safety with injectables >

new and revised

October 2016 >

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dear colleague

> october 2016

Formerly, educational initiatives by professional organizations have been directed towards technical matters of how to use injectables (fillers and neurotoxins) and the training of subordinate injectors working under the direct supervision of their physician employer.

Given the choices of cosmetic and therapeutic injectables currently approved and with more coming in each category, the question arises, "How do physicians and their staff develop processes to deliver operational excellence with injectables?" This includes steps to address infection control, prevent injection errors, and maximize patient satisfaction when using injectables. While didactic education and hands-on training in the use of injectables is helpful, there has not been a substantive focus on other important parts of the process that relate to patient safety with injectables.

Medication errors occur all too frequently in patient care situations involving incorrect drug concentrations (concentrated heparin used to flush IV catheters), wrong drug (insulin mistaken for saline IV flush), and situations involving unsafe injection practices resulting in disease transmission of Hepatitis C and bacterial infections.

This monograph provides practitioners with a variety of templates, documents, and policies and procedures that address important components of a comprehensive process that can be developed in your clinic. This program provides practitioners with a variety of templates, documents, and policies and procedures that address important components of a comprehensive process that can be developed in your clinic. This product is offered to you as a member of professional organizations that are affiliated with the Coalition.

We believe that it is important to have a great process for the safe use of injectables. The materials that are part of this offering will give you the framework for your own customized program of injectable safety. Such a program will help differentiate Core-trained injectors from others that cannot implement patient safety and quality when using injectables.

Please feel free to customize material within this workbook to meet your specific needs. Additionally, we have included a chapter on Risk Mitigation regarding how to discuss with patients the FDA-mandated boxed warning and medication guide for neurotoxin use.

Sincerely,

Mark L. Jewell, MD

Mark L. Jewell, M.D.
Past President, The Aesthetic Society

Jennifer L. Walden, M.D.
Communications Commissioner

license agreement

Board certified and board eligible plastic surgeons are hereby granted a license to download, modify and use the materials contained within the Safety With Injectables™ Workbook for their individual practices. This license may not be modified or expanded, whether for third party release or to permit either the sale or commercial use of these materials, unless explicit written permission is first obtained from The American Society for Aesthetic Plastic Surgery (ASAPS).

The Idea in Brief

This is an overview of the Safety With Injectables™ project. The materials supplied within this monograph will allow you to develop your own specific program for injectable safety that will best fit your needs. Having a great process for the use of injectables goes beyond improving quality of outcomes and patient satisfaction, it also provides a framework that thoroughly documents all aspects of using injectables clinically.

Getting Started: *Safety With Injectables*™ Program

Within this monograph are a variety of templates, documents, and policies/procedures that core injectors can adapt to their individual practices. The next step comes down to you to develop your own specific process within your practice: feel free to customize and adapt the material to best suit your needs.

Once you have completed this exercise in injectable safety, you will have defined specific policies and procedures that will help your patients obtain the best and safest outcomes. We believe that the material offered in this monograph will enhance the way you use injectables instead of making it overly complex and burdensome. This material fits well with existing safety and quality programs used by Core-trained injectors. The templates included are adaptable to electronic medical records (EMR).

None of the material contained within this monograph is intended to suggest or establish a particular standard of care. It is provided as a resource to clinicians in order for them to develop their own program of injectable safety, policies and procedures for their use.

Leadership

The physician is ideally suited to lead their staff in developing specific injectable policies and procedures within your practice setting. Clearly designate responsibility for oversight and monitoring. Periodically review staff practices to ensure compliance. Establish procedures and responsibilities for reporting and investigating breaches in infection-control policy and medication errors. Finally, this will be an ongoing process improvement and education activity, especially as new injectables are added to each category.

Patient safety when using injectables helps prevent avoidable catastrophic events resulting from unsafe practices that transmit disease or produce mistakes in medication use.

Many of the concepts elaborated here have their origins in the Toyota Production System and the Lean process improvement for movement in healthcare. These principles have an emphasis on ways to deliver operational excellence, mistake-proof work, and ongoing quality improvement. Both of these approaches are extremely applicable to healthcare. Choose to surround yourself and your employees with a great process for the safe use of cosmetic and therapeutic injectables. It will greatly simplify their use and improve the quality of your outcomes.

References:

Graban M. Lean Hospitals: Improving Quality Patient Safety and Employee Satisfaction. CRC Press; 2008. [ISBN 978-1-4200-8380-4]

Magee D. How Toyota Became #1. Penguin Books; 2007. [ISBN 978-1-59184-179-1]

Spear SJ. Fixing healthcare from the inside, today. *Harvard Business Review*. September 1, 2005.

Stewart TA, Raman AP. Toyota's long drive, an interview with katsuaki watanabe. *Harvard Business Review*. July-August 2007.

Cosmetic and Therapeutic Injectables: Neurotoxins and Synthetic Fillers

getting started

Process Development Start with a staff meeting to outline the program and develop staff support for the Safety With Injectables Program™

1. Service mapping of process for injectables
   a. Define what is needed at each point of the process
      i. Services, staff, documentation, supplies
   b. Define what procedures, policies, patient education materials, and templates are necessary to ensure a safe and effective process
   c. Define measures to document and manage potential adverse events (AE's) that can occur following the use of injectables
   d. Define ways to deliver consistent operational excellence in the use of injectables
2. Have a process to measure quality and patient satisfaction with injectables
3. Have a process to improve the quality of outcomes and fine tune results if necessary
4. Have a process to manage scheduling and recalls for follow up injection treatments
5. Have a process to manage adverse events (AE's) that potentially can occur with the use of injectables.

Supplies Needed:

Notebook- 3 ring
Avery tabbed dividers
High-quality inkjet paper or laser printer 92 brightness
Inkjet or color laser printer (patient templates are in color)
Kinko's or similar facility to laminate quick reference guides in plastic

Disclaimer

The forms, templates, and documents contained within the Safety With Injectables™ Initiative are not intended to represent a standard of care. These documents are offered as a starting point for practitioners to develop their own specific program of policies, procedures, documents, and templates for the safe use of injectables. Each of the components of this initiative must be customized for your particular practice.

It is recommended that you confirm that there are not any specific regulations regarding restrictions on vial splitting of single use vials or off-label use of injectables in the state where you practice. Additionally, it is important to verify that subordinate injectors are working within the scope of their particular state practice licensing act.

The Idea in Brief

Each office needs to develop its own specific policies and procedures regarding the 7 topics below. These items serve as a starting point for the development of policies and procedures regarding injectables. It is important that you have your own specific set of policies and procedures regarding injectables, as this will document that you have a specific process for their use according to labeling and off-label use regarding administration in other anatomic areas, vial splitting procedures, and administration beyond the manufacturer's time limit.
Take a few minutes to write policies and procedures for your office/clinic, based on the material in this section that will cover the following topics.

Office Policies and Procedures

1. Office Policy Regarding Personnel Having Access to Injectables
2. Ordering Procedure for Injectables
3. Policy and Procedure for Reconstitution of Neurotoxin
4. Policy for On-label and Off-label usage Neurotoxin
5. Policy for On-label and Off-label usage Tissue filler
6. Patient Care Pathway for Injectables
7. Emergency Scenarios

1. Office Policy Regarding Personnel Having Access to Injectables

Administrative Staff, Medical Office Assistant

- May order product, receive and unpack shipments, and enter product into inventory

Registered Nurses, Physician Assistant (Subordinate Injectors)

- May order product, receive and unpack shipments and enter product into inventory. Can reconstitute injectables according to established office policy and procedures with sterile technique
- Can draw up injectables and prepare syringes for injection, according to office policy and procedures with sterile technique
- Can draw up injectables and prepare syringes for injection, according to office policy and procedures with sterile technique
- Can administer injectables as a subordinate injector under the direct supervision of physician employer, according to office policy and procedures and the scope of their professional license.

Physician

- Can order product, receive and unpack shipments and enter product into inventory
- Can reconstitute injectables according to established office policy and procedures with sterile technique
- Can draw up injectables and prepare syringes for injection, according to office policy and procedures with sterile technique
- Can administer injectables as indicated according to established policies and procedures.

2. Ordering Procedure for Injectables:

1. Use of approved vendors and legitimate distribution channels to obtain approved injectables and devices
    a. Avoidance of illicit product, reimportation, non-approved distribution channels
    b. Defined vendor for each injectable, contact numbers, and ordering process
2. Documentation of order, fulfillment, and shipping method
3. Documentation of receipt of shipment in good quality

What is needed here: Forms: Order/Receipt

Receiving, Storage, and Inventory of Injectables

1. Inventory - when received, when used
2. Storage of product according to labeling
3. Safety Engineering
    a. Segregation of injectables in labeled storage containers/areas to avoid mistakes in usage
    b. Safety Engineering Chapter, Safety With Injectables™

3. Policy and Procedure for Reconstitution of Neurotoxin

General Principles:

1. Have an established policy for specific injectables that require reconstitution regarding concentration of reconstituted product according to "X" units per cc of injectable, i.e. BOTOX® Cosmetic will be reconstituted with X cc of saline to produce a concentration of XX units/cc for patient use. Generally, a standardized dilution regimen for neurotoxins of "X" units per ml. helps prevent mistakes in dosing.
2. Use of quick reference cards that define volumes of diluent liquid used for reconstitution of specific injectables (Produce in MS Word, laminate in plastic, have available at nursing station where injectables are reconstituted. If different brands of neurotoxins are being used in the same clinical situation, consider printing the quick reference cards on different colors of paper to prevent mistakes).

Procedure for Reconstitution of Injectables:

1. Wash hands
2. Cleanse work surface with germicidal cleaner
3. Identify product, remove from packaging, verify lot # and expiration date of un-reconstituted product.
4. Do not reconstitute two different brands of neurotoxins simultaneously in order to avoid mistakes
5. Cleanse vial tops with alcohol-impregnated pad
6. Reconstitute injectable according to office policy regarding sterile technique and planned concentration of reconstituted product
7. Dispose of syringes/needles in red medical waste box
8. Label vial:
    a. Concentration of reconstituted injectable
    b. Date of reconstitution
    c. Date of expiration
9. Complete log form to document: lot # reconstitution date, concentration, expiration date
10. Utilize injectable product according to labeling or off-label, discard unused/expired product and vial as medical waste

What is needed here: Quick Reference Tables For Reconstitution of Specific Brand Neurotoxin, Neurotoxin Reconstitution Form

Resources for supplies:

a. TimeMed Labels (www.timemed.com) TimeMed will make custom stick-on labels. Alternatively, simple mailing labels (Avery) can be used with MS Word to produce specific labels to identify neurotoxins
b. Rubbermaid™ or Snapware™ plastic containers with lid
c. Label maker - Brother or Casio brand (office supply store)
d. Sharpie™ micro tip marker

4. Policy for On-label and Off-label Neurotoxin Use

1. On label: Administer neurotoxin in a specific anatomic area, according to labeling. Use neurotoxin vial labeled “for single patient use” “use within “X” time period,” with wastage of unused product according to labeling. If the vial is labeled as a “multi-use vial,” it may be used in this manner, with appropriate infection control precautions.
2. Off-label use: Administer neurotoxin for an indication not in the approved labeling. Use neurotoxin vial labeled “for single patient use” “use within “X” time period” for multiple patients (splitting of vial contents) and beyond labeled time for use.

a. Alternative Procedure "1" - use vial as a "multi-use" vial, with multiple product withdrawals, each with a new needle/syringe
b. Alternative Procedure "2" - split vial contents into sub-units, with storage in capped syringes that are appropriately labeled

Establishing an Expiration Date for Reconstituted Injectables

1. On-label use - establish expiration date according to labeling
2. Off-label use - establish an expiration date "XX" days post reconstitution as part of your office policies and procedures.
3. Ensure that reconstituted product will not be used beyond established expiration date and that unused product reaching expiration date will be discarded as medical waste

Knowledge base regarding off-label use and storage:

Peer-reviewed scientific articles from medical literature give information regarding off-label storage reconstituted neurotoxins and use beyond labeled "use within "X" hours" and demonstrate that with proper sterile technique that microbial growth within the vial of reconstituted product does not occur.

Maintenance of potency and Lack of documented microbial growth

References:

Parsa AA, Lye KD, Parsa FD. Reconstituted botulinum type a neurotoxin: clinical efficacy after long-term freezing before use. *Aesthetic Plast Surg*. 2007 Mar-Apr;31(2):188-91; discussion 192-3.
In contrast to common belief, reconstituted BoNTA may be frozen, thawed, and injected without losing its potency for up to 6 months, with efficacy equivalent to that of freshly prepared BoNTA.

Krishtul A, Lamba A, Bottone EJ, Gordon M. Lack of Microbial Contamination After Prolonged Storage of Partially Used Botulina Toxin A Preparations. *Cosmet Dermatol*. 2002:15(9); 61-64.
25 vials of BTX-A were reconstituted with unpreserved saline and refrigerated at 2 to 8 degrees C for 6 hours to 62 days. After storage, all vials were cultured and tested negative for microbial contamination.

Alam M, Yoo SS, Wrone DA, White LE, Kim JY. Sterility assessment of multiple use botulinum A exotoxin vials: a prospective simulation, *J AM Acad Dermatol*. 2006 Aug;55(2):272-5.
Routine refrigerator storage of medication vials containing reconstituted botulinum toxin does not result in microbial contamination of the contents even after serial re-extraction of solution from these vials, and after handling of such vials by multiple personnel. Storage and subsequent reuse of botulinum toxin appears safe for at least 7 weeks after reconstitution.

Hexsel DM, De Almeida AT, Rutowitsch M et al. Multicenter, double-blind study of the efficacy of injections with botulinum toxin type a reconstituted up to six consecutive weeks before application. *Dermatol Surg*. 2003 May;29(5):523-9.
BTX-A may be applied up to 6 weeks after reconstitution without losing its effectiveness.

Garcia A, Fulton JE Jr. Cosmetic denervation of the muscles of facial expression with botulina toxin, a dose-response study. *Dermatol*. 1996 Jan;22(1):39-43.
Toxin that was reconstituted 30 days produced the same loss of muscle tone as freshly mixed toxin.

Sloop R, Cole BA, Escutin RO. Reconstituted Botulina Toxin Type A Does Not Loose Potency In Humans If It is Refrozen or Refrigerated For Two Weeks Before Use. *Neurology*. 1997:48(1); 249-253.
Reconstituted BTX-A that is subsequently refrigerated or refrozen for two weeks does not lose potency in humans.

Paik NJ, Seo K, Eun HC. Reduced potency after refrigerated storage of botulitum toxin a: human extensor digitorum brevis muscle study movement disorders. *Mov Disord.* 2006 Oct;21(10):1759-63.
Mean compound muscle action potential amplitudes expressed as a percentage of the baseline amplitude were more reduced in sides injected with immediately reconstituted BTA than in sides injected with BTA stored for 1 week or more (P < 0.05). No bacterial growth was observed in any stored BTA samples.

5. Policy for On-label and Off-label Tissue Filler Use

On label use tissue filler according to labeling regarding a specific anatomic area.

Off-label use tissue filler for an indication not in the approved labeling

Source: US FDA http://www.fda.gov/OC/OHRT/IRBS/offlabel.html

"Off-Label" Use of Marketed Drugs, Biologics and Medical Devices

Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment. If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects. Use of a marketed product in this manner when the intent is the "practice of medicine" does not require the submission of an Investigational New Drug Application (IND), Investigational Device Exemption (IDE) or review by an Institutional Review Board (IRB).

Physicians are not permitted to advertise off-label usage of drugs or devices, as the decision to use them for an indication not in the approved labeling is determined following the establishment of a physician-patient relationship and determination of a therapeutic plan. It is important to document in your medical record the decision to use drugs and devices off-label and to incorporate this into informed consent discussions.

While physicians may discuss off-label usage of drugs and devices as part of CME-related activities, there have been instances of severe penalties and criminal prosecution when off-label usage is promoted during speaker bureau or similar marketing activities. Be certain that issues of compliance with applicable regulations of promotion of drugs and devices are followed.

6. Patient Care Pathway for Safe Administration of Injectables

1. Obtain medical history including stated interest in undergoing treatment with cosmetic or therapeutic injectable product
    a. List of medications, including non-prescription NSAID, herbs, etc
    b. List of allergies, including latex

2. Perform a focused physical examination regarding the use of injectables
3. Develop treatment plan:
    a. Review contraindications including patients taking anticoagulants, anti platelet drugs (Plavix®, aspirin, non steroidal anti inflammatory)
    b. If this is a repeat injection, make assessment of effect and duration of earlier injection treatments, with adjustments/fine tuning as needed
4. Photographic documentation pre/post injection, including animated views if neurotoxin is being injected
5. Informed consent document
6. Documentation of treatment
    a. Attach or enter label information to medical record, containing lot #, date of reconstitution, concentration, expiration date,
    b. Document amount of product used and anatomic location(s) of injections
    c. Disposal of medical waste
7. Follow up call-quality assurance/patient satisfaction/schedule touch up injection if necessary
8. Process for documentation and management of AE's if they occur

7. Emergency Situations that Involve injectables

Occasionally, patients will experience physiologic responses to cosmetic injectables such as a vasovagal episode or tachycardia. While these are generally self-limiting, there is the need to manage these events in order that no harm come to your patient. Individuals who experience vasovagal episodes can be injured if they fall and strike the floor. Develop office policies and procedures for situations of vasovagal episodes, tachycardia and similar events.

Other types of events may be more uncommon such as lightheadedness or tachycardia that relates to local anesthetic injections containing epinephrine that may be used for nerve blocks or direct infiltrations prior to filler injections and light-based procedures.

Most surgical offices have crash carts with equipment for monitoring ECG, SaO2, blood pressure. Supplemental oxygen/ventilation bag also may be necessary during an event. IV access and medications also may be a consideration if there is an event that requires immediate treatment (anaphylaxis, cardiac arrest, seizure, etc). Otherwise, if a severe event occurs during an injection, it may require calling 911 for paramedic transport to the hospital.

Staff training regarding emergency situations that may occur during cosmetic injection procedures is an additional consideration in developing a comprehensive process of patient safety. Periodic review of emergency procedures and response to situations may be a consideration.

In addition to the aforementioned emergency situations, preparation for adverse events associated with injectables such as accidental intra-arterial injection, skin blanching from arterial occlusion in the lip area, "allergic/anaphylactic" reactions and extremely rare granulomas occurring after cosmetic injectables is a good idea. The Safety With Injectables Workbook contains an Adverse Event form to document the occurrence. Additional considerations would consist of having requisite emergency medications such as parenteral steroids, antihistamines, nitroglycerine paste, low molecular weight heparin, intravenous acetozolamide, hyaluronidase available in the office, depending on the extent of usage of cosmetic injectables. We acknowledge the input of Claudio DeLorenzi, MD from Toronto, Canada on this subject.

The workbook chapter on Adverse Events contains a variety of published references relating to management of injection-related AE's.

The Idea in Brief

The importance of having policies and process for infection control when using injectables will prevent disease transmission. Safety engineering will prevent mistakes in medication administration: important references from the Center for Disease Control (CDC) are listed regarding management of needle sticks and exposure to blood/body fluids.

The Role of Infection Control and Safety Engineering

The Center for Disease Control (CDC) defines these as "Never Events" in which there were breaches in injection safety and infection control. Injection safety includes practices intended to prevent transmission of infectious diseases between one patient and another, between a patient and healthcare provider, and also to prevent harm such as needle stick injuries or exposure to blood-borne pathogens. Safety engineering processes involve steps taken to prevent mistakes in administering injectables to prevent mistakes in administering the wrong injectable, wrong concentration, and incorrect site of injection. The combination of practices to prevent disease transmission and errors with injectables is something that every practice needs.

Disease transmission can be virtually eliminated if there are established policies and procedures regarding:

- Hand washing and sanitation of work surface where injectables are prepared
- Aseptic technique in the handling, reconstitution, and administration of injectables
- Not leaving needles/syringes inserted into vials - this is a direct route for microbial contamination of vial contents
- Non reuse of needles, syringes, or gel cooling packs that have had patient contact (dispose as medical waste)
- Never allowing a needle/syringe that has had patient contact to be reinserted into the medication vial or IV bag/IV line
- Never recap and store a partially-used syringe of injectable material for future use by the same patient
- Medications should be discarded upon expiration or any time there are concerns regarding the sterility of the medication
- Leftover parenteral medications should never be pooled for later administration
- Use latex or nitrile gloves and universal precautions regarding needle stick injuries and exposure to blood and body fluid

In an ideal world, the contents of an injectable vial would be for a single patient and there would be no multi-use vials. In reality, medication sharing occurs as a common practice. Multi-use vials such as vaccines or local anesthetics are commonly used to treat multiple patients. Other situations relate to a single patient use vial that is split between several patients in an off-label fashion. An example of this is the use of a 100 unit vial of BOTOX Cosmetic® as a multi-use vial. The CDC views these practices with great concern because of the possibility of disease transmission due to breaches in injection safety and infection control. While a vial may be partially used by a single patient and unused product discarded, this becomes a very expensive process.

Provided that all of the precautions listed above are taken, the risk of disease transmission when a vial is split into sub-units is very low. Studies in the medical literature in small series have reported that there is a lack of microbial contamination of vials reconstituted BOTOX® when sterile technique is utilized to withdraw individual aliquots for patient use. Establish within your practice specific policies and procedures regarding the handling, reconstitution, and administration of injectables to prevent disease transmission. Once implemented, these will provide a framework that documents safety and minimizes mistakes.

Emergency Information Regarding Needlestick Injuries and exposure to blood/body fluid:

The Center for Disease Control (CDC) and the National Institute for Occupational Safety and Health (NIOSH) have the following resources regarding needlestick and exposure to blood/body fluids:

Internet-based Resources:

- CDC-NIOSH Blood borne Infectious Disease Home Page:
  http://www.cdc.gov/niosh/topics/bbp/default.html
- Recommendations for Management of Occupational Exposures to Blood
  http://www.cdc.gov/mmwr/PDF/rr/rr5011.pdf
- Emergency Needle stick Information
  http://www.cdc.gov/niosh/topics/bbp/emrgnedl.html
- Post Exposure Prophylaxis Hotline (24Hr.)
  http://www.nccc.ucsf.edu/Hotlines/PEPline.html

The Idea in Brief

Safety engineering can help prevent errors and mistakes in the use of cosmetic and therapeutic injectables. Simple steps are identified that can be implemented by every clinic to help avoid injecting the wrong drug, wrong concentration and wrong site.

Injectables: Safety Engineering to Reduce Risk of Errors and Mistakes: Neurotoxins and Fillers

This chapter of the workbook is focused on safety engineering to prevent errors in administering the wrong injectable in an incorrect concentration, and in the wrong location.

For many years, there has been only one approved neurotoxin, BOTOX®/BOTOX® Cosmetic (Allergan, Irvine, CA) available in the United States. With the approval of DYSPORT®, there becomes the possibility of mistaking it for BOTOX Cosmetic®. Both DYSPORT® (Ipsen-Medicis, Scottsdale, AZ) and BOTOX®/BOTOX® Cosmetic are unique neurotoxins with slightly different performance characteristics and dosing requirements. Although equivalency ratios have been discussed in publications, it would be safer to use each neurotoxin as a unique drug versus mathematical exercises that could induce errors in dosing and safety.

Both of these drugs are clear, indistinguishable colorless liquids, once reconstituted. If both are being used within the same clinic, mistakes and errors could occur. It is a good idea to develop policies and procedures that would minimize the risk of mistaking these two; neurotoxins and producing adverse events if the wrong one were to be administered in the wrong concentration. Outside of the US, there may be four or more neurotoxins available for clinical use. There is no such entity as a "generic" neurotoxin, which can be used without consideration of pharmacokinetics and biologic response.

Steps can be taken to avoid mistakes in the use of similar neurotoxins:

- Store vials of neurotoxins in specific clear plastic boxes with lids (example: Rubbermaid® or Snapware™); label each box accordingly.
- When starting the process of reconstitution, identify product by brand, remove from packaging, verify lot # and expiration date of un-reconstituted product.
- Reconstitute each specific neurotoxin according to established policies for potency in terms of "XX" units per ml, with "X" ml of diluent to be used according to the specific neurotoxin. Do not simultaneously reconstitute both in order to avoid mistakes. Use a quick reference sheet that gives specific instructions and volume of diluent used to reconstitute each neurotoxin.

- Label syringes that contain a specific neurotoxin as to its brand, concentration, and established expiration date- It may be an excellent idea to obtain color-coded custom labels from one of the vendors that produces labels for healthcare (TimeMed Labels, www.timemed.com). Alternatively, Avery mailing labels can be produced with your computer's word processor that can be color coded and produced on a simple inkjet printer. If there is doubt as to the contents of a syringe of neurotoxin, it must be discarded.
- Utilize specific worksheets, templates, and informed consents for each brand of neurotoxin.
- Use quick reference sheets that detail dosing of each brand of neurotoxin, according to anatomic area.
- Verify visually and verbally that you are receiving a specific brand of neurotoxin from a subordinate when injecting a neurotoxin.
- Do not utilize conversion ratios in which you try to equate "X" units of one neurotoxin brand of equates to "Y" units of the other brand. Each neurotoxin is unique in its pharmacokinetics and effect, dosing regimen and longevity. Each one should be dosed according to training and your clinical experience with each patient, according to their individualized response.
- Even if you plan to only have one brand of neurotoxin available, consider having established policies and procedures regarding reconstitution of a specific neurotoxin at "XX" units per ml. This implies specific instructions regarding reconstitution of a vial of "XX" units with "X" ml of diluent liquid.

The most straightforward way to avoid mistakes with neurotoxins is to utilize only one of the approved brands versus having two different brands with different dosing requirements and performance characteristics. In reality, many practitioners may elect to have more than one brand of neurotoxin available, just like they do with having an assortment of tissue fillers. The important thing to remember is which one you are using and that you can document a process for its safe use through all persons who have had contact with this class of biological drugs

The other part of this discussion is focused on safety engineering to prevent errors in administering the wrong injectable in an incorrect concentration, and in the wrong location. Tissue fillers within the hyaluronic acid (HA) family look remarkably similar, yet with performance characteristics that are different. Other classification of tissue fillers such as calcium hydroxyl apatite, porcine collagen-based, and polymethylmecryalte microspheres probably should not be injected in the lips due to reports of lumpiness. While most fillers are used in an off-label fashion at the discretion of the physician to meet patient needs, training is needed to understand where a particular filler works optimally and what anatomic areas should be avoided.

adverse events with injectables

The Idea in Brief

Adverse events can occur when injectables are used for cosmetic or therapeutic purposes. Rarely occurring SAE's (serious adverse events) may occur. If adverse events occur, it is worthwhile to document their occurrence. While most AE's can be minor in nature and self-limited, more serious ones may rarely occur that need intervention.

Adverse Events With Injectables

While there is the possibility of adverse events (AE's) or serious adverse events (SAE'S) occurring every time that a cosmetic or therapeutic injectable is given, the probability of these occurring is small. Often times, normal occurrences associated with injections are wrongly considered to be AE's.

Normal occurrences with injections:

- Bleeding and Bruising
- Swelling
- Erythema (Skin Redness)
- Needle marks
- Acne-like skin eruptions
- Skin Lumpiness
- Asymmetry
- Pain

AE's and SAE's associated with injectables would consist of the following:

- Scarring
- Hyperpigmentation/Hypopigmentation
- Infection
- Damage to deeper structures
- Visible Tissue Filler Material
- Accidental Intraarterial injection
- Vision loss
- Skin Necrosis
- Granulomas
- Allergic Reactions and Hypersensitivity, Anaphylaxis
- Migration of Tissue Filler or Neurotoxin
- Chronic Inflammation, Lymphedema, Nodules, Tissue Stiffness (reported with PMMA permanent fillers, Selles, PRS, 2008)

Information supplied by manufacturers in the packaging (DFU, directions for use) contains information regarding the occurrence of AE's and SAE's from clinical studies. Other factors that may be involved are specific anatomic location, type of filler, and experience level of the injector. Published reports in the peer-reviewed medical literature can be used to reference additional AE's and SAE's.

Unsatisfactory Result

At all times, there is the possibility that cosmetic or therapeutic injections alone may not produce an outcome that meets patient expectations for improvement in wrinkles or soft tissue depressions. There is the possibility of a poor or inadequate response. Additional injections may be necessary. Surgical procedures or other treatments may be recommended in additional to tissue filler treatments. For these reasons, an unsatisfactory result can occur without AE's or SAE's.

The sample informed consents that are part of the Safety With Injectables™ workbook contain explanations of potential AE's, SAE's, and normal occurrences associated with injectables. The possibility of an unsatisfactory outcome is addressed. Patients must acknowledge that they have been informed about risk and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all future treatments.

Documentation and Management of AE's and SAE's

Just as you have a process for patient evaluation and planning for the use of injectables, a process to evaluate and treat AE's and SAE's is needed. The workbook contains templates for documenting AE's and SAE's. A quality improvement/patient satisfaction form may also be used here.

If an AE or SAE occurs, try to document it as completely as possible, including photography. The importance of good patient communication and frequency of follow up care must be emphasized. Most of the normal occurrences associated with injections are self-limited and patients need supportive care. AE's and SAE's require more careful treatment and possibly other treatments/procedures. The judicious use of consultants and second opinions to help manage AE's and SAE's is often helpful.

Depending on the AE or SAE, there can be some exacting treatments needed. A reasoned, document approach is optimal versus defaulting to a steroid injection because it is the only tool available. Contact the manufacturer for additional treatment resources and to report the AE/SAE event.

The Toyota Production System's process of asking why may lead to an explanation of AE's and SAE's. Such a process is helpful to gain understanding of the mechanism of AE's and how to prevent them in the future.

While the possibility of anaphylaxis and other serious events from injectables is rare, make certain that your office crash cart has necessary supplies (epinephrine, antihistamines, IV fluids, airway support/ventilator bag, and oxygen). Staff training to recognize and manage serious events must be ongoing.

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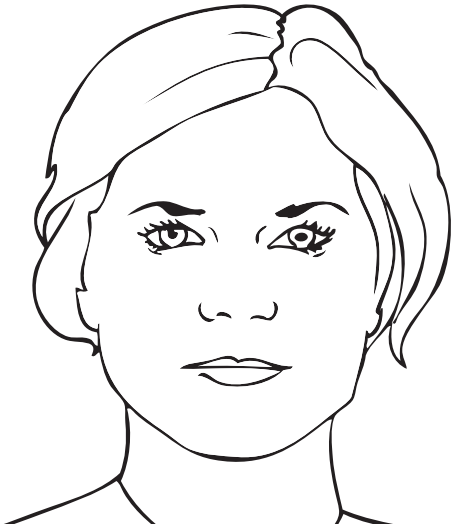
Adverse Event Report Injectables

Date: _____

Name: _____



Description of Adverse Event: _____

_____

Documentation: _____

Injectable, lot #, units/amount administered _____

Severity: _____

Remedy: _____

Follow up: _____

Form completed by:_____

patient satisfaction with injectables

The Idea in Brief

Patient satisfaction with the use of cosmetic or therapeutic injectables is paramount to continued success in cosmetic medicine. The quality of the patient's experience determines the suitability of these treatments as something that they are willing to endure on a repeated basis. Besides patient satisfaction, the quality of the outcome is important from a technical perspective. Quality improvement when using injectables should be an ongoing process.

Quality Improvement/Patient Satisfaction With Injectables

Patient satisfaction with cosmetic and therapeutic injectables is essential to the ongoing success of their use within your practice. Quality improvements should be ongoing. The process should be monitored from the perspective of patient satisfaction, occurrence of adverse events, technical issues, and ways to improve both outcomes and the patient's experience. There should also be ways of solving problems associated with the administration of injectables.

While there is the possibility of adverse events (AE's) or serious adverse events (SAE'S) occurring every time that a cosmetic or therapeutic injectable is given, the probability of these occurring is small. Often times, normal occurrences associated with injections are wrongly considered to be AE's. Even if it's a normal occurrence, it can cause dissatisfaction. Communication skills are necessary to help accurately portray what generally will happen with the use of injectables. Informed consent documents are also necessary to accurately describe both normal and adverse events.

At all times, there is the possibility that cosmetic or therapeutic injections alone may not produce an outcome that meets patient expectations for improvement in wrinkles or soft tissue depressions. There is the possibility of a poor or inadequate response. Additional injections may be necessary. Surgical procedures or other treatments may be recommended in addition to tissue filler treatments.

For these reasons, an unsatisfactory result and dissatisfaction can occur without AE's or SAE's. Just as you have a process for patient evaluation and planning for the use of injectables, there must also be a process to evaluate patient satisfaction and improve quality. A quality improvement/patient satisfaction template is included in the workbook materials.

Other approaches to improve quality and patient satisfaction involve service mapping to understand the steps and resources needed for the use of injectables and patient surveys.

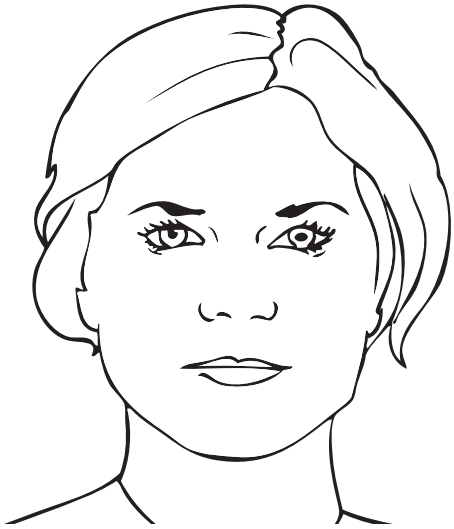
Consider using a simple survey regarding comfort during the procedure and the patient's perception of their outcome. From a technical perspective, you may want to document how often you need to perform secondary treatments for "touch ups" or the effectiveness of topical versus nerve blocks for patient comfort. Patient satisfaction and quality are two important parts of the process for using injectables. Improvements and fine tuning is possible if you have a process that incorporates patient feedback and outcome data.

The ability to deliver operational excellence and high level of patient satisfaction when using injectables will differentiate Core trained injectors from others. This in addition to the other components of the *Safety With Injectables™* workbook will help you and your staff achieve better, safer outcomes with injectables.

Quality Assurance-Patient Satisfaction Template

Date: _____

Name: _____



Injectable used, lot #, units/amount, anatomic area: _____

_____

Initial Quality Assessment: Satisfaction/Dissatisfaction: _____

_____

Interval Supplemental Injection?: _____

Recommendation for future treatment: _____

Form completed by: _____

informed consent

a. Risk Mitigation With Neurotoxins

b. FDA DYSPORT® Medication Guide

c. Neurotoxin Consent

d. HA Filler Consent

e. Calcium Hydroxylapatite Filler Consent

f. PMMA Filler Consent

g. Poly-l Lactic Acid Consent

h. Kybella Consent

The Idea in Brief

Within this monograph are two sample informed consents for a neurotoxin and hyaluronic acid tissue filler. These can serve as a framework for an informed consent process within your office. The consents can be adapted and customized to specific brands of neurotoxins and fillers.

Informed Consent and Injectables

There are many different approaches to informed consent for surgical procedures and treatments. Each state has specific requirements for informed consent that must be followed when practicing medicine. In most situations the P-A-R-Q process of discussion of the proposed procedure, listing alternatives, discussion of risk, and answering of questions is the accepted format. While informed consent for a procedure or treatment may be short and fit on a single page of paper, it may not contain specific discussions apropos to the use of injectables. A more detailed informed consent document may be helpful for risk disclosure and delineation of responsibilities.

Each patient processes information differently and informed consent discussions must be accomplished in a way that patients understand both the potential benefits and risks associated with a treatment. Additionally, discussions of financial responsibility are important regarding the potential need to undergo supplementary injections to enhance the results from the initial injection or responsibility for the cost of treating adverse events following use of injectables.

Disclosure of off-label practices regarding indications for injectables outside of labeling is important. It is also a good practice to disclose vial-splitting practices with appropriate safety precautions and the use of reconstituted neurotoxins beyond the manufacturer's established time limit after reconstitution.

The process of informed consent when using injectables is straightforward. Have the patient read the consent, initial each page, and sign the last page. A witness must also sign the last page of the consent.

Within this workbook are generic informed consent templates for:

- > Generic neurotoxin
- > Hyaluronic acid tissue filler
- > Poly-l lactic acid tissue filler
- > Calcium hydroxyapatite tissue filler
- > Polymethylmethycrylate permanent tissue filler
- > Deoxycholate for Injectable Lipolysis

These documents represent a framework for you to produce your own customized informed consents for specific neurotoxins and hyaluronic acid fillers. Feel free to customize the language, add or delete risk information, etc. Refer to manufacturer's DFU (directions for use) and published literature reports for additional information regarding risk, adverse events, and advisories from the FDA regarding "Black Box Warnings" for neurotoxins. These generic consents can be customized for approved tissue fillers or neurotoxin brand.

Suggestions for producing customized informed consents:

Designate a font and font size for the document. The default font is Arial 10 point size. Sans-serif fonts such as Arial or Calibri are easier to read than Times Roman or Courier. Insert a customized header that gives the name of your practice/clinic Insert your name on the last page of the consent "I hereby authorize Dr._____."

Microsoft Word has a specific find and replace utility (Ctrl-F) that will locate the generic terminology as BONTA and HA in the consents and replace it with brand names such as BOTOX® Cosmetic or DYSPORT® when using neurotoxins or Juvederm Ultra™/UltraPlus™ or Restylane™/Restylane Lyft™ when using hyaluronic acid origin tissue fillers. Specific consent documents and treatment templates for each product help reduce medication errors and mistakes.

BE CERTAIN to proofread the document in order to make certain that it is grammatically correct. When performing a find and replace operation within MS Word, normal words such as "has" may become garbled when you instruct the program to replace HA with one of the known brand names of hyaluronic acid fillers. It may appear as "Restylanes" or "Juve'derms."

PMMA, Bellafill® - Permanent Tissue Filler

An informed consent template for the use of PMMA is included within the workbook, designed for colleagues who are international members and candidates of ASAPS. This consent template would not be applicable in countries where PMMA fillers are no longer sold. Their web site is: http://www.bellafill.com/

The Idea in Brief

The US FDA has determined that Botulinum neurotoxins have the possibility of producing serious adverse events (SAE's) and/or adverse events (AE's). The agency has placed its strongest "boxed warning" on this class of biological and has required a risk evaluation and mitigation strategy (REMS) which includes a patient medication guide to be distributed with the product by the dispensing physician. DYSPORT® (abobotulinumtoxinA) was recently approved with this stipulation; BOTOX®/BOTOX® Cosmetic and Myobloc® will require similar warnings. While it is important to distinguish between the high-unit dosing for functional neuromuscular disorders and the low-unit dosing for cosmetic wrinkle treatments, all of the biologics in this class nevertheless carry these warnings. Communication strategies to address patient questions are an integral part of informed consent for their use.

Risk Evaluation and Mitigation Strategies for Neurotoxins - Foreward/Introduction: Risk Mitigation (7)

The recent release of DYSPORT®, the second FDA approved neurotoxin designed to treat glabellar wrinkles, it is useful to consider the "boxed warning" as it relates to cosmetic patients. It is very clear that botulinum toxin A used for treatment of cosmetic concerns is amongst the safest in clinical medicine. BOTOX® and BOTOX® Cosmetic are often used synonymously when it comes to public perception, an important false medical myth. Neurotoxins have been used for more than 30 years to treat a variety of medical conditions, including the treatment of individuals with severe underlying medical conditions that render them "high risk patients" for medical treatments in general. To confuse the use of high dose botulinum toxin for severe, life-impairing conditions with the use of low doses for cosmetic conditions is not appropriate. This lack of differentiation has led to much confusion in the media and amongst physicians in general. It is because of this confusion, we have put together the current material.

In January 2008, a public health advocacy group, Public Citizen reported to the FDA on approximately 16 deaths that were alleged to be related to the use of BOTOX® in the treatment of functional neuromuscular disorders such as cervical dystonia. This involved the alleged injection of high-unit amounts of neurotoxin in compromised patients. According to the Botox® Cosmetic DFU, there was a single patient who died from a fatal case of anaphylaxis in which lidocaine was used as the diluent and consequently the causal agent cannot be reliably determined.

In response to concerns of deaths allegedly associated with the use of neurotoxins to treat functional disorders, the FDA has taken two steps, that of placing a "boxed warning" on all Botulinum neurotoxin containing products and requiring a risk evaluation and mitigation strategy be implemented for this class of biologics.

A "boxed warning" is a type of warning that appears on the package insert for prescription drugs/biologicals that may cause serious adverse effects. It is so named for the black border that usually surrounds the text of the warning. This warning means that medical studies indicate that the drug carries a significant risk of serious or even life-threatening AE's or SAE's. The U.S. Food and Drug Administration (FDA) can require a pharmaceutical company to place a "boxed warning" on the labeling of a prescription drug and in literature describing its use. It is the strongest warning required by the FDA. There are many drugs that carry these warnings, such as Depo-Provera® for bone loss, Warfarin for bleeding, Retinoids for teratogenic potential and Fluoroquinolone antibiotics for tendon rupture.

A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage a known or potential serious risk associated with a drug or biological product. A REMS will be required if FDA finds that a REMS is necessary to ensure that the benefits of the drug or biological product outweigh the risks of the product, and FDA notifies the sponsor. REMS can include a Medication Guide, Patient Package Insert, a communication plan, elements to assure safe use, and an implementation system, and must include a timetable for assessment of the REMS. Some drug and biological products that previously were approved/licensed with risk minimization action plans (Risk MAPs) will now be deemed to have REMS. http://www.fda.gov/cder/regulatory/FDAAA/FR_QA.htm.

Safe use of injectables such as the neurotoxins to treat cosmetic or functional problems does require a discussion with patients regarding the "boxed warning" and the Medication Guide portion of the REMS. Taken at face value, the REMS medication guide for neurotoxins is potentially frightening to patients in terms of all of the SAE's that might occur following neurotoxin injections. As a document, it lacks balance between mention of the benefits of therapeutic use of neurotoxins and patient satisfaction with outcomes. Most patients do not have the background to process the information contained within this document and to

understand that given millions of neurotoxin injections over many years, there were SAE's and AE's seen in compromised patients who received large-unit injections to treat functional neuromuscular disorders. This is a completely different situation of small-unit injections of neurotoxin for the cosmetic treatment of wrinkles or excessive sweating.

While it is recommended to discuss both the "boxed warning" and the REMS medication guide with patients, each patient processes information differently and informed consent discussions must be accomplished in a way that patients understand both the potential benefits and risks associated with a treatment. Much of this comes down to what would the reasonable person want to know.

Discussions with patients center around specific dimensions of risk:

1. What are the pertinent undesirable outcomes? (Identification)
2. How permanent is the potential undesirable outcome? (Permanence)
3. When might the unwanted outcome occur? (Timing)
4. What is the probability of the unwanted outcome? (Probability)
5. How significant is the unwanted outcome to the patient? (Subjective badness)

Patients commonly misinterpret risk:

- Personal values, biases, and media influences (I read on the web that patients die after neurotoxin injections)
- Anchoring bias estimate their risks on the basis of familiar risks ("my aunt had eyelid ptosis after neurotoxin injection")
- Overestimate a risk factor that has achieved notoriety in the media (death)
- Compression bias (overestimating small risks and underestimating large risks)
- Miscallibration of confidence (this will not happen to me)

The question comes then on how outcome data should be presented to patients? It has been shown a long time ago that how these risks are presented will influence decision making. In most situations, qualitative expressions are often more "accessible" to consumers or patients, i.e. "the risk of eyelid ptosis following cosmetic neurotoxin is low" or the risk of eyelid ptosis following cosmetic neurotoxin is less than 3%. Even physicians have trouble sometimes when it comes to talking about relative risk, quantitative risk, attributable risk and the range of confidence associated with statistical evaluation of risk. Other risk dimensions center around how the patient interprets the occurrence as "dreaded" versus something totally "unknown".

This represents useful information that injectors can use to discuss risk-related matters with patients contemplating cosmetic neurotoxin injections. BOTOX® Cosmetic is indicated for the temporary improvement in the appearance of moderateto severe glabellar lines associated with corrugator and/or procerus muscle activity in adultpatients 65 years of age. BOTOX® Cosmetic is also indicated for the temporary improvement in the appearance of moderate to severe lateral canthal lines, known as crow's feet, in adult patients 65 years of age. Xeomin™ and Dysport™ are also FDA-approved neurotoxins. For full details, please see the individual product full package inserts. It is incumbent upon the injector being familiar with the individual directions for usage and safety profile of every cosmetic injectable used.

Instructions

This is an informed-consent document which has been prepared to help inform you concerning cosmetic Botulina-Origin Neurotoxin Type A neurotoxin injections, their 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 this procedure as proposed by your physician

Instruction

Clostridia botulina bacteria produce a class of chemical compounds known as “toxins.” The Botulina-Origin Neurotoxin Type A “BONTA” is processed and purified to produce a sterile product suitable for specific therapeutic uses. Once the diluted toxin is injected, it produces a temporary paralysis (chemodenervation) of muscle by preventing transmission of nerve impulses to muscle.

BONTA has been used to treat functional disorders that involve muscle spasticity and cosmetic conditions of muscle-induced skin wrinkles of the forehead. It has been used in an “off-label” manner to treat facial wrinkles, excessive sweating, migraine headaches, and colorectal disorders.

Cosmetic BONTA intramuscular injections are customized for every patient, depending on their needs. BONTA cannot stop the process of aging. It can however, temporarily diminish the look of wrinkles caused by muscle groups or treat other conditions.

US Food and Drug Black Box Warning regarding the administration of neurotoxins:

Distant Spread of Toxin Effect Post marketing reports indicate that the effects of all Botulina toxin products may spread from the area of injection to produce symptoms consistent with Botulina toxin effects. This may include asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, and breathing difficulties. These symptoms have been reported hours to weeks after injections. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity, but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have underlying conditions that would predispose them to these symptoms. In unapproved uses, including spasticity in children and adults, and in unapproved indications, cases of spread of effect have been reported at doses comparable to those used to treat cervical dystonia and at lower doses.

Alternative Treatments

Alternative forms of management include not treating the skin wrinkles by any means. Improvement of skin wrinkles may be accomplished by other treatments or alternative types of surgery. Minor skin wrinkling may be improved through chemical skin-peels, lasers, injection of filling material, or other skin treatments. Risks and potential complications are associated with alternative forms of treatment.

Risks Of Bonta (Botulina Type A Toxin) Injections

Every procedure involves a certain amount of risk, and it is important that you understand the risks. Your decision to undergo this procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience the following complications, you should discuss each of them with your physician to make sure you understand the risks, potential complications, and consequences of BONTA injections to improve facial wrinkling.

Bleeding - It is possible, though unusual, to have a bleeding episode from a BONTA injection. Bruising may occur. Serious bleeding around the eyeball during deeper BONTA injections for crossed eyes (strabismus) has occurred. Should you develop post-injection bleeding, it may require emergency treatment or surgery. Do not take any aspirin or anti-inflammatory medications for seven days before BONTA injections, as this may contribute to a greater risk of bleeding.

Damage to deep structures - Deeper structures such as nerves, blood vessels, and the eyeball may be damaged during the course of BONTA injection. Injury to deeper structures may be temporary or permanent.

Pain - Discomfort associated with BONTA injections is usually short in duration. It is possible to have a fainting episode (vasovagal) from discomfort or anxiety about the injections. Headaches have been reported post BONTA injection.

Migration of BONTA - BONTA may migrate from its original injection site to other areas and produce temporary paralysis of other muscle groups or other unintended effects (see FDA “Black Box” warning page 1).

Skin disorders - Skin rash and swelling may rarely occur following BONTA injection.

Eye-related problems:

- Corneal exposure problems - Some patients experience difficulties closing their eyelids after BONTA injections and problems may occur in the cornea due to dryness. Should this rare complication occur, additional treatments, protective eye drops, contact lenses, or surgery may be necessary.
- Dry eye problems - Individuals who normally have dry eyes may be advised to use special caution in considering BONTA injections around the eyelid region.
- Drooping Eyelid (Ptosis) - Muscles that raise the eyelid may be affected by BONTA, should this material migrate downward from other injection areas.
- Double Vision - Double vision may be produced if the BONTA migrates into the region of muscles that control movements of the eyeball.
- Eyelid Ectropion - Abnormal looseness of the lower eyelid can occur following BONTA injection.
- Other Eye Disorders - Functional and irritative disorders of eye structures may rarely occur following BONTA injections.
- Blindness - Blindness is extremely rare after BONTA injections. However, it can be caused by internal bleeding around the eyeball or needle stick injury.

Asymmetry -The human face and eyelid region is normally asymmetrical with respect to structural anatomy and function. There can be a variation from one side to the other in terms of the response to BONTA injection.

Unknown risks - The long term effect of BONTA on tissue is unknown. There is the possibility that additional risk factors may be discovered.

Unsatisfactory result - There is the possibility of a poor or inadequate response from BONTA injection. Additional BONTA injections may be necessary.

Allergic reactions - As with all biologic products, allergic and systemic anaphylactic reactions may occur. Allergic reactions may require additional treatment.

Antibodies to BONTA - Presence of antibodies to BONTA may reduce the effectiveness of this material in subsequent injections. The health significance of antibodies to BONTA is unknown.

Long-term effects - Subsequent alterations in face and eyelid appearance may occur as the result of aging, weight loss or gain, sun exposure, or other circumstances not related to BONTA injections. BONTA injection does not arrest the aging process or produce permanent tightening of the eyelid region. Future surgery or other treatments may be necessary.

Risks of BONTA Injections, continued

Infection - Infection is extremely rare after BONTA injection. BONTA is contraindicated if there is an infection at the injection site.

Pregnancy and nursing mothers - Animal reproduction studies have not been performed to determine if BONTA could produce fetal harm. It is not known if BONTA can be excreted in human milk.

Drug Interactions - The effect of BONTA may be potentiated by aminoglycoside antibiotics or other drugs known to interfere with neuromuscular transmission.

Off-label usage of BONTA - BONTA, depending on its manufacturer is labeled for specific use. The use of BONTA for other conditions and disorders would be considered "off-label" usage by your physician. FDA defines off label use as, "Use for indication, dosage form, dose regimen, population or other use parameter not mentioned in the approved labeling." The FDA recognizes that off label use of drugs by prescribers is often appropriate and may receive endorsement from published literature. BONTA may be used according to a physician's
practice beyond the manufacturer's time limit following reconstitution. Contents of a BONTA vial may be split into sub-units and given to multiple patients, using appropriate sterile technique and precautions.

Health Insurance

Most health insurance companies exclude coverage for cosmetic surgical procedures and treatments or any complications that might occur from the same. Please carefully review your health insurance subscriber information pamphlet.

Additional Treatment Necessary

There are many variable conditions in addition to risk and potential complications that may influence the long term result of BONTA injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with BONTA injections. Other complications and risks can occur but are even more uncommon. Should complications occur, other treatments may be necessary. 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.

Financial Responsibilities

The cost of BONTA injection may involve several charges. This includes the professional fee for the injections, follow up visits to monitor the effectiveness of the treatment, and the cost of the BONTA product. It is unlikely that BONTA injections to treat cosmetic problems would be covered by your health insurance. Additional costs of medical treatment would be your responsibility should complications develop from BONTA injections. You may require additional treatments with BONTA to enhance the effect of the initial treatment.

Disclaimer

Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or 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. Your physician may provide you with additional or different information which is based on all of the facts pertaining to your particular case and the state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of 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 of your questions answered before signing the consent on the next page.

CONSENT FOR SURGERY/PROCEDURE or TREATMENT

1. I hereby authorize Dr._____ and such assistants as have been selected to perform the following procedure or treatment:

   I have received the following information sheet:
   INFORMED-CONSENT for BONTA Injection
   Medication Guide Document for Neurotoxins

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 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 at the time the procedure is begun.
3. I consent to the administration of local anesthesia (regional nerve blocks , direct infiltration, or topical) to diminish discomfort of injection.
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 or televising 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 treatment room.
7. 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 (1-7). I AM SATISFIED WITH THE EXPLANATION.

_____
Patient or Person Authorized to Sign for Patient

_____
Date Witness

hyaluronic acid tissue fillers (ha)

Instructions

This is an informed-consent document which has been prepared to help inform you concerning HA Tissue Filler injection therapy, 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 this procedure as proposed.

Introduction

Hyaluronic acid is a naturally occurring substance that is found within all mammals. It is a material that is contained in various soft tissues. Hyaluronic acid is synthetically produced from a process of bacterial fermentation, chemically stabilized, and purified for use as an injectable soft tissue filler.

HA tissue filler has been approved to treat areas of facial wrinkling and soft tissue depressions.

HA tissue filler injections are customized for every patient, depending on their particular needs. These can be performed in areas involving the face and eyelid region, forehead, and lips. HA tissue filler cannot stop the process of aging. It can however, temporarily diminish the appearance of wrinkles and soft tissue depressions. HA tissue filler injections may be performed as a singular procedure, in combination with other treatments such as neurotoxins, or as an adjunct to a surgical procedure. HA tissue injections require regional nerve blocks or topical anesthetic to diminish discomfort. Soft tissue fillers produce temporary swelling, redness, and needle marks, which resolve after a few days time.

Continuing treatments are necessary in order to maintain the effect of tissue fillers over time. HA tissue filler once injected will be slowly absorbed by the body. The length of effect for tissue filler injections is variable.

Alternative Treatments

Alternative forms of management include not treating the skin wrinkles or soft tissue depressions by any means. Improvement of skin wrinkles and soft tissue depressions may be accomplished by other treatments: laser treatments, chemical skin-peels, other skin procedures, or dermabrasion, alternative types of tissue fillers, or surgery such as a blepharoplasty, face or brow lift when indicated. Risks and potential complications are associated with alternative forms of medical or surgical treatment.

Risks Of Ha Tissue Filler Injections

Every procedure to inject soft tissue filler materials involves a certain amount of risk, and it is important that you understand the risks involved. An individual's choice to undergo this procedure is based on the comparison of the risk to potential benefit. Although the majority

of patients do not experience the following, you should discuss each of them with your physician to make sure you understand the risks, potential complications, limitations, and consequences of HA tissue filler injections. Additional information may be obtained from the package-insert sheets supplied by the manufacturer.

Problems associated with the use of tissue fillers can relate to normal occurrences following tissue filler injections, or potential complications following tissue filler injections, including HA tissue filler. Additional advisory information should be reviewed by patients considering tissue filler treatments that involve HA tissue filler.

Normal occurrences during tissue filler injections, including HA TISSUE FILLER

Patients undergoing injections of HA tissue filler may normally experience the following events:

Bleeding and Bruising - It is possible, though unusual, to have a bleeding episode from an injection or local anesthesia used during the procedure. Bruising in soft tissues may occur. Should you develop post-injection bleeding, it may require emergency treatment or surgery. Aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, Vitamin E, Ginko biloba and other “herbs/homeopathic remedies” may contribute to a greater risk of a bleeding problem. Do not take any of these for seven days before injections. Bleeding and bruising can produce permanent tissue color changes.

Swelling - Swelling (edema) is a normal occurrence following the injections. It decreases after a few days. If swelling is slow to resolve, medical treatment may be necessary.

Erythema (Skin Redness) - Erythema in the skin occurs after injections. It can be present for a few days after the procedure.

Needle marks - Visible needle marks from the injections occur normally and resolve in a few days.

Acne-like skin eruptions - Acneiform skin eruptions can occur following the injection of tissue fillers. This generally resolves within a few days.

Skin Lumpiness - Lumpiness can occur following the injection of HA tissue filler. This tends to smooth out over time. In some situations, it may be possible to feel the injected tissue filler material for long periods of time.

Asymmetry - The human face and eyelid region is normally asymmetrical in its appearance and anatomy. It may not be possible to achieve or maintain exact symmetry with tissue filler injections. There can be a variation from one side to the other in terms of the response to HA tissue filler injection. This may require additional injections to improve your outcome.

Pain - Discomfort associated with tissue filler injections is normal and usually of a short duration. It is possible to have a fainting episode (vasovagal) from discomfort or anxiety about the injections.

Complications (adverse events)

Potential complications attributable to the injection of soft tissue fillers, including HA tissue filler:

Infection - Although infection following injection of tissue fillers is unusual, bacterial, fungal, and viral infections can occur. Herpes simplex virus infections around the mouth, can occur following a tissue filler treatment. This applies to both individuals with a past history of Herpes simplex virus infections and individuals with no known history of Herpes simplex virus infections in the mouth area. Specific medications must be prescribed and taken both prior to and following the treatment procedure in order to suppress an infection from this virus. Should any type of skin infection occur, additional treatment including antibiotics may be necessary.

Damage to deeper structures - Deeper structures such as nerves, blood vessels, and the soft tissues may be damaged during the course of injection. Injury to deeper structures may be temporary or permanent.

Visible Tissue Filler Material - It may be possible to see any type of tissue filler material that was injected in areas where the skin is thin.

Skin Necrosis - It is very unusual to experience death of skin and deeper soft tissues after HA tissue filler injections. Skin necrosis can produce unacceptable scarring. Should this rare complication occur, additional treatments, or surgery may be necessary.

Granulomas - Painful masses in the skin and deeper tissues after a HA tissue filler injection are extremely rare. Should these occur, additional treatments including antibiotics or surgery may be necessary. Granulomas may produce scarring within the skin and deeper structures.

Allergic Reactions and Hypersensitivity - As with all biologic products, allergic reactions may occur. Allergic reactions may require additional treatment. It is unknown if HA tissue filler is associated with serious systemic anaphylactic allergic reactions.

Antibodies to HA TISSUE FILLER - Presence of antibodies to HA tissue fillers may in theory reduce the effectiveness of this material or produce a reaction in subsequent injections. The health significance of antibodies to hyaluronic acid tissue fillers is unknown.

Accidental Intraarterial injection - It is extremely rare that during the course of injection, that tissue filler could be accidentally injected into arterial structures and produce a blockage of blood flow. This may produce skin necrosis in facial structures or damage blood flow to the eye, resulting in loss of vision. The risk and consequences of accidental intravascular injection is unknown and not predictable.

Under/Over Correction - The injection of soft tissue fillers to correct wrinkles and soft tissue contour deficiencies may not produce the desired outcome. The amount of correction may be inadequate or excessive. It may not be possible to control the process of injection of tissue fillers due to factors attributable to each patient's situation. If under correction occurs, you may be advised to consider additional injections of tissue filler materials. Over correction may require removal of tissue filler material.

Additional Advisories

Advisories for patients considering non-permanent tissue filler injections:

Off-label usage of HA - HA, depending on its manufacturer is labeled for specific use. The use of HA for other conditions and disorders would be considered "off-label" usage by your physician. FDA defines off label use as, "Use for indication, dosage form, dose regimen, population or other use parameter not mentioned in the approved labeling." The FDA recognizes that off label use of drugs by prescribers is often appropriate and may receive endorsement from published literature. HA may be used according to a physician's practice to treat other conditions.

Unsatisfactory Result - HA tissue filler injections alone may not produce an outcome that meets your expectations for improvement in wrinkles or soft tissue depressions. There is the possibility of a poor or inadequate response. Additional injections may be necessary. Surgical procedures or other treatments may be recommended in additional to tissue filler treatments.

Unknown Risks - There is the possibility that additional risks and complications attributable to the use of tissue fillers may be discovered.

Migration of Tissue Filler - Product may migrate from its original injection site and produce visible fullness in adjacent tissue or other unintended effects.

Drug and Local Anesthetic Reactions - There is the possibility that a systemic reaction could occur from either the topical or local anesthetic or epinephrine used for sensory nerve block anesthesia when tissue filler injections are performed. This would include the possibility of light-headedness, rapid heart beat (tachycardia), and fainting. Medical treatment of these conditions may be necessary.

Combination of Procedures - In some situations, neurotoxin injections or other types of tissue filler materials may be used in addition to HA tissue filler in order to specifically treat areas of the face or to enhance the outcome from tissue filler therapy. The effect of other forms of external skin treatments (laser and other light therapies, microdermabrasion, dermabrasion, or chemical peels) on skin that has been treated with tissue fillers is unknown. The effect of HA tissue filler injections into tissue that has been formerly treated with other types of temporary or permanent tissue fillers is unknown.

Pregnancy and Nursing Mothers - Animal reproduction studies have not been performed to determine if HA tissue filler could produce fetal harm. It is not known if HA tissue filler or its breakdown products can be excreted in human milk. It is not recommended that pregnant women or nursing mothers receive tissue filler treatments.

Drug Interactions - It is not known if HA tissue filler reacts with other drugs within the body.

Long-Term Effects - HA tissue filler injections should not be considered as a permanent treatment for the correction of wrinkles and soft tissue depressions. Over time, the HA tissue filler material is slowly absorbed by the body and wrinkles or soft tissue depressions will reappear. Continuing HA tissue filler treatment (injections) are necessary in order to maintain the effect. Subsequent alterations in face and eyelid appearance may occur as the result of aging, weight loss of gain, sun exposure, or other circumstances not related to tissue filler injections. Future surgery or other treatments may be necessary. Tissue filler injections do not arrest the aging process or produce permanent tightening of the skin or improvement in wrinkles.

Health Insurance

Most health insurance companies exclude coverage for cosmetic surgical procedures and treatments or any complications that might occur from the same. Health insurance companies may not pay for tissue filler injections used to treat medical conditions. Please carefully review your health insurance subscriber information pamphlet.

Additional Treatment Necessary

There are many variable conditions in addition to risk and potential complications that may influence the long-term result of HA tissue filler injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with HA tissue filler injections. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or other treatments may be necessary. You are advised to seek medical care should complications or adverse events

occur after tissue filler treatments. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained with the use of HA tissue filler injections. The practice of medicine and surgery is not an exact science.

Financial Responsibilities

This treatment provides a defined amount of HA tissue filler for the treatment of wrinkles and other conditions. If additional interim injections of HA tissue filler are needed in order to maintain or improve results, you will be responsible for these costs in addition to the cost of this treatment session. It is unlikely that tissue filler injections to treat cosmetic problems would be covered by your health insurance. Additional costs of medical treatment would be your responsibility should complications develop from HA tissue filler injections. You would also be responsible for additional forms of treatments or surgery recommended to improve the appearance of facial wrinkles and soft tissue depressions. In signing the consent for this surgery/procedure, you acknowledge that your have been informed about its risk and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all future treatments.

Disclaimer

Informed-consent documents are used to communicate information about the proposed treatment of a disease or 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. Your physician may provide you with additional or different information which is based on all of the facts pertaining to your particular case and the state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of 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 of your questions answered before signing the consent on the next page.

CONSENT FOR SURGERY/PROCEDURE or TREATMENT

1. I hereby authorize Dr._____ and such assistants as have been selected to perform the following procedure or treatment:

_____HA TISSUE FILLER INJECTIONS: _____

I have received the following information sheet:
INFORMED-CONSENT for HA TISSUE FILLER Injection

2. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
3. I consent to the administration of local anesthesia (regional nerve blocks , direct infiltration, or topical) to diminish discomfort of injection.
4. I consent to the photographing or televising 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.
5. For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.
6. 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
   d. THAT I ACCEPT RESPONSIBILITY FOR THE CLINICAL DECISIONS MADE ALONG WITH THE FINANCIAL COSTS OF ALL FUTURE TREATMENTS TO REVISE, OPTIMIZE OR IMPROVE OUTCOMES.

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-6). I AM SATISFIED WITH THE EXPLANATION THAT I HAVE RECEIVED BEFORE DECIDING TO UNDERGO THE TREATMENT OR PROCEDURE. I ACCEPT RESPONSIBILITY FOR THE RISKS, CONSEQUENCES, AND BENEFITS OF THIS DECISION.

_____
Patient or Person Authorized to Sign for Patient

_____
Date Witness

informed-consent-calcium hydroxyapatite tissue fillers (caha)

Instructions

This is an informed-consent document which has been prepared to help inform you concerning CaHA Tissue Filler injection therapy, 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 this procedure as proposed.

Introduction

Calcium hydroxyapatite is a calcium-containing substance found in bone and teeth. It can be formulated into a tissue filler material by forming it into micro beads and mixing it with a gel material for use as a tissue filler.

CaHA tissue filler has been approved to treat moderate to severe folds and wrinkles.

CaHA tissue filler injections are customized for every patient, depending on their particular needs. These can be performed in areas involving the face and eyelid region and forehead. CaHA tissue filler cannot stop the process of aging. It can however, temporarily diminish the appearance of wrinkles and soft tissue depressions. CaHA tissue filler injections may be performed as a singular procedure, in combination with other treatments such as neurotoxins, or as an adjunct to a surgical procedure. CaHA tissue injections require regional nerve blocks or topical anesthetic to diminish discomfort. Soft tissue fillers produce temporary swelling, redness, and needle marks, which resolve after a few days time.

Continuing treatments are necessary in order to maintain the effect of tissue fillers over time. CaHA tissue filler once injected will be slowly absorbed by the body. The length of effect for tissue filler injections is variable.

Alternative Treatments

Alternative forms of management include not treating the skin wrinkles or soft tissue depressions by any means. Improvement of skin wrinkles and soft tissue depressions may be accomplished by other treatments: laser treatments, chemical skin-peels, other skin procedures, or dermabrasion, alternative types of tissue fillers, or surgery such as a blepharoplasty, face or brow lift when indicated. Risks and potential complications are associated with alternative forms of medical or surgical treatment.

Risks Of CaHA Tissue Filler Injections

Every procedure to inject soft tissue filler materials involves a certain amount of risk, and it is important that you understand the risks involved. An individual's choice to undergo this procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience the following, you should discuss each of them with your physician to make sure you understand the risks, potential complications, limitations, and consequences

of CaHA tissue filler injections. Additional information may be obtained from the package-insert sheets supplied by the manufacturer.

Problems associated with the use of tissue fillers can relate to normal occurrences following tissue filler injections, or potential complications following tissue filler injections, including CaHA tissue filler. Additional advisory information should be reviewed by patients considering tissue filler treatments that involve CaHA tissue filler.

Normal occurrences during tissue filler injections, including CaHA TISSUE FILLER
Patients undergoing injections of CaHA tissue filler may normally experience the following events:

Bleeding and Bruising - It is possible, though unusual, to have a bleeding episode from an injection or local anesthesia used during the procedure. Bruising in soft tissues may occur. Should you develop post-injection bleeding, it may require emergency treatment or surgery. Aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, Vitamin E, Ginko biloba and other "herbs/homeopathic remedies" may contribute to a greater risk of a bleeding problem. Do not take any of these for seven days before injections. Bleeding and bruising can produce permanent tissue color changes.

Swelling - Swelling (edema) is a normal occurrence following the injections. It decreases after a few days. If swelling is slow to resolve, medical treatment may be necessary.

Erythema (Skin Redness) - Erythema in the skin occurs after injections. It can be present for a few days after the procedure.

Needle marks - Visible needle marks from the injections occur normally and resolve in a few days.

Acne-like skin eruptions - Acneiform skin eruptions can occur following the injection of tissue fillers. This generally resolves within a few days.

Skin Lumpiness - Lumpiness can occur following the injection of CaHA tissue filler. This tends to smooth out over time. In some situations, it may be possible to feel the injected tissue filler material for long periods of time.

Asymmetry - The human face and eyelid region is normally asymmetrical in its appearance and anatomy. It may not be possible to achieve or maintain exact symmetry with tissue filler injections. There can be a variation from one side to the other in terms of the response to CaHA tissue filler injection. This may require additional injections to improve your outcome.

Pain - Discomfort associated with tissue filler injections is normal and usually of a short duration. It is possible to have a fainting episode (vasovagal) from discomfort or anxiety about the injections.

Complications (adverse events)

Potential complications attributable to the injection of soft tissue fillers, including CaHA tissue filler:

Infection - Although infection following injection of tissue fillers is unusual, bacterial, fungal, and viral infections can occur. Herpes simplex virus infections around the mouth, can occur following a tissue filler treatment. This applies to both individuals with a past history of Herpes simplex virus infections and individuals with no known history of Herpes simplex virus infections in the mouth area. Specific medications must be prescribed and taken both prior to and following the treatment procedure in order to suppress an infection from this virus. Should any type of skin infection occur, additional treatment including antibiotics may be necessary.

Damage to deeper structures - Deeper structures such as nerves, blood vessels, and the soft tissues may be damaged during the course of injection. Injury to deeper structures may be temporary or permanent.

Visible Tissue Filler Material - It may be possible to see any type of tissue filler material that was injected in areas where the skin is thin. CaHa tissue filler material is visible on x-ray and CT scans.

Skin Necrosis - It is very unusual to experience death of skin and deeper soft tissues after CaHA tissue filler injections. Skin necrosis can produce unacceptable scarring. Should this rare complication occur, additional treatments, or surgery may be necessary. Injections of CaHa into the glabellar folds is contraindicated because of tissue necrosis risk. Fistula and extrusion may occur following CaHa injections.

Pruritis (Itching) - Itching has been reported following injection of CaHa tissue filler material.

Granulomas - Masses (lumps) in the skin and deeper tissues after a CaHA tissue filler injection are extremely rare. Should these occur, additional treatments including antibiotics or surgery may be necessary. Granulomas may produce scarring within the skin and deeper structures.

Allergic Reactions and Hypersensitivity - It is unknown if CaHA tissue filler is associated with serious systemic anaphylactic allergic reactions.

Accidental Intraarterial injection - It is extremely rare that during the course of injection, that tissue filler could be accidentally injected into arterial structures and produce a blockage of blood flow. This may produce skin necrosis in facial structures or damage blood flow to the eye, resulting in loss of vision. The risk and consequences of accidental intravascular injection is unknown and not predictable.

Under/Over Correction - The injection of soft tissue fillers to correct wrinkles and soft tissue contour deficiencies may not produce the desired outcome. The amount of correction may be inadequate or excessive. It may not be possible to control the process of injection of tissue fillers due to factors attributable to each patient's situation. If under correction occurs, you may be advised to consider additional injections of tissue filler materials. Over correction may require removal of tissue filler material.

Additional Advisories

Advisories for patients considering semi-permanent tissue filler injections: Off-label usage of CaHA- CaHA, depending on its manufacturer is labeled for specific use. The use of CaHA for other conditions and disorders would be considered "off-label" usage by your physician. FDA defines off label use as, "Use for indication, dosage form, dose regimen, population or other use parameter not mentioned in the approved labeling." The FDA recognizes that off label use of drugs by prescribers is often appropriate and may receive endorsement from published literature. CaHA may be used according to a physician's practice to treat other conditions.

Unsatisfactory Result - CaHA tissue filler injections alone may not produce an outcome that meets your expectations for improvement in wrinkles or soft tissue depressions. There is the possibility of a poor or inadequate response. Additional injections may be necessary. Surgical procedures or other treatments may be recommended in additional to tissue filler treatments.

Unknown Risks - There is the possibility that additional risks and complications attributable to the use of tissue fillers may be discovered.

Migration of Tissue Filler - Product may migrate from its original injection site and produce visible fullness in adjacent tissue or other unintended effects.

Drug and Local Anesthetic Reactions - There is the possibility that a systemic reaction could occur from either the topical or local anesthetic or epinephrine used for sensory nerve block anesthesia when tissue filler injections are performed. This would include the possibility of light-headedness, rapid heart beat (tachycardia), and fainting. Medical treatment of these conditions may be necessary.

Combination of Procedures - In some situations, neurotoxin injections or other types of tissue filler materials may be used in addition to CaHA tissue filler in order to specifically treat areas of the face or to enhance the outcome from tissue filler therapy. The effect of other forms of external skin treatments (laser and other light therapies, microdermabrasion, dermabrasion, or chemical peels) on skin that has been treated with tissue fillers is unknown. The effect

of CaHA tissue filler injections into tissue that has been formerly treated with other types of temporary or permanent tissue fillers is unknown. It is not recommended that CaHa be injected into areas treated with liquid silicone or particle fillers

Pregnancy and Nursing Mothers - Animal reproduction studies have not been performed to determine if CaHA tissue filler could produce fetal harm. It is not known if CaHA tissue filler or its breakdown products can be excreted in human milk. It is not recommended that pregnant women or nursing mothers receive tissue filler treatments.

Drug Interactions - It is not known if CaHA tissue filler reacts with other drugs within the body.

Long-Term Effects- CaHA tissue filler injections should not be considered as a permanent treatment for the correction of wrinkles and soft tissue depressions. Over time, the CaHA tissue filler material is slowly absorbed by the body and wrinkles or soft tissue depressions will reappear. Continuing CaHA tissue filler treatment (injections) are necessary in order to maintain the effect. Subsequent alterations in face and eyelid appearance may occur as the result of aging, weight loss of gain, sun exposure, or other circumstances not related to tissue filler injections. Future surgery or other treatments may be necessary. Tissue filler injections do not arrest the aging process or produce permanent tightening of the skin or improvement in wrinkles.

Health Insurance

Most health insurance companies exclude coverage for cosmetic surgical procedures and treatments or any complications that might occur from the same. Health insurance companies may not pay for tissue filler injections used to treat medical conditions. Please carefully review your health insurance subscriber information pamphlet.

Additional Treatment Necessary

There are many variable conditions in addition to risk and potential complications that may influence the long-term result of CaHA tissue filler injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with CaHA tissue filler injections. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or other treatments may be necessary. You are advised to seek medical care should complications or adverse events occur after tissue filler treatments. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained with the use of CaHA tissue filler injections. The practice of medicine and surgery is not an exact science.

Financial Responsibilities

This treatment provides a defined amount of CaHA tissue filler for the treatment of wrinkles and other conditions. If additional interim injections of CaHA tissue filler are needed in order to maintain or improve results, you will be responsible for these costs in addition to the cost of this treatment session. It is unlikely that tissue filler injections to treat cosmetic problems would be covered by your health insurance. Additional costs of medical treatment would be your responsibility should complications develop from CaHA tissue filler injections. You would also be responsible for additional forms of treatments or surgery recommended to improve the appearance of facial wrinkles and soft tissue depressions.

In signing the consent for this surgery/procedure, you acknowledge that you have been informed about its risk and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all future treatments.

Disclaimer

Informed-consent documents are used to communicate information about the proposed treatment of a disease or 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. Your physician may provide you with additional or different information which is based on all of the facts pertaining to your particular case and the state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of 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 of your questions answered before signing the consent on the next page.

CONSENT FOR SURGERY/PROCEDURE or TREATMENT

1. I hereby authorize Dr._____ and such assistants as have been selected to perform the following procedure or treatment:

_____CaHA TISSUE FILLER INJECTIONS: _____

I have received the following information sheet:
INFORMED-CONSENT for CaHA TISSUE FILLER Injection

2. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
3. I consent to the administration of local anesthesia (regional nerve blocks , direct infiltration, or topical) to diminish discomfort of injection.
4. I consent to the photographing or televising 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.
5. For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.
6. 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
   d. THAT I ACCEPT RESPONSIBILITY FOR THE CLINICAL DECISIONS MADE ALONG WITH THE FINANCIAL COSTS OF ALL FUTURE TREATMENTS TO REVISE, OPTIMIZE OR IMPROVE OUTCOMES.

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-6). I AM SATISFIED WITH THE EXPLANATION THAT I HAVE RECEIVED BEFORE DECIDING TO UNDERGO THE TREATMENT OR PROCEDURE. I ACCEPT RESPONSIBILITY FOR THE RISKS, CONSEQUENCES, AND BENEFITS OF THIS DECISION.

_____
Patient or Person Authorized to Sign for Patient

_____
Date Witness

informed-consent-polymethylmethacrylate tissue fillers (pmma)

Instructions

This is an informed-consent document which has been prepared to help inform you concerning PMMA Tissue Filler injection therapy, 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 this procedure as proposed.

Introduction

Polymethylmethacrylate is a synthetic polymer. It is a material that is formed into microscopic-sized beads and mixed with bovine-origin collagen. It is injected as permanent soft tissue filler. Once injected, the collagen component is absorbed, leaving the PMMA beads. PMMA tissue filler has been approved to treat the areas of nasolabial folds. A skin test injection with collagen tissue filler is necessary prior to the PMMA tissue filler treatment to determine that patients are not allergic to the bovine collagen contained with the PMMA tissue filler material.

PMMA tissue filler injections are customized for every patient, depending on their particular needs. PMMA tissue filler cannot stop the process of aging. It can however, diminish the appearance of wrinkles and soft tissue depressions. PMMA Tissue Filler injections may be performed as a singular procedure, in combination with other treatments such as neurotoxins, or as an adjunct to a surgical procedure. PMMA tissue injections require regional nerve blocks or topical anesthetic to diminish discomfort. Soft tissue fillers produce temporary swelling, redness, and needle marks, which resolve after a few days time.

Alternative Treatments

Alternative forms of management include not treating the skin wrinkles or soft tissue depressions by any means. Improvement of skin wrinkles and soft tissue depressions may be accomplished by other treatments: laser treatments, chemical skin-peels, other skin procedures, or dermabrasion, alternative types of tissue fillers, or surgery such as a blepharoplasty, face or brow lift when indicated. Risks and potential complications are associated with alternative forms of medical or surgical treatment.

Risks Of Pmma Tissue Filler Injections

Every procedure to inject soft tissue filler materials involves a certain amount of risk, and it is important that you understand the risks involved. An individual's choice to undergo this procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience the following, you should discuss each of them with your physician to make sure you understand the risks, potential complications, limitations, and consequences of permanent PMMA tissue filler injections. Additional information may be obtained from the package-insert sheets supplied by the manufacturer.

Problems associated with the use of tissue fillers can relate to normal occurrences following tissue filler injections, or potential complications following tissue filler injections, including PMMA tissue filler. Additional advisory information should be reviewed by patients considering tissue filler treatments that involve PMMA tissue filler.

Normal occurrences during tissue filler injections, including PMMA TISSUE FILLER

Patients undergoing injections of PMMA tissue filler may normally experience the following events:

Bleeding and Bruising - It is possible, though unusual, to have a bleeding episode from an injection or local anesthesia used during the procedure. Bruising in soft tissues may occur. Should you develop post-injection bleeding, it may require emergency treatment or surgery. Aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, Vitamin E, Ginko biloba and other "herbs/homeopathic remedies" may contribute to a greater risk of a bleeding problem. Do not take any of these for seven days before injections. Bleeding and bruising can produce permanent tissue color changes.

Swelling - Swelling (edema) is a normal occurrence following the injections. It decreases after a few days. If swelling is slow to resolve, medical treatment may be necessary.

Erythema (Skin Redness) - Erythema in the skin occurs after injections. It can be present for a few days after the procedure.

Needle marks - Visible needle marks from the injections occur normally and resolve in a few days.

Acne-like skin eruptions - Acneiform skin eruptions can occur following the injection of tissue fillers. This generally resolves within a few days.

Skin Lumpiness - Lumpiness can occur following the injection of PMMA tissue filler. In some situations, it may be possible to feel the injected tissue filler material for long periods of time.

Asymmetry - The human face and eyelid region is normally asymmetrical in its appearance and anatomy. It may not be possible to achieve or maintain exact symmetry with tissue filler injections. There can be a variation from one side to the other in terms of the response to PMMA tissue filler injection. This may require additional injections to improve your outcome.

Pain - Discomfort associated with tissue filler injections is normal and usually of a short duration. It is possible to have a fainting episode (vasovagal) from discomfort or anxiety about the injections.

Complications (adverse events)

Potential complications attributable to the injection of permanent soft tissue fillers, including PMMA tissue filler:

Infection - Although infection following injection of tissue fillers is unusual, bacterial, fungal, and viral infections can occur. **Herpes simplex virus** infections around the mouth, can occur following a tissue filler treatment. This applies to both individuals with a past history of Herpes simplex virus infections and individuals with no known history of Herpes simplex virus infections in the mouth area. Specific medications must be prescribed and taken both prior to and following the treatment procedure in order to suppress an infection from this virus. Should any type of skin infection occur, additional treatment including antibiotics may be necessary.

Damage to deeper structures - Deeper structures such as nerves, blood vessels, and the soft tissues may be damaged during the course of injection. Injury to deeper structures may be temporary or permanent.

Visible Tissue Filler Material - It may be possible to see any type of tissue filler material that was injected in areas where the skin is thin.

Skin Necrosis - It is very unusual to experience death of skin and deeper soft tissues after PMMA tissue filler injections. Skin necrosis can produce unacceptable scarring. Should this rare complication occur, additional treatments, or surgery may be necessary.

Granulomas - Painful masses in the skin and deeper tissues after a PMMA tissue filler injection are rare. Should these occur, additional treatments including antibiotics, injections, or surgery may be necessary. Granulomas may produce scarring within the skin and deeper structures.

Lip complications - Lip complications, such as stiffness, lymphedema, and nodules have been reported in patients who underwent lip injections with PMMA permanent tissue fillers.

Allergic Reactions and Hypersensitivity - As with all biologic products, allergic reactions may occur. PMMA permanent tissue fillers contain bovine collagen. Individuals with a know allergy to bovine collages should not undergo PMMA permanent tissue filler injections. Allergic reactions may require additional treatment. It is unknown if PMMA tissue filler is associated with serious systemic anaphylactic allergic reactions.

Antibodies to PMMA TISSUE FILLER - Presence of antibodies to collagen component of PMMA tissue fillers may in theory reduce the effectiveness of this material or produce a reaction in subsequent injections. The health significance of antibodies is unknown.

Accidental Intraarterial injection - It is extremely rare that during the course of injection, that tissue filler could be accidentally injected into arterial structures and produce a blockage of blood flow. This may produce skin necrosis in facial structures or damage blood flow to the eye, resulting in loss of vision. The risk and consequences of accidental intravascular injection is unknown and not predictable.

Under/Over Correction - The injection of soft tissue fillers to correct wrinkles and soft tissue contour deficiencies may not produce the desired outcome. The amount of correction may be inadequate or excessive. It may not be possible to control the process of injection of tissue fillers due to factors attributable to each patient's situation. If under correction occurs, you may be advised to consider additional injections of tissue filler materials. Over correction may require removal of tissue filler material.

Additional Advisories

Advisories for patients considering non-permanent tissue filler injections: Off-label usage of PMMA- PMMA is labeled for specific use approved to treat areas of deep facial wrinkles such as nasolabial folds. The use of PMMA for other conditions and disorders would be considered "off-label" usage by your physician. FDA defines off label use as, "Use for indication, dosage form, dose regimen, population or other use parameter not mentioned in the approved labeling." The FDA recognizes that off label use of drugs by prescribers is often appropriate and may receive endorsement from published literature. PMMA may be used according to a physician's practice to treat other conditions.

Unsatisfactory Result - PMMA tissue filler injections alone may not produce an outcome that meets your expectations for improvement in wrinkles or soft tissue depressions. There is the possibility of a poor or inadequate response. Additional injections may be necessary. Surgical procedures or other treatments may be recommended in additional to tissue filler treatments. Complications and adverse events associated with permanent fillers may be of greater severity and permanence than temporary fillers.

Unknown Risks - There is the possibility that additional risks and complications attributable to the use of tissue fillers may be discovered. There is the risk of adverse and serious adverse events occurring years following the injection of all permanent filers, including PMMA.

Migration of Tissue Filler - Product may migrate from its original injection site and produce visible fullness in adjacent tissue or other unintended effects.

Drug and Local Anesthetic Reactions - There is the possibility that a systemic reaction could occur from either the topical or local anesthetic or epinephrine used for sensory nerve block anesthesia when tissue filler injections are performed. This would include the possibility of light-headedness, rapid heart beat (tachycardia), and fainting. Medical treatment of these conditions may be necessary.

Pregnancy and Nursing Mothers - Animal reproduction studies have not been performed to determine if PMMA tissue filler could produce fetal harm. It is not known if PMMA tissue filler or its breakdown products can be excreted in human milk. It is not recommended that pregnant women or nursing mothers receive tissue filler treatments.

Combination of Procedures - In some situations, neurotoxin injections or other types of tissue filler materials may be used in addition to PMMA tissue filler in order to specifically treat areas of the face or to enhance the outcome from tissue filler therapy. The effect of other forms of external skin treatments (laser and other light therapies, microdermabrasion, dermabrasion, or chemical peels) on skin that has been treated with tissue fillers is unknown. The effect of PMMA tissue filler injections into tissue that has been formerly treated with other types of temporary or permanent tissue fillers is unknown.

Drug Interactions - It is not known if PMMA tissue filler reacts with other drugs within the body. Long-Term Effects- PMMA tissue filler injections should not be considered as a permanent treatment for the correction of wrinkles and soft tissue depressions. Subsequent alterations in face and eyelid appearance may occur as the result of aging, weight loss of gain, sun exposure, or other circumstances not related to tissue filler injections. Future surgery or other treatments may be necessary. Tissue filler injections do not arrest the aging process or produce permanent tightening of the skin or improvement in wrinkles. .

Health Insurance

Most health insurance companies exclude coverage for cosmetic surgical procedures and treatments or any complications that might occur from the same. Health insurance companies may not pay for tissue filler injections used to treat medical conditions. Please carefully review your health insurance subscriber information pamphlet.

Additional Treatment Necessary

There are many variable conditions in addition to risk and potential complications that may influence the long-term result of PMMA tissue filler injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with PMMA tissue filler injections. Other complications and risks can occur but are even

more uncommon. Should complications occur, additional surgery or other treatments may be necessary. You are advised to seek medical care should complications or adverse events occur after tissue filler treatments. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained with the use of PMMA tissue filler injections. The practice of medicine and surgery is not an exact science.

Financial Responsibilities

This treatment provides a defined amount of PMMA tissue filler for the treatment of wrinkles and other conditions. If additional interim injections of PMMA tissue filler are needed in order to maintain or improve results, you will be responsible for these costs in addition to the cost of this treatment session. It is unlikely that tissue filler injections to treat cosmetic problems would be covered by your health insurance. Additional costs of medical treatment would be your responsibility should complications develop from PMMA tissue filler injections. You would also be responsible for additional forms of treatments or surgery recommended to improve the appearance of facial wrinkles and soft tissue depressions.

In signing the consent for this surgery/procedure, you acknowledge that you have been informed about its risk and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all future treatments.

Disclaimer

Informed-consent documents are used to communicate information about the proposed treatment of a disease or 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. Your physician may provide you with additional or different information which is based on all of the facts pertaining to your particular case and the state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of 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 of your questions answered before signing the consent on the next page.

CONSENT FOR SURGERY/PROCEDURE or TREATMENT

1. I hereby authorize Dr. _____ and such assistants as have been selected to perform the following procedure or treatment:

_____PMMA TISSUE FILLER INJECTIONS: _____

I have received the following information sheet:
INFORMED-CONSENT for PMMA TISSUE FILLER Injection

2. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
3. I consent to the administration of local anesthesia (regional nerve blocks , direct infiltration, or topical) to diminish discomfort of injection.
4. I consent to the photographing or televising 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.
5. For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.
6. 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
   d. THAT I ACCEPT RESPONSIBILITY FOR THE CLINICAL DECISIONS MADE ALONG WITH THE FINANCIAL COSTS OF ALL FUTURE TREATMENTS TO REVISE, OPTIMIZE OR IMPROVE OUTCOMES.

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-6). I AM SATISFIED WITH THE EXPLANATION THAT I HAVE RECEIVED BEFORE DECIDING TO UNDERGO THE TREATMENT OR PROCEDURE. I ACCEPT RESPONSIBILITY FOR THE RISKS, CONSEQUENCES, AND BENEFITS OF THIS DECISION.

_____
Patient or Person Authorized to Sign for Patient

_____
Date Witness

informed-consent-poly-l lactic acid tissue fillers (pll)

Instructions

This is an informed-consent document which has been prepared to help inform you concerning PLL Tissue Filler injection therapy, 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 this procedure as proposed.

Introduction

Poly-l lactic acid (PLL) is a synthetic tissue filler material that is a polymer of lactic acid molecules. Lactic acid polymers have been used to produce absorbable suture and orthopedic bone screws/plates.

PLL tissue filler is intended for restoration and/or correction of the signs of facial fat loss (lipoatrophy) in people with human immunodeficiency virus. Its use as a cosmetic tissue filler is considered off-label usage.

PLL tissue filler injections are customized for every patient, depending on their particular needs. These can be performed in areas involving the face and eyelid region, forehead, and lips. PLL tissue filler cannot stop the process of aging. It can however, temporarily diminish the appearance of wrinkles and soft tissue depressions. PLL Tissue Filler injections may be performed as a singular procedure, in combination with other treatments such as neurotoxins, or as an adjunct to a surgical procedure. PLL tissue injections require regional nerve blocks or topical anesthetic to diminish discomfort. Soft tissue fillers produce temporary swelling, redness, and needle marks, which resolve after a few days time.

Continuing treatments are necessary in order to maintain the effect of tissue fillers over time. PLL tissue filler once injected will be slowly absorbed by the body. The length of effect for tissue filler injections is variable. PLL tissue filler treatments require several injection sessions to produce an effect.

Alternative Treatments

Alternative forms of management include not treating the skin wrinkles or soft tissue depressions by any means. Improvement of skin wrinkles and soft tissue depressions may be accomplished by other treatments: laser treatments, chemical skin-peels, other skin procedures, or dermabrasion, alternative types of tissue fillers, or surgery such as a blepharoplasty, face or brow lift when indicated. Risks and potential complications are associated with alternative forms of medical or surgical treatment.

Risks Of Pll Tissue Filler Injections

Every procedure to inject soft tissue filler materials involves a certain amount of risk, and it is important that you understand the risks involved. An individual's choice to undergo this

procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience the following, you should discuss each of them with your physician to make sure you understand the risks, potential complications, limitations, and consequences of PLL tissue filler injections. Additional information may be obtained from the package-insert sheets supplied by the manufacturer.

Problems associated with the use of tissue fillers can relate to normal occurrences following tissue filler injections, or potential complications following tissue filler injections, including PLL tissue filler. Additional advisory information should be reviewed by patients considering tissue filler treatments that involve PLL tissue filler.

Normal occurrences during tissue filler injections, including PLL Tissue Filler

Patients undergoing injections of PLL tissue filler may normally experience the following events:

Bleeding and Bruising - It is possible, though unusual, to have a bleeding episode from an injection or local anesthesia used during the procedure. Bruising in soft tissues may occur. Should you develop post-injection bleeding, it may require emergency treatment or surgery. Aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, Vitamin E, Ginko biloba and other “herbs/homeopathic remedies” may contribute to a greater risk of a bleeding problem. Do not take any of these for seven days before injections. Bleeding and bruising can produce permanent tissue color changes.

Swelling - Swelling (edema) is a normal occurrence following the injections. It decreases after a few days. If swelling is slow to resolve, medical treatment may be necessary.

Erythema (Skin Redness) - Erythema in the skin occurs after injections. It can be present for a few days after the procedure.

Needle marks - Visible needle marks from the injections occur normally and resolve in a few days.

Acne-like skin eruptions - Acneiform skin eruptions can occur following the injection of tissue fillers. This generally resolves within a few days.

Skin Lumpiness - Lumpiness can occur following the injection of PLL tissue filler. This tends to smooth out over time. In some situations, it may be possible to feel the injected tissue filler material for long periods of time.

Asymmetry - The human face and eyelid region is normally asymmetrical in its appearance and anatomy. It may not be possible to achieve or maintain exact symmetry with tissue filler injections. There can be a variation from one side to the other in terms of the response to PLL tissue filler injection. This may require additional injections to improve your outcome.

Pain - Discomfort associated with tissue filler injections is normal and usually of a short duration. It is possible to have a fainting episode (vasovagal) from discomfort or anxiety about the injections.

Complications (adverse events)

Potential complications attributable to the injection of soft tissue fillers, including PLL tissue filler:

Infection - Although infection following injection of tissue fillers is unusual, bacterial, fungal, and viral infections can occur. Herpes simplex virus infections around the mouth, can occur following a tissue filler treatment. This applies to both individuals with a past history of Herpes simplex virus infections and individuals with no known history of Herpes simplex virus infections in the mouth area. Specific medications must be prescribed and taken both prior to and following the treatment procedure in order to suppress an infection from this virus. Should any type of skin infection occur, additional treatment including antibiotics may be necessary.

Damage to deeper structures - Deeper structures such as nerves, blood vessels, and the soft tissues may be damaged during the course of injection. Injury to deeper structures may be temporary or permanent.

Visible Tissue Filler Material - It may be possible to see any type of tissue filler material that was injected in areas where the skin is thin.

Skin Necrosis - It is very unusual to experience death of skin and deeper soft tissues after PLL tissue filler injections. Skin necrosis can produce unacceptable scarring. Should this rare complication occur, additional treatments, or surgery may be necessary.

Granulomas - Painful masses in the skin and deeper tissues after a PLL tissue filler injection are extremely rare. Should these occur, additional treatments including antibiotics, injections, or surgery may be necessary. Granulomas may produce scarring within the skin and deeper structures.

Allergic Reactions and Hypersensitivity - It is unknown if PLL tissue filler is associated with serious systemic anaphylactic allergic reactions.

Accidental Intraarterial injection - It is extremely rare that during the course of injection, that tissue filler could be accidentally injected into arterial structures and produce a blockage of blood flow. This may produce skin necrosis in facial structures or damage blood flow to the

eye, resulting in loss of vision. The risk and consequences of accidental intravascular injection is unknown and not predictable.

Under/Over Correction - The injection of soft tissue fillers to correct wrinkles and soft tissue contour deficiencies may not produce the desired outcome. The amount of correction may be inadequate or excessive. It may not be possible to control the process of injection of tissue fillers due to factors attributable to each patient's situation. If under correction occurs, you may be advised to consider additional injections of tissue filler materials. Over correction may require removal of tissue filler material.

Additional Advisories

Advisories for patients considering semi-permanent tissue filler injections:

Off-label usage of PLL - PLL is labeled for specific use, the treatment of facial volume loss in HIV patients.. The use of PLL for other conditions and disorders would be considered "off-label" usage by your physician. FDA defines off label use as, "Use for indication, dosage form, dose regimen, population or other use parameter not mentioned in the approved labeling." The FDA recognizes that off label use of drugs by prescribers is often appropriate and may receive endorsement from published literature. PLL may be used according to a physician's practice to treat other conditions.

Unsatisfactory Result - PLL tissue filler injections alone may not produce an outcome that meets your expectations for improvement in wrinkles or soft tissue depressions. There is the possibility of a poor or inadequate response. Additional injections may be necessary. Surgical procedures or other treatments may be recommended in addition to tissue filler treatments.

Unknown Risks - There is the possibility that additional risks and complications attributable to the use of tissue fillers may be discovered.

Migration of Tissue Filler - Product may migrate from its original injection site and produce visible fullness in adjacent tissue or other unintended effects.

Drug and Local Anesthetic Reactions - There is the possibility that a systemic reaction could occur from either the topical or local anesthetic or epinephrine used for sensory nerve block anesthesia when tissue filler injections are performed. This would include the possibility of light-headedness, rapid heart beat (tachycardia), and fainting. Medical treatment of these conditions may be necessary.

Combination of Procedures - In some situations, neurotoxin injections or other types of tissue filler materials may be used in addition to PLL tissue filler in order to specifically treat areas

of the face or to enhance the outcome from tissue filler therapy. The effect of other forms of external skin treatments (laser and other light therapies, microdermabrasion, dermabrasion, or chemical peels) on skin that has been treated with tissue fillers is unknown. The effect of PLL tissue filler injections into tissue that has been formerly treated with other types of temporary or permanent tissue fillers is unknown.

Pregnancy and Nursing Mothers - Animal reproduction studies have not been performed to determine if PLL tissue filler could produce fetal harm. It is not known if PLL tissue filler or its breakdown products can be excreted in human milk. It is not recommended that pregnant women or nursing mothers receive tissue filler treatments.

Drug Interactions - It is not known if PLL tissue filler reacts with other drugs within the body.

Long-Term Effects - PLL tissue filler injections should not be considered as a permanent treatment for the correction of wrinkles and soft tissue depressions. Over time, the PLL tissue filler material is slowly absorbed by the body and replaced with collagen. Wrinkles or soft tissue depressions will reappear. Continuing PLL tissue filler treatment (injections) are necessary in order to maintain the effect. Subsequent alterations in face and eyelid appearance may occur as the result of aging, weight loss of gain, sun exposure, or other circumstances not related to tissue filler injections. Future surgery or other treatments may be necessary. Tissue filler injections do not arrest the aging process or produce permanent tightening of the skin or improvement in wrinkles.

Health Insurance

Most health insurance companies exclude coverage for cosmetic surgical procedures and treatments or any complications that might occur from the same. Health insurance companies may not pay for tissue filler injections used to treat medical conditions. Please carefully review your health insurance subscriber information pamphlet.

Additional Treatment Necessary

There are many variable conditions in addition to risk and potential complications that may influence the long-term result of PLL tissue filler injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with PLL tissue filler injections. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or other treatments may be necessary. You are advised to seek medical care should complications or adverse events occur after tissue filler treatments. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained with the use of PLL tissue filler injections. The practice of medicine and surgery is not an exact science.

Financial Responsibilities

This treatment provides a defined amount of PLL tissue filler for the treatment of wrinkles and other conditions. If additional interim injections of PLL or other tissue fillers are needed in order to maintain or improve results, you will be responsible for these costs in addition to the cost of this treatment session. It is unlikely that tissue filler injections to treat cosmetic problems would be covered by your health insurance. Additional costs of medical treatment would be your responsibility should complications develop from PLL tissue filler injections. You would also be responsible for additional forms of treatments or surgery recommended to improve the appearance of facial wrinkles and soft tissue depressions.

In signing the consent for this surgery/procedure, you acknowledge that you have been informed about its risk and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all future treatments.

Disclaimer

Informed-consent documents are used to communicate information about the proposed treatment of a disease or 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. Your physician may provide you with additional or different information which is based on all of the facts pertaining to your particular case and the state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of 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 of your questions answered before signing the consent on the next page.

CONSENT FOR SURGERY/PROCEDURE or TREATMENT

1. I hereby authorize Dr. _____ and such assistants as have been selected to perform the following procedure or treatment:

_____PLL TISSUE FILLER INJECTIONS: _____

I have received the following information sheet:
INFORMED-CONSENT for PLL TISSUE FILLER Injection

2. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
3. I consent to the administration of local anesthesia (regional nerve blocks , direct infiltration, or topical) to diminish discomfort of injection.
4. I consent to the photographing or televising 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.
5. For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.
6. 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
   d. THAT I ACCEPT RESPONSIBILITY FOR THE CLINICAL DECISIONS MADE ALONG WITH THE FINANCIAL COSTS OF ALL FUTURE TREATMENTS TO REVISE, OPTIMIZE OR IMPROVE OUTCOMES.

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-6). I AM SATISFIED WITH THE EXPLANATION THAT I HAVE RECEIVED BEFORE DECIDING TO UNDERGO THE TREATMENT OR PROCEDURE. I ACCEPT RESPONSIBILITY FOR THE RISKS, CONSEQUENCES, AND BENEFITS OF THIS DECISION.

_____
Patient or Person Authorized to Sign for Patient

_____
Date Witness

Instructions

This is an informed-consent document which has been prepared to help inform you concerning deoxycholate injection therapy (DC, Kybella®), 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 this procedure as proposed.

Introduction

Deoxycholate (DC) is a naturally occurring substance that is found within all mammals. It is a material that is contained bile. DC is synthetically produced and purified by Kythera for use as an injectable to reduce fatty deposits under the chin and jawline. This is as drug that is formulated to destroy fat cells that are located between the skin and the muscles of the neck. DC has been FDA-approved to treat areas of soft tissue fullness in the chin and jawline. DC may not improve chin and jawline contour if a patient is obese because fat deposits in this area may be influenced by dietary intake.

DC injections are customized for every patient, depending on their particular needs. These can be performed in areas involving the chin and jawline region. DC tissue filler cannot stop the process of aging. It can however, temporarily diminish the appearance of fullness in the chin and jawline through a series of injection sessions. DC injections may be performed as a singular procedure, in combination with other treatments such as neurotoxins, or as an adjunct to a surgical or non-invasive procedure. DC tissue injections typically require regional local anesthetic injections to diminish discomfort. DC injections typically produce temporary swelling, redness, and needle marks, which resolve after a few days' time.

Serial injection sessions are necessary in order to improve neck and jawline contour.

Alternative Treatments

Alternative forms of management include not treating the fullness in the neck and jawline by any means. Improvement of fullness may be accomplished by other treatments: laser treatments, liposuction, other skin procedures (radiofrequency), or high-intensity focused ultrasound (HIFU). Risks and potential complications are associated with alternative forms of medical or surgical treatment.

Risks Of DC Tissue Filler Injections

Every procedure to inject DC involves a certain amount of risk, and it is important that you understand the risks involved. An individual's choice to undergo this procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience the following, you should discuss each of them with your physician to make sure

you understand the risks, potential complications, limitations, and consequences of DC tissue injections. Additional information may be obtained from the package-insert sheet on Kybella® that is supplied by the manufacturer.

Problems associated with the use of DC can relate to normal occurrences following injections, or potential complications following injections.

Normal occurrences during DC Injections

Patients undergoing injections of DC tissue injections may normally experience the following events:

Bleeding and Bruising - It is possible, though unusual, to have a bleeding episode from an injection or local anesthesia used during the procedure. Bruising in soft tissues may occur. Should you develop post-injection bleeding, it may require emergency treatment. Aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, Vitamin E, Ginko biloba and other "herbs / homeopathic remedies" may contribute to a greater risk of a bleeding problem. Do not take any of these for seven days before injections. Bleeding and bruising can produce tissue color changes. In DC clinical trials, approximately 72% of subjects experienced bruising.

Swelling - Swelling (edema) is a normal occurrence following the DC injections. It decreases after a few days. If swelling is slow to resolve, medical treatment may be necessary.

Erythema (Skin Redness) - Erythema in the skin occurs after injections. It can be present for a few days after the procedure.

Needle marks - Visible needle marks from the injections occur normally and resolve in a few days.

Acne-like skin eruptions - Acneiform skin eruptions can occur following the injection of DC. This generally resolves within a few days.

Skin Lumpiness - Lumpiness can occur following the injection of DC. This tends to smooth out over time. In some situations, it may be possible to feel firmness in the tissue for long periods of time from the tissue effect of DC.

Asymmetry - The human face and neck region is normally asymmetrical in its appearance and anatomy. It may not be possible to achieve or maintain exact symmetry with DC injections. There can be a variation from one side to the other in terms of the response to DC injection. This may require additional injections or treatments to improve your outcome.

Pain - Discomfort associated with DC injections is normal and usually of a short duration. It is possible to have a fainting episode (vasovagal) from discomfort or anxiety about the injections. Procedural discomfort is managed with oral pain medicine, local anesthesia injections before DC is injected, and over the counter analgesics.

Complications (adverse events)

Potential complications attributable to the injection of DC for fat reduction in the chin and jawline are:

Damage to Marginal Mandibular Nerve - DC injections in the area of the marginal mandibular nerve, which is located in the vicinity of the jaw bone can occur. This would produce diminished motion in the corner of the mouth. According to data from the research on DC, this is a rare complication and generally resolves over time.

Difficulty to swallow - Difficulty to swallow has been reported in a few patients that have undergone DC injections. Typically, this resolves. Individuals who have a history of swallowing difficulties may not be suitable for DC injections.

Infection - Although infection following injection of DC is unusual, bacterial, fungal, and viral infections can occur. Should any type of skin infection occur, additional treatment including antibiotics may be necessary.

Damage to deeper structures - Deeper structures such as nerves, salivary glands, and the neck muscles may be damaged during the course of injection. Injury to deeper structures may be temporary or permanent. Temporary numbness can occur in the area where DC is injected.

Skin Necrosis - It is very unusual to experience death of skin and deeper soft tissues after DC injections. Skin necrosis can produce unacceptable scarring. Should this rare complication occur, additional treatments, or surgery may be necessary.

Granulomas and Fat Necrosis - Painful masses in the skin and deeper tissues after a DC injection are extremely rare. Should these occur, additional treatments including antibiotics or surgery may be necessary. These may produce scarring within the skin and deeper structures.

Allergic Reactions and Hypersensitivity - As with all injectable products, allergic reactions may occur. Allergic reactions may require additional treatment. It is unknown if DC is associated with serious systemic anaphylactic allergic reactions.

Accidental Intra-arterial injection - One of the risks with using this product is unintentional injection into a blood vessel. The chances of this happening are very small and may not be of consequence, as DC has been given intravenously to treat medical conditions.

Under / Over Correction - The injection of DC to fullness in the chin and jawline may not produce the desired outcome. The amount of correction may be inadequate or excessive. It may not be possible to control the process of injection of DC due to factors attributable to each patient's situation. If under correction occurs, you may be advised to consider additional injections of DC. Over correction may require additional treatment.

Additional Advisories

Advisories for patients considering DC injections:

Off-label usage of DC- DC, is labeled for specific use in the reduction of fat deposits of the chin and jawline. The use of DC for other conditions and disorders would be considered "off-label" usage by your physician. FDA defines off label use as, "Use for indication, dosage form, dose regimen, population or other use parameter not mentioned in the approved labeling." The FDA recognizes that off label use of drugs by prescribers is often appropriate and may receive endorsement from published literature. DC may be used according to a physician's practice to treat other conditions.

Unsatisfactory Result - DC injections alone may not produce an outcome that meets your expectations for improvement in fullness of the chin and jawline. There is the possibility of a poor or inadequate response. Additional injections may be necessary. Surgical procedures or other treatments may be recommended.

Unknown Risks - There is the possibility that additional risks and complications attributable to the use of DC injections may be discovered.

Migration of DC - DC may migrate from its original injection site and produce changes in adjacent tissue or other unintended effects.

Drug and Local Anesthetic Reactions - There is the possibility that a systemic reaction could occur from either the topical or local anesthetic or epinephrine used for sensory nerve block anesthesia when DC injections are performed. This would include the possibility of light-headedness, rapid heartbeat (tachycardia), and fainting. Medical treatment of these conditions may be necessary.

Combination of Procedures - In some situations, off-label neurotoxin injections or other types of treatments may be used in addition to DC in order to specifically treat areas of the chin and jawline or to enhance the outcome from DC therapy. The effect of other forms of external skin treatments (laser and HIFU therapies, on tissue that has been treated with DC is unknown. The effect of DC injections into tissue that has been formerly treated with other types of treatments (laser, liposuction) is unknown.

Pregnancy and Nursing Mothers - Animal reproduction studies have not been performed to determine if DC could produce fetal harm. It is not known if DC or its breakdown products can be excreted in human milk. It is not recommended that pregnant women or nursing mothers receive DC treatments.

Drug Interactions - It is not known if DC reacts with other drugs within the body.

Long-Term Effects - DC injections should not be considered as a permanent treatment for fullness in the chin and neck region. Over time, wrinkles or soft tissue looseness may appear. Subsequent alterations in face and neck appearance may occur as the result of aging, weight loss of gain, sun exposure, or other circumstances not related to DC injections. Future surgery or other treatments may be necessary. DC injections do not arrest the aging process or produce permanent tightening of the skin or improvement in wrinkles of the chin and jawline.

Health Insurance

Most health insurance companies exclude coverage for cosmetic surgical procedures and treatments or any complications that might occur from the same. Health insurance companies may not pay for DC injections used to treat medical conditions. Please carefully review your health insurance subscriber information pamphlet.

Additional Treatment Necessary

There are many variable conditions in addition to risk and potential complications that may influence the long-term result of DC injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with DC injections. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or other treatments may be necessary. You are advised to seek medical care should complications or adverse events occur after tissue filler treatments. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained with the use of DC injections. The practice of medicine and surgery is not an exact science.

Financial Responsibilities

This treatment provides a defined amount of DC for the treatment of fullness under the chin and jawline due to fat deposits. If additional interim injections of DC are needed in order to maintain or improve results, you will be responsible for these costs in addition to the cost of this treatment session. It is unlikely that DC injections to treat cosmetic problems would be covered by your health insurance. Additional costs of medical treatment would be your responsibility should complications develop from DC injections. You would also be responsible for additional forms of treatments or surgery recommended to improve the appearance of fullness under the chin and jawline.

In signing the consent for this surgery/procedure, you acknowledge that your have been informed about its risk and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all future treatments.

Disclaimer

Informed-consent documents are used to communicate information about the proposed treatment of a disease or 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. Your physician may provide you with additional or different information which is based on all of the facts pertaining to your particular case and the state of medical knowledge.

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

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of 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 of your questions answered before signing the consent on the next page.

CONSENT FOR SURGERY/PROCEDURE or TREATMENT

1. I hereby authorize Dr. _____ and such assistants as have been selected to perform the following procedure or treatment:

_____Deoxycholate, Kybella® INJECTIONS: _____

I have received the following information sheet:

INFORMED-CONSENT for DC, Kybella® Injection

2. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
3. I consent to the administration of local anesthesia (regional nerve blocks , direct infiltration, or topical) to diminish discomfort of injection.
4. I consent to the photographing or televising 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.
5. For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.
6. 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
   d. THAT I ACCEPT RESPONSIBILITY FOR THE CLINICAL DECISIONS MADE ALONG WITH THE FINANCIAL COSTS OF ALL FUTURE TREATMENTS TO REVISE, OPTIMIZE OR IMPROVE OUTCOMES.

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-6). I AM SATISFIED WITH THE EXPLANATION THAT I HAVE RECEIVED BEFORE DECIDING TO UNDERGO THE TREATMENT OR PROCEDURE. I ACCEPT RESPONSIBILITY FOR THE RISKS, CONSEQUENCES, AND BENEFITS OF THIS DECISION.

_____

Patient or Person Authorized to Sign for Patient

_____

Date Witness

forms

a. Injectable Order Form

b. Neurotoxin Reconstitution Form

c. Patient History and Treatment Female

d. Patient History and Treatment Male

e. BOTOX® Cosmetic Reconstitution Reference Sheet

f. BOTOX® Cosmetic Administration Reference Sheet

g. DYSPORT® Reconstitution Reference Sheet

h. DYSPORT® Administration Reference Sheet

i. XEOMIN® Reconstitution Reference Sheet

j. XEOMIN® Administration Reference Sheet

safety with injectables™ order form

	Date Ordered	Ordered By:	#Vials Ordered	Injectable	Vendor	Confirmation #	Date Received	OK?
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								

Reconstitute BOTOX® Cosmetic 100 Unit vial with "X" ml of diluent = "XX" units per ml
Reconstitute DYSPORT® 300 unit vial with "X" ml of diluent = "XX" units per ml

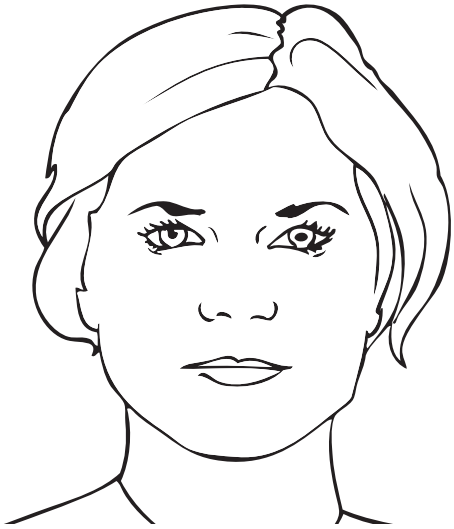
	Date	Toxin Brand	Lot #	Vial Expiration date	Volume Diluent Added	Concentration units / ml	Expiration date reconstituted product	Name of individual who performed reconstitution
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								

Patient History and Treatment (FEMALE)

Date: _____

Name: _____

Examination:



Medical History including prior cosmetic treatment / procedures: _____

_____

Medications including ASA, NSAID, Herbs: _____

Allergies, including LATEX: _____

Treatment Plan: _____

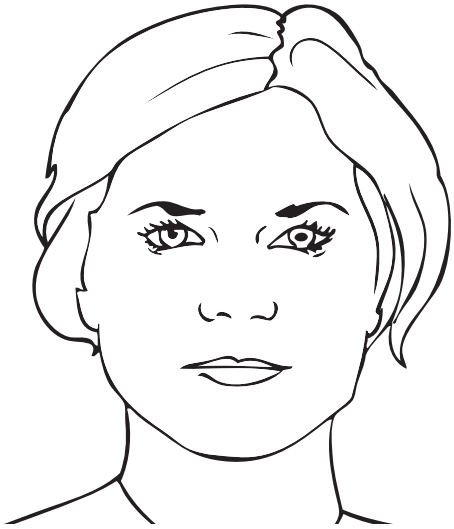
_____

patient history template (female)

Injectable Treatment Template

Date: _____

Name: _____



Injectable(s): _____

Injectable labels/lot #'s: _____

Total Units/Volume: _____

Anesthesia: _____

Photography: _____

Comments: _____

_____

_____

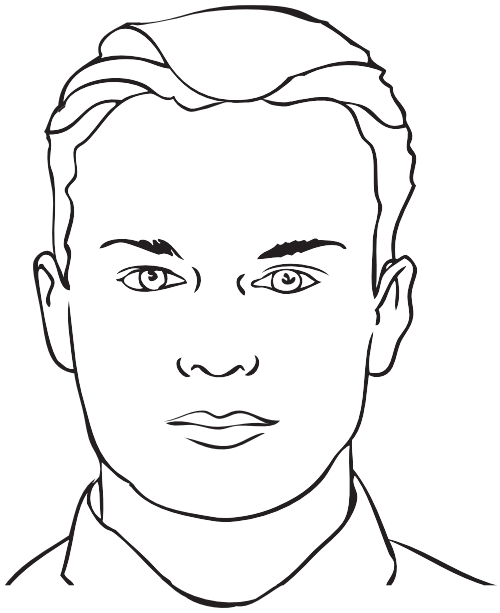
_____

Treatment provider: _____

Patient History and Treatment (MALE)

Date: _____

Name: _____



Examination:

Medical History including prior cosmetic treatment/procedures: _____

_____

Medications including ASA, NSAID, Herbs: _____

Allergies, including LATEX: _____

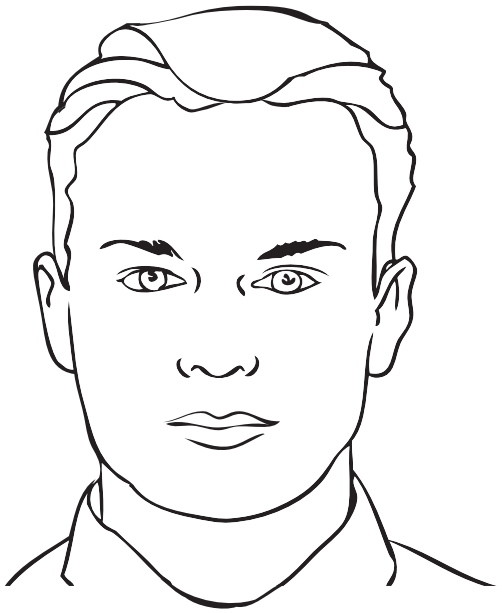
Treatment Plan: _____

_____

Injectable Treatment Template

Date: _____

Name: _____



Injectable(s): _____

Injectable labels/lot #'s: _____

Total Units/Volume: _____

Anesthesia: _____

Photography: _____

Comments: _____

_____

_____

_____

Treatment provider: _____

botox® cosmetic (allergan) reconstitution reference

Instructions For Reconstitution at XX Units/ml

Reconstitution Protocol for BOTOX® Cosmetic at XX units/ ml

1. Verify that expiration date on BOTOX® Cosmetic package and vial is correct.
2. Follow Infection Control Procedure: Wash hands, sanitize work surface, use alcohol swab to disinfect top of diluent vial and 100 unit BOTOX® Cosmetic vial
3. With sterile technique draw up into a sterile syringe, XX ml of diluent
4. With sterile technique, add diluent to vial of 100 unit BOTOX® Cosmetic
5. Dispose of used syringe and needle as medical waste.
6. Write date of reconstitution, concentration (units), date of expiration on BOTOX® Cosmetic vial with Sharpie™ micro tip marker
7. Store reconstituted BOTOX® Cosmetic vial in refrigerator
8. Complete BOTOX® Cosmetic Reconstitution Log Form
9. Use reconstituted BOTOX® Cosmetic according to office policy and procedures

Patient Safety Tips:

- Do not leave needles/syringes inserted into vials- this is a direct route for microbial contamination of vial contents
- Do not reuse needles, syringes, or gel cooling packs that have had patient contact (dispose as medical waste)
- Never allow a needle/syringe that has had patient contact to be reinserted into the medication vial or IV bag/IV line
- Never recap and store a partially-used syringe of injectable material for future use by the same patient
- Medications should be discarded upon expiration or any time there are concerns regarding the sterility of the medication
- Leftover parenteral medications should never be pooled for later administration

botox® cosmetic (allergan) administration reference

Corrugator: "XX-XX" units in divided injections

Procerus: "XX-XX" units in divided injections

Frontalis: "XX-XX" units in divided injections*

Orbicularis, lateral (Crows Feet): "XX-XX" units in divided injections*

Tail of lateral brow: "XX-XX" units in divided injections*

Nasalis (bunny lines): "XX-XX" units in divided injections*

Depressor Angularis Oris: "XX-XX" units in divided injections*

Platysma: "XX-XX" units in divided injections*

Other: "XX-XX" units in divided injections*

*Disclose off-label usage

For Administration at XX Units/ml (On and Off-label)

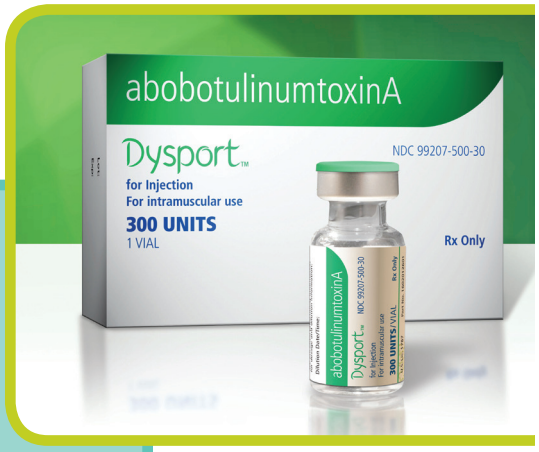
Administration Protocol for BOTOX® Cosmetic at XX units/ ml

1. Verify that expiration date on reconstituted BOTOX® Cosmetic vial is correct
2. Follow Infection Control Procedure: Wash hands, sanitize work surface, use alcohol swab to disinfect top of BOTOX® Cosmetic vial
3. With sterile technique draw up into a sterile syringe, BOTOX® Cosmetic, discard needle used for draw up and place needle for injection (30-32 gauge)
4. Perform injection of BOTOX® Cosmetic according to label or off-label.
5. Dispose of used syringe and needles as medical waste.
6. Complete patient treatment form regarding treatment areas, units used, lot number, etc.
7. Return reconstituted BOTOX® Cosmetic vial to refrigerator for storage

Patient Safety Tips:

- Do not leave needles/syringes inserted into vials- this is a direct route for microbial contamination of vial contents
- Do not reuse needles, syringes, or gel cooling packs that have had patient contact (dispose as medical waste)
- Never allow a needle/syringe that has had patient contact to be reinserted into the medication vial or IV bag/IV line
- Never recap and store a partially-used syringe of injectable material for future use by the same patient
- Medications should be discarded upon expiration or any time there are concerns regarding the sterility of the medication
- Leftover parenteral medications should never be pooled for later administration

dysport® (galderma) reconstitution reference



Instructions For Reconstitution at XX Units/ml

1. Verify that expiration date on DYSPORT® package and vial is correct.
2. Follow Infection Control Procedure: Wash hands, sanitize work surface, use alcohol swab to disinfect top of diluent vial and 300 unit DYSPORT® vial
3. With sterile technique draw up into a sterile syringe, XX ml of diluent
4. With sterile technique, add diluent to vial of 300 unit DYSPORT®
5. Dispose of used syringe and needle as medical waste.
6. Write date of reconstitution, concentration (units), date of expiration on DYSPORT® vial with Sharpie™ micro tip marker
7. Store reconstituted DYSPORT® vial in refrigerator
8. Complete DYSPORT® Reconstitution Log Form
9. Use reconstituted DYSPORT® according to office policy and procedures

Patient Safety Tips:

- Do not leave needles/syringes inserted into vials- this is a direct route for microbial contamination of vial contents
- Do not reuse needles, syringes, or gel cooling packs that have had patient contact (dispose as medical waste)
- Never allow a needle/syringe that has had patient contact to be reinserted into the medication vial or IV bag/IV line
- Never recap and store a partially-used syringe of injectable material for future use by the same patient
- Medications should be discarded upon expiration or any time there are concerns regarding the sterility of the medication

dysport® (galderma) administration reference

Corrugator: "XX-XX" units in divided injections

Procerus: "XX-XX" units in divided injections

Frontalis: "XX-XX" units in divided injections*

Orbicularis, lateral (Crows Feet): "XX-XX" units in divided injections*

Tail of lateral brow: "XX-XX" units in divided injections*

Nasalis (bunny lines): "XX-XX" units in divided injections*

Depressor Angularis Oris: "XX-XX" units in divided injections*

Platysma: "XX-XX" units in divided injections*

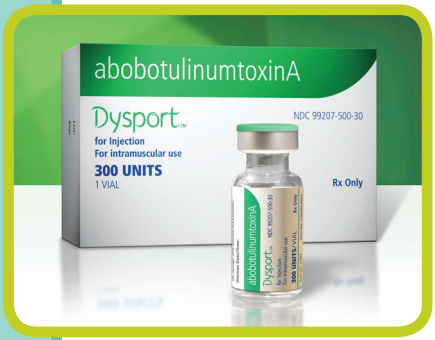
Other: "XX-XX" units in divided injections*

*Disclose off-label usage

For Administration at XX Units/ml (On and Off-label)

Administration Protocol for DYSPORT® Cosmetic at XX units/ ml

1. Verify that expiration date on reconstituted DYSPORT® vial is correct
2. Follow Infection Control Procedure: Wash hands, sanitize work surface, use alcohol swab to disinfect top of DYSPORT® vial
3. With sterile technique draw up into a sterile syringe, DYSPORT® , discard needle used for draw up and place needle for injection (30-32 gauge)
4. Perform injection of DYSPORT® according to label or off-label
5. Dispose of used syringe and needle as medical waste
6. Complete patient treatment form regarding treatment areas, units used, lot number, etc.
7. Return reconstituted DYSPORT® vial to refrigerator for storage



Patient Safety Tips:

- Do not leave needles/syringes inserted into vials- this is a direct route for microbial contamination of vial contents
- Do not reuse needles, syringes, or gel cooling packs that have had patient contact (dispose as medical waste)
- Never allow a needle/syringe that has had patient contact to be reinserted into the medication vial or IV bag/IV line
- Never recap and store a partially-used syringe of injectable material for future use by the same patient
- Medications should be discarded upon expiration or any time there are concerns regarding the sterility of the medication
- Leftover parenteral medications should never be pooled for later administration

xeomin® (merz) reconstitution reference

Instructions For Reconstitution at XX Units/ml

Reconstitution Protocol for Xeomin® at XX units/ ml

1. Verify that expiration date on reconstituted Xeomin® vial is correct
2. Follow Infection Control Procedure: Wash hands, sanitize work surface, use alcohol swab to disinfect top of Xeomin® vial
3. With sterile technique draw up into a sterile syringe, Xeomin®, discard needle used for draw up and place needle for injection (30-32 gauge)
4. Perform injection of Xeomin® according to label or off-label.
5. Dispose of used syringe and needles as medical waste.
6. Complete patient treatment form regarding treatment areas, units used, lot number, etc.
7. Return reconstituted Xeomin® vial to refrigerator for storage

Patient Safety Tips:

- Do not leave needles/syringes inserted into vials- this is a direct route for microbial contamination of vial contents
- Do not reuse needles, syringes, or gel cooling packs that have had patient contact (dispose as medical waste)
- Never allow a needle/syringe that has had patient contact to be reinserted into the medication vial or IV bag/IV line
- Never recap and store a partially-used syringe of injectable material for future use by the same patient
- Medications should be discarded upon expiration or any time there are concerns regarding the sterility of the medication
- Leftover parenteral medications should never be pooled for later administration

xeomin® (merz) administration reference

Corrugator: "XX-XX" units in divided injections

Procerus: "XX-XX" units in divided injections

Frontalis: "XX-XX" units in divided injections*

Orbicularis, lateral (Crows Feet): "XX-XX" units in divided injections*

Tail of lateral brow: "XX-XX" units in divided injections*

Nasalis (bunny lines): "XX-XX" units in divided injections*

Depressor Angularis Oris: "XX-XX" units in divided injections*

Platysma: "XX-XX" units in divided injections*

Other: "XX-XX" units in divided injections*

*Disclose off-label usage

For Administration at XX Units/ml (On and Off-label)

Administration Instructions

1. Verify that expiration date on reconstituted Xeomin® vial is correct
2. Follow Infection Control Procedure: Wash hands, sanitize work surface, use alcohol swab to disinfect top of Xeomin® vial
3. With sterile technique draw up into a sterile syringe, Xeomin®, discard needle used for draw up and place needle for injection (30-32 gauge)
4. Perform injection of Xeomin® according to label or off-label.
5. Dispose of used syringe and needles as medical waste.
6. Complete patient treatment form regarding treatment areas, units used, lot number, etc.
7. Return reconstituted Xeomin® vial to refrigerator for storage

Patient Safety Tips:

- Do not leave needles/syringes inserted into vials- this is a direct route for microbial contamination of vial contents
- Do not reuse needles, syringes, or gel cooling packs that have had patient contact (dispose as medical waste)
- Never allow a needle/syringe that has had patient contact to be reinserted into the medication vial or IV bag/IV line
- Never recap and store a partially-used syringe of injectable material for future use by the same patient
- Medications should be discarded upon expiration or any time there are concerns regarding the sterility of the medication
- Leftover parenteral medications should never be pooled for later administration