

Office Based Minor Surgical Procedures - Preparing the Patient, The Room, and YOU !



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has no financial relationships to disclose. She is an Independent Continuing Education Consultant.



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There are a number of "in office" procedures that can occur daily in an Ophthalmology office:

1. Lids (chalazions, lid lacerations, BOTOX)
2. Retina (diabetic lasers, intravitreal injections)
3. Intraocular injections
4. Cornea (lacerations/trauma, LASIK)
5. Pediatrics (muscle adjustments post surgery, lacrimal probing)
6. YAG



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But there is nothing "minor" about any procedure...from installing drops all the way to performing surgery on the eye or surrounding adnexa. We need to adhere to the same standards as if the patient was having a surgical procedure in the OR !



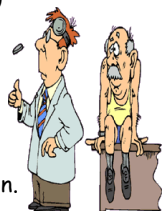
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What Is Minor Surgery/Procedure?

" A procedure that can be performed safely with a minimum of discomfort and where the likelihood of complications requiring hospitalization is minimal." (AMA)

- Procedures performed with local or topical anesthesia

Office based surgery is any surgical or invasive procedure requiring **minimal** sedation, requiring general anesthesia, moderate sedation, or deep sedation.



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Factors To Consider

- Mental status of the patient
- Language barriers
- Co-morbidities (one or more disease processes)
- Ability to position the patient correctly for procedure
- Medications the patient is taking
- **The more complex the surgery, the less amenable it may be for the office.** Complexity includes: multiple surgical sites, difficulty to anesthetize the site, risk of blood loss and risk of infection



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Preparing The Patient

We need to remember that while we think the procedure is minor in nature, the patient will still have the same amount of anxiety and questions. And, even though it is "minor", they still are going to have a "procedure" performed on them !



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Define "Procedure" !

In who's terms ??



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Informed Consent

The failure to obtain informed consent is a form of **NEGLIGENCE** and can result in professional liability. Informed consent is more than getting a patient to "sign" a written consent form. It is defined as a **process of communication** between a **patient** and **physician** that results in the patient's authorization/agreement to undergo a specific medical intervention. (American Medical Association)



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This is defined as a process where the patient has the ability to ask questions and to have those questions answered **by their physician** !



Therefore...**it is an interactive process.**

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Did You Know ?!

A study asked physicians how long they spent performing informed consent. Their response: 7- 10 minutes.

The physicians were then video taped and found to spend **ONE minute** on average performing informed consents !



(MMIC: Minn. Medical Insurance Company)

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What About Watching A Video ?

- There should be a note in the chart that they viewed/*or* refused to view the video.
- Videos are NOT enough... the doctor still needs to give the patient the opportunity to ask questions.
- Same with sending the consent home with them to read, sign and bring back the day of the procedure. *Are you sure it was the patient that signed the form ???!*



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The physician providing/ performing the treatment / procedure (not a delegated representative) should disclose and discuss:

- The patient's diagnosis, if known
- The nature and purpose of a proposed treatment / procedure
- Risks and benefits of a proposed treatment / procedure
- Alternatives (regardless of their cost or the extent to which the treatment options are covered by health insurance)
- Risks and benefits of the alternative treatment / procedure
- Risks and benefits of not receiving or undergoing a treatment or procedure (*Ethics in Medicine*)



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In turn, the patient needs to have the opportunity to ask questions to ensure they have an understanding of the treatment/ procedure, so they can make an informed decision to proceed or to refuse a the recommended medical intervention.

This communication process is both an ethical obligation *and* a legal requirement in all 50 states !



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The patient must be considered **competent** to make the decision and the consent must be **voluntary**.

It is easy for coercion to happen because patients often feel powerless. The doctor is obligated to provide a recommendation and to share their reasoning process with the patient using "people talk" when discussing the treatment/options !



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Patients have the right to refuse medical care.

Their reasons can include religious reasons as well as any other personal reasons they choose, even if you consider their reasons to be frivolous or in poor judgment !

Patients who are legally competent have the legal, and moral right, to refuse any or all treatment. This holds true even if the patient chooses to make a "bad decision" that may result in serious disability or even death !



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Informed consent **must** be obtained by the health care provider who is reasonably involved with the patient's care. Ex: A medical student can not obtain consent because they are not allowed to be responsible for patient care. The **legal** requirement to obtain informed consent rests with the physician. They can delegate this responsibility to another **health care provider** but they remain responsible and liable.



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When Is Consent "Implied" ?

* Implied consent is consent by "inference" from the patient's behavior. Ex: the patient standing in line to receive a vaccination is inferring that they agree to receive the injection!

* For **invasive tests or for treatments with significant risk**, a written consent form and a verbal explanation is required.

Preferably in their **native language**.

*The consent form should be signed and dated by the doctor and the patient. Parents sign for their child.

* Patients can ask for a copy of the signed consent form.



wikipedia.com

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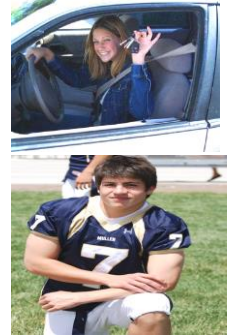
What Is Express Consent ?

- Express consent is what is normally thought of by "consent"
- Written consent is required for invasive cases. In other cases, the law simply requires consent, but **written consent is suggested for the purpose of proof.**
- Telephone consent is acceptable, when necessary. It is a good idea to have a second person on the telephone, again for the purpose of proof.
- Informed consent is valid for a reasonable period of time. **Per JCAHO, this period of time consists of 30 days.** When treatments are planned in advance, such as chemotherapy, consent may be obtained for the treatments to be provided up to 6 months in advance.

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How About Minors??

In most cases, the law defines a "minor" as being anyone under the age of 18. This can vary from state to state - but 18 y.o. seems to be the age regardless if they are driving to their appointment and come alone !



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When Is A Minor Considered An Adult ?

It is never acceptable to consent a minor for a medical or surgical procedure.

Consent must be received from the parents or the person responsible for the minor.

There are exceptions to this rule:

- * minors legally treated as adults
- * emancipated minors (paying their own bills)
- * married minors
- * minors who are parents or are pregnant
- * minors in military service.



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To Enhance Informed Consent

- Use non medical terms
- Use simpler words (start versus commence)
- Use short sentences
- Use pictures to help describe
- Use teach back methods
- Provide written information to augment the discussion. **80% of patient forget what they were told as soon as they left the office**
- Provide interpreters for patients with limited English ability and provide forms in their language



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The Room & The Staff

There are two primary reasons to do "minor procedures" in your office: convenience and cost.

Since you control your office - you control the patient flow and the scheduling of procedures.

Patients are already familiar with your office, and can

usually come for their procedure surgery without any/much preparation. In most cases, patient satisfaction is usually higher and the cost is much less than the standard OR cost.



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Staff needs to be properly trained to assist and manage office based procedures, including any postoperative and emergency situations.

Also consider any state regulations that govern surgery performed in the office!



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Staff Training

- **CPR annually**
- Continuing Education Updates
- Specimen Handling and Documentation Procedures
- Procedures:
 - * Consent Signed
 - * Site Isolated and Agreed On
- Aseptic Technique
 - Gowning and Gloving
 - Cleaning, Handling and Storage of equipment
 - Cleaning of the room
 - Site preparation



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Levels Of Sedation

	Minimal Sedation (Anxiolysis)	Moderate Sedation/ Analgesia ("Conscious Sedation")	Deep Sedation/ Analgesia	General Anesthesia
Responsiveness	Normal response to verbal stimulation	Purposeful response to verbal or tactile stimulation	Purposeful response** after repeated or painful stimulation	Unarousable even with painful stimulus
Airway	Unaffected	no intervention required	Intervention may be required	Intervention often required
Spontaneous Ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular Function	Unaffected	Usually maintained	Usually maintained	May be impaired

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Doctors that sedate patients in their office must be skilled in advanced airway management, **pediatric advanced life support** and in assessing a patient for changing levels of sedative effects.

(Children's Memorial Hospital Anesthesia Guidelines)



Table 1 EQUIPMENT REQUIRED FOR ALL LEVELS OF SEDATION

- Positive-pressure oxygen delivery system capable of administering greater than 90% oxygen at a 15 L/minute flow for at least 60 minutes
- Appropriate sized masks and oral airways
- Appropriate drug reversal agents
- Suction apparatus with suction catheters
- Monitors capable of measuring oxygenation (pulse oximeter), blood pressure, heart rate (electrocardiogram or pulse oximeter), and temperature (thermometer)
- ECG and defibrillator
- Warming devices
- Appropriate intravenous equipment
- Emergency resuscitation equipment
- Telephone or other device for summoning emergency assistance

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What Are The Levels Of Sedation ?

General Anesthesia:

- Drug induced depression of consciousness where the patient is not arousable - even to pain
- Ability to maintain an airway by patient is impaired
- Patient requires assistance with breathing via ventilation
- Heart function may be impaired



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Deep sedation:

A drug induced depression of consciousness where a patient cannot be easily aroused but responds to painful stimulation

- Patient's ability to breathe on their own may be impaired and the patient may need help with maintaining a patient airway
- Spontaneous ventilation may be needed
- Heart function needs to be monitored during procedure



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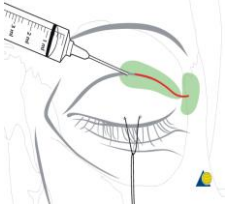
Minimal sedation (Conscious Sedation):

- Minimally depressed level of consciousness in which the patient responds to verbal commands, either alone or by light tactile stimulation
- No intervention is required to maintain an airway
- Patient can breathe on their own
- Patient's heart works on its own



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Local Anesthesia:
Local anesthesia is given to that "part" of the body having the Procedure causing the nerve to have a transient loss of sensation.
ALL local anesthetics have the ability to effect seizures and/or loss of consciousness.



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How About Giving Children Sedation ?

Procedures for which sedatives are given include :

- diagnostic imaging studies
- laceration repair
- foreign body removal
- spinal taps

Regardless of procedure, children are **deeply** sedated in order to provide adequate working conditions. There is no such thing as "light sedation" or "twilight sleep" that will help a child stay immobile.




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Preventing Infection

The body has (3) lines of defense from microorganisms.


A> The **skin and mucous membranes** are the primary defense
 B> The body's **inflammatory response** - how the body "responds" to prevent pathogens from reproducing is second
 C> The third line of defense is activated **after** inflammation begins and is called the "immunological defense". Antibodies reacting to an antigen are rushed to the injury site .
 A break in **any part** of this defensive mechanism increases the likelihood of infection.



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Hand washing

You cannot sterilize your skin but using hand sanitizers and hand washing can reduce microbial contamination. Antiseptics are used to control and/or kill microorganisms that contaminate the skin or other tissues. Such antiseptics contain some of the same chemicals that are used to disinfect objects at home or at work.




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Cleaning The Surgical Area

- Put on sterile gloves
- Start the preparation at the eyelid. Prep in a spiral pattern around the eye to within approx an inch of the hairline.

Never go backwards


- Do NOT allow the prep solution to drain into the ear. Iodophor (Iodine & Povidone) are effective but must be rinsed after using it as it can be sometimes toxic to the skin.



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Identifying The Surgical Site

Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards, states that all accredited health care facilities are required to follow established patient safety goals. The majority of surgical site marking pens contain **gentian violet ink**, a water based ink. It also has antifungal properties. The site mark should not be easy to remove during the skin prep but should not be so permanent as to last weeks after the surgery!



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Pre/Post Surgical Monitoring

- Pulse oximeter
- BP
- Level of Consciousness
- Respirations
- **Don't leave the patient alone during or after the procedure**



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Instrument & Room Cleaning

The cleaning of surgical instruments involves disinfection and/or sterilization. Each instrument falls into a category which determines what type of sterilization or disinfection method is required to clean it.



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TASS (Toxic Anterior Segment Syndrome)

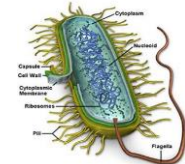
A sterile, non-infectious, acute postoperative inflammation that is caused by a noninfectious substance that enters the anterior segment causing toxic damage to intraocular tissues. Often occurs within 12 - 24 hours after cataract/anterior segment surgery as an inflammatory process limited to the anterior segment. It usually improves with steroid treatment. The primary differential diagnosis is infectious endophthalmitis, although the onset of infectious endophthalmitis is usually between 72 - 96 hours after surgery. (Review Of Ophthal)



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Potential Reasons TASS Occurs

There often isn't enough time to adequately clean **reusable** hand pieces and reusable instruments used in phacoemulsification. Manufacturers recommend that these hand pieces get flushed with 120 cc of fluid, it is difficult to achieve that level of flushing between cases. This allows residual cortex, viscoelastic or other materials left on the hand pieces. Protocols need to be followed to ensure you are adequately flushing and cleaning the instruments with sterile de-ionized or distilled water in between cases



Detergent residues can also cause outbreaks of TASS due to contamination of the instruments during sterilization. Water baths, ultrasound baths and autoclave reservoirs need to be cleaned regularly to prevent Gram-negative bacteria.

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Steps To Processing Instruments/Equipment

Cleaning: the physical removal of all visible soil, dust, foreign materials. Detergent is essential to dissolve proteins and oil that can stay on instruments/equipment after use (**biofilm**). The solution used most often to clean is an enzymatic pre-soak (protease formula) that dissolves protein. Do **NOT** use BSS (balanced salt solution) as it can damage micro-instruments. Use distilled water.



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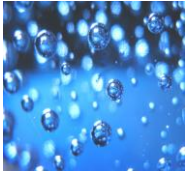
Ultrasound Cleaning

An **ultrasonic cleaner** is a cleaning device that uses ultrasound (usually from 20-400 kHz) and an appropriate cleaning solvent to clean delicate instruments. The ultrasound can be used with only water but use of a solvent (**low foaming detergent**) appropriate for the item to be cleaned and the soiling enhances the effect. Cleaning normally lasts between three and six minutes. Do **NOT** use foam!



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Cavitation is the formation and immediate implosion of cavities in a liquid (small liquid-free zones = "bubbles"). These are the consequence of the forces acting upon the liquid. They occur when a liquid is subjected to rapid changes of pressure. Cavitation bubbles induced by the agitation act on contaminants that adhere to metals, plastics, glass, and rubber. The intention is to thoroughly remove all traces of contamination tightly adhering or embedded onto solid surfaces.



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What Is The Difference Between Sterilization and Disinfection ?

Disinfection is aimed at killing microbes to a level that an infection does not get transmitted. It does not necessarily kill all the microorganisms present in the equipment being disinfected.

Sterilization is a process of decontamination where **all** the microorganisms present on the surface of the equipment is killed and the object is called as sterile. Sterilization process is also known to kill **all the spores** present on the object to be sterilized. Sterilization kills all the viable microorganism whereas disinfection only *reduces* the number of viable microorganisms.



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Spaulding Classification For Sterilization

- Critical Devices:** any equipment/instrument that enters into body cavity must be sterilized.
- Semi Critical:** Any instrument/equipment that comes into contact with non-sterile mucous membranes or non-intact skin must be sterilized or receive high level disinfection (kills all vegetative bacteria, fungi and viruses, but not all bacterial endospores)
- Non-critical devices:** i.e. blood pressure cuffs, stethoscope, walls. These come into contact with intact skin and are cleaned with soap and water or low level disinfectant



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Spaulding Classification System

Device classification	Device (examples)	Spaulding process classification	EPA product classification
Critical (enters sterile tissue or vascular system)	Implants, scalpels, needles, other surgical instruments, etc.	Sterilization - sporicidal Chemical prolonged contact	Sterilant/disinfectant
Semicritical (touches mucous membranes (except dental))	Flexible endoscopes, laryngoscopes, endotracheal tubes, and other similar instruments	High-level disinfection- Sporicidal- chemical; short contact	Sterilant/disinfectant
Noncritical (touches intact skin)	Thermometers, hydrotherapy tanks, Biotopes, stethoscopes, bedpans, etc.	Intermediate-level disinfection Low-level disinfection	Hospital disinfectant with label claim for tuberculocidal activity Hospital disinfectant without label claim for tuberculocidal activity

American Journal Of Infection Control

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Single Use Instruments/Equipment

These may be used in critical, semi-critical, or noncritical areas but are designed as **single use** items. They are prepackaged with the appropriate level of disinfection/sterilization and are designed to be disposed of after a single use.

Examples: gloves, needles, syringes, and tongue depressors



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Disinfection

Disinfection is the process that kills/destroys disease producing microorganisms (except spores) and can be carried out either by thermal or chemical means.

Thermal disinfection is preferred whenever possible. It is more reliable than chemical, leaves no residues, easier to control, and is non-toxic. Heat sensitive items have to be reprocessed with a chemical disinfectant.

Organic matter (serum, blood, pus) interferes with the antimicrobial efficiency of either method. The larger the number of microbes present, the longer it takes to disinfect.



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Levels Of Disinfection: High Level Disinfection- Boiling

High level disinfection is best achieved by hot water pasteurization (30 minutes in **80 -100°C** for one minute holding time), which kills all organisms *except* for bacterial spores. Used for instruments that come into contact with mucous membranes (semi -critical). Note: boiling equipment/items in water will not achieve sterilization!



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Levels Of Disinfection: High Level Disinfection- Chemical

Chemical disinfection is used most commonly for heat unstable equipment (e.g. stethoscope, tubing) and where single use is not cost effective.

A limited number of disinfectants can be used for this purpose:

- **Glutaraldehyde** 2% for 20 min. Good instrument and equipment disinfectant but not appropriate for floors and walls
- **Hydrogen peroxide** 6% - 7.5% for 20 - 30 min.
- **Phenolic disinfectants** and **QUATS** (quaternary ammonium chlorides) - floors, surfaces and some non critical instruments.



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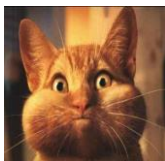
Glutaraldehyde

Glutaraldehyde solution is irritating to the skin, eyes, and the respiratory tract. It is a disinfectant/sterilant that has been linked to a number of health issues - ranging from mild to severe, including:

- * Asthma & breathing difficulties
- * respiratory irritation
- * skin rashes

There are different types of glutaraldehyde : Cidex®, Sonacide®, Sporicidin®, Hospex®, etc. Personal protective equipment (PPE) should be worn (gloves, safety eyewear, and gowns, lab coats, and aprons).

Minimum air exchange rate of 10 air exchanges per hour (ANSI/AAMI, 1996) or higher (15 air exchanges per hour)



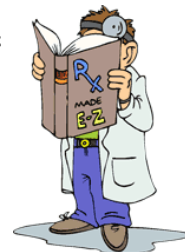
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Sterilization

A process that achieves the **complete** destruction/killing of **all** microorganisms, *including bacterial spores*.

Sterilization is accomplished by:

- Steam under pressure (Autoclaving)
- Dry heat (Hot Air Oven)
- Chemicals, like ethylene oxide gas



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Pressure Steam Sterilization: High Pressure Autoclaving

Steam sterilization is the most common, and preferred, method used for sterilization of all items that penetrate the skin and mucosa *if* they are heat stable. Steam sterilization is dependable, non toxic, inexpensive, sporicidal, has rapid heating and good penetration of fabrics.



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Autoclaving Instruments

- * **Log in notebook** date and name of instruments and how many of each instrument that are being autoclaved with each load.
- Place instrument in **peel pack** with name of instrument and the **date** that instrument is run through autoclave.
- Place an Attest control in a peel pack and run with every load.
- Place the (autoclaved) control Attest in incubator along with controlled (non-sterilized) Attest and incubate for 48 hours.
- Log in Steam Log Book date and time of start and date and time of results after 48 hours.
- If you have questions refer to your Attest Biological Monitoring System Steam Log Book.

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Biological Indicators (BI) are the most accepted means of monitoring the sterilization process because they directly determine whether the most resistant microorganisms are present rather than merely determine whether the physical and chemical conditions necessary for sterilization are met.



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Flash Sterilizers

Normally located in operating room suite. This gives a quick sterilization cycle at 134°C for 3-4". Should only be used only when there is insufficient time to sterilize an instrument by the preferred method. Flash sterilization often uses an open pan. This increases the risk of contamination transporting the instruments. Therefore, flash sterilized instruments should be used as soon as possible.



Wrapped instruments can be stored indefinitely without fear of contamination.

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Ethylene Oxide Gas

Ethylene oxide can be used to sterilize most articles that can withstand temperatures of 50-60 °C (120-140F). Because it is very toxic, and explosive, it needs to be used under carefully controlled conditions. It is very versatile and can be used for heat intolerant equipment, fluids, and rubber. There is a long period of aeration to remove all traces of the gas required before the equipment can be used. The operating cycle ranges from 2-24 hrs and it is an expensive process. Sterilization with EO should be monitored by using bacterial spore tests.



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There is nothing "minor" about minor procedures. We need to treat it as seriously as major surgery - and make sure that we have placed all the pieces together to ensure the patient, you and your practice are safeguarded all the way through !



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