AESTHETIC INJECTABLE POLICY & PROCEDURE MANUAL TEMPLATES

Treatment guidelines are a crucial part of your medical aesthetic practice and should be in place before utilizing aesthetic medical injectables. This document features the Dermal Filler, Hyaluronidase, Neurotoxin, Sculptra® Aesthetic, Kybella®, Autologous Platelet Rich Plasma (A-PRP), and QWO® (collagenase clostridium histolyticum-aaes) Aesthetic Policy and Procedure Protocol Templates. Each topic includes the following sections:

- Purpose
- Scope
- Settings
- Qualifications
- Administration
- Indications – On-Label Use, Off-Label Use
- Contraindications, Warnings & Precautions
- Patient Assessment & Consultation
- Pre-Treatment
- Technique & Procedure
- Documentation
- Follow-Up & Problem Management
- Side Effects & Complications
- Approval & Review/Updating of Standardized Procedure
- Protocol Review & Documented Findings

Save hours of time.

These guidelines are based upon information from the manufacturer of each product described herein and with input from physicians, nurses, attorneys, and a compliance specialist. Because laws and regulations governing aesthetic injectables vary from state to state, however, you will need to follow and incorporate your own state laws and guidelines as you use the Manual to develop protocols for your own practice. Therefore, the protocol manual you develop for your office should be reviewed by your legal counsel prior to implementation and personalized to encompass your individual practice's needs. These treatment guide templates will save you hours of time as you develop your own written protocols, so you can spend more time with your patients.

Ensure your protective mechanism is in place.
It is critical that clinics have proper written policy and procedure protocols in place. Treatment guidelines are evolving and so your protocols should be reviewed and updated on an annual basis. By developing, implementing, and updating proper written protocols for your practice, you are demonstrating your commitment to safe and effective treatment for your patients, which may be of assistance to your clinic if legal action is ever brought against your staff, your medical director and/or your clinic. And, while these guidelines are focused on the injectables, it is also important to have other policies and procedures in place for lasers, or skin care, or any other service you provide.

Develop your own manual; modify forms/language to fit your practice.
These sample templates forms will provide a foundation from which to develop your own written policy and procedure injectable protocol manual that aligns with your particular medical aesthetic practice. Once the order is received, we will send you Word version templates to use as a guide to create your own injectable procedures manual. Please ensure you are able to provide these types of services within your authorized scope of practice for the state in which you are currently licensed.

PLEASE NOTE: Please download your documents from the link provided as soon as possible as **this link will only be active for 5 days from the date of purchase.**

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POLICY & PROCEDURE PROTOCOL FOR DERMAL FILLERS

PURPOSE

The purpose of this Policy and Procedure Protocol is to ensure the safe and effective treatment of patients undergoing injection of dermal fillers for the augmentation of the soft tissues and the reduction of lines and wrinkles.

SCOPE

The protocol applies to all Aesthetic Health Care Providers (AHCP) injecting dermal fillers. The appropriate and current product inserts (PI) for each dermal filler the practice is using is attached by the practice at the end of the dermal filler section in the protocol manual, and will be updated as the manufacturer revises its package inserts.

SETTING

Injections of dermal fillers should be performed in an appropriate facility under the direction of a physician/provider in accordance with all applicable local, state or other laws and manufacturer directions.

QUALIFICATIONS

Licensed and Registered Physicians, Physician Assistants, Nurse Practitioners and Nurses with appropriate education, training and privileges are eligible to perform these treatments in accordance with the established protocol if permitted by applicable state guidelines for scope of practice. The treating AHCP should be familiar with the manufacturer's current package insert for each dermal filler, which this practice has included as an appendix to the Dermal Fillers section of the manual. Dermal fillers have been classified as a medical device and the performance of such treatments is the practice of medicine.

ADMINISTRATION

Dermal fillers may be injected by any properly credentialed individual(s) under the direction of this protocol and/or a licensed physician/provider.

INDICATIONS

Injection with dermal fillers is indicated for the temporary treatment of facial lines, scars, creases, and other depressed contour irregularities not amenable to other treatments. Each dermal filer is indicated by the FDA (Food and Drug Administration) for various areas and depth of the tissue of the face. It is important that the AHCP is familiar with each FDA indication of each product they are using. For the purposes of this protocol, the only areas authorized for treatment under the direction of the delegating/supervising physician or licensed provider should be those areas in which the physician/provider has determined the AHCP has demonstrated appropriate skill, knowledge, and judgement in the use dermal fillers.

On-Label Use: The injection of dermal fillers is approved by the FDA for the treatment of various areas, and depth, depending on the dermal filler used. It is imporant for the AHCP to make mention to all patients, which areas are on-label and which areas are off-label use. The appropriate product inserts (PI) for each dermal filler the practice is using need to be attached at the end of the dermal filler area in the protocol manual.

Off-Label Use: Any areas of the face or body that are not mentioned in the PI of the dermal fillers are considered off-label and should be explained to the patient as such.

CONTRAINDICATIONS, WARNINGS & PRECAUTIONS

A review of the patient's medical history including, but not limited to, medical problems, allergies, hypersensitivities, history of autoimmune disease, history previous treatments, and procedures at the site of the treatment area should be conducted during the patient's assessment. Upon review of the assessment, the following protocols related to indications, contraindications and exclusions should be observed (see package inserts for individual product prescribing information).

The injection of dermal fillers is contraindicated in the following conditions (see package inserts for product information and individual prescribing recommendations):

- ❑ Pregnancy and breast feeding
- ❑ The presence of infection or any other inflammatory condition at the proposed treatment site
- ❑ A history of hypersensitivity or allergic reaction to previous injection with dermal fillers
- ❑ A history of repeated unsuccessful treatments with dermal fillers
- ❑ A history of hypersensitivity or allergic reaction to gram-positive bacteria or products containing gram-positive bacteria proteins
- ❑ A history of anaphylaxis or anaphylactoid reaction to injected medications
- ❑ A history of non-compliance with post-injection instructions
- ❑ Intoxication or influence of illicit drugs
- ❑ Immunodeficiency such as active viral infection
- ❑ Poorly controlled diabetes
- ❑ Use of chronic anticoagulation[1]
- ❑ Use with caution in patients on immunosuppressive therapy

Patients with any of the above conditions should be excluded from treatment until the condition is controlled or resolved.

1. Patients taking chronic anticoagulation drugs should provide approval for treatment from their primary care physician/provider.
2. Do NOT overtreat/overfill the contour deficiency of the nasolabial fold contour defect because the depression is expected to gradually improve over several weeks after injection.
3. Do not implant into blood vessels which could cause vascular occlusion and/or infarction or embolic phenomena.
4. Injection site reactions have included delayed occurrence of subcutaneous papules and nodules, hematoma, bruising-ecchymosis, bleeding, edema, discomfort, inflammation and erythema. Subcutaneous papules and nodules were often confined to the injection site, typically palpable, asymptomatic and non-visible, occurring days to months after injections and had a prolonged time course to resolution.
5. Long term safety and effectiveness of dermal fillers beyond two years after last injection have not been investigated in clinical trials.

PATIENT ASSESSMENT & CONSULTATION

- Properly consult and assess patient for appropriate indications and contraindications for treatment.
- Use a mirror and/or photos of the patient to engage the patient in the process of assessment and planning.
- Discuss patient asymmetries or irregularities.
- Document details in the patient's medical record.
- Discuss the common adverse reactions to the derml filler, treatment procedures, post treatment care and expectations following the procedure.
- If this is a repeat injection, make assessment of the effect and duration of earlier injection treatment, then customize the treatment to the patient's needs.

- Set patient expectations about the risks of bruising, unusual adverse events, and social down time.
- Advise that repeat treatments should be approximately 4 weeks apart to allow for swelling and filler to settle.
- Compliance with the Health Insurance Portability and Accountability Act ("HIPAA") should be followed in relation to patient care.

PRE-TREATMENT

- Verify patient's current history, risk factors, exam, diagnosis, and treatment plan by the appropriate AHCP.
- **INFORMED VERBAL AND WRITTEN CONSENTS SHOULD BE OBTAINED, SIGNED AND WITNESSED PRIOR TO PROCEEDING WITH TREATMENT.**
- Review possible side effects and complications associated with treatment.
- Take photographs pre-treatment prior to marking the patient and after marking the patient.
- Mark out appropriate areas to inject.
- Verify markings of locations with the patient using a mirror and/or photograph.
- For the prevention of herpes outbreak, standing orders for antiviral medications are on file (see this practice's standing drug order).

TECHNIQUE & PROCEDURE

- Juvéderm® Ultra, Juvéderm ® Ultra XC, Juvéderm ® Ultra Plus, Juvéderm ® Ultra Plus XC, Juvéderm Volbella® XC, Juvéderm Vollure™ XC, Juvéderm Voluma® XC and Juvéderm Volux® XC are supplied by Allergan; Radiesse® and Belotero Balance® are supplied by Merz Aesthetics; and Restylane®, Restylane-L®, Restylane Contour® Restylane Defyne®, Restylane Kysse®, Restylane Lyft®, Restylane Refyne® and Restylane Silk® are supplied by Galderma Laboratories; RHA® 2, RHA® 3, RHA® 4 and RHA Redensity™ are supplied by Revance Aesthetics; Revanesse® Versa™ and Revanesse® Versa+™ are supplied by Prollenium. They are packaged in sterile, disposable syringes with sterile needles to be used for injection. They should be stored in accordance with the manufacturers' packaged insert guidelines. They should not be stored or used past the expiration date printed on the package.

- Once the area to be treated is defined, and an appropriate examination is completed, the patient is seated. If topical anesthetic is to be used, it is applied liberally to the treatment areas and should be allowed to work for at least 15 minutes prior to injection.

- The appropriate syringe of the dermal filler for the treatment area is opened and removed from its package (the packaging is not sterile and should not be used as a tray during the procedure). The needle is attached in accordance with the manufacturer's instructions. Use of this needle should minimize the chances of dislodging the needle while injecting the viscous dermal filler. The material in the syringe should be inspected, and if it is not clear and lacking particulate matter (except in the case of Radiesse®), it should not be used, and the manufacturer should be notified. A different syringe of dermal filler should then be selected for this treatment. Once selected, the adhesive patient record label from the syringe or packaging should be removed and placed in the appropriate location on the treatment record in the patient's chart or transferred to the electronic record (keep consistent with clinical charting).

- The treatment area should be prepped by removing any topical anesthetic and/or makeup and cleansing the skin with a surgical prep solution.

- Correct injection technique is critical to the success of the procedure in achieving the desired results. The needle and/or cannula should be inserted into the treatment site with the tip ending up at an appropriate depth within the facial tissue. The dermal filler should then be injected using slow, even pressure watching