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 and Sculptra® Aesthetic Policy and Procedure Protocols. Each topic includes the following sections:

• Purpose
• Scope
• Settings
• Qualifications
• Administration
• Patient Assessment
• Indications
• Contraindications, Warnings and Precautions
• Techniques
• Documentation
• Follow-Up and Problem Management
• Side Effects and Complications
• Development and Approval of Standardized Procedure
• Protocol Review and Documented Findings

Save hours of time.
These guidelines are based upon information from the manufacturer of each product described herein and have been thoroughly reviewed by multiple physicians, nurses, attorneys, and a compliance specialist. They should be reviewed by your counsel prior to implementation, and personalized to encompass your individual practice’s needs. This detailed and thorough treatment guide will save you hours of time so you can spend more time with your patients.

Ensure your protective mechanism is in place.
It is critical that clinics have proper policy and procedure protocols in place. Treatment guidelines are evolving and should be reviewed on an annual basis. These guidelines will serve as a protective mechanism for 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 forms will provide a foundation upon which to develop your own policy and procedure injectable protocol manual that aligns with your particular medical aesthetic practice; simply modify the templates herein. Please ensure you are able to provide these types of services within your scope of practice for the state in which you are currently licensed. These forms will evolve over time as new products and techniques are introduced.
DISCLAIMER

THE INFORMATION PRESENTED HEREIN IS PROVIDED “AS-IS” AND WITHOUT WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED INCLUDING BUT NOT LIMITED TO, WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE, MERCHANTABILITY, OR FREEDOM FROM INFRINGEMENT OF PATENT, TRADEMARK, OR COPYRIGHT.

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The user acknowledges state laws vary on whom can provide the aesthetic services identified in these documents and further acknowledges and accepts full responsibility to follow her/his state law without exception.

These documents are templates/samples/forms/suggestions of what may be appropriate for use, but should first take into consideration individual personalization and clear directives on compliance as it pertains to the individuals licensing state requirements.
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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 injecting dermal fillers.

SETTING

Injections of dermal fillers should be performed in an appropriate facility under the direction of a physician/provider in accordance with local state statutes.

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 this protocol (check state guidelines for scope of practice). The treating Aesthetic Health Care Provider should be familiar with the manufacturer’s package insert for each dermal filler, which is included as an appendix to 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.

PATIENT ASSESSMENT

Patients should be properly consulted and assessed for appropriate indications and contraindications for treatment, and a record of that assessment should be documented in the patient’s medical record. INFORMED VERBAL AND WRITTEN CONSENTS SHOULD BE OBTAINED PRIOR TO PROCEEDING WITH TREATMENT. Patients will be consulted regarding any common adverse reactions to the medical device, treatment procedures, post treatment care and expectations following the procedure. Patients should also be informed regarding possible side effects and complications associated with treatment. Compliance with the Health Insurance Portability and Accountability Act (“HIPAA”) should be followed in relation to patient care.
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. Juvéderm Voluma® is indicated for deep (subcutaneous and/or supraperiosteal) injection for cheek augmentation to correct age-related volume deficit in the mid-face in adults over the age of 21. In addition, it is used off label for the augmentation of the volume of the soft tissues in locations such as the lips, malar regions, brows, earlobes, and tear troughs. The injection of dermal fillers is approved by the FDA for the treatment of moderate to severe wrinkles and folds. It is indicated for deep (subcutaneous and/or supraperiosteal) injection for cheek augmentation to correct age-related volume deficit in the mid-face in adults over the age of 21. 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 Aesthetic Health Care Provider has demonstrated appropriate skill, knowledge, and judgement in the use dermal fillers.

CONTRAINDICATIONS, WARNINGS & PRECAUTIONS

A review of the patient’s medical history including, but not limited to, medical problems, allergies, history of 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
- 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.

PRE-TREATMENT

For the prevention of herpes outbreak, standing orders for antiviral medications are on file (see standing drug order).
TECHNIQUES

1. Juvéderm® Ultra, Juvéderm® Ultra XC, Juvéderm® Ultra Plus, Juvéderm® Ultra Plus XC, Juvéderm Volbella® and Juvéderm Voluma® are supplied by Allergan; Radiesse® and Belotero Balance® are supplied by Merz Aesthetic; and Restylane®, Restylane-L®, Restylane Lyft® and Restylane Silk® are supplied by Galderma Laboratories. 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.

2. 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.

3. The appropriate syringe of the dermal filler for the treatment area is opened and removed from its package. 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 it should be returned to the manufacturer for a refund. 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).

4. The treatment area should be prepped by cleansing and removing the topical anesthetic and/or makeup.

5. Correct injection technique is critical to the success of the procedure in achieving the desired results. The needle should be inserted into the treatment site with the tip ending up at an appropriate depth within the skin. The dermal filler should then be injected using slow, even pressure watching for the lifting and filling of tissues in the area being injected. OVERCORRECTION (more product than deficit/overfilled) IS GENERALLY NOT NEEDED AND IS TO BE AVOIDED.

6. Once the injection site is appropriately filled, the needle is inserted into the next adjacent location, and the process is repeated. Care should be taken to adequately assess the entire area to be treated with the selected amount of dermal filler to ensure even and symmetrical distribution of the material.

7. Once the injection is completed, the treated areas should be gently massaged, compressing the material into a “strip” or flattening it into a smooth contour, as opposed to allowing it to remain in clumps or beads. More vigorous massage may result in additional swelling, bruising or dispersement of the filler material.

8. The patient should be informed that the treated area may remain swollen, irregular in shape, and bruised for several days. Ice or a cold compress can be applied intermittently the first 48 hours post treatment.

9. The patient should be advised to allow healing for at least two weeks before any assessment is made of final volume and contour. If the outcome is satisfactory, no further treatment is indicated. If the outcome is unsatisfactory, the appropriate Aesthetic Health Care Provider should be contacted to arrange for an evaluation of the patient. If the patient desires further correction the procedure may be repeated, adding only the appropriate amount of dermal filler to bring the volume to the desired level.