BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

Contents

1. Device Description

Black Design™ is a sterile, non-pyrogenic, biodegradable, viscoelastic gel composed of non-animal stabilized hyaluronic acid (HA). It is intended for injection into the skin to temporarily add volume and correct facial wrinkles or folds. The hyaluronic acid used in *Black Design™* is cross-linked with 1,4-butanediol diglycidyl ether (BDDE), making it a durable filler designed to provide long-lasting results.

Composition (per mL):

- Hyaluronic Acid: 25 mg
- Phosphate-buffered saline: q.s. to 1 mL (pH 7.0)

2. Intended Use/Indications

Black Design™ is indicated for:

- The correction of moderate to severe facial wrinkles and folds, such as nasolabial folds, through injection into the mid-to-deep dermis.
- Chin augmentation for patients with mild to moderate chin retrusion, improving the chin profile and enhancing overall facial balance. In this case, the product is injected into the deep dermal, subcutaneous, and/or supraperiosteal layers.

This product is approved for use in adults aged 21 and older.

3. Contraindications

Black Design™ should not be used in patients with the following conditions:

1. Severe Allergies and Anaphylaxis:
    - *Black Design™* is contraindicated in individuals with a known history of severe allergic reactions, particularly anaphylaxis. This includes those with hypersensitivity to hyaluronic acid-based products or any components of *Black Design™*, such as

lidocaine. Anaphylactic reactions can be life-threatening and require immediate medical intervention.

- Before treatment, healthcare providers should assess the patient's allergy history. If there is any uncertainty about potential allergic reactions, pre-treatment testing or alternative treatment options should be considered.

2. Active Skin Infections and Inflammation:
   - Avoid injecting *Black Design™* into areas with active infections, such as:
     - Herpes simplex (cold sores)
     - Acne
     - Impetigo
     - Cysts
   - Injection into infected or inflamed areas may exacerbate the condition and lead to complications such as abscess formation, delayed healing, or spreading of the infection.
   - If the patient presents with signs of skin inflammation (e.g., redness, swelling, or heat in the area), treatment should be postponed until the infection or inflammation has resolved.
3. Autoimmune Diseases:
   - Patients with autoimmune disorders or compromised immune systems may experience an increased risk of adverse reactions or prolonged healing. *Black Design™* is contraindicated in patients with uncontrolled autoimmune conditions such as rheumatoid arthritis, lupus erythematosus, or scleroderma, as these conditions may trigger an inflammatory response to the filler material.
   - While some patients with stable autoimmune conditions may be treated, the risks should be carefully weighed, and treatment should proceed only with informed consent and close monitoring.
4. Bleeding Disorders or Anticoagulant Therapy:
   - Patients with bleeding disorders (such as hemophilia) or those taking anticoagulant medications (such as warfarin, heparin, or aspirin) are at a higher risk of experiencing significant bruising or bleeding at the injection site. *Black Design™* should be avoided in

these individuals unless absolutely necessary, and a detailed consultation with the patient's physician should take place.

- In cases where treatment is deemed essential, precautions should be taken to minimize bleeding and bruising, and patients should be closely monitored for excessive bleeding.

5. Hypersensitivity to Gram-Positive Bacterial Proteins:
   - *Black Design™* contains hyaluronic acid derived from fermentation of gram-positive bacteria. Patients with known hypersensitivity to gram-positive bacterial proteins should not be treated with this product, as they may experience allergic reactions.
   - Hypersensitivity reactions can range from mild irritation to severe allergic responses, including anaphylaxis, and should be taken seriously when evaluating a patient's medical history.
6. Pregnancy and Breastfeeding:
   - The safety of *Black Design™* has not been studied in pregnant or breastfeeding women. As a result, the product is contraindicated during pregnancy and lactation due to the potential unknown risks to the mother or child.
   - If treatment is necessary, it should be postponed until after the patient is no longer pregnant or breastfeeding.
7. Patients with a History of Keloid or Hypertrophic Scarring:
   - Patients who are prone to keloid formation or hypertrophic scarring should avoid *Black Design™* injections. Injecting into patients with these conditions may increase the risk of adverse scarring or unwanted tissue reactions.
   - Discuss the potential risks with patients who have a history of abnormal scar formation, and consider alternative treatment options if necessary.
8. Presence of Permanent Implants in the Treatment Area:
   - *Black Design™* should not be injected into areas where permanent facial implants (e.g., silicone, Gore-Tex) are present. Interference with or damage to the implants may occur, and the combination of temporary and permanent fillers may result in unpredictable or adverse aesthetic outcomes.

- Evaluate the treatment area thoroughly for any pre-existing implants or foreign materials before proceeding with the injection.

4. Warnings

1. Intravascular Injection Risk:
    - Accidental injection of *Black Design™* into blood vessels can lead to severe and potentially life-threatening complications such as vascular occlusion, ischemia, necrosis, embolism, or even blindness.
    - The practitioner should exercise extreme caution when injecting near areas with significant vasculature, such as the glabella, periorbital region, and nose. If an intravascular injection is suspected, treatment should be discontinued immediately, and appropriate measures (such as administering hyaluronidase) should be taken.
    - Aspirate before injecting to ensure that the needle is not inside a blood vessel. If blood is visible in the syringe during aspiration, reposition the needle before injecting.
2. Avoid Injection in Areas of Active Inflammation or Infection:
    - Do not inject *Black Design™* into areas with active inflammation, such as acne, rashes, cold sores (herpes simplex), or any other skin infection.
    - Injection in such areas could exacerbate the infection, lead to abscess formation, or prolong the healing process.
    - It is recommended to delay treatment until the infection or inflammatory condition has resolved to minimize the risk of complications.
3. Delayed Hypersensitivity Reactions:
    - Although rare, delayed hypersensitivity reactions to hyaluronic acid fillers have been reported. These reactions can manifest as redness, swelling, nodules, or lumps at the injection site days or even weeks after the procedure.
    - In such cases, corticosteroid therapy or hyaluronidase injections may be required to resolve the condition.
    - Practitioners should inform patients about the possibility of delayed hypersensitivity and monitor for any adverse reactions after treatment.
4. Patients with a History of Severe Allergies:

- *Black Design™* is contraindicated in patients with a known history of severe allergic reactions (including anaphylaxis). These individuals may experience life-threatening allergic reactions even to small doses of the filler or lidocaine.
- A detailed allergy history should be obtained from the patient before treatment. If there is any uncertainty regarding potential allergies, consider performing a skin test or using an alternative dermal filler that does not contain lidocaine.
- Emergency interventions such as epinephrine and antihistamines should be readily available in case of anaphylactic reactions.

5. Increased Risk of Bruising and Bleeding:
    - Injection of dermal fillers, including *Black Design™*, may cause bruising, hematomas, or bleeding, particularly in patients who are taking anticoagulants, aspirin, NSAIDs, or other medications that affect platelet function.
    - Advise patients to discontinue the use of blood-thinning medications, if medically safe to do so, at least 1 week prior to treatment to minimize the risk of bruising or bleeding. Always consult with the patient's physician before recommending medication changes.
    - Injection should be performed with minimal trauma to the tissue to reduce the likelihood of post-treatment bruising.
6. Patients with Compromised Healing or Immune Function:
    - Use caution when treating patients with compromised immune systems, such as those undergoing chemotherapy, radiation therapy, or immunosuppressive treatments. These patients may have a higher risk of infection and may experience delayed wound healing.
    - Additionally, patients with autoimmune diseases (e.g., lupus, rheumatoid arthritis) may experience flare-ups or increased risk of complications. If treatment is necessary, proceed with extreme caution and provide adequate post-treatment monitoring.
7. Vision Changes and Ocular Complications:
    - In rare cases, accidental intravascular injection of dermal fillers in the periorbital region has been associated with vision changes, blurred vision, permanent

blindness, or stroke. If the patient reports any vision changes during or after the injection, stop the procedure immediately and seek emergency medical assistance.

- Prompt recognition and treatment are crucial to minimize long-term damage. Possible treatments include administering hyaluronidase, anticoagulants, or other supportive measures.

8. Granuloma and Nodule Formation:
    - Delayed formation of granulomas, nodules, or lumps may occur weeks to months after the procedure. These formations can sometimes be mistaken for infection, but they are often an immune response to the filler material.
    - If granulomas or nodules develop, treatment may include injections of hyaluronidase, corticosteroids, or surgical excision in severe cases. Patients should be informed of this possibility before treatment, especially those with a history of such reactions.
9. Interaction with Laser or Other Skin Treatments:
    - Avoid performing laser treatments, chemical peels, dermabrasion, or other abrasive skin treatments in the same area shortly after *Black Design™* injections. These treatments may cause an inflammatory reaction or degrade the filler prematurely.
    - If these procedures are required, allow adequate time (at least 2 weeks) for the filler to settle and the skin to recover before undergoing any additional cosmetic treatments.
10. Use in Areas with Prior Implants or Fillers:

- *Black Design™* should not be injected in areas where patients have permanent implants (such as silicone or other non-biodegradable fillers) to avoid unpredictable results and complications.
- Exercise caution when injecting into areas previously treated with other dermal fillers, as this may cause uneven distribution or migration of the product.

11. Risk of Infection:

- Although *Black Design™* is a sterile product, improper handling of the syringe, needle, or injection site can introduce bacteria, leading to infection. Symptoms of infection include redness, swelling, pain, heat, and the presence of pus at the injection site.
- Practitioners must follow strict aseptic techniques to minimize the risk of infection. If an infection occurs, initiate appropriate treatment with antibiotics and monitor the patient for signs of worsening or systemic infection.

5. Precautions

A. Practitioner Qualifications

- *Black Design™* should only be administered by a licensed and experienced healthcare provider trained in facial anatomy and dermal filler injection techniques. Improper injection technique or placement can lead to serious complications, such as vascular occlusion, migration, or lumps.
- Practitioners should undergo specific training on the use of *Black Design™* to ensure correct product handling and application, particularly for sensitive areas such as the nasolabial folds and chin.

B. Injection Site and Technique

1. Correct Injection Depth:
    - The success of treatment with *Black Design™* depends heavily on the injection being administered at the correct depth. For treating nasolabial folds, the filler should be injected into the mid-to-deep dermis, while for chin augmentation, it should be injected into the subcutaneous or supraperiosteal layer.
    - Incorrect depth can lead to poor results, lumps, uneven texture, or more serious complications such as skin necrosis.
2. Aspirate Before Injection:
    - Always aspirate (gently pull back the syringe plunger) before injecting to ensure the needle is not in a blood vessel. This helps to prevent the risk of vascular occlusion, which can lead to skin necrosis or more severe complications such as blindness.

3. **Minimize Tissue Trauma**:
    - Practitioners should use minimal pressure during injections and ensure the treatment area is handled delicately to reduce trauma and the risk of bruising, swelling, and inflammation.

C. Sterility and Safety Measures

1. Single-Use Only:
    - Each *Black Design™* syringe and needle are intended for single-patient use only. Do not reuse or attempt to sterilize the syringe or needle, as this increases the risk of infection and contamination.
    - After each treatment, immediately discard the used syringe and needle in an appropriate sharps disposal container.
2. **Sterile Handling**:
    - Follow strict aseptic techniques to ensure that the product and treatment area are sterile throughout the procedure. The injection site should be thoroughly cleaned and disinfected before the injection to reduce the risk of infection.
    - Always wear sterile gloves and use clean, sterile instruments during the procedure.

D. Avoiding Complications

1. Patients with Bleeding Disorders:
    - Use caution when treating patients with bleeding disorders (e.g., hemophilia) or those taking anticoagulant medications (e.g., aspirin, warfarin, NSAIDs). These patients are at a higher risk of prolonged bleeding or significant bruising at the injection site.
    - Advise patients to discontinue the use of blood-thinning medications at least 1 week prior to treatment, if medically safe to do so, to minimize the risk of bruising or bleeding. Always consult with the patient's physician before making any changes to medication.

2. **Compromised Healing or Immune Function**:
    - Exercise caution when injecting patients who are immunocompromised or have delayed wound healing due to conditions such as diabetes, HIV/AIDS, or those undergoing chemotherapy or steroid treatment. These patients may be more prone to infections or prolonged recovery periods.
3. **Risk of Herpes Reactivation**:
    - Patients with a history of herpes simplex virus (cold sores) are at risk of experiencing a flare-up following treatment. In such cases, prophylactic antiviral therapy (e.g., acyclovir) may be prescribed prior to the injection to prevent outbreaks.
    - If the patient has active herpes lesions, the procedure should be delayed until the outbreak has fully healed.
4. **Avoid Overcorrection**:
    - Overcorrection can result in unnatural or undesirable aesthetic outcomes. Practitioners should inject small aliquots of filler and gradually build up volume to achieve the desired result. In areas requiring deeper volume (e.g., chin), a layering technique should be used to ensure smooth and even results.
5. **Avoid Injection into Scar Tissue**:
    - Do not inject into areas with thick scar tissue, as the product may not integrate well with the surrounding tissue and could result in lumps, nodules, or uneven results.
    - Previous facial trauma or surgeries may also complicate the treatment process and require additional consideration.

E. Pre-Treatment and Post-Treatment Considerations

1. **Sun and Heat Exposure**:
    - Patients should avoid exposure to the sun, tanning beds, or heat (e.g., saunas) for at least 24 hours post-treatment. Excessive heat may exacerbate swelling and inflammation.
    - Patients should also avoid strenuous exercise immediately following the injection to minimize bruising and swelling.
2. **Post-Treatment Massage**:

- Gentle post-injection massage may be required to ensure even distribution of the filler. The practitioner should assess the treated area for any signs of irregularities or lumps after the injection. However, patients should avoid massaging the area themselves unless instructed by their healthcare provider.

3. **Makeup and Skincare**:
   - Patients should be advised to avoid applying makeup, skincare products, or other topical treatments on the treated area for at least 6 hours after the procedure. Applying products too soon can irritate the skin and may introduce bacteria to the injection site, increasing the risk of infection.
4. **Cold Compress**:
   - A **cold compress** (wrapped in a cloth, never applied directly to the skin) may be applied immediately following the procedure to reduce swelling or discomfort. Patients should be informed that swelling, redness, or bruising are common post-treatment effects and typically resolve within a few days.

F. Special Patient Populations

1. **Pregnancy and Breastfeeding**:
   - The safety of *Black Design™* in pregnant or breastfeeding women has not been established. Therefore, it is recommended to avoid treatment in these populations due to the lack of safety data.
2. **Patients Prone to Keloids**:
   - Individuals with a history of keloid or hypertrophic scar formation should avoid dermal filler treatments, as they may be prone to unwanted scarring or granuloma formation at the injection site.

G. Handling Delayed Adverse Reactions

1. **Granuloma and Nodule Formation**:
    - Granulomas or nodules may develop as a delayed immune response to the filler. These lumps or swellings may appear weeks or even months after the injection. If granulomas develop, treatment options may include corticosteroid therapy, hyaluronidase injections, or surgical excision in severe cases.
2. **Hypersensitivity Reactions**:
    - Although rare, hypersensitivity reactions can occur following dermal filler injections. These reactions may include redness, swelling, and itching and could last for several days or weeks. In severe cases, systemic corticosteroids may be required to manage the reaction.

6.Post Marketing Surveillance

Since the introduction of *Black Design™* into the global market, post-marketing surveillance has been a key component in monitoring the ongoing safety and efficacy of the product. Adverse events reported through voluntary submission, clinical observations, and literature reviews have been documented to ensure the highest standards of patient safety.

The data collected from post-marketing reports has allowed for a comprehensive understanding of both common and rare complications associated with the use of Black Design™. Below is a summary of the key findings from these reports:

1. Common Adverse Events

The most frequently reported adverse events following the use of *Black Design™* have been temporary and typically mild to moderate in severity. These side effects generally resolve on their own within 1 to 2 weeks. The most commonly reported adverse reactions include:

- Swelling (Edema): Temporary swelling at the injection site is common, especially in the areas treated for volume enhancement.

- Bruising (Ecchymosis): Bruising can occur after injections, especially in areas with dense vasculature, such as the lips and nasolabial folds.
- Tenderness: Patients may experience localized tenderness or discomfort at the injection site for a few days post-treatment.
- Redness (Erythema): Redness at the injection site is a common reaction that usually subsides within a few hours to days.
- Itching (Pruritus): Mild itching is occasionally reported, particularly in sensitive skin types or areas prone to irritation.
- Lumps or Nodules: Small lumps or nodules may form due to improper filler placement or product migration. These are typically transient but may require massage or additional treatment to resolve.

2. Less Common Adverse Events

Less frequently, but still documented, are the following adverse reactions:

- Delayed Onset Nodules: Granuloma formation or persistent lumps may develop weeks to months after treatment. These may require medical intervention such as corticosteroid injections, hyaluronidase administration, or, in rare cases, surgical excision.
- Discoloration: Some patients may experience hyperpigmentation or hypopigmentation at the injection site, particularly in patients with darker skin tones. This is typically temporary but may take several weeks or months to fully resolve.
- Asymmetry: In some cases, patients have reported uneven results or asymmetry following treatment. Touch-up treatments may be necessary to correct any imbalances in facial volume.
- Vascular Compromise: Although rare, inadvertent intravascular injection can lead to vascular occlusion, ischemia, or necrosis. Early intervention with hyaluronidase and appropriate medical management is essential in these cases.
- Infection: While rare, infections at the injection site can occur. Signs of infection include increasing redness, warmth, tenderness, and the presence of pus. Immediate antibiotic treatment is recommended to prevent more serious complications.

3. Serious Adverse Events

Serious adverse events have been reported very rarely in association with *Black Design™*. These include:

- Vascular Occlusion: Unintentional injection into blood vessels has been linked to severe complications, including tissue necrosis and, in extreme cases, blindness. Immediate intervention with hyaluronidase, anticoagulants, or vasodilators may be required if vascular occlusion is suspected.
- Allergic Reactions: Severe allergic reactions, including anaphylaxis, have been reported in rare cases. Symptoms such as hives, swelling, or difficulty breathing require urgent medical intervention.
- Blindness or Vision Impairment: In rare instances, injection near the periorbital area has resulted in vision loss or blurred vision. This is typically caused by intravascular injection or embolization. Immediate treatment is crucial to minimize permanent damage.

4. Reporting Adverse Events

Healthcare professionals are encouraged to report any adverse events or unexpected complications associated with *Black Design™* to the manufacturer and relevant regulatory authorities. This allows for continuous monitoring and improvement of product safety.

Contact Information:

- **Telephone Number**: 021-284208
- **Email**: info@poltechnologies.com
- **Website**: www.poltechnologies.com

5. Monitoring and Future Improvements

The information gathered from post-marketing surveillance is reviewed regularly to ensure that any emerging risks are promptly addressed. If necessary, updates to the product's Instructions for Use (IFU), safety protocols, or formulation are made to enhance patient outcomes and reduce the risk of complications.

Post-marketing data is essential for the continuous improvement of *Black Design™*, ensuring that the product remains both safe and effective for patients worldwide. Healthcare professionals are encouraged to participate in this ongoing monitoring effort by reporting any adverse events and providing feedback on product performance.

7.Clinical Studies

1. Pivotal Study for Black Design™ in Correction of Moderate to Severe, Deep Facial Wrinkles and Folds (e.g., Nasolabial Folds)

Study Design

A pivotal multi-center, double-blinded (subject and evaluator), randomized, active-controlled clinical trial was conducted to evaluate the safety and effectiveness of *Black Design™* for the treatment of moderate to severe nasolabial folds (NLFs). Subjects were treated with *Black Design™* on one side of the face, and a comparator dermal filler (non-lidocaine containing) was used on the other side in a split-face design.

Each subject underwent up to two treatments: an initial injection followed by a touch-up treatment approximately 3 weeks later. Retreatment was offered 48 weeks after the initial injection. Subjects returned for follow-up visits at Weeks 3, 12, 24, 36, and 48 after the initial treatment to evaluate both safety and effectiveness.

Study Endpoints

The primary effectiveness endpoint was the change in the Wrinkle Severity Rating Scale (WSRS) score from baseline to Week 24 after treatment. Secondary effectiveness endpoints included

change in WSRS at follow-up visits through Week 48, and patient-reported outcomes using the Self-Assessment of Wrinkle Severity and the Numeric Pain Intensity Scale (NPIS).

Study Population

The study enrolled 162 subjects, of which 96.3% were female, and the median age was 53 years. The majority of the subjects were of Caucasian descent (80%), followed by Black (12%) and Hispanic (6%) participants. At baseline, 73% of the subjects had moderate wrinkles, and 27% had severe wrinkles based on the WSRS.

Effectiveness Results

The primary endpoint was achieved. At Week 24, subjects treated with *Black Design™* demonstrated an average reduction of 1.1 points in WSRS, which was comparable to the control treatment. By Week 48, 69.7% of the subjects treated with *Black Design™* maintained a clinically significant improvement in the severity of their nasolabial folds (≥ 1-point reduction in WSRS). Additionally, 64.4% of patients reported sustained improvement in self-assessments through 1 year.

Pain Assessment

Subjects consistently reported less pain with *Black Design™* injections compared to the control product. On the Numeric Pain Intensity Scale, subjects rated pain as 3.2/10 with *Black Design™* compared to 5.3/10 with the comparator.

2. Pivotal Study for Black Design™ in Augmentation of the Chin Region

Study Design

A separate randomized, evaluator-blinded, multicenter study was conducted to evaluate the effectiveness and safety of *Black Design™* for chin augmentation. Subjects were treated either with *Black Design™* or were assigned to a no-treatment control group. Subjects in the treatment group received an initial injection, and touch-up treatments were offered 4 weeks later if necessary. Follow-up visits occurred at Weeks 2, 4, 12, 24, 36, and 48.

Study Endpoints

The primary endpoint was the proportion of subjects who showed at least a 1-point improvement in chin profile on the Galderma Chin Retrusion Scale (GCRS) at Week 12. Secondary endpoints included patient satisfaction using the FACE-Q Satisfaction with Chin questionnaire, as well as global aesthetic improvement evaluations using the Global Aesthetic Improvement Scale (GAIS).

Study Population

A total of 140 subjects were randomized, with 56 subjects having mild chin retrusion and 84 subjects having moderate retrusion. 89.3% of the participants were female, and 75.7% were of Caucasian descent.

Effectiveness Results

The primary endpoint was achieved, with 86.1% of subjects in the treatment group showing at least 1-point improvement in chin profile at Week 12, compared to 6.5% in the control group. This statistically significant improvement was maintained throughout Week 48. Patient satisfaction was also high, with 84.8% - 99.0% of subjects reporting aesthetic improvements at each follow-up visit.

8. Instructions for Use

A. Preparing for Injection

1. Pre-Treatment Evaluation: Before initiating treatment, assess the patient's medical history and ensure there are no contraindications (e.g., allergies, infections, or recent facial procedures).
2. Inspect the Syringe: Verify that the syringe packaging is intact, and the product has not expired. If the packaging shows signs of tampering or damage, discard the product.
3. Sterilize the Treatment Area: Thoroughly cleanse and disinfect the injection site using an appropriate antiseptic solution to reduce the risk of infection.
4. Attach the Needle: Attach the sterile needle to the pre-filled syringe. Ensure the needle is securely attached by twisting it firmly into place.

5. Aspirate Before Injection: Before injecting the filler, always pull back the plunger slightly (aspirate) to ensure the needle is not in a blood vessel. If blood is drawn into the syringe, reposition the needle before proceeding with the injection.

B. Injection Techniques

1. Nasolabial Folds:
    - Injection Technique: Use a linear threading technique or serial puncture injections along the length of the nasolabial fold.
    - Injection Depth: The filler should be injected into the mid-to-deep dermis layer for optimal wrinkle correction.
    - Post-Injection Care: After the injection, gently massage the area to ensure even distribution of the filler and smooth out any irregularities.
2. Chin Augmentation:
    - Injection Technique: For chin augmentation, use the bolus technique or retrograde linear threading technique to achieve enhanced contouring and volume.
    - Injection Depth: The filler should be injected into the subcutaneous or supraperiosteal plane, depending on the degree of augmentation required.
    - Post-Injection Care: After completing the injections, gently massage the area to ensure smooth and even filler distribution.
3. Layering and Volume Control:
    - When correcting deeper folds or enhancing the chin, use a layering technique by injecting small amounts of filler in increments. This helps avoid overfilling and ensures the filler integrates smoothly with the surrounding tissue.

C. Post-Injection Care

1. Cold Compress: After the procedure, apply a cold compress to minimize swelling and discomfort. Avoid direct application of ice to the skin, as this may cause frostbite or skin damage.

2. Avoid Excessive Movement: Patients should avoid excessive movement of the treated area for the first 24 hours after the procedure.
3. Avoid Heat and Sun Exposure: Patients should be advised to avoid extreme temperatures, sun exposure, tanning beds, and strenuous exercise for at least 24 hours following the procedure to prevent swelling and redness.
4. Disposal: Safely dispose of the syringe and needle after use in accordance with local biohazard waste disposal regulations. Do not reuse or resterilize any of the components.

D. Injection Volumes and Retreatment

1. Volume: The maximum recommended injection volume for nasolabial folds is 2 mL per fold. For chin augmentation, the recommended injection volume is up to 4 mL per session (2 mL in the chin and 2 mL in adjacent areas).
2. Touch-up and Retreatment: If necessary, a touch-up session can be performed 2 to 4 weeks after the initial treatment to achieve optimal results. Further treatments may be scheduled based on the patient's needs and treatment plan.

9.Post treatment care

Following the administration of *Black Design™*, appropriate aftercare is essential to ensure optimal results and reduce the risk of potential side effects. Patients should follow the recommendations outlined below to promote healing and prevent complications:

1. Avoid Touching or Pressing the Treated Area:
    - Refrain from touching, rubbing, or pressing the treated area immediately after the procedure. This helps prevent irritation or displacement of the filler. Patients should avoid applying makeup, creams, or other cosmetic products to the treated area for at least 6 hours after treatment to reduce the risk of infection.
2. Use Cold Compress to Reduce Swelling:
    - A cold compress may be applied to the treated area to minimize any swelling, bruising, or discomfort. However, ice packs should be wrapped in a cloth to avoid

direct contact with the skin and prevent thermal injury, especially if the area is still numb from anesthesia.

3. Avoid Extreme Temperatures:
    - Exposure to extreme temperatures, including saunas, steam rooms, tanning beds, or direct sunlight, should be avoided for at least 24 hours after treatment. Extreme temperatures can exacerbate swelling and bruising.
    - If necessary, patients should apply a sunscreen with a high SPF to protect the treated area from UV radiation.
4. Refrain from Strenuous Activities:
    - Patients should avoid engaging in strenuous exercise, heavy lifting, or any other physically demanding activities for 24 to 48 hours post-treatment. Physical exertion can increase blood flow and exacerbate swelling and bruising.
5. Swelling and Bruising:
    - Some swelling and bruising at the injection sites are normal and typically resolve within 1 to 2 weeks. Patients can expect the treated areas to appear fuller initially due to swelling, but the final results will be visible once the swelling subsides.
6. Pain or Discomfort:
    - Mild pain or tenderness is expected following the procedure. If discomfort persists, over-the-counter pain relievers such as acetaminophen (Tylenol®) may be recommended. However, patients should avoid nonsteroidal anti-inflammatory drugs (NSAIDs), such as aspirin or ibuprofen, as these can increase the risk of bruising.
7. Massage Instructions:
    - The healthcare provider may recommend gentle massage to smooth out any lumps or ensure even distribution of the filler. However, patients should only massage the area if specifically instructed to do so by their practitioner. Excessive manipulation can interfere with the results.
8. Monitor for Signs of Complications:
    - Patients should be instructed to monitor for signs of complications, such as increasing redness, swelling, pain, or the appearance of nodules or lumps. While

these reactions are uncommon, any persistent or worsening symptoms should be reported to the healthcare provider.

9. Delayed Results:
    - Patients should be advised that the final results of the treatment may not be immediately apparent. Initial swelling may obscure the final outcome, which can take up to two weeks to become fully visible. Patience is key as the filler settles and integrates with the surrounding tissue.
10. Follow-Up Appointments:

- Patients may be scheduled for a follow-up appointment within two weeks to evaluate the results of the treatment and, if necessary, administer additional filler or perform a touch-up. It is important that patients attend this appointment to ensure optimal outcomes.

11. Contact Your Practitioner:

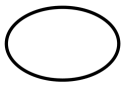
- In the event of any concerns, unusual symptoms, or complications, such as severe pain, bruising lasting longer than two weeks, or vision changes, patients should immediately contact their healthcare provider. Immediate medical attention may be necessary for rare complications like vascular occlusion.

10. Storage and Handling

- Store at room temperature between 2°C and 25°C .
- Do not freeze the product or expose it to excessive heat or direct sunlight.
- Do not use the product if the packaging is damaged or if the expiration date has passed.
- Each syringe is for single use only and must be discarded immediately after use.
- To place an order, contact Pol Tech Central Office: 021-284208

11. Glossary Symbols

Symbol	Symbol Title	Explanatory Text

	Manufacturer	Indicates the medical device manufacturer
	Use-by date	Indicates the date after which the medical device is not to be used.
	Lot code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Consult instructions for use	Indicates that important information regarding safety, usage, and precautions is contained in the documentation, and this information should be reviewed before using the product.
	Sterilized using steam	Indicates a medical device that has been sterilized using steam.
	Single sterile barrier system	Indicates a single sterile barrier system. The packaging system for a sterile medical device is composed of one or more sterile barriers.
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator

		awareness or operator action in order to avoid undesirable consequences.
	Temperature limit	indicates the recommended storage temperature range for a medical device or product.

Manufactured by:

Pol Tech. Tehran, Iran

Phone: 021-284208