

Preparation for ERCP

Patient Name- _____

Procedure Date and Time- _____

Please do not take any Aspirin products for four days prior to this procedure, unless instructed by your doctor.

There is nothing to eat, drink, smoke or chew after midnight the night before the procedure.

At _____ proceed directly to the:

- Mirage Endoscopy Center (Blue map given)
- Dolores Hope, First Floor Registration
- Main Hospital Lobby

We do ask that your family member or friend who will be accompanying you for your procedure remain at the _____ until you are ready to leave.

The doctor will see you following the procedure.

You may take any necessary medications the morning of the procedure (Heart medication, Blood pressure medication) with a tiny sip of water unless otherwise instructed by the office.

***** If your procedure is late in the day, you may have clear liquids until _____ . *****

INFORMED CONSENT FOR ERCP

EXPLANATION OF PROCEDURE:

ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY OR ERCP IS A SPECIALIZED TECHNIQUE USED TO STUDY THE DUCTS OF THE GALLBLADDER, LIVER AND PANCREAS. DUCTS ARE DRAINAGE ROUTES; THE DRAINAGE CHANNELS FROM THE LIVER ARE CALLED BILE OR BILIARY DUCTS. DURING ERCP, YOUR DOCTOR WILL PASS AN ENDOSCOPE THROUGH YOUR MOUTH, ESOPHAGUS AND STOMACH INTO THE DUODENUM (FIRST PART OF SMALL INTESTINE). AN ENDOSCOPE IS A THIN, FLEXIBLE TUBE THAT LETS YOUR DOCTOR SEE INSIDE YOUR BOWELS. AFTER YOUR DOCTOR SEES THE COMMON OPENING TO DUCTS FROM LIVER AND PANCREAS, YOUR DOCTOR WILL PASS A NARROW PLASTIC TUBE CALLED A CATHETER THROUGH THE ENDOSCOPE AND INTO THE DUCTS. YOUR DOCTOR WILL INJECT A CONTRAST MATERIAL (DYE) INTO THE PANCREATIC OR BILIARY DUCTS AND WILL TAKE X-RAYS. HOWEVER, MOST ERCPs ARE ACTUALLY DONE FOR TREATMENT AND NOT JUST PICTURE TAKING. WHEN AN ERCP IS DONE TO ALLOW TREATMENT, IT IS CALLED THERAPEUTIC ERCP.

BRIEF DESCRIPTION OF ERCP AND THERAPEUTIC ERCP

1. **ERCP (ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY) - SPECIALIZED TECHNIQUE USED TO STUDY THE DUCTS OF THE GALLBLADDER, LIVER AND PANCREAS.**
2. **SPHINCTEROTOMY-** CUTS THE MUSCLE THAT SURROUNDS THE OPENING OF THE DUCTS, OR THE PAPILLA. THE CUT IS MADE TO ENLARGE THE OPENING. A SMALL WIRE ON A SPECIALIZED CATHETER USES ELECTRIC CURRENT TO CUT THE TISSUE. A SPHINCTEROTOMY DOES NOT CAUSE DISCOMFORT; YOU DO NOT HAVE NERVE ENDINGS THERE. THE ACTUAL CUT IS QUITE SMALL, USUALLY LESS THAN ½ INCH. THIS SMALL CUT ALLOWS VARIOUS TREATMENTS IN THE DUCTS. MOST COMMONLY THE CUT IS DIRECTED TOWARD THE BILE DUCT AND IS CALLED A BILIARY SPHINCTEROTOMY. OCCASIONALLY, THE CUT IS DIRECTED TOWARDS THE PANCREATIC DUCT, DEPENDING ON WHAT TYPE OF TREATMENT YOU NEED.
3. **STONE REMOVAL-** THE MOST COMMON TREATMENT THROUGH ERCP IS REMOVAL OF BILE DUCT STONES. THESE STONES MAY HAVE FORMED IN THE GALLBLADDER AND TRAVELLED INTO THE BILE DUCT OR MAY FORM IN THE DUCT ITSELF YEARS AFTER YOUR GALLBLADDER MAY HAVE BEEN REMOVED. AFTER A SPHINCTEROTOMY IS PERFORMED TO ENLARGE THE OPENING OF THE BILE DUCT. STONES CAN BE PULLED FROM THE DUCT INTO THE BOWEL. A VARIETY OF BALLOONS AND BASKETS ATTACHED TO SPECIALIZED CATHETERS CAN BE PASSED THROUGH THE ERCP SCOPE INTO THE DUCTS ALLOWING STONE REMOVAL. VARY LARGE STONE MAY REQUIRE CRUSHING WITH A SPECIALIZED BASKET SO THE FRAGMENTS CAN BE PULLED THROUGH THE SPHINCTEROTOMY.
4. **STENT PLACEMENT-** STENTS ARE PLACED INTO THE BILE OR PANCREATIC DUCTS TO BYPASS STRICTURE, OR NARROWED PARTS OF THE BILE DUCT. THESE NARROWED AREAS OF THE BILE OR PANCREATIC DUCT ARE DUE TO SCAR TISSUE OR TUMORS THAT CAUSE BLOCKAGE OF NORMAL DUCT DRAINAGE. THERE ARE TWO TYPES OF STENTS THAT ARE COMMONLY USED. THE FIRST IS MADE OF PLASTIC AND LOOKS LIKE A SMALL STRAW. A PLASTIC STENT CAN BE PUSHED THROUGH THE ERCP SCOPE INTO THE BLOCKED DUCT TO ALLOW NORMAL DRAINAGE. THE SECOND TYPE OF STENT IS MADE OF METAL WIRES THAT LOOKS LIKE THE CROSS-WIRES OF A FENCE. THE METAL STENT IS FLEXIBLE AND SPRINGS OPEN TO A LARGER DIAMETER THAN PLASTIC STENTS. BOTH PLASTIC AND METAL STENTS TEND TO CLOG UP AFTER SEVERAL MONTHS AND YOU MAY REQUIRE ANOTHER ERCP TO PLACE A NEW STENT. METAL STENTS ARE PERMANENT WHILE PLASTIC STENTS ARE EASILY REMOVED AT A REPEAT PROCEDURE. YOUR DOCTOR WILL CHOOSE THE BEST TYPE OF STENT FOR YOUR PROBLEM.
5. **BALLOON DILATION-** THERE ARE ERCP CATHETERS FITTED WITH DILATING BALLOONS THAT CAN BE PLACED ACROSS A NARROWED AREA OR STRICTURE. THE BALLOON IS THEN INFLATED TO STRETCH OUT THE NARROWING. DILATION WITH BALLOONS IS OFTEN PERFORMED WHEN THE CAUSE OF THE NARROWING IS BENIGN (NOT A CANCER). AFTER BALLOON DILATION, A TEMPORARY STENT MAY BE PLACED FOR A FEW MONTHS TO HELP MAINTAIN THE DILATION.

6. **TISSUE SAMPLING-** A PROCEDURE THAT IS COMMONLY PERFORMED THROUGH THE ERCP SCOPE IS TO TAKE SAMPLES OF TISSUE FROM THE PAPANICOLAOU OR FROM THE BILE OR THE PANCREATIC DUCTS. THERE ARE SEVERAL DIFFERENT SAMPLING TECHNIQUES ALTHOUGH THE MOST COMMON IS TO BRUSH THE AREA WITH SUBSEQUENT EXAMINATION OF THE CELLS OBTAINED. TISSUE SAMPLES CAN HELP DECIDE IF A STRICTURE, OR NARROWING, IS DUE TO CANCER. IF A SAMPLE IS POSITIVE FOR CANCER, IT IS VERY ACCURATE. UNFORTUNATELY, A TISSUE SAMPLING THAT DOES NOT SHOW CANCER MAY NOT BE ACCURATE.

****** POSSIBLE COMPLICATIONS INVOLVED WITH ERCP******

ERCP IS GENERALLY A LOW RISK PROCEDURE. THE OVERALL ERCP COMPLICATION RATE REQUIRING HOSPITALIZATION IS 6-10 %. DEPENDING ON YOUR AGE, YOUR OTHER MEDICAL PROBLEMS, WHAT THERAPY IS PERFORMED, AND THE INDICATION FOR YOUR PROCEDURE, YOUR COMPLICATION RATE MAY BE HIGHER OR LOWER THAN THE AVERAGE. HOWEVER, ALL OF THE BELOW ARE POSSIBLE. YOUR PHYSICIAN WILL DISCUSS THEIR FREQUENCY WITH YOU, IF YOU DESIRE, WITH PARTICULAR REFERENCE TO YOUR OWN INDICATIONS FOR THE ERCP. *YOU MUST ASK YOUR PHYSICIAN IF YOU HAVE ANY UNANSWERED QUESTIONS ABOUT YOUR TEST. PLEASE NOTE THAT RISKS MAY VARY BECAUSE OF:*

- A) WHY THE TEST IS DONE
 - B) WHAT IS FOUND DURING THE PROCEDURE
 - C) WHAT TREATMENT IS DONE
 - D) WHETHER YOU HAVE MAJOR HEALTH PROBLEMS
1. **PANCREATITIS-** INFLAMMATION OF THE PANCREAS IN 1 IN 20 PEOPLE. THIS MAY NEED A STAY IN THE HOSPITAL FOR PAIN RELIEF. MOST CASES WILL SETTLE OVER THE NEXT 24-48 HOURS AND WILL NOT CAUSE LONG TERM DAMAGE TO THE PANCREAS. VERY RARELY THIS CAN BE VERY SEVERE AND WILL NEED FURTHER TREATMENT, WHICH MAY ALSO INCLUDE SURGERY. DEATH HAS BEEN REPORTED FROM PANCREATITIS AFTER ERCP.
 2. **PERFORATION-** PASSAGE OF THE INSTRUMENT MAY RESULT IN AN INJURY TO THE GASTROINTESTINAL TRACT WALL WITH POSSIBLE LEAKAGE OF GASTROINTESTINAL CONTENTS INTO THE BODY CAVITY. IF THIS OCCURS, SURGERY TO CLOSE THE LEAK AND/OR DRAIN THE AREA IS USUALLY REQUIRED. A SURGERY WILL REQUIRE A HOSPITAL STAY OF AT LEAST A WEEK WITH AN AVERAGE RECOVERY TIME AT HOME OF ONE MONTH. PAIN AND LOSS OF CONSORTIUM CAN BE EXPECTED.
 3. **BLEEDING-** BLEEDING, (1 IN 100 PEOPLE) CAN BE A COMPLICATION OF A CUT MADE IN THE BILE DUCT (SPHINCTEROTOMY) WHERE THE DUCTS JOIN THE BOWEL. MANAGEMENT OF THIS COMPLICATION MAY CONSIST OF CAREFUL OBSERVATION, TRANSFUSIONS, REPEAT ENDOSCOPY OR A SURGICAL OPERATION.
 4. **MEDICATION PHLEBITIS-** MEDICATIONS USED FOR SEDATION MAY IRRITATE THE VEIN IN WHICH THEY ARE INJECTED. THIS CAUSES A RED, PAINFUL SWELLING OF THE VEIN AND SURROUNDING TISSUE. THE AREA COULD BECOME INFECTED. DISCOMFORT IN THE AREA MAY PERSIST FOR SEVERAL WEEKS TO SEVERAL MONTHS.
 5. **INFECTON-** INFECTION CAN BE CAUSED BY YOUR OWN GERMS THAT HAVE INFECTED THE BLOCKED DUCT. THESE GERMS CAN SPREAD INTO THE BLOODSTREAM (SEPTICEMIA). THIS IS TREATED WITH ANTIBIOTICS. LUNG INFECTION IS UNCOMMON AND IS DUE TO VOMIT GOING INTO THE LUNGS. INFECTION MAY OCCUR AT THE INTRAVENOUS SITE. MANAGEMENT IS SPECIFIC TO EACH SITUATION.
 6. **OTHER RISKS-** INCLUDES DRUG REACTIONS AND COMPLICATIONS FROM OTHER DISEASES THAT YOU MAY ALREADY HAVE. DEATH IS EXTREMELY RARE, BUT REMAINS A REMOTE POSSIBILITY. YOU MUST INFORM YOUR PHYSICIAN OF ALL YOUR ALLERGIES AND MEDICAL PROBLEMS. SORE THROAT, HOARSENESS AND POTENTIAL VOCAL CORD DAMAGE ARE POSSIBLE.
 7. **DIAGNOSTIC ERROR-** IT IS POSSIBLE TO MISS A GROWTH OR CANCER IN AN ERCP. THE SCOPE USED FOR ERCP CANNOT EXAMINE THE ESOPHAGUS OR STOMACH WELL. ANOTHER LIMITATION OF AN ERCP IS THAT A SPECIFIC DIAGNOSIS OR SOURCE FOR A PARTICULAR SIGN OR SYMPTOM MAY NOT BE FOUND. THE EXAM MAY BE NORMAL IN CERTAIN CASES. IF YOUR SYMPTOMS SHOULD CONTINUE, FURTHER EVALUATION MAY BE NEEDED. IT IS YOUR RESPONSIBILITY TO NOTIFY YOUR DOCTOR.

8. **CONSCIOUS SEDATION**- EVERY EFFORT IS MADE TO MAKE YOUR EXAM AS COMFORTABLE AS POSSIBLE. CONTRARY TO POPULAR BELIEF, SOME PEOPLE REMEMBER THE EXAM. THIS IS NOT DUE TO IMPROPER SEDATION PRACTICES, IT IS RELATED TO THE DOCTORS NEED TO KNOW WHEN YOU ARE EXPERIENCING PAIN. IN ORDER TO MINIMIZE RISK IN SOME PATIENTS, MORE SEDATION CANNOT BE GIVEN DUE TO A LOW BLOOD PRESSURE, LOW OXYGEN LEVEL OR OTHER ABNORMAL VITAL SIGNS. IN ADDITION, PATIENTS AT HIGHER RISK DUE TO OTHER MEDICAL PROBLEMS SUCH AS LUNG DISEASE SOMETIMES CANNOT BE SEDATED TO THE LEVEL OF NOT REMEMBERING.

9. **DENTAL INJURY**- WE WILL NOT ACCEPT LIABILITY FOR ANY MOUTH OR TOOTH INJURY. IN ALL UPPER ENDOSCOPIES AND ERCPS, PROTECTIVE MOUTH PIECES ARE USED. DESPITE THIS, SOME PATIENTS DEVELOP INJURIES TO EXISTING TEETH OR DENTAL IMPLANTS, BRIDGES, ETC. IF YOU HAVE LOOSE TEETH OR PARTIAL DENTURES YOUR RISK OF INJURY IS GREATER. ANY COST DUE TO MISHAP IS THE RESPONSIBILITY OF THE PATIENT.

10. **BLOOD THINNER CONSENT**- I UNDERSTAND THAT BEING OFF OF BLOOD THINNING MEDICATION INCREASES A RISK OF A STROKE, HEART ATTACK OR BLOOD CLOT. EVEN IF IT HAS BEEN STOPPED IN THE PAST WITHOUT PROBLEMS, THE RISK STILL EXISTS. AFTER AN ERCP, RESTARTING MY BLOOD THINNING MEDICATION DOES INCREASE THE RISK FOR BLEEDING. I UNDERSTAND AND ACCEPT THIS RISK. _____ (INITIAL HERE)

*** PLEASE DISCONTINUE THE FOLLOWING MEDICATIONS _____ DAYS PRIOR TO YOUR PROCEDURE.

_____ BABY ASPIRIN	_____ ASPIRIN	_____ AGGRENOX
_____ COUMADIN	_____ PLAVIX	_____ PERSANTINE
_____ OTHER- _____		

ALTERNATIVES TO ERCP

I ACKNOWLEDGE THAT THE DOCTOR HAS EXPLAINED MY MEDICAL CONDITION AND PROPOSED PROCEDURE. I UNDERSTAND THE RISKS OF THE PROCEDURE, INCLUDING THE RISKS THAT ARE SPECIFIC TO ME, AND THE LIKELY OUTCOMES. THE DOCTOR HAS EXPLAINED OTHER RELEVANT TREATMENT OPTIONS AND THEIR ASSOCIATED RISKS. THE DOCTOR HAS EXPLAINED MY PROGNOSIS AND THE RISKS OF NOT HAVING THE PROCEDURE.

I WAS ABLE TO ASK QUESTIONS AND RAISE CONCERNS WITH THE DOCTOR ABOUT MY CONDITION, THE PROCEDURE AND ITS RISKS, AND MY TREATMENT OPTIONS. MY QUESTIONS AND CONCERNS HAVE BEEN DISCUSSED AND ANSWERED TO MY SATISFACTION.

I UNDERSTAND THAT THE PROCEDURE MAY INCLUDE A BLOOD TRANSFUSION.

THE DOCTOR HAS EXPLAINED TO ME THAT IF IMMEDIATE LIFE-THREATENING EVENTS HAPPEN DURING THE PROCEDURE, THEY WILL BE TREATED ACCORDINGLY. I UNDERSTAND THAT NO GUARANTIES HAVE BEEN MADE THAT THE PROCEDURE WILL IMPROVE MY CONDITION, AND THAT THE PROCEDURE MAY MAKE MY CONDITION WORSE. ON THE BASIS OF THE PREVIOUS STATEMENTS, I HEREBY AUTHORIZE DR. GARY ANNUNZIATA / DR. ANH DUONG/ DR. JONATHAN LIN AND WHOMEVER HE MAY DESIGNATE AS HIS ASSISTANT (S) TO PERFORM UPON ME A :

ERCP WITH POSSIBLE SPHINCTEROTOMY, STONE REMOVAL AND/OR STENT PLACEMENT

IF FOR ANY UNFORESEEN CONDITION SHOULD ARISE DURING THIS PROCEDURE CALLING FOR, IN THE PHYSICIAN'S JUDGEMENT, ADDITIONAL PROCEDURES, TREATMENTS OR OPERATIONS, I AUTHORIZE HE TO DO WHATEVER HE DEEMS ADVISABLE. I AM AWARE THAT THE PRACTICE IF MEDICINE AND SURGERY IS NOT AN EXACT SCIENCE. I ACKNOWLEDGE THAT NO GUARANTIES HAS BEEN MADE TO ME CONCERNING THE RESULT OF THIS PROCEDURE.

PATIENT NAME- PLEASE PRINT

PATIENT SIGNATURE

TODAYS DATE

WITNESS

AFTER THE PROCEDURE

- **AFTER THE ERCP IS COMPLETE YOU WILL GO TO A RECOVERY AREA UNTIL THE SEDATION EFFECTS SUBSIDE. SOME PATIENTS ARE ADMITTED TO THE HOSPITAL FOR A DAY BUT MANY GO HOME FROM THE RECOVERY UNIT. YOU SHOULD NOT DRIVE A CAR FOR THE REST OF THE DAY ALTHOUGH MOST PATIENTS CAN RETURN TO FULL ACTIVITY THE NEXT DAY.**

- **FOLLOWING YOUR PROCEDURE, THE DOCTOR WILL SPEAK TO YOU ABOUT THE FINDINGS. DUE TO THE SEDATION YOU MAY NOT REMEMBER THIS DISCUSSION. IF THERE ARE NO BIOPSIES OR BRUSHINGS TAKEN, YOU WILL BE NOTIFIED BY MAIL OR YOU WILL RECEIVE A PHONE CALL FROM THE OFFICE REGARDING EXAM FINDINGS AND TIME OF YOUR NEXT APPOINTMENT. IF YOU DO NOT RECEIVE NOTIFICATION FROM THE OFFICE, IT IS YOUR RESPONSIBILITY TO CONTACT THE OFFICE.**

- **IF THERE WERE BIOPSIES OR BRUSHINGS TAKEN DURING YOUR PROCEDURE, THE OFFICE STAFF WILL CONTACT YOU AT LEAST 72 HOURS AFTER THE PROCEDURE WITH THE RESULTS. IF YOU DO NOT HEAR FROM US, DO NOT ASSUME “NO NEWS IS GOOD NEWS” AND PLEASE CONTACT THE OFFICE.**

PATIENT SIGNATURE

BILLING REGARDING THIS PROCEDURE

THIS IS TO INFORM YOU THAT YOU HAVE THE POSSIBILITY OF RECEIVING THREE BILLS WHEN UNDERGOING THIS PROCEDURE. THE BILLS WILL CONSIST OF THE PHYSICIAN BILL FOR PERFORMING THE PROCEDURE (FROM OUR OFFICE), A BILL FROM THE FACILITY THAT THE PROCEDURE IS BEING PERFORMED AT (EISENHOER MEDICAL CENTER), AND IF THERE ARE BIOPSIES RETRIEVED THEN YOU WILL BE SUBJECT TO A BILL FROM PATHOLOGY.

PATIENT SIGNATURE

I CERTIFY THAT I HAVE RECEIVED A COPY OF THIS ENTIRE CONSENT FORM TODAY.

PATIENT SIGNATURE

DATE

Desert Gastroenterology Consultants

The office of:

Gary M. Annunziata, D.O., F.A.C.P. / Anh T. Duong, M.D. / Jonathan C. Lin, M.D., MPH

Patient Name- _____
Anesthesia Waiver

Most patients who undergo endoscopic procedures are generally comfortable and do not recall the procedure with a standard sedation technique called **conscious sedation (CS)**. This involves the use of a short acting narcotic and a Valium-like medicine that creates sedation that is generally tolerable and safe. **Conscious sedation** is the standard care for endoscopic procedure.

Although we make every attempt to ensure that you are comfortable during the procedure we cannot always predict in advance of an endoscopic procedure who is going to experience pain, discomfort, or other reactions to the CS.

There is another type of sedation available called **deep sedation (DS)**. Insurance companies traditionally do not pay for this; however, it assures that there is generally no recollection of the procedure. **Deep sedation** is done under the care of an anesthesiologist.

You have the option to request **DS** in advance of your procedure; however, this cannot be done during the procedure in the event that you experience pain that is not responding to the traditional sedation method.

Therefore we are asking you to choose deep sedation or conscious sedation.

If you want **DS**, we will arrange to have your procedure done under anesthesia; cost estimates will be provided in this circumstance. Please notify the scheduling office staff.

If you do choose to use a deep sedation technique during your procedure there may be an increased risk of complications related to deep sedation and an increased risk of perforation of the gastrointestinal tract. By signing below you are agreeing to this increased risk and that you have a copy of this document.

I am waiving my option to the deep sedation; I am requesting conscious sedation, signed:

_____/_____/_____/_____ Print/Signature/Date/Time

I am requesting deep sedation as done by an anesthesiologist and accept the associated risk:

_____/_____/_____/_____ Print/Signature/Date/Time

**DESERT GASTROENTEROLOGY CONSULTANTS
A MEDICAL CORPORATION**

PATIENT MEMORANDUM

TO: OUR PATIENTS

FROM: GARY ANNUNZIATA, D.O., ANH DUONG, M.D.,
JONATHAN C. LIN, M.D., MPH

SUBJECT: DISCLOSURES

FINANCIAL DISCLOSURE

Gary Annunziata, D.O., Anh Duong, M.D. and Jonathan C. Lin, M.D., (collectively the "Physicians") have ownership interest in DESERT GASTROENTEROLOGY CONSULTANTS, a Medical Corporation which owns and operates the clinical pathology laboratory located in the Physician's office. The Physicians generally refer their clinical pathology laboratory work to the on-site clinical pathology laboratory operated by DESERT GASTROENTEROLOGY CONSULTANTS, a Medical Corporation. You have the right to choose another clinical pathology laboratory for the purpose of having any of your pathology work or assignment performed. If you desire to choose another clinical pathology laboratory to have pathology work or assignment performed please let the office manager or your Physician know.

Acknowledgment of Receipt:

Patient Name- Please Print

Dated: _____

Patient Signature