

INFORMED CONSENT FOR
MYELLEVATE NECK REJUVENATION
(SUTURE SUSPENSION INCLUDING TRAMPOLINE PLATYSMAPLASTY)
___ **WITH NECK & SUBMENTAL LIPOSUCTION**

PLEASE REVIEW AND BRING WITH YOU ON THE DAY OF YOUR PROCEDURE

PATIENT NAME _____

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(THE PHYSICIANS)

INSTRUCTIONS

This is an informed-consent document that has been prepared to help your plastic surgeon inform you concerning suture suspension platysmaplasty surgery, with or without liposuction, its risks, and alternative treatments.

It is important that you read this information carefully and completely. Please initial each page, indicating that you have read the page and sign the consent for surgery as proposed by your plastic surgeon(s) and agreed upon by you.

GENERAL INFORMATION

Platysmaplasty surgery is a surgical procedure to improve visible signs of aging of the neck. As aging proceeds, cervical support for the platysma muscle becomes attenuated. This is often associated with laxity of sub mental skin, as well as subcutaneous accumulation of fat within the neck. This loss of cervical support tends to highlight the platysma bands and the glandular structures underneath the jawline. There is a great deal of variation among patients in the appearance and quality of the platysma muscle; therefore, platysmaplasty surgery is individualized for each patient. The MyEllevate procedure is used to lift and shape the back part of the chin and neck thus supporting and elevating the glands and muscles and deeper structures etc. underneath the jawline.

Platysmaplasty surgery can be performed alone, or in conjunction with other procedures, such as: suction-assisted lipectomy of the neck, energy-based treatments, facelift surgery, eyelid surgery, chin augmentation surgery, or nasal surgery, etc.

The best candidates for suture suspension platysmaplasty surgery have a neck, and neckline with prominent “bands”, accumulation of subplatysmal fat, and a weakening and sagging of the platysma muscle. Traditional neck muscle tightening surgery requires the separation of the neck skin from the underlying muscle to allow the sewing of the muscle under direct vision. In certain cases, the platysma muscle is cut or repositioned to allow the neck lift to be performed. This approach usually requires an incision under the chin to allow access to the region under the jaw line.

Suture suspension using the percutaneous Trampoline Platysmaplasty and/or MyEllevate procedure is a less-invasive approach to approximate and elevate the underlying muscles and glands of the neck that does not require an incision under the chin. This technique allows the placement of a suture “lattice” similar to a shoelace that spans the entire region underneath the jaw line. This support system is created by weaving suture material under the skin through a series of small punctures. The placement of the suture strands is guided by LED light illumination of the suture needle. Once the lacing is completed, the suture is tightened and secured thus resulting in the lifting and smoothing of the neck skin, underlying muscles and glands simultaneously.

In rare instances, it may not be possible to weave the suture material underneath the skin due to scar tissue, or certain anatomic variations. In these cases, the surgeon may elect to open the neck through the traditional incision underneath the chin, thus allowing the direct visualization and sewing of the neck muscles.

The Platysmaplasty Surgery does not stop the process of aging. As in all cosmetic procedures, this procedure resets the aging clock that will start moving forward after the procedure.

ALTERNATIVE TREATMENTS

Alternative forms of management consist of not treating the laxity in the neck area, liposuction, open Platysmaplasty, facelifts and neck lifts etc. Improvement of skin laxity, skin wrinkles and fatty deposits

may be attempted by other non-surgical treatments such as Ulthera, radiofrequency, chemical peels, LASER treatments, facial fillers, neuromodulators, etc. or surgery such as liposuction alone. Risks and potential complications are also associated with alternative forms of treatment.

RISKS OF PLATYSMAPLASTY SURGERY

Every surgical procedure involves a certain amount of risk and it is important that you understand the risks involved with Platysmaplasty Surgery. An individual's choice to undergo a surgical procedure is based on the comparison of the potential risks to benefits. Although the majority of patients do not experience complications, you should discuss each of them with your plastic surgeon to make sure you understand the risks, potential complications, and consequences of Platysmaplasty surgery and associated procedures, such as concomitant liposuction.

SPECIFIC RISKS OF SUTURE SUSPENSION (TRAMPOLINE PLATYSMAPLASTY / MYELLEVATE) SURGERY

Previous Surgical Scars - Surgical scars from previous facial or neck surgery or treatments may limit the amount of skin tightening that can be produced, and may cause contour irregularities, or result in wound formation.

Asymmetry - Symmetrical face and neck appearance may not result after surgery. Factors such as skin tone, fatty deposits, skeletal prominence, and muscle tone may contribute to normal asymmetry. Nearly all patients have differences between the right and left side of their face/neck before surgery. Surgery may improve this asymmetry, but it is impossible to surgically create perfect symmetry.

Seroma - Infrequently, fluid may accumulate between the skin and the underlying tissues following surgery, trauma or vigorous exercise. Should this problem occur, it may require additional procedures for drainage of fluid. Seromas should be addressed to prevent an unfavorable outcome. Should this problem occur, notify your surgeon(s). Additional procedures for drainage of fluid may be required. A seroma following surgery usually resolves with repeated aspiration.

Recurrence of Signs of Aging - The exact duration or longevity of your post-platysmaplasty results can be dependent upon many factors including your bone structure, weight gain/loss, skin quality and skin damage. The procedure cannot stop the process of aging. It can improve the most visible signs of aging by tightening deeper structures, and removing selected areas of fat if liposuction is included.

GENERAL RISKS OF SURGERY

Healing Issues - Certain medical conditions, dietary supplements and medications may delay and interfere with healing. There are general risks associated with almost all surgery, such as delayed healing or wound healing problems, skin color changes, contour changes. Patients with significant skin laxity may continue to have the same lax skin after surgery. The quality or elasticity of skin will not change, and recurrence of skin laxity will occur at some point in the future, quicker for some than others.

Smokers have a greater risk of skin loss and wound healing complications.

Bleeding- It is possible, though unusual, to experience a bleeding episode during or after surgery. Should bleeding occur, it may require emergency treatment to stop the bleeding, drain accumulated blood or you may require a blood transfusion, though such occurrences are rare. The collection of blood that can occur under your skin following surgery is referred to as a hematoma. Increased activity too soon after surgery can lead to increased chance of bleeding and additional surgery. It is important to follow postoperative instructions and limit exercise and strenuous activity for the instructed time. Non-prescription "herbs" and dietary supplements can increase the risk of surgical bleeding, and

should be stopped (see “Medications to Avoid” Instructions). Hypertension (high blood pressure) that is not under good medical control may cause bleeding during or after surgery. Accumulations of blood under the skin may delay healing, and could cause scarring.

Infection - Infection, although uncommon, can occur after surgery. Should an infection occur, additional treatment including antibiotics, hospitalization, or additional surgery may be necessary. Post-operative infections often result in more extensive scarring and predispose to revision surgery.

Scarring - All surgery leaves scars, some more visible than others. Although good wound healing after a surgical procedure is expected, abnormal scars may occur within the skin and deeper tissues. Scars may be unattractive, raised, and a different color than the surrounding skin. Scars may be asymmetrical (appear different on the right and left side of the body). There is the possibility of visible marks in the skin from sutures. In some cases, scars may require surgical revision or other treatment.

Revision Surgery - Every effort is made for you to have a favorable outcome, but unforeseen events can occur that may require revisional surgery. Patients with multiple medical problems, massive weight loss patients, smokers, patients that develop infections after surgery and other high risk patients have a greater propensity to require revisional surgery. Issues that may need to be addressed in the post-operative period include but are not limited to skin excess, asymmetry, contour irregularities, folds, wrinkles, and loose skin.

Firmness - Excessive firmness can occur after surgery due to internal scarring. The occurrence of this is not predictable. Additional treatments, including surgery, may be necessary.

Skin Sensitivity - Itching, tenderness, or exaggerated responses to hot or cold temperatures may occur after surgery. Usually this resolves during healing, but in rare situations it may be chronic.

Sutures - Most surgical techniques use deep sutures. You may notice these sutures after your surgery. Sutures may be palpable, spontaneously poke through the skin, become visible or produce irritation. This may require additional treatment.

Damage to Deeper Structures - There is the potential for injury to deeper structures including nerves, blood vessels, lymphatics, and muscles during surgery. There could also be temporary weakness of lower facial muscles or numbness due to swelling after surgery. Injury to these structures may be temporary or permanent. Permanent loss of function is extremely rare.

Fat Necrosis - Fatty tissue found deep to the skin might die. This may produce areas of firmness within the skin. Additional surgery to remove areas of fat necrosis may be necessary. There is the possibility of contour irregularities in the skin that may result from fat necrosis.

Surgical Anesthesia - Both local and general anesthesia involves risk. There is the possibility of complications, injury, and even death from all forms of surgical anesthesia or sedation.

Pain - You will experience pain after your surgery. Pain of varying intensity and duration may occur and persist after surgery. If you suffer from chronic pain, and are treated/ followed by a Pain Therapy Practitioner, you may be asked to see this practitioner preoperatively to assist you in the management of your pain disorder in the post-operative period. Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue, suture or due to tissue stretching.

Allergic Reactions - In rare cases, local allergies to tape, suture material and glues, blood products, topical preparations or injected medications have been reported. Serious systemic reactions, including shock (anaphylaxis), may occur in response to medications used during surgery and prescription medications. Allergic reactions may require additional treatment. It is important to notify your physician of any previous allergic reactions.

Drug Reactions - Unexpected drug allergies, lack of proper response to medication, or illness caused by the prescribed drug are possibilities. It is important for you to inform your physician of any problems you have had with any medication or allergies to medication, prescribed or over the counter, as well as medications you now regularly take. Provide your surgeon(s) with a list of medications and supplements you are currently taking.

Shock - In rare circumstances, your surgical procedure could cause severe trauma, particularly when multiple or extensive procedures are performed. Although serious complications are infrequent, infections or excessive fluid loss can lead to severe illness and even death. If surgical shock occurs, hospitalization and additional treatment would be necessary.

Surgical Wetting Solutions - There is the possibility that large volumes of fluid containing dilute local anesthetic drugs and epinephrine that is injected into tissues during surgery may contribute to fluid overload or systemic reaction to these medications. Additional treatment including hospitalization may be necessary.

Unsatisfactory Result - Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. The face and body are not symmetric and almost everyone has some degree of asymmetry which may not be recognized in advance. Some of these asymmetries cannot be fully corrected with surgery. The more realistic your expectations of your results, the better your results will appear to you. Some patients never achieve their desired goals or results, at no fault of the surgeon(s) or surgery. You may be disappointed with the results of surgery. Asymmetry, unanticipated shape and size, loss of function, wound disruption, poor healing, and loss of sensation may occur after surgery. There is also a 5% risk that when combined with energy-based skin tightening the skin may not contract an adequate amount after a period of 1 year. If this occurs the patient may require more surgery to remove some of the redundant excess skin that did not respond to the energy-based tightening. Subsequent surgery would be at the expense of the patient. There is no way to absolutely predict who will not respond to energy-based tightening. Unsatisfactory surgical scar location or appearance may occur. It may be necessary to perform additional surgery to improve your results. Unsatisfactory results may NOT improve with each additional treatment.

ADDITIONAL ADVISORIES

Medications and Herbal Dietary Supplements - There are potential adverse reactions that occur as the result of taking over-the-counter, herbal, and/or prescription medications. Aspirin and medications that contain aspirin interfere with forming blood clots, and therefore may contribute to more bleeding issues. If you have a medical condition (such as heart arrhythmia, heart stent, blood vessels with blockages, or blood clots) and are taking medications to thin your blood and prevent clotting such as Plavix, Warfarin, Coumadin, Xarelto, Effient or Pradaxa, discuss management of these medications around the time of surgery with your plastic surgeon(s). Your plastic surgeon(s) may sometimes coordinate a plan for these medications with the doctor that prescribed them for your medical condition. If you have been prescribed drugs for a medical condition, do not stop them without discussing it first with your plastic surgeon(s). Stopping these medications abruptly may result in a heart attack, stroke, or death. Be sure to check with your physician about any drug interactions that may exist with medications which you are already taking. If you have an adverse reaction, stop the drugs immediately and call your plastic surgeon(s) for further instructions. If the reaction is severe, go immediately to the nearest emergency room.

When taking the prescribed pain medications after surgery, realize that they can affect your thought process and coordination. Do not drive, do not operate complex equipment, do not make any important decisions and do not drink any alcohol while taking these medications. Be sure to take your prescribed medication only as directed.

Sun Exposure – Direct or Tanning Salon - The effects of the sun are damaging to the skin. Exposing the treated areas to sun may result in increased scarring, color changes, and poor healing. Patients who tan, either outdoors or in a salon, should inform their surgeon(s) and either delay treatment, or avoid tanning until the surgeon(s) say(s) it is safe to resume. The damaging effect of sun exposure occurs even with the use sun block or clothing coverage.

Travel Plans - Any surgery holds the risk of complications of delayed healing and your return to normal life. Please let the surgeon(s) know of any travel plans, important commitments already scheduled or planned, or time demands that are important to you, so that appropriate timing of surgery can occur. There are no guarantees that you will be able to resume all activities in the desired time frame. Allow at least 10-14 days to travel via airplane.

Female Patient Information - It is important to inform your plastic surgeon(s) if you use birth control pills, estrogen replacement, or if you suspect you may be pregnant. Many medications including antibiotics may neutralize the preventive effect of birth control pills, allowing for conception and pregnancy.

Intimate Relations After Surgery - Surgery involves coagulating of blood vessels and increased activity of any kind may open these vessels leading to a bleed, or hematoma. Activity that increases your heart rate may cause additional bruising, swelling, and the need for return to surgery to control bleeding. It is wise to refrain from intimate physical activities until your physician states it is safe.

Mental Health Disorders and Elective Surgery - It is important that all patients seeking to undergo elective surgery have realistic expectations that focus on improvement rather than perfection. Complications or less than satisfactory results are sometimes unavoidable, may require additional surgery and often are stressful. Please openly discuss with your surgeon(s), prior to surgery, any history that you may have of significant emotional depression or mental health disorders. Although many individuals may benefit psychologically from the results of elective surgery, effects on mental health cannot be accurately predicted.

Smoking, Second-Hand Smoke Exposure, Nicotine Products (Patch, Gum, Nasal Spray) -

Patients who are currently smoking or use tobacco or nicotine products (patch, gum, or nasal spray) are at a greater risk for significant surgical complications of skin loss and delayed healing and additional scarring. Individuals exposed to second-hand smoke are also at potential risk for similar complications attributable to nicotine exposure. Additionally, smoking may have a significant negative effect on anesthesia and recovery from anesthesia, with coughing possibly increasing bleeding risk. Individuals who are not exposed to tobacco smoke or nicotine-containing products have a significantly lower risk of these type of complications. Please indicate your current status regarding these items below:

I am a non-smoker and do not use nicotine products. I understand the potential risk of second-hand smoke exposure causing surgical complications.

I am a smoker or use tobacco / nicotine products. I understand the risk of surgical complications due to smoking or use of nicotine products.

I have smoked and stopped approximately _____ ago. I understand I may still have the effects and therefore risks from smoking in my system, if not enough time has lapsed.

I have been advised to stop smoking immediately and have been informed of the risks, benefits, expectations and alternatives to my surgery if I continue smoking.

It is important to refrain from smoking at least 6 weeks before surgery and until your physician states it is safe to return, if desired. I acknowledge that I will inform my physician if I continue to smoke within this time frame, and understand that for my safety, the surgery, if possible, may be delayed or cancelled.

Smoking may have such a negative effect on your surgery that a urine or blood test just before surgery may be done which will prove the presence of Nicotine. If positive, your surgery may be cancelled and your surgery, scheduling fee, and other prepaid amounts may be forfeited. Honestly disclose smoking to your surgeon(s).

Sleep Apnea / CPAP - Individuals who have breathing disorders such as “Obstructive Sleep Apnea” and who may rely upon CPAP devices (continuous positive airway pressure) or utilize nighttime oxygen are advised that they are at a substantive risk for respiratory arrest and death when they take narcotic pain medications following surgery. This is an important consideration when evaluating the safety of surgical procedures in terms of very serious complications, including death, that relate to pre-existing medical conditions. Surgery may be considered only with monitoring afterwards in a hospital setting in order to reduce risk of potential respiratory complications and to safely manage pain following surgery.

I have been tested for Sleep Apnea

I have diagnosed with Sleep Apnea and/or use a CPAP

I have NOT been diagnosed with Sleep Apnea and do not use a CPAP

Please consider the following symptoms of sleep apnea:

I am frequently tired upon waking and throughout the day

I have trouble staying asleep at night

I have been told that I snore or stop breathing during sleep

- ___ I wake up throughout the night or constantly turn from side to side
- ___ I have been told that my legs or arms jerk while I'm sleeping
- ___ I make abrupt snorting noises during sleep
- ___ I feel tired or fall asleep during the day

It is important for you to inform and discuss any of the above symptoms that you have experienced with your surgeon(s).

ADDITIONAL SURGERY (Re-Operations) - There are many variable conditions that may influence the long-term result of surgery. It is unknown how your tissue may respond or how healing will occur after surgery. Secondary treatments or surgery may be necessary to perform additional tightening or repositioning of face and neck. Should complications occur, additional surgery or other treatments may be necessary. Even though complications occur infrequently, the risks & complications cited are associated with this surgery. Other complications and risks can occur but are less common. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. In some situations, it may not be possible to achieve optimal results with a single surgical procedure. You and your surgeon(s) will discuss the options available should additional surgery be advised. There may be additional costs and expenses for such additional procedures, including surgical fees, facility and anesthesia fees, pathology and lab testing.

PATIENT COMPLIANCE - Follow all physician instructions carefully; this is essential for the success of your outcome. It is important that the surgical incisions are not subjected to excessive force, swelling, abrasion, or motion during the time of healing. Personal and work activity needs to be restricted. Protective dressings should not be removed unless instructed by your plastic surgeon(s). Successful post-operative function depends on both surgery and subsequent care. Physical activity that increases your pulse or heart rate may cause bruising, swelling, fluid accumulation and the need for additional surgery. It is important that you follow all instructions, participate in follow-up care and return for aftercare to promote your recovery after surgery.

DISCLAIMER

Informed consent documents are used to communicate information about the proposed treatment of a condition along with disclosure of risks and alternative forms of treatment(s). The informed consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances.

However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered.

Informed consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined based on all the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

It is important that you read the above information carefully and have all your questions answered before signing the consent on the next page.

CONSENT FOR SURGERY/ PROCEDURE OR TREATMENT

1. I hereby authorize Dr. Karol Gutowski and/or Dr. Andrea Martin, and such assistants as may be selected, to perform the following procedure or treatment:

MyEllevate Neck Rejuvenation (Suture Suspension Including Trampoline Platysmaplasty) with or without liposuction of the chin and neck area

I have received the following information sheet:

INFORMED CONSENT for MYELLEVATE NECK REJUVENATION (SUTURE SUSPENSION INCLUDING TRAMPOLINE PLATYSMAPLASTY) WITH OR WITHOUT LIPOSUCTION OF THE CHIN AND NECK

2. I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician(s) and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician(s) at the time the procedure is begun.
3. I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.
4. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
5. I consent to the photographing, video recording of the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
6. For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
7. I consent to the disposal of any tissue, medical devices or body parts which may be removed.
8. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.
9. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
 - a. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
 - b. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
 - c. THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-9). I AM SATISFIED WITH THE EXPLANATION.

Patient or Person Authorized to Sign for Patient

Witness

Date _____

Time _____

INFORMED CONSENT – MYELLEVATE TRAMPOLINE PLATYSMAPLASTY – Cont.

AUTHORIZATION & CONSENT FOR RELEASE OF MEDICAL IMAGES

It is important that you read this information carefully and completely. After reviewing, please sign the consent as proposed by The Physicians or their representatives.

INTRODUCTION

For your medical records, images (photographs, slides, videos, interviews or any other images of you, or components of your medical record) may be taken before, during, or after a surgical procedure or treatment. These images may be needed to document your medical condition, used as supporting material for authorizing medical coverage and payments, and treatment planning. Consent is required to take, use and release such images. Since The Physicians are also educators of other physicians, researchers, and healthcare providers, your images may be used for other purposes as described below.

1. CONSENT TO TAKE PHOTOGRAPHS, SLIDES, DIGITAL IMAGES, AND VIDEOGRAPHY

I hereby authorize The Physicians and/or their associates to take any images before, during and after my treatments or surgeries.

2. CONSENT FOR RELEASE OF PHOTOGRAPHS/SLIDES/ VIDEOGRAPHY

I hereby authorize The Physicians and their associates to use any of these images for professional medical purposes deemed appropriate including but not limited to showing these images on public or commercial television, electronic digital networks including the internet, print or visual or broadcast media, for purposes of examination, testing, credentialing and/or certifying purposes for medical education, patient education, lay publication, or during lectures to medical or lay groups, for marketing and advertising, and for use in medical teaching, research or dissemination of medical information to medical and nonmedical audiences, including, but not limited to, journal or book publications, presentations, conferences, and print marketing material (magazine, newspaper, etc.) or electronic media (television, internet, etc.).

3. CONSENT FOR RELEASE TO PROFESSIONAL ORGANIZATIONS

I further authorize The Physicians and their associates to release such images to the American Society of Plastic Surgeons (ASPS), the American Society for Aesthetic Plastic Surgery (ASAPS), the American Board of Plastic Surgery (ABPS), the American Academy of Facial Plastic and Reconstructive Surgery (AAFPRS), and the American Board of Facial Plastic and Reconstructive Surgery (ABFPRS). I provide this authorization as a voluntary contribution in the interests of public education. The images may be used for publication in print, visual or electronic media, specifically including, but not limited to, medical journals (such as *Plastic and Reconstructive Surgery*, *Annals of Plastic Surgery*, *Aesthetic Plastic Surgery*), textbooks, lay publications, patient education or during lectures for the purpose of informing the medical profession or the general public about plastic surgery methods, medical education or examination material by ASPS, ASAPS, ABPS, AAFPRS and ABFPRS. I understand that such images shall become the property of ASPS, ASAPS, ABPS, AAFPRS and ABFPRS and may be retained or released by these organizations for the limited purpose mentioned above. I also grant permission for the use of any of my medical records including illustrations, photographs, video or other imaging records created in my case, for use in examination, certifying and/or re-certifying purposes by ABPS and ABFPRS.

I understand that I will not be identified by name in any release of these materials but in some cases the images may contain features that may make my identity recognizable. I release and discharge The Physicians and all parties acting on their authority from all rights that I may have in these images, and from any claims that I have related their use in the above-mentioned manner.

I also release The Physicians and any employees or agents from all liability, including any claims of libel or invasion of privacy, directly or indirectly connected with, arising out of or resulting from the taking and authorized use of these images or recorded interviews.

I understand that I have the right to request cessation of recording or filming at any time. I understand that I will not be entitled to monetary payment or any other consideration as a result of use of these images and /or my interview.

Patient Name _____

Patient Signature _____

Date _____

Witness or Guardian/Parent _____

Date _____