOUR EYE WILL BE PREPPED AND DRAPED AND ANESTHESIA WILL BE ADMINISTERED. SEVERAL INCISIONS WILL BE MADE IN THE SCLERA (THE FRONT OUTER LAYER OF THE EYE). USING THE AMO SIGNATURE PHACOEMULSIFICATION DEVICE, THE FRAGMENTS OF THE CATARACT WILL BE REMOVED WITH ULTRASOUND ENERGY.

MODERN CATARACT SURGERY REQUIRES THE IMPLANTATION OF AN **INTRAOCULAR LENS (IOL)** AT THE TIME THE CATARACT IS REMOVED. THE **INTRAOCULAR LENS** IS A SMALL PLASTIC ARTIFICIAL LENS (USUALLY MADE OF ACRYLIC POLYMER) SURGICALLY PLACED PERMANENTLY INSIDE THE EYE. WITH THE INTRAOCULAR LENS THERE IS NO APPARENT CHANGE IN THE SIZE OF OBJECTS SEEN. HOWEVER, IOL IMPLANTATION IS NOT REFRACTIVE SURGERY AND CONVENTIONAL EYEGASSES MAY BE REQUIRED TO ACHIEVE THE BEST VISION POSSIBLE.

COMPLICATIONS

ALTHOUGH CATARACT SURGERY USING THE FEMTOSECOND LASER IS A VERY SAFE PROCEDURE, POSSIBLE COMPLICATIONS, ALTHOUGH VERY RARE, CAN INCLUDE, BUT ARE NOT LIMITED TO: INCOMPLETE OR INTERRUPTED CAPSULOTOMY OR FRAGMENTATION, ANTERIOR CAPSULAR TEAR, POSTERIOR CAPSULAR TEAR WITH LENS FRAGMENT DISLOCATION INTO THE VITREOUS, CORNEAL ABRASION OR DEFECT, PAIN, INFECTION, BLEEDING, CHRONIC INFLAMMATION, DAMAGE TO INTRAOCULAR STRUCTURES, ANTERIOR CHAMBER FLUID LEAKAGE, ANTERIOR CHAMBER COLLAPSE, LOSS OF CORNEAL CLARITY, UVEITIS (AN INFLAMMATION INSIDE THE EYE), IRIS ATROPHY, GLAUCOMA, INABILITY TO DILATE THE PUPIL, DISLOCATION OF THE LENS, TEMPORARY OR PERMANENT BLURRING OF VISION BECAUSE OF RETINAL SWELLING, RETINAL DETACHMENT, PTOSIS OF THE LID (LID LAXITY) AND DOUBLE VISION. IN SOME CASES, COMPLICATIONS MAY DEVELOP DAYS, WEEKS OR EVEN YEARS LATER. AT SOME FUTURE TIME, ALTHOUGH AN EXTREMELY RARE OCCURANCE, THE LENS IMPLANTED IN MY EYE MAY HAVE TO BE REPOSITIONED OR REMOVED SURGICALLY.

COMPLICATIONS OF SURGERY IN GENERAL

AS WITH ALL TYPES OF SURGERY THERE IS THE POSSIBILITY OF OTHER COMPLICATIONS DUE TO ANESTHESIA OR DRUG REACTIONS. LOCAL COMPLICATIONS OF ANESTHESIA INJECTIONS AROUND THE EYE CAN INCLUDE PERFORATION OF THE EYEBALL, DESTRUCTION OF THE OPTIC NERVE, INTERFERENCE WITH THE CIRCULATION OF THE RETINA, DROOPING OF THE EYELID, RESPIRATORY DEPRESSION AND HYPOTENSION. SINCE IT IS IMPOSSIBLE TO STATE EVERY COMPLICATION THAT MAY OCCUR AS A RESULT OF SURGERY, THE LIST OF COMPLICATIONS IN THIS FORM IS INCOMPLETE.

THE BASIC PROCEDURES OF FEMTOSECOND LASER-ASSISTED CATARACT SURGERY AND THE ADVANTAGES AND DISADVANTAGES, RISKS, POSSIBLE COMPLICATIONS AND ALTERNATIVE TREATMENTS HAVE BEEN EXPLAINED TO ME. ALTHOUGH IT IS IMPOSSIBLE TO BE INFORMED OF EVERY POSSIBLE COMPLICATION THAT MAY OCCUR, ALL MY QUESTIONS HAVE BEEN ANSWERED TO MY SATISFACTION. IN SIGNING THIS INFORMED CONSENT FOR CATARACT OPERATION AND/OR IMPLANTATION OF AN INTRAOCULAR LENS, I AM STATING I HAVE READ THIS INFORMED CONSENT (OR IT HAS BEEN READ TO ME) AND I FULLY UNDERSTAND IT AND THE POSSIBLE RISKS, COMPLICATIONS AND BENEFITS THAT CAN RESULT FROM THE SURGERY.

CONSENT FOR OPERATION

IN GIVING MY PERMISSION FOR A CATARACT EXTRACTION AND/OR FOR THE POSSIBLE IMPLANTATION OF AN INTRAOCULAR LENS IN MY EYE, I DECLARE I UNDERSTAND THE FOLLOWING INFORMATION:

- ◆ CATARACT SURGERY, BY ITSELF, MEANS THE REMOVAL OF THE NATURAL LENS OF THE EYE BY A SURGICAL TECHNIQUE. IN ORDER FOR AN INTRAOCULAR LENS TO BE IMPLANTED IN MY EYE, I UNDERSTAND I MUST HAVE CATARACT SURGERY PERFORMED EITHER AT THE TIME OF THE LENS IMPLANTATION OR BEFORE LENS IMPLANTATION.
- ◆ INTRAOCULAR LENS IMPLANTATION IS A SURGICAL PROCEDURE. IT IS INTENDED THAT THE SMALL PLASTIC LENS (PERHAPS WITH POLYPROPYLENE, A SPECIAL FORM OF PLASTIC, OR SILICON) WILL BE LEFT IN MY EYE PERMANENTLY.
- ◆ THE RESULT OF SURGERY IN MY CASE, AS IN ANY CASE, CANNOT BE GUARANTEED.
- ◆ AT THE TIME OF SURGERY, DR. RUBMAN MAY DECIDE TO INSERT A DIFFERENT TYPE OF IOL THAN ORIGINALLY PLANNED OR MAY DECIDE NOT TO IMPLANT AN IOL IN MY EYE EVEN THOUGH I HAVE GIVEN PRIOR PERMISSION TO DO SO.
- ◆ IF I HAVE ANY ADDITIONAL QUESTIONS, NOW OR IN THE FUTURE, I UNDERSTAND THAT I WILL BE ABLE TO CONTACT DR. RUBMAN AND/OR HIS STAFF.
- ◆ IF I DECIDE TO HAVE AN OPERATION, I AGREE TO HAVE THE TYPE OF OPERATION LISTED BELOW WHICH I HAVE INDICATED BY MY SIGNATURE.

I WISH TO HAVE A CATARACT OPERATION USING:

CATALYS LASER-ASSISTED SURGERY *

(SELECT ONE IMPLANT AND THE EYE THAT IS GOING TO HAVE SURGERY)

MULTIFOCAL INTRAOCULAR LENS IMPLANT *

TORIC MONOFOCAL INTRAOCULAR LENS IMPLANT *

(TO CORRECT OR REDUCE CORNEAL ASTIGMATISM)

MONOFOCAL INTRAOCULAR LENS IMPLANT

RIGHT EYE

LEFT EYE

PATIENT SIGNATURE _____

PATIENT'S NAME (PRINTED) _____

AGE _____ DATE _____

WITNESS' SIGNATURE _____

DOCTOR'S SIGNATURE _____

***NOTE: THESE ARE CONSIDERED 'PREMIUM' TECHNOLOGY/INTRAOCULAR LENS IMPLANTS AND THEIR COST IS NOT COVERED BY INSURANCE.**

MOST INSURANCE COMPANIES REQUIRE SUBJECTIVE DOCUMENTATION TO JUSTIFY CATARACT SURGERY IN ADDITION TO DR. RUBMAN'S EXAMINATION. PLEASE GIVE A SPECIFIC REASON YOU FEEL YOUR LIFESTYLE IS BEING IMPAIRED BECAUSE OF YOUR FAILING EYESIGHT. IN OTHER WORDS, PLEASE CHOOSE WHICH PARTICULAR ACTIVITY YOU FEEL IS MOST AFFECTED BY YOUR DECREASED VISION OR GLARE DISABILITY.

CATARACT SURGERY SUBJECTIVE DOCUMENTATION

MY LIFESTYLE IS BEING IMPAIRED BECAUSE OF MY FAILING EYESIGHT. MY CHIEF COMPLAINT AND REASON FOR WANTING CATARACT SURGERY IS:

- MY EYEGLASSES DO NOT HELP ME SEE WELL ENOUGH.
- I NEED TO DRIVE, BUT THERE IS TOO MUCH GLARE FROM THE SUN OR HEADLIGHTS.
- I WAS UNABLE TO PASS MY DRIVERS' LICENSE TEST.
- I CAN NO LONGER WATCH TELEVISION OR MOVIES.
- I CAN NO LONGER EMBROIDER, KNIT, OR SEW.
- I DO NOT SEE WELL ENOUGH TO DO MY BEST AT WORK.
- I AM NO LONGER ABLE TO PARTAKE IN MY USUAL HOBBY, OR HOBBIES, SUCH AS:

- I AM AFRAID I WILL BUMP INTO SOMETHING OR FALL.
- MY ACTIVITIES OF DAILY LIVING SUCH AS _____
ARE AFFECTED.
- OTHER _____

PATIENT SIGNATURE _____

PATIENT'S NAME (PRINTED) _____

DATE _____