

CLINIC	N° HISTORY
FIRST NAME AND SURNAME OF THE PATIENT	AGE
ADDRESS	I.D. OR PASSPORT
FIRST AND SURNAME OF THE PATIENT'S LEGAL REPRESENTATIVE	AGE
ADDRESS	I.D. OR PASSPORT
As a	of
LEGAL REPRESENTATIVE, RELATIVE, LEGAL GUARDIAN)	FIRST NAME AND SURNAME OF THE PATIENT

**I STATE THAT**

\_\_\_\_\_  
NAME OF THE DOCTOR WHO GIVES THE INFORMATION

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N° OF MEMBER OF THE PROFESSIONAL BODY (IF APPLICABLE)

has explained to me that in my situation it is advised that I be treated with **Macrolane™ VRF20** and/or **Macrolane™ VRF30**.

1. I have been informed that **Macrolane™ VRF20** and **Macrolane™ VRF30** (hereafter referred to as Macrolane) are products based on NASHA™ gel, a gel containing stabilized hyaluronic acid of non-animal origin. Hyaluronic acid is a substance that can be found in the tissue of all species.

Macrolane is biodegradable and it contains approximately 2% hyaluronic acid (w/w) and 98% water. The rate of degradation of Macrolane in the body varies between individuals. After the first treatment, additional injections of Macrolane gel may be necessary to achieve and maintain the desired aesthetic result.

2. Macrolane is intended for breast enhancement, volume restoration and contouring of body surfaces. The choice between Macrolane VRF30 and Macrolane VRF20 depends on the doctor's judgment and the area to be treated.

3. The treatment consists of introducing a cannula through a small incision in the skin and injecting Macrolane in the desired areas.

4. For this treatment, local anesthesia is required in the areas where Macrolane is going to be injected. My doctor has informed me about the risks of local anesthesia.

5. I have been specifically informed of the following: After the treatment, some common treatment-related reactions might occur. These reactions include redness, swelling, tenderness, pain, bruising or itching at the implant site. Typically these reactions occur in immediate connection to treatment and disappear spontaneously within one or two weeks, but some reactions can also appear later and remain longer and sometimes require medical interventions.

As with any injection, bleeding at the puncture site can occur and this can be readily treated. Patients who are using substances that affect coagulation, such as acetylsalicylic acid (aspirin) or anti-inflammatory drugs, may experience an increased risk of bruising or bleeding. Scarring might also occur at the insertion site. Local mobility or displacement of the injected material and lumps have been observed in the treated area. Leakage of material through the skin incision and leakage that leads to a collection of Macrolane at insertion site have also been observed. This can be prevented by following the post-treatment care instructions including the use of supportive clothing such as sports bra.

I have been advised that, as with any such procedure, injection of Macrolane is associated with a risk of infection. Soft tissue infections following injection treatment have been reported. Symptoms may include any combination of pain, redness, swelling and fever. Treatment, including antibiotics and in pronounced cases removal of the injected material, may be required. Symptoms of inflammation including a combination of pain, redness and swelling have also been reported. Decrease/increase in nipple sensation was reported in a clinical study, but no treatment was required for these events.

I have been informed that there is a low risk of the material being inadvertently injected into blood vessels, which could lead to damage to surrounding tissue. As with any injection there is also a low risk that e.g. nerves, vessels and viscera close to the injection site may be affected.

It has been explained to me that encapsulation of Macrolane occurs, similar to permanent implants, as part of the healing process. The encapsulation can sometimes contract leading to symptoms of pain and/or more rounded breasts. These contractures, reported in clinical studies and via post market complaints, require manual rupture if they become symptomatic or puncture with a needle or in very rare cases release by surgery.

In case of breast treatment, I have been informed of the need to comply with standard breast screening procedures. If a mammography is planned I should inform the radiologist about the breast implant and provide the radiologist with information about Macrolane. I have been advised that Macrolane is detectable on breast radiology and might affect the interpretation of mammography. This means that additional examinations such as ultrasound and/or MRI might be required to provide additional diagnostic information. I have also been instructed that during self examination of the breast the texture of implanted Macrolane gel may be different from that of breast tissue.

Unlike permanent breast implants where long-term follow up data have shown that the implant does not increase the risk of breast cancer, such data are not yet available for Macrolane because the treatment is new and a smaller group of women have been treated.

In order to avoid a possible risk of local product mobility, I have been advised to avoid massaging the treatment site or applying pressure to the area for 2-3 weeks after the injection. The use of supportive clothing during the same time may also be useful. In the case of breast treatment, I should also avoid activities that can be associated with excessive movements of the breasts such as jogging and jumping and avoid sleeping on my stomach for 2-3 weeks. For breast treatment the use of supportive clothing such as sports bra is useful during the same time. I have been informed to keep the injection site dry the first day after treatment to avoid a possible risk of infection.

6. I have been specifically informed that I should get in contact with my treating physician or other health care provider in case any post-treatment discomfort becomes pronounced or prolonged, if such discomfort does not respond to over-the-counter analgesics, if I develop a fever or other symptoms of infection in the post-treatment period or if I develop other symptoms that I find alarming.

7. In my personal case, it has been considered that this treatment is appropriate, although there are other alternatives that could be indicated under different circumstances. I have been informed that individual variability exists regarding duration and that an individual treatment program needs to be established to maintain the effect long-term. I have had the opportunity to discuss with my doctor about these alternatives and the advantages, drawbacks and possible risks of the chosen treatment.

I have informed my doctor about all my clinical data such as allergies, previous and current illnesses and conditions including bleeding disorders as well as previous and current treatments and medications. I have also informed my doctor about any treatments with other materials that I have had in the areas that are going to be treated.

Currently, I confirm that I am not pregnant or breast-feeding.

Other risks and complications that can occur because of my personal circumstances are:

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