

## **Patient Information Form:**

### **Follow-up care for men who have chosen to use Male Thermal Contraception (MTC)**

#### **For all doctors and their patients in France**

#### **1. What is the purpose of this document?**

The purpose of this document is to give you the latest scientific information about Male Thermal Contraception (MTC). It will help you decide if it's right for you and whether you would like to participate in a study.

#### **2. Should I participate in the study?**

If, having read all the information, you decide to use this contraceptive method, we will offer you regular medical consultations to ensure that everything goes smoothly.

#### **3. What do the medical consultations involve?**

During the first consultation, called "pre-contraception", the different MTC methods will be explained to you:

Two of them use the artificial cryptorchidism method developed by Dr Mieusset and Dr Bujan where 'heating briefs' need to be worn for 15 hours a day, 7 days a week:

- Heating briefs (called the Toulouse "ball-lifters"): are not available from pharmacies or online, but can be made at home. There are numerous tutorials, and we recommend this one:

[https://www.youtube.com/watch?v=io9frNy31Ts&ab\\_channel=ThomasBoulo%C3%B9](https://www.youtube.com/watch?v=io9frNy31Ts&ab_channel=ThomasBoulo%C3%B9)

- The silicone ring (« Androswitch »): available on the internet (<https://thoreme.com/>)

A third device using external testicular heating at 41°C that needs to be worn 3 hours a day, 7 days a week uses the "SpermaPause" - a pair of briefs containing battery-powered heating pads that are available online (<https://www.jemaya-innovations.com/fr/>)

It is worth noting that the results of clinical trials testing this technique, based on artificial cryptorchidism through testicular lifting using a device, have confirmed the effectiveness of male thermal contraception.

A 2017 study found that a total of 50 couples who were followed over 537 cycles had an unplanned pregnancy due to incorrect use of the technique. The Pearl Index for MTC is therefore less than 0.5, which is equivalent to the effectiveness of female hormonal contraception. So far no complications have been reported.

## Updating you on MTC:

- The technique has not been recognised as an official contraceptive method with European certification. It is not recognised by AMELI in France and therefore is not reimbursed by the social security system and cannot be prescribed.

- No thermal contraceptive device currently complies with existing medical legislation.

<sup>1</sup> Mieuxset R., Bujan L. The potential of mild testicular heating as safe, effective, and reversible contraception method for men. International journal of andrology 1994, 17:186-192

<sup>2</sup> Mieuxset R., Bujan L. The potential of mild testicular heating as safe, effective, and reversible contraception method for men. International journal of andrology 1994, 17:186-192

<sup>3</sup> J.C. Soufir : Hormonal, chemical and thermal inhibition of spermatogenesis: contribution of French teams to international data with the aim of developing male contraception in France. Basic and Clinical Andrology (2017) 27:3

<sup>4</sup> ANSM : <https://ansm.sante.fr/qui-sommes-nous/notre-perimetre/les-dispositifs-medicaux-et-les-dispositifs-medicaux-de-diagnostic-in-vitro/p/les-dispositifs-medicaux-et-les-dispositifs-medicaux-de-diagnostic-in-vitro-dmdiv t>

- The technique has been confirmed as safe, reversible and without sequela over a period of 4 consecutive years.
- It is recommended, as a precaution, to take a break of 3 to 6 months between each 4-year cycle of wearing the device.
- To this day, the long-term effects on the testicles or prostate are still unknown (see document on testicular cancer in appendix 2)
- It has been tested on healthy men with a normal semen analysis prior to starting the contraceptive process.
- Testicular lifting devices are varied (pants, jockstrap, ring) and not available in pharmacies. These are medical devices that can either be home-made (tutorials on the internet) or ordered online.
- During the contraceptive period, if a pregnancy should occur, termination of the pregnancy is recommended. This is because during the contraceptive period MTC induces a modification (reversible when contraception is stopped) of the genetic material of spermatozoa with potentially harmful consequences on fertilisation and the foetus. However, no clinical trials have proven that the effect on the spermatozoa genes adversely affects the foetus.

During this **first consultation**, we examine your **medical history** in depth to ensure that you have no contraindications for the thermal method (principally a history of varicocele, cryptorchidism at birth or inguinal hernia). We will then carry out a **physical examination** and prescribe a **semen analysis** ( the laboratory examination of the sperm and spermatozoa).

An absence of contraindications, normal physical examination results and a semen analysis are the three **medical prerequisites** for using the thermal contraception.

It is essential to understand that contraception is not immediate and requires a period of about **3 months of continuous wear**, regardless of the device.

That is why, at the end of the first three months we will ask you to complete a second semen analysis in order to assess whether the contraceptive threshold has been reached (i.e.  $\leq 1$  million spermatozoa / ml). If this is not the case, you will be offered a consultation to discuss your options and a re-evaluation of the semen analysis.

Thereafter, a semen analysis should be carried out every 3 months to ensure that the ring is being used correctly, and that the user remains under the contraceptive threshold. The laboratory will communicate the results to you by email, or you can also contact them by phone. Your doctor remains contactable throughout the process, and we invite you to consult them if there is any problem.

<sup>5</sup> Abdelhamid HMH & al. Experimental mild increase in testicular temperature has drastic, but reversible, effect on sperm aneuploidy in men: A pilot study.

You need to inform your partner of the potential adverse effects of MTC on genetic material of the spermatozoa and the unknown consequences on the foetus, should fertilisation take place.

It takes on average 3 to 6 months after stopping contraception to return to normal sperm count values. During this period a different contraceptive technique should be used, for the same reasons as mentioned above, and as a precautionary measure.

#### **4. Confidentiality and data protection:**

In accordance with the provisions of the French law relating to Information Technology, data files and individual liberties (Law No. 78-17 dated 6 January 1978, amended by Law No. 2018-493 dated 20 June 2018 relating to the protection of personal data) and the General Data Protection Regulation (EU Regulation 2016/679), you have the right to access and rectify your personal information.

In certain cases, you may also request a limit on the processing of your personal data, object to certain kinds of processing of your personal data, request that your personal data be erased and request that your personal data be provided to you or a third party in a digital format (the right to data portability).

You can exercise these rights through a written request addressed to your doctor.

They will answer your requests in accordance with their other legal and regulatory obligations and where required by law. You also have the right to object to the transmission of information covered by the obligation of professional secrecy.

In application of the provisions of article L1111-7 of the public health code, you may also access all your medical data directly or through the intermediary of a doctor of your choice. These rights are exercised through your current general practitioner or another doctor who knows your identity.

The ethics committee and the competent authorities may have access to your medical records in order to verify the accompanying procedures and/or the accuracy of the data collected, without breaching confidentiality. Such access is under the responsibility of your personal physician and will always be bound either by professional secrecy or by a confidentiality agreement. By signing the consent form, you give your permission for this access.

#### **5. Ethical protection**

If, despite the measures put in place by the promoter, you feel that your rights have not been respected, you may file a complaint with the competent data protection authority in your country of residence (the CNIL in France) <https://www.cnil.fr/webform/adresser-une-plainte>.

If, after reading this information sheet, you agree to use male thermal contraception, you will need to sign the attached 'Informed Consent' document.

**Follow-up of men who have opted for Male Thermal Contraception (MTC):**

**For all doctors and their patients in France**

Patients / Participants

Surname and first name (in capital letters):

Date of birth:

Telephone number:

Email address:

I declare that I have been informed about the different types of male contraception currently available. I am requesting the family planning centre to monitor my use of thermal male contraception which I have decided to initiate with full knowledge of the facts.

Signature:

Date:

Attending physician:

I, the undersigned, confirm that I have informed the above-mentioned patient orally and in writing of the purpose, nature, duration, foreseeable effects and procedures of this medical care. The patient freely consents to participate in male thermal contraception and has confirmed this by signing this document.

## The

Testicular cancer is a rare tumour (1 to 2% of all cancers), which can be characterised by two points: the young age of diagnosis (mostly between puberty and 45 years of age), and the good prognosis with almost 90% cure. In the embryo, the testicles are located in the abdomen. During fetal life, they gradually descend through the inguinal canal into the scrotum (skin of the bursa) and remain there permanently. The testicle is the male sex gland. In this gland there are two types of cells:

- germ cells, which produce spermatozoa,
- the so-called non-germ cells.

There are different types of testicular cancer depending on the cells involved:

1) Germ cell tumours, the most common with two subtypes:

- Seminomatous tumours (or seminoma): 30 to 40% of cases; age: 35 to 45 years.
- Non-seminomatous tumours (choriocarcinoma and/or vitelline tumour and/or embryonal carcinoma and/or teratoma): 60 to 70% of cases

2) Non-germ cell tumours (Leydig cell or Sertoli cell tumours, sarcomas) are much rarer (5% of cases).

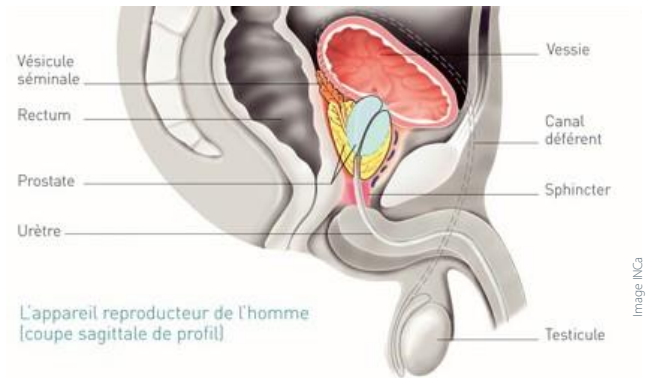


Image (NCA)

## Diagnostic steps

### Risk factors

Testicular ectopia or cryptorchidism (absence of testicular descent in the bursa in childhood); testicular atrophy (following an infection such as mumps, or after trauma) are all risk factors. There is no hereditary transmission.

### Symptoms

Symptoms may be an increase in the size of a testicle, the perception of a hard nodule, a feeling of tension or heaviness, or more rarely pain. The diagnosis can also be made during a fertility test. More rarely, the diagnosis is made on the basis of breast tension (gynecomastia) related to the secretion of a hormone (Chorionic Gonadotropin Hormone HCG), or on the basis of symptoms related to an extension of the disease to other organs (back pain (lymph nodes), coughing, shortness of breath (lungs), etc.)

## Diagnosis

It will be discussed by :

- on clinical examination by the consistency of the tumour on palpation,
- by performing a testicular ultrasound, which will show a more or less well limited, hypervascular nodule (numerous vessels),
- a possible increase in tumour markers (proteins measured in the blood by blood test): Alpha-fetoprotein, HCG, and LDH (lactate dehydrogenase)

Depending on the presentation, an extension work-up including a thoracoabdominopelvic CT scan will be performed to confirm the localized nature of the tumor. Prior to surgery, it is recommended that sperm be preserved in a CECOS (Centre de COnservation du Sperme).

# Testicular cancer

## Treatment

If all these examinations point to a testicular tumour, the diagnosis of certainty will be made by removal of the testicle (orchietomy), with the possibility of fitting a prosthesis during the same operation, if the patient so wishes. This operation is performed "by the upper route", i.e. with an incision in the groin. This is the first stage of treatment; more exceptionally, only the tumour is removed (lumpectomy; for specific types of tumour and after discussion with the patient). Biopsy (puncture) is not recommended.

Further management depends on the tumour (seminomatous/non-seminomatous), whether it is localised (stage I) or whether it has secondary localisations (metastases) at a distance (most often lymph nodes (stage II), sometimes lungs, more rarely elsewhere). It may be based on surveillance, radiotherapy or chemotherapy. In the case of distant extension, the treatment is based on chemotherapy, with the need to discuss surgery to remove residual masses, lymph nodes or remaining masses (pulmonary or other) if images are present on the end-of-treatment scan. Even if the treatment is more complex, the prognosis is generally good.

This specific management demonstrates the importance of a collegial management, associating urological surgeon, radiotherapist, radiologist and medical oncologist. In case of pulmonary localisation, the intervention of a team of thoracic surgeons is also required. All these specialities are represented at the Bordeaux University Hospital.

## Follow-up

After the treatment, monitoring is necessary in all cases, and will be based on a clinical examination by the urologist and/or radiotherapist and/or oncologist, alternately and according to the treatments administered. In addition, biological examinations (determination of markers in the town laboratory) and radiological examinations (scanner, testicular ultrasound, abdominal ultrasound) will be proposed according to a precise rhythm and adapted to the presentation of the disease and its management.

In addition, depending on the presentation of the disease, free and voluntary participation in national therapeutic trials may be offered.

## For more

High Authority for Health

[www.has-sante.fr](http://www.has-sante.fr)

Information platform of the National Cancer Institute (INCa)

[www.e-cancer.fr/cancer-info](http://www.e-cancer.fr/cancer-info)

National Cancer League

[www.ligue-cancer.net](http://www.ligue-cancer.net)

Uropage.com: the urology patient website

[http://www.uropage.com/ART\\_testi2.php](http://www.uropage.com/ART_testi2.php)