MERZ AESTHETICS

Patient Medical History and Consent Form

CONFIDENTIAL

Patient's Name:

Date Completed:

All patient notes, treatment details and contact information are confidential and your clinic is obliged to store and manage this information in accordance with the Data Protection Act 2018.

Patient Personal Information

Title_____ First Name _____ Middle Name(s)_____

Surname_____

Address _____

_____

Postcode _____ Telephone Number_____

Date of Birth _____ Age_____ Male/Female _____

Email_____

Next of Kin_____ Relationship _____

Next of Kin Telephone Number_____

Name and address of GP _____

_____

(We will not routinely contact your GP or your next of kin. This is for emergency use only.)

Patient General Lifestyle Information

Occupation _____

Do you smoke?_____ If so, how many a day?_____

If you have stopped smoking, when did you give up? _____

Do you drink alcohol? _____ If so, how many units a week*?_____

What is your height? _____ Weight _____

Do you take regular exercise? _____Type _____

Do you follow any special diet?_____

*A medium (175ml) glass of wine is two units; a single spirit measure is one unit and a pint of beer is 2-3 units.

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Patient Medical History

Please complete the following medical questionnaire. If you are unsure of any details, please discuss with the practitioner

Section A

Are you currently pregnant or breast feeding? Yes ☐ No ☐

Are you trying to conceive or undergoing IVF treatment? Yes ☐ No ☐

Section B

Do you suffer from or have you previously suffered from:

Pigment disorders? Yes ☐ No ☐

Increased scar formation? Yes ☐ No ☐

Increased light sensitivity? Yes ☐ No ☐

Herpes infections (shingles, chicken pox, cold sores, genital herpes sores)? Yes ☐ No ☐

Skin cancer? Yes ☐ No ☐

Keloid scarring? Yes ☐ No ☐

Acne, psoriasis or any other active skin condition or infection in the area(s) you wish to have treated? Yes ☐ No ☐

Myasthenia gravis, Eaton-Lambert syndrome, amyotrophic lateral sclerosis, multiple sclerosis? Yes ☐ No ☐

Impaired ability to swallow or dysphagia? Yes ☐ No ☐

Angina, cardiac infarction? Yes ☐ No ☐

High/low blood pressure? Yes ☐ No ☐

Emotional or neurological disorders, e.g. seizures (epilepsy), paralyses, depression, M.E. (Myalgic Encephalomyelitis)? Yes ☐ No ☐

Migraine? Yes ☐ No ☐

Bell's palsy or a stroke? Yes ☐ No ☐

Glaucoma? Yes ☐ No ☐

Asthma? Yes ☐ No ☐

Diabetes? Yes ☐ No ☐

Thyroid problems? Yes ☐ No ☐

HIV, hepatitis, rheumatoid arthritis or other auto-immune diseases? Yes ☐ No ☐

Nosebleeds, bruises (e. g. after a light touch) or coagulation disorders or bleeding disorders? Yes ☐ No ☐

Metal stents in the area of treatment Yes ☐ No ☐

Open wounds and lesions on the face Yes ☐ No ☐

Do you or does anyone in your family suffer from a hereditary disease? If yes, please specify Yes ☐ No ☐

_____

_____

_____

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Section B Continued

Do you have any allergies or hypersensitivities?
e.g. hay fever, asthma, hypersensitivity (e.g. to collagen-containing products, lidocaine, painkillers, anaesthetics, foods, medications, plasters, latex)? _____ Yes ☐ No ☐

If so, to what? _____

Have you ever been in hospital with a severe allergic reaction? _____ Yes ☐ No ☐

Are you currently undergoing any desensitisation treatment? _____ Yes ☐ No ☐

If you have an allergy card, please present it.

Have you recently taken any medication or are you currently taking medication?
Painkillers, coagulation inhibitors, antibiotics, steroids, muscle relaxants (e.g. aspirin, warfarin, ibuprofen) or herbal preparations, vitamins and supplements. If yes, please specify: _____ Yes ☐ No ☐

_____

_____

Have you taken Roaccutane or Isotretinoin (for acne) in the past 12 months? _____ Yes ☐ No ☐

Have you had any recent immunisations? _____ Yes ☐ No ☐

Have you had any major surgery in the last six weeks? _____ Yes ☐ No ☐

Are you planning or currently undergoing dental treatment? _____ Yes ☐ No ☐

Have you previously undergone operations in your facial area (e.g. laser, skin peel, facelift, IPL skin resurfacing, plastic surgery, injury, etc)? _____ Yes ☐ No ☐

Do you have a phobia about blood or needles? _____ Yes ☐ No ☐

Are you prone to bruising? _____ Yes ☐ No ☐

Section C

Have you received local anaesthetic injections at your dental practice? _____ Yes ☐ No ☐

Any problems with dental local anaesthetics? _____ Yes ☐ No ☐

Have you received Botulinum toxin injections previously, such as Botox?
If yes, how long ago? _____ Yes ☐ No ☐

Did you experience any side effects, adverse events or allergies to this treatment? _____ Yes ☐ No ☐

Have you received dermal filler injections? If yes, how long ago? _____ Yes ☐ No ☐

Do you know the name of the dermal filler used? If yes, please specify: _____ Yes ☐ No ☐

_____

Did you experience any side effects, adverse events or allergies to this treatment? _____ Yes ☐ No ☐

Do you have any permanent implants in your face/body (e.g. Chin, cheek, jaw or breast, or other area of treatment) including any pacemakers and electronic device implants? _____ Yes ☐ No ☐

Did you experience any side effects, adverse events or allergies to this treatment? _____ Yes ☐ No ☐

Which aspects of your face are you concerned about?

_____

_____

Do you have any worries or concerns about treatments or anything else that you wish to tell us?

_____

_____

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Covid-19 Medical History

1. Have you had a COVID-19 vaccine? Yes ☐ No ☐

2. Are you currently suspected of having COVID-19? Yes ☐ No ☐

   Or have you had COVID-19 recently. Yes ☐ No ☐

3. Have you been in contact with or are living with

   someone suspected or confirmed of having COVID-19? Yes ☐ No ☐

4. Do you have a fever, or have you had a high temperature in the last 14 days Yes ☐ No ☐

   (a fever is a temperature greater than 37.8°c?)

5. Have you had a cough or any other respiratory signs in the last 14 days? Yes ☐ No ☐

6. Do you suffer from any of the following?

   - Diabetes Yes ☐ No ☐
   - Cardiovascular disease (including hypertension) Yes ☐ No ☐
   - Chronic lung disease Yes ☐ No ☐
   - Immunodeficiency Yes ☐ No ☐
   - Cancer - are you under active treatment ? Yes ☐ No ☐

7. Are you over 70 years of age? Yes ☐ No ☐

8. Do you think you have had COVID-19? Yes ☐ No ☐

9. Have you been tested for COVID-19? What were the results. Yes ☐ No ☐

Consent:

I understand that performing _____ procedure at this time, despite my own efforts and those of my doctor, may increase the risk of my exposure to COVID-19. I am aware that exposure to COVID-19 can lead to serious illness, intensive care therapy, prolonged intubation and/or ventilator support, life-threatening consequences to my health and even death. I have been informed that my treatment can also be postponed to a time when there may be better treatment against COVID-19 or a vaccine. I expressly do not wish a postponement.

I also understand that performing my procedure at this time increases the risk of COVID-19 being transmitted to my doctor. This virus has a long incubation period, there may still be unknown aspects of its transmission, and I am aware that I may be contagious whether I have been tested or have no symptoms.

In order to reduce the possibility of exposure or transmission of COVID-19 at my doctor's clinic, I accept that my doctor will establish infection control procedures before, during and after my procedure for my own protection and that of my doctor, which I must follow. I understand that my cooperation is mandatory, whether or not I personally consider such COVID-19 procedures and/or preventive measures necessary.

I confirm I have read and understood the clinic policies and procedures and agree to follow and abide by these procedures. I understand that failure to abide by the policies and procedures will result in cancellation of my treatment.

I have informed my doctor about all COVID-19 tests that I or a person living with me have had in the last 14 days and the results of these tests. Even though testing is currently limited, I understand that my doctor may require me to be tested, possibly at my own expense and independently of any previous tests, and that the results of these tests must be negative before I am cleared for treatment.

I certify that neither I nor any person living with me or anyone I have been in contact with, is suspected of having COVID-19 symptoms; neither I nor any person living with me, or anyone I have been in contact with, has experienced any such symptoms in the past 14 days; and I and all persons living with me have practiced all personal hygiene, social distancing and other COVID-19 recommendations contained in all government regulations issued by my city and region in the past 14 days. I understand that I must honestly disclose this information in order not to endanger myself or others.

I am aware that even if I have been tested for COVID-19 and got a negative test result, in some cases the tests cannot detect the virus or I have been infected with COVID-19 after the test. I understand that if I have COVID-19 infection, and even if I have no symptoms, performing this predictable treatment may result in a higher risk of complications.

All of the above issues were discussed with me, I was able to ask all the questions and all my questions were answered to my satisfaction. As I am fully informed, I accept the risk of exposure to COVID-19.

Side effects of fillers:

There have been reported cases of nodules forming after dermal filler treatments associated with viral flu like illness, it is possible that COVID-19 may also pose a risk of nodule development after dermal filler, or may pose additional risks that at this point are not known. Currently available data for Belotero® range has demonstrated a low rate of adverse events related to inflammation.

Reasons for Treatment and Expected Outcomes

- The reason I have chosen to have this treatment is…

- My expected outcome for the treatment is…

Patient Consent Form for Treatment

- The risk, use of, and indications for the products I will be treated with have been explained to me by my practitioner and I have had the opportunity to have all questions answered to my satisfaction and to read any appropriate Patient Information Leaflet (or similar). I have been specifically informed of the following: after the treatment some common injection related reactions might occur. These reactions include redness, swelling, pain, itching, bruising and tenderness at the treatment site. These reactions are generally described as mild to moderate and typically resolve spontaneously a few days after treatment.

  Your initials indicate that you have read and understood this information:_____

- Other types of reaction are rare, one study found that 1 in 1400 patients experienced a localised hypersensitivity reaction after one or more injection treatments with a dermal filler[1]. These have usually consisted of swelling and firmness at the treatment site, sometimes affecting the surrounding tissues. Redness, tenderness and rarely acne-like formations have also been reported. These reactions have either started a few days after injection or after a delay of several weeks. They have been described as mild to moderate and self-limiting, with an average duration of 15 days[1]. In rare instances such reactions or lumps have occurred, the incidence ranging from 0.02% - 0.4%[1]. An increase in delayed onset nodules have been noticed with some dermal fillers, it is recommended to discuss this with your healthcare practitioner.

  Your initials indicate that you have read and understood this information:_____

- Abscess formation is a rare (between 1 in 1,000 and 1 in 10,000) complication that can occur any time after a dermal filler procedure[2]. Other less common side effects include infection, tissue death, nerve damage[2]. A study published in 2015 reviewed adverse events connected to the eyes and vision that had occurred over a 20 year period (1995 – 2015) and found 20 case reports of adverse effects to the eyes (including blindness) after dermal filler treatments in areas including forehead, cheeks and nose.[3]

  Your initials indicate that you have read and understood this information:_____

- My practitioner has also informed me that depending on the product used, area treated, skin type and the injection technique, the effect of treatment can last 6 – 18 months[2]. In some cases the duration may be shorter or longer. Follow-up treatment will help to maintain the desired correction. My practitioner has advised me of the amount of product required and the cost of the treatment which I agree to pay in full at the time of treatment.

  Your initials indicate that you have read and understood this information:_____

All patient notes, treatment details and contact information are confidential and your clinic is obliged to store and manage this information in accordance with the Data Protection Act 2018.

Patient Consent Form for Treatment Continued

- For muscle relaxation injections with Botulinum toxin Type A, I have been advised by my practitioner of the expected outcomes and risks associated with this treatment based on the current product Summary of Product Characteristics (SmPC). In particular, we have discussed realistic outcomes regarding the onset of action and the duration of effect, together with the potential side effects including those relating to the site of injection and the generalised common and uncommon side effects including headaches, muscle activity disorders (raised eyebrows), feeling of heaviness in the upper part of the face, accumulation of fluid in the eyelids (eyelid oedema), drooping eyelids (eyelid ptosis), inflammation of the eyelid, eye pain, blurred vision, fainting, noises in the ears (tinnitus), nausea, dizziness, muscle twitching, muscle cramps, localised muscle weakness in the face (drooping eyebrow), dry mouth, flu symptoms, influenza, bronchitis, inflammation of the nose and throat, infection and in rare cases, excessive muscle weakness and difficulties in swallowing. In the event of an adverse event my practitioner has advised me to seek medical care immediately.

Your initials indicate that you have read and understood this information:_____

- The information provided in this consent form will be kept confidential. Your personal data will only be shared with those who have a genuine need for it for the purpose of delivering the treatment or providing care relating to your treatment, such as the clinics, aesthetic practitioners and medical professionals assisting with any stage of your treatment. I acknowledge that, for example, my personal data may be shared with Merz Pharma UK Limited and its group of companies for the purpose of adverse event reporting or for the administrative aspects of the treatment. All personal information will be processed and stored in accordance with the obligations under the relevant data legislation and in accordance with the clinics' Privacy Policy. Any person who receives your personal data from the clinic is also under a legal duty to keep the information confidential and comply with their obligations under the relevant data legislation.

Your initials indicate that you have read and understood this information:_____

Patient Declarations

The information that I have given is to the best of my knowledge correct. _____ ☐

I have not knowingly withheld any medical or surgical information. _____ ☐

I agree to inform my practitioner of any changes to my medication or health in the future. _____ ☐

I have read the above information fully and understand the possible complications that could occur. _____ ☐

I have discussed these with my practitioner and agree to treatment. _____ ☐

I have been given sufficient time to consider the information, risks and likely outcome of the proposed treatment. ___ ☐

I understand that I can withdraw my consent to treatment at any time up to and after the start of the treatment, we will stop the treatment as soon as it is safe to do so. _____ ☐

I consent to the use of a topical anesthetic. _____ ☐

I consent to the use of lidocaine (injected anesthetic) products during treatment. _____ ☐

I consent to information regarding the treatment being sent to my GP. _____ ☐

I consent for my image to be used for Social Media, Marketing and Educational purposes for Merz Aesthetics and Merz affiliated companies worldwide_____ ☐

I consent to my next of kin being contacted and information regarding my treatment being shared with my next of kin for emergency purposes. _____ ☐

Name _____

Signature _____ Date

_____ Thank you for providing this information. All patient notes, treatment details and contact information are confidential.

All patient notes, treatment details and contact information are confidential and your clinic is obliged to store and manage this information in accordance with the Data Protection Act 2018.

Injectables Consultation Record

THIS SECTION FOR HEALTH-CARE PROFESSIONAL USE ONLY

Treatment Checklist

I have performed a capacity assessment:- _____ Yes ☐ No ☐

The patient has had sufficient time to consider the information provided to them:- _____ Yes ☐ No ☐

The patient has been given details of who to contact should they have any concerns:- _____ Yes ☐ No ☐

Follow up requirements and aesthetic care plan have been discussed with the patient:- _____ Yes ☐ No ☐

Pre-treatment photos taken:- _____ Yes ☐ No ☐

Patient questions have been answered:- _____ Yes ☐ No ☐

I have reviewed the treatment with the patient. I have explained the benefits, risks, downsides and material information according to the IFU / Summary of Product Characteristics (SPC) / Patient Information Leaflet (PIL) regarding the proposed treatment plan to the patient:- _____ Yes ☐ No ☐

The patient has read the Consent to Treatment information fully and we have discussed the possible complications that could occur. The patient has agreed to the treatment:- _____ Yes ☐ No ☐

I have talked through the information to the patient in the following patient brochures (quote brochure name or code):

_____

_____

_____

_____

_____

Merz Aesthetics wishes to bring the following to your attention:

- you and/or the clinic are personally responsible for the care and treatment of your patients. To the extent permitted by law, Merz disclaims all liability in respect of the delivery of treatments to your patients;
- you and/or the clinic are personally responsible for obtaining and maintaining all relevant licences, qualifications and training to carry out the performance of the treatment, including all before and after care;
- you recognise and acknowledge that there are principles of best practice associated with obtaining the patient's consent and performing the treatment that you must adhere to, including those principles set out in guidance supplied by regulatory bodies such as the General Medical Council, General Dental Council and Nursing and Midwifery Council;
- you are responsible for ensuring that you have all relevant patient consents for obtaining, using and sharing patient before and after images and any other relevant personal data you collect.

Name of practitioner _____ Date _____

Signature of practitioner _____

References:
1 Abduljabbar et al., Complications of hyaluronic acid fillers and their management – Journal of Dermatology & Dermatologic Surgery, 2016:20, 100-106
2 Funt et al., Dermal fillers in aesthetics: an overview of adverse events and treatment approaches – Clinical, Cosmetic and Investigational Dermatology, 2013:6, 295-316
3 Ricci et al., Ocular adverse effects after facial cosmetic procedures: a review of case reports – Journal of Cosmetic Dermatology, 2015:14, 145-151

Patient Treatment Form – Visit No. 1

The information that I have given is to the best of my knowledge correct. _____ ☐

I have not knowingly withheld any medical or surgical information. _____ ☐

I agree to inform my practitioner of any changes to my medication or health in the future. _____ ☐

I have read the Consent to Treatment information fully and understand the possible complications that could occur. I have discussed these with my practitioner and have had sufficient time to consider the information and agree to treatment. I understand that I can withdraw my consent at any time, as long as it is safe and practical to do so. _____ ☐

I agree to the treatment described as _____

_____ Yes ☐ No ☐

Name _____

Signature _____ Date _____

Practitioner's notes

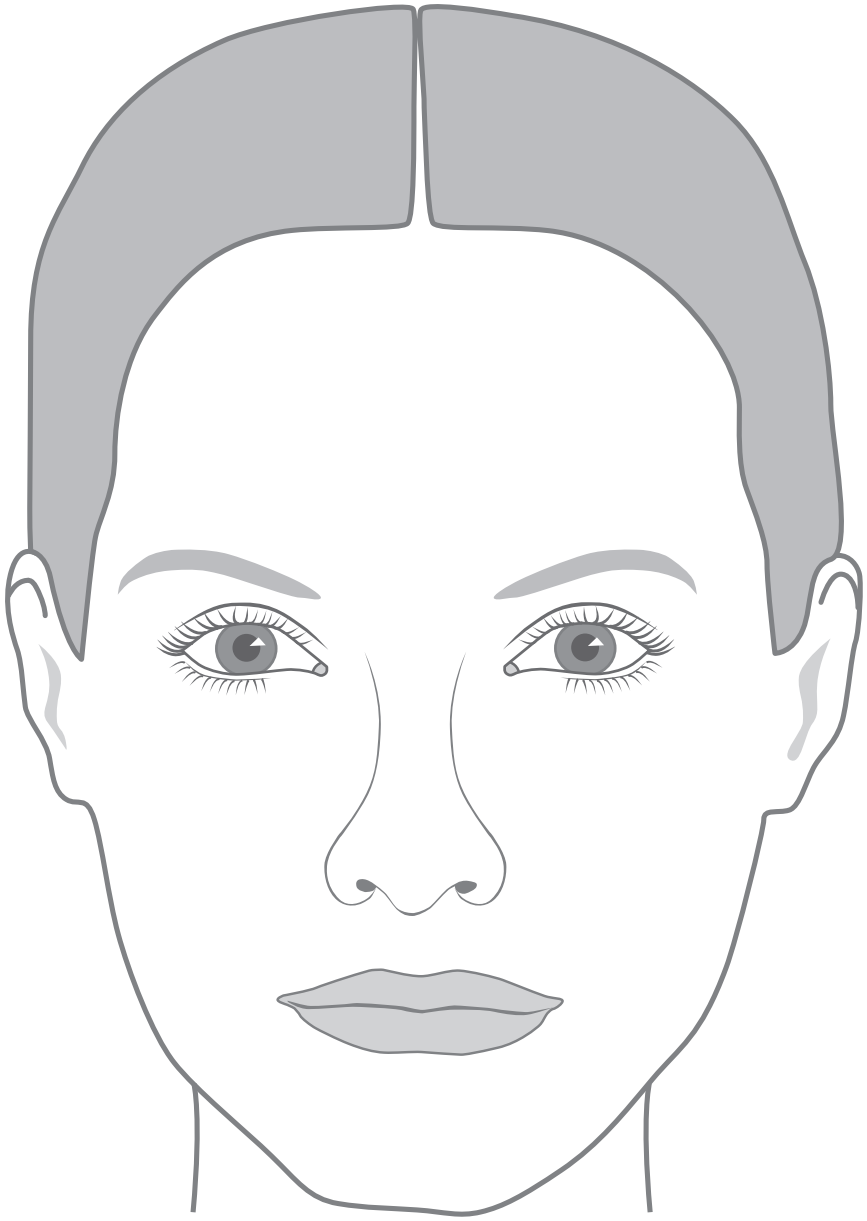
Name (Registered Nurse/Doctor/Dentist) _____

Signature _____ Date _____

All patient notes, treatment details and contact information are confidential and your clinic is obliged to store and manage this information in accordance with the Data Protection Act 2018.

Place product sticker here

Date of treatment:



Indicate areas of treatment and dosage on the diagram

Place product sticker here

All patient notes, treatment details and contact information are confidential and your clinic is obliged to store and manage this information in accordance with the Data Protection Act 2018.

Patient Treatment Form – Visit No. 2

The information that I have given is to the best of my knowledge correct. _____ ☐

I have not knowingly withheld any medical or surgical information. _____ ☐

I agree to inform my practitioner of any changes to my medication or health in the future. _____ ☐

I have read the Consent to Treatment information fully and understand the possible complications that could occur. I have discussed these with my practitioner and have had sufficient time to consider the information and agree to treatment. I understand that I can withdraw my consent at any time, as long as it is safe and practical to do so. _____ ☐

I agree to the treatment described as _____

_____ Yes ☐ No ☐

Name _____

Signature _____ Date _____

Practitioner's notes

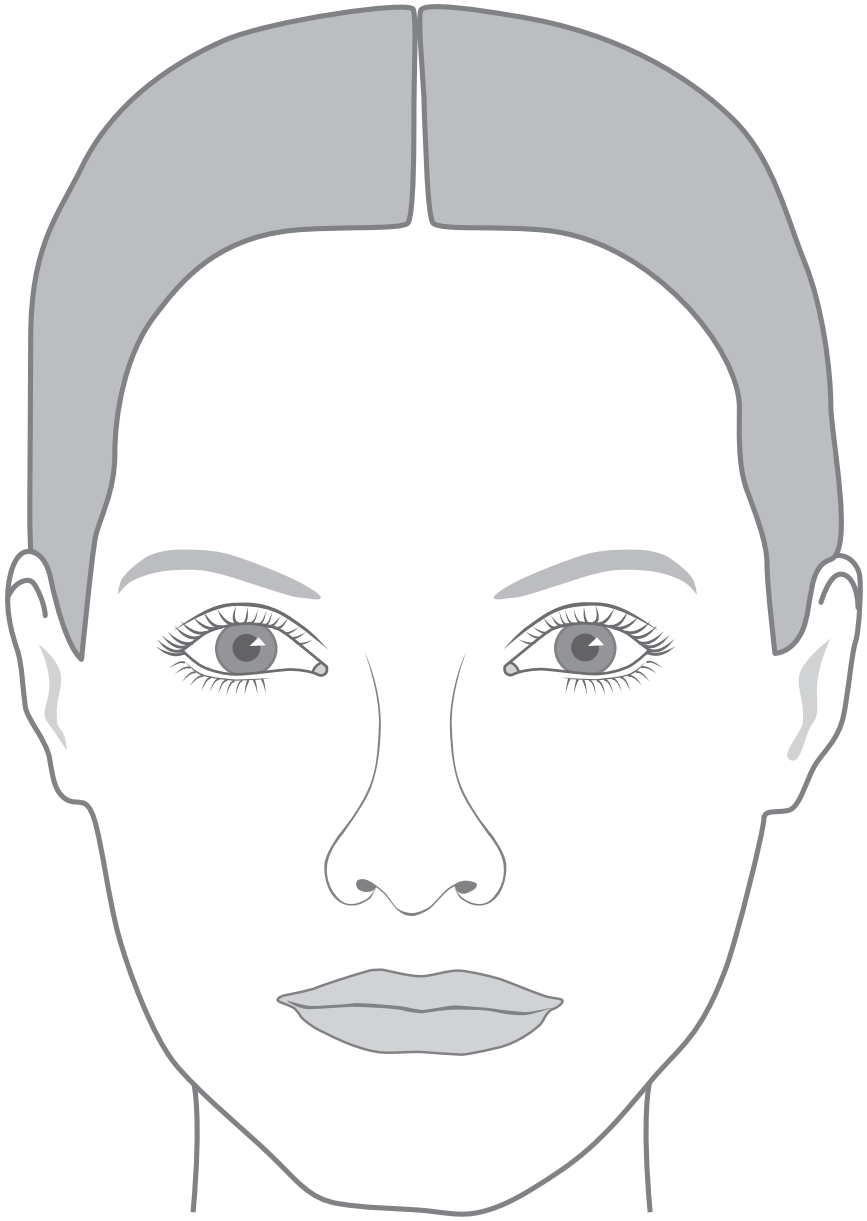
Name (Registered Nurse/Doctor/Dentist) _____

Signature _____ Date _____

All patient notes, treatment details and contact information are confidential and your clinic is obliged to store and manage this information in accordance with the Data Protection Act 2018.

Place product sticker here

Date of treatment:



Indicate areas of treatment and dosage on the diagram

Place product sticker here

All patient notes, treatment details and contact information are confidential and your clinic is obliged to store and manage this information in accordance with the Data Protection Act 2018.

Patient Treatment Form – Visit No. 3

The information that I have given is to the best of my knowledge correct. _____ ☐

I have not knowingly withheld any medical or surgical information. _____ ☐

I agree to inform my practitioner of any changes to my medication or health in the future. _____ ☐

I have read the Consent to Treatment information fully and understand the possible complications that could occur. I have discussed these with my practitioner and have had sufficient time to consider the information and agree to treatment. I understand that I can withdraw my consent at any time, as long as it is safe and practical to do so. _____ ☐

I agree to the treatment described as _____

_____ Yes ☐ No ☐

Name _____

Signature _____ Date _____

Practitioner's notes

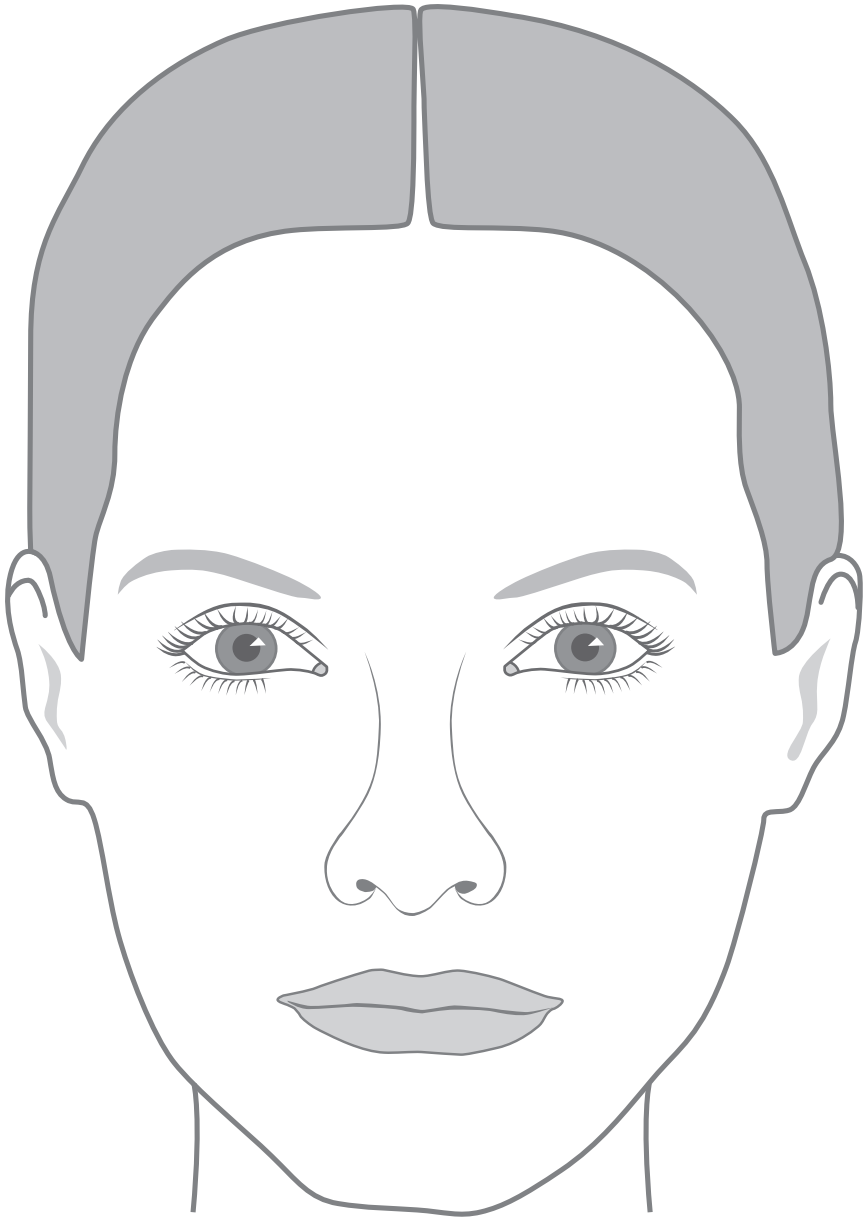
Name (Registered Nurse/Doctor/Dentist) _____

Signature _____ Date _____

All patient notes, treatment details and contact information are confidential and your clinic is obliged to store and manage this information in accordance with the Data Protection Act 2018.

Place product sticker here

Date of treatment:



Indicate areas of treatment and dosage on the diagram

Place product sticker here

All patient notes, treatment details and contact information are confidential and your clinic is obliged to store and manage this information in accordance with the Data Protection Act 2018.

Patient Treatment Form – Visit No. 4

The information that I have given is to the best of my knowledge correct. _____ ☐

I have not knowingly withheld any medical or surgical information. _____ ☐

I agree to inform my practitioner of any changes to my medication or health in the future. _____ ☐

I have read the Consent to Treatment information fully and understand the possible complications that could occur. I have discussed these with my practitioner and have had sufficient time to consider the information and agree to treatment. I understand that I can withdraw my consent at any time, as long as it is safe and practical to do so. _____ ☐

I agree to the treatment described as _____

_____ Yes ☐ No ☐

Name _____

Signature _____ Date _____

Practitioner's notes

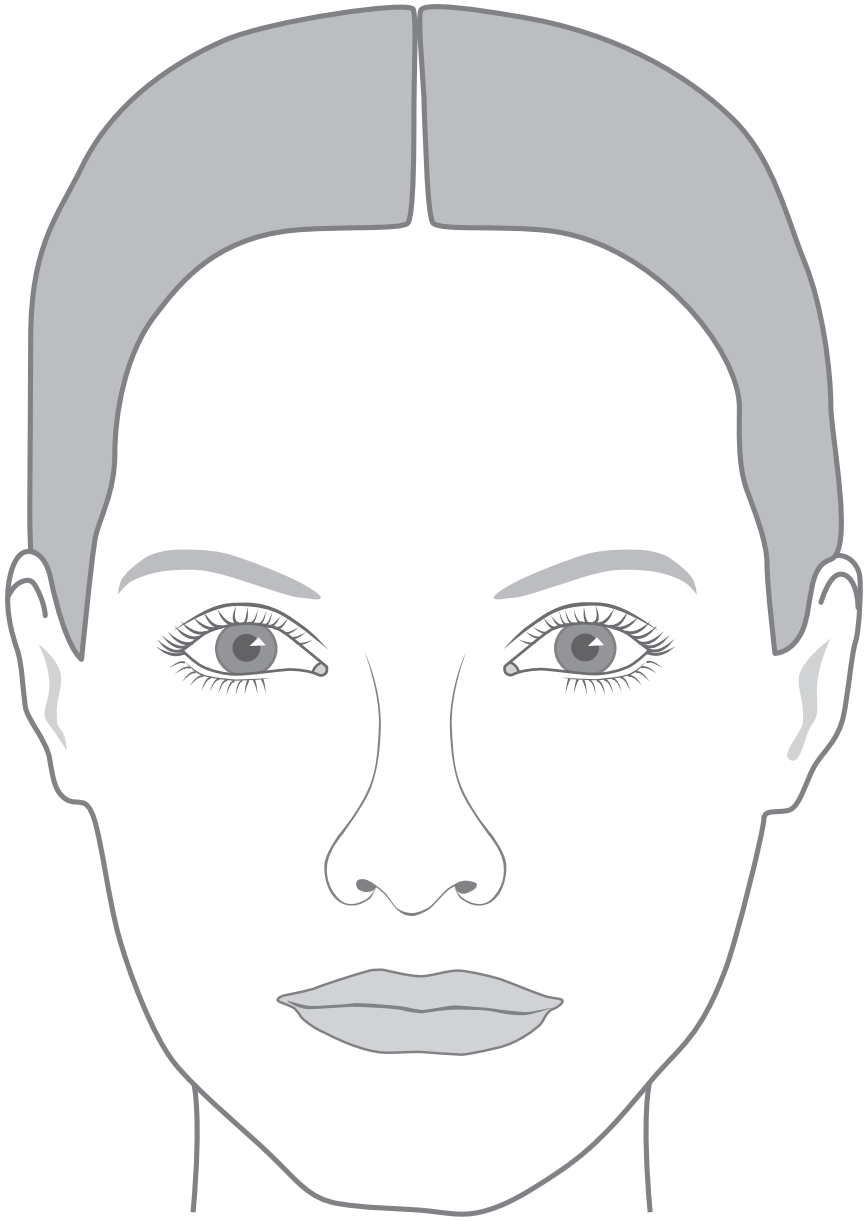
Name (Registered Nurse/Doctor/Dentist) _____

Signature _____ Date _____

All patient notes, treatment details and contact information are confidential and your clinic is obliged to store and manage this information in accordance with the Data Protection Act 2018.

Place product sticker here

Date of treatment:



Indicate areas of treatment and dosage on the diagram

Place product sticker here

All patient notes, treatment details and contact information are confidential and your clinic is obliged to store and manage this information in accordance with the Data Protection Act 2018.

MERZ AESTHETICS

Please read this consent form carefully

Merz Aesthetics wishes to bring to your attention that you are personally responsible for obtaining and maintaining all relevant licences, qualifications and training to carry out the performance of the treatment, including all before and after care. You must adhere to all relevant legislation, regulations and guidance for the purposes of carrying out the treatment.

You recognise that there are principles of best practice associated with obtaining the patient's consent and performing the treatment that you must adhere to, including those principles set out in guidance supplied by regulatory bodies such as the General Medical Council, General Dental Council and Nursing and Midwifery Council.

You must ensure that you have discussed all relevant treatment information with the patient and sought their consent before proceeding with the treatment. You are responsible for ensuring that you have all relevant patient consents for obtaining, using and sharing patient before and after images.

Merz Pharma UK Ltd.
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Hertfordshire, WD6 3SR
Tel +44 (0) 333 200 4140
Email: customerservices@merz.com

Adverse events should be reported. Reporting forms and information for United Kingdom can be found at www.mhra.gov.uk/yellowcard. Reporting forms and information for Republic of Ireland can be found at https://www.hpra.ie/homepage/about-us/report-an-issue/mdiur. Adverse events should also be reported to Merz Pharma UK Ltd by email to UKdrugsafety@merz.com or on +44 (0) 333 200 4143.

All patient notes, treatment details and contact information are confidential and your clinic is obliged to store and manage this information in accordance with the Data Protection Act 2018.

M-MA-UKI-1173 Date of Preparation June 2020