1987-Teoxane Consent Form

[COMPANYLOGO]

MEDICAL QUESTIONNAIRE PRIOR TO INJECTION OF TEOSYAL HYALURONIC ACID

SUBJECT TO MEDICAL SECRECY. FOR THE PRACTITIONER, TEOXANE LABORTORIES WILL GIVE THIS QUESTIONNAIRE TO THE PRACTITIONER

First Name(s): _____ **Last Name:** _____

DOB: _____ dd / mm / yyyy **Email Address:** _____

Please boxes:

- ☐ Male
- ☐ Female
- ☐ Prefer not to say

Are you pregnant or breastfeeding?

○ No ○ Yes

Are you currently taking any medications? (including aspirin, anti-inflammatory drugs, anticoagulants, vitamin E etc.)

○ No ○ Yes

If yes please specify:

Do you suffer from hypersensitivities or allergies? (e.g. food, cosmetics, hyaluronic acid, latex, lidocaine, vitamins)

○ No ○ Yes

If yes please specify:

Have you ever had problems with anaesthesia (local or general)?

○ No ○ Yes

If yes please specify:

Have you undergone a dental procedure recently?

○ No ○ Yes

If yes please specify:

Date of procedure: _____ dd / mm / yyyy

Are you planning to undergo a dental procedure in the near future?

◯ No ◯ Yes

If yes please specify:

Date of procedure: _____ dd / mm / yyyy

Have you undergone any surgical interventions?

◯ No ◯ Yes

If yes please specify:

Have you had any problems with healing after these surgeries?

◯ No ◯ Yes

If yes please specify:

Have you undergone any cosmetic surgery? (e.g. lifting, liposuction, eyelid surgery, nose surgery, jaw surgery, breast surgery, etc.)

◯ No ◯ Yes

If yes please specify:

Date of procedure: _____ dd / mm / yyyy

Have you already undergone aesthetic procedures? (Laser, Peeling, Dermabrasion, Injection, Golden Thread, Ultrasound, Other)

◯ No ◯ Yes

If yes please specify:

Date of procedure: _____ dd / mm / yyyy

Have these previous aesthetic procedures caused any undesirable reactions?

◯ No ◯ Yes

If yes please specify:

Have you ever had wrinkle filling injections?

◯ No ◯ Yes

If yes please check the areas below:

Was it with:

☐ Hyaluronic Acid

☐ Botulin Toxin

☐ HA + other products

If other, please specify:

Date: _____ dd / mm / yyyy **Area:** _____

Product: _____

Have you ever received mesotherapy?

◯ No ◯ Yes

If yes please specify the area and name of the product below:

Date of procedure: _____ dd / mm / yyyy

MEDICAL HISTORY: PLEASE INDICATE ALL YOUR RECENT OR CURRENT PATHOLOGIES, AS WELL AS YOUR CHRONIC ILLNESSES

Do you suffer from an auto-immune disease or a disease that affects the immune system? (e.g. type I diabetes, rheumatoid arthritis, psoriasis, thyroid disorders, scleroderma, inflammatory bowel diseases, lupus, multiple sclerosis, ulcerative colitis...)

◯ No ◯ Yes

If yes please specify:

Is there any history of autoimmune disease in your family?

◯ No ◯ Yes

If yes please specify:

Do you suffer from skin infections, inflammation or infection on the face? Do you have chronic skin reactions such as herpes, acne, rosacea?

◯ No ◯ Yes

If yes please specify:

Do you have a history of cardiovascular disease (e.g. high blood pressure, Raynaud's disease, thromboembolic disease)?

◯ No ◯ Yes

If yes please specify:

Do you have a tendency to bleed?

◯ No ◯ Yes

If yes please specify:

Do you suffer from liver or kidney disease (e.g. hepatocellular insufficiency or kidney failure)?

◯ No ◯ Yes

If yes please specify:

Do you suffer from rheumatism?

◯ No ◯ Yes

If yes please specify:

Do you suffer from epilepsy?

◯ No ◯ Yes

If yes please specify:

Would you like to inform us of any other information about your health:

INFORMATION SHEET

PRIOR TO THE INJECTION, PLEASE READ THIS DOCUMENT CAREFULLY DON'T HESITATE TO ASK QUESTIONS IF YOU FEEL THE INFORMATION IS NOT CLEAR. YOUR PRACTITIONER, WHO IS TRAINED IN THE INJECTION TECHNIQUES, WILL BE AVAILABLE TO ANSWER YOUR QUESTIONS.

1. TEOSYAL® PRODUCTS AND INDICATIONS

The TEOSYAL® range includes cross-linked and no n cross-linked gels (cross-linking is a process which can transform a liquid gel to a viscoelastic gel), as well as gels with or without anaesthetic (lidocaine). An exhaustive product list is available on the website: www.teoxane.com Products in the Teosyal® range are viscoelastic gels of cross-linked hyaluronic acid (except for TEOSYAL® Meso and TEOSYAL® PureSense Redensity [I]), sterile, of non-animal origin, to be injected in the dermis. They are designed for filling wrinkles and lines, correcting the facial oval and/or increasing lip volume. Cross-linked products in the TEOSYAL® range have a 6 to 18 months duration. This mean duration depends on several factors: the patient's skin type, the severity of the wrinkle to be corrected, the injection zone and the volume injected. TEOSYAL® Meso and TEOSYAL® PureSense Redensity [I] non-cross-linked hyaluronic acid gels are designed to improve skin hydration and radiance. Your practitioner will help you to choose the product for injection according to you aesthetic requirement.

2. PRECAUTIONS FOR USE

LIDOCAINE: Products in the TEOSYAL® PureSense range contain lidocaine. Ask your injector for guidance in case of • Known hypersensitivity, allergy to lidocaine and/or local anaesthetics of the amide type; • Athletes: Lidocaine can induce a positive reaction to anti-doping tests; • Heart disease and/or patient under treatment for heart disease (beta-blockers). Inform your injector about your situation and we therefore recommend that you do not use products from the TEOSYAL® PureSense range. There is a range of TEOSYAL® products without lidocaine. • Report any chronic skin diseases (herpes, acne, rosacea). • Report any complications after surgery. • Report aesthetic treatments performed previously. As interactions with other filling implants have not been studied, it is recommended not to inject TEOSYAL® products in areas where other dermal fillers are present.

3. CONTRAINDICATIONS

• Pregnant or breastfeeding women and children. • In case of inflammatory or infected skin conditions in the area to be treated, or close to this area. • History of hypersensitivity to any of the components of the injected products (hyaluronic acid, lidocaine, other local anaesthetics, one of the ingredients of the phosphate buffer supplement*), anaphylactic shock or severe allergy. • History of autoimmune diseases or diseases that affect the immune system (type I diabetes, polyarthritis, rheumatoid arthritis, ankylosing spondylitis, psoriasis, thyroid disorders, scleroderma, inflammatory bowel diseases, lupus, multiple sclerosis, haemorrhagic recto colitis) and/or hepatocellular diseases. • People with epilepsy or porphyria. • Unhealed skin alterations. Inflammation or infection of the skin at the time of treatment. • Injection of permanent products (silicone, acrylic polymers, dextran). • Untreated infectious periodontitis, pulpitis, cellulitis of dental or ENT origin, dental abscesses not treated or treated less than a week ago. • In association with peeling, laser treatment or ultrasonic type treatment. • For treatments or areas of the body in which the product is not indicated.

4. SIDE EFFECTS

As with all hyaluronic acid-based products, the products in the TEOSYAL® range may have side effects. These reactions are most often temporary and common, and result in: • redness, bruising, haematomas, bumps, oedema, erythema, temporary loss of sensation, itching, pain and dyschromia at the injection site. You must see a doctor if your symptoms do not improve. • swelling or nodules that may appear in a delayed manner at the injection site. In that case, consult your doctor. Despite being rare, serious side effects may occur: abscess, granuloma, immediate hypersensitivity which may even lead to anaphylactic shock, vascular complications which may extend to necrosis of the injected area, visual disturbances or even blindness.

5. PRE & POST INJECTION RECOMMENDATIONS

Pre-injection recommendations • Inform the injecting doctor: – all your recent or current pathologies , as well as your chronic illnesses; – all your chronic or current allergies; – all your chronic or ongoing treatments. • Avoid getting an injection if you have had a dental procedure within the previous 15 days. • Avoid taking aspirin, anti-inflammatory drugs, anticoagulants, and vitamin E during the week prior to the injection. Ask your doctor for advice prior to stopping any treatment. • Avoid drinking alcohol or exposing yourself to strong sunlight the day before and on the day of the injection. • Remove your make-up thoroughly prior to entering the injection room. • Wash your hands prior to entering the injection room. Post-injection recommendations • Within 12 hours following the injection: do not apply make-up, avoid any violent effort and avoid any air travel. • During the week following the treatment: avoid drinking alcohol, prolonged exposure to the sun or UV rays, temperatures below 0°C, as well as the practice of sauna or hammam. • Within 15 days following the treatment: do not perform dental or other aesthetic procedures. • Keep the elements handed over by your injector (batch numbers and injection history); they will be necessary in the event of a claim or if you wish to repeat a treatment at a later date. I have also been informed that rare cases of medical device vigilance have been described in the literature: Necrosis in the glabella region, abscess, granuloma, and hypersensitivity following injections of hyaluronic acid. However, if you notice a side effect after a TEOSYAL injection, you must contact your practitioner immediately.

CONSENT FORM

First Name(s): _____ **Last Name:** _____

Agree to receive injection from the TEOSYAL product range of TEOXANE laboratories. The objectives and methods of the injection procedure have been clearly explained to me by the practitioner.

1. I have received, read and understood the information sheet supplied by the practitioner or on behalf of TEOXANE SA. Prior to the injection I have had the opportunity to ask any necessary questions.

2. I understand the pre and post-injection recommendations and I agree to follow them.

3. I acknowledge that I had the time required for consideration and to make my decision.

4. I acknowledge that I have been clearly informed of the side-effects and the rare cases of medical device vigilance.

5. I freely and voluntarily consent to receiving injections.

PATIENT SIGNATURE:

DATE: _____ dd / mm / yyyy **PRACTIONER NAME:** _____

PRACTITIONER SIGNATURE:

DATE: _____ dd / mm / yyyy

AREAS TREATED

DATE: _____ dd / mm / yyyy **Area:** _____

Traceability label or lot. No.: _____ **Injected area(s):** _____

Volume (ml): _____

Additional Notes:

☐ I can confirm that nothing in my consultation or medical history has changed since my last treatment

SIGNATURE

DATE: _____ dd / mm / yyyy