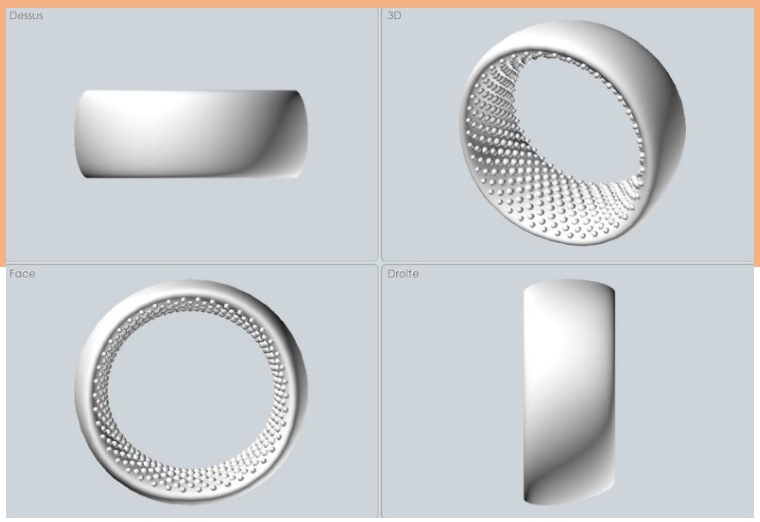
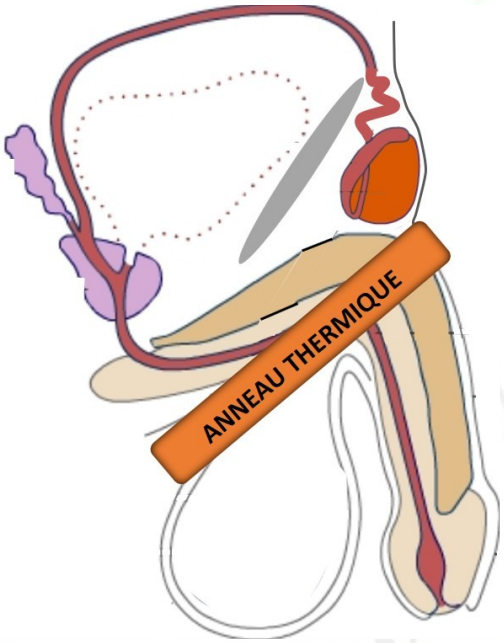
Product sheet

ANDRO-SWITCH



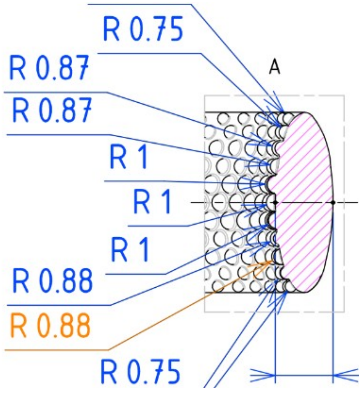
Thermal ring: penoscrotal annular device designed to maintain the testes in an upward position in order to apply the male thermal contraception (MTC) protocol.

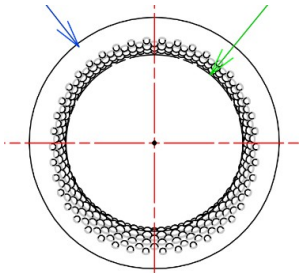
Concept	Specifically designed to maintain – temporarily – the testes above the scrotum. The rise in the testes' temperature to match that of the body leads to **temporary and reversible infertility**.
Characteristics	**Long-term, non-hormonal** and topical male contraception. Contraceptive threshold: sperm count **< 1 million/ml.** **Efficient, reversible, cost-effective.** **Push-up effect** to help maintain the testes upward. **Non-slip effect and breathable** internal side. Ergonomic, comfortable, no constriction risks for the penis. Non-sterile, reusable, **individual use only**. 5 available sizes.
Material	100% platinum-catalysed silicone, **certified biocompatible (ISO 10993-10** Skin Safe), flexible and clinically tested for extended skin contact. **Hypoallergenic**, latex-free, does not contain any colouring, BPA, phtalates, plastic, bleaching agents or toxins.
Indications	Any person wishing to practice MTC, **with their general practitioner's approval.** Can be used for wellness purposes.
Side effects	MTC is not an instant process. Becoming infertile and recovering normal fertility levels will take a few months' time. No side effects have been observed while wearing the thermal ring. May cause itching (due to the extended contact between the device and the skin). If you feel any pain or discomfort, stop using the ring and inform your general practitioner or pharmacist.
Use	**Insert the penis** inside the thermal ring. **Gently slide the scrotum skin** into the device until it is completely inserted. Lacking space, **the testes** will then **naturally move back up in the inguinal sac,** at the root of the penis.

	Make sure that the testes are in the inguinal sac with a light palpation Can be covered with standard underwear. Can be placed and removed in any position. You do not need to use a lubricant for placement and removal or while wearing the ring. You can urinate, have sexual intercourse, get erections and go about your daily and professional business just like you normally would. 
Hygiene & Storage	Clean the product before and after each use with lukewarm water and **gentle soap.** Only use water-based lubricants.
Wearing period	**15 hours a day** / maximum 4 years in a row using this contraception method
Contraindications	Any anomalies of the groin, the pubis, the penis, and the testes; inguinal hernia; testicular cancer; strength decline in the hands; obesity; local skin infections around the penis, scrotum, groin and pubis area; contact dermatitis in the penis, scrotum, groin and pubis area; penile edema.

- Practising MTC and wearing the annular ring will not provide any protection against sexually transmitted diseases (STD) or infections (STI), against which the condom is the only effective barrier.
- Before using this product, please refer to your general practitioner.
- Make sure you always wear the device strictly following the instructions from the MTC protocol and those given to you by your GP. If you have any doubts, ask your GP or your pharmacist.

https://thoreme.org **FB: slow.contraception** **contact@thoreme.org**





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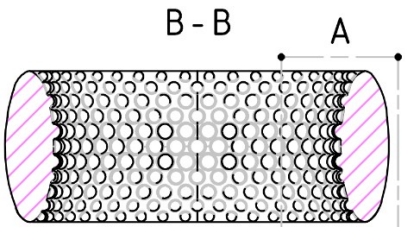
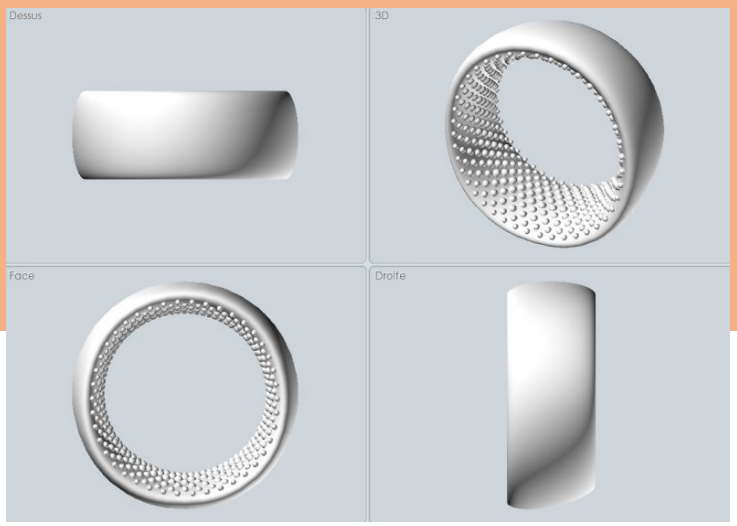


Instructions for use: PLACEMENT & REMOVAL

ANDRO-SWITCH



Using the thermal ring

Here is the testicular lifting protocol using the thermal ring.

Notes:

The first placement must be done with your general practitioner.

When putting the ring on for the first time, **it is recommended to be standing upright.**

The thermal ring has an internal and external side. **The internal side is uneven and presents specifically designed bumps** that create a **non-slip effect** which will keep the device from slipping and a **breathable effect** to evacuate moisture.

You want to take your time. What you will be doing manually happens regularly and naturally whenever you are cold, for instance. Testicular lifting is **painless**. You will only be experiencing new sensations consciously. All the men who practice MTC were able to do it, so will you.

Don’t forget that when you were born, your testicles were located in your abdomen. They migrated down into the inguinal sac a little later then down again through the inguinal canals to settle in the scrotum.

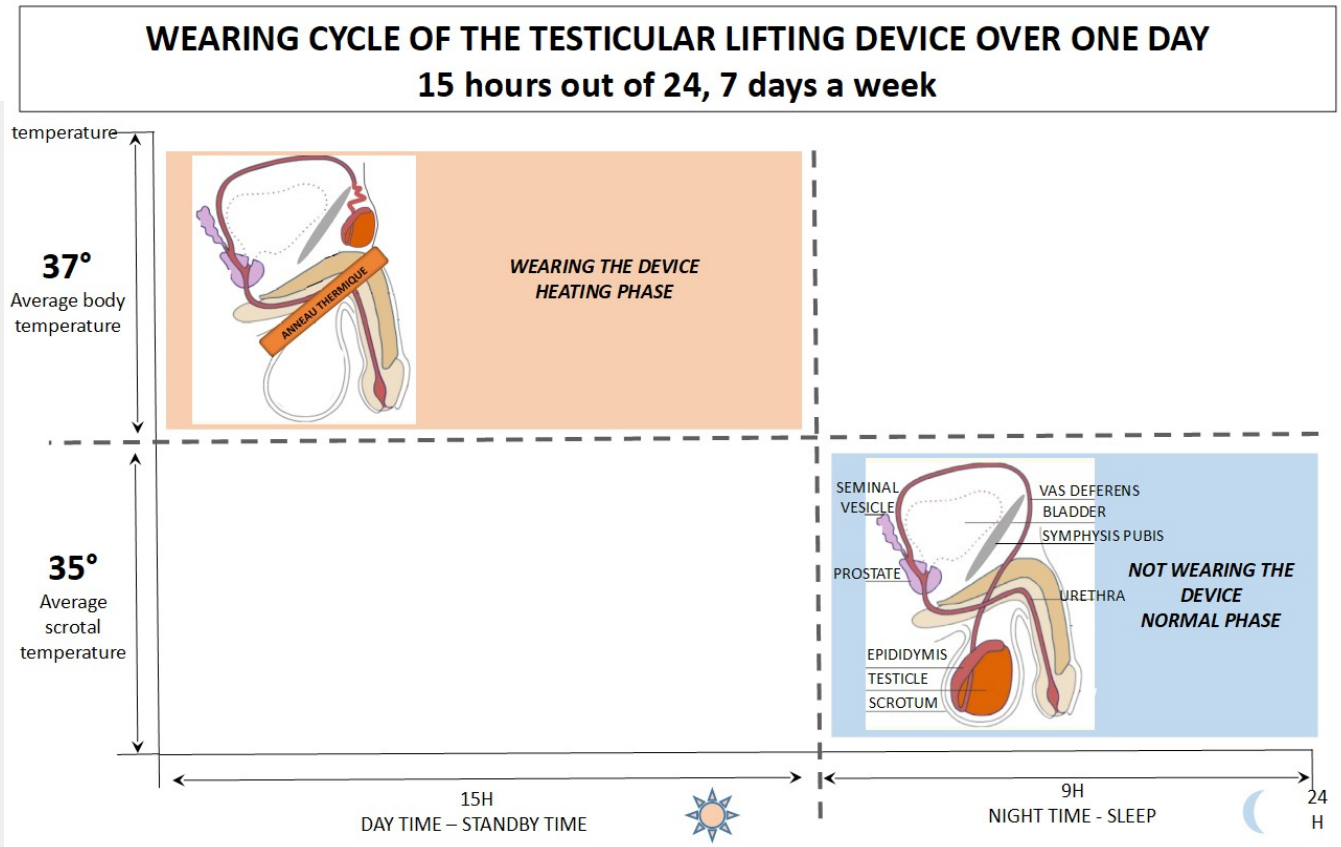
The first few placements will require a few minutes. But afterwards, placing and removing the ring will only be a matter of seconds. The gesture will feel natural and you’ll do it however fits you best.

Remember that you won't have to touch the testicles directly at any point. They will migrate by themselves for lack of space. This means that the skin around your penis and scrotum will naturally **stretch a little bit.** Once the placement is done, **the testicles must be placed above the thermal ring, in the inguinal sac**, where the exposure to the body heat is optimal. The MTC protocol will only work if this condition is met. When wearing the device on a daily basis, you will have to check **with a light palpation** or with the feeling that the testicles are still in the inguinal sac above the ring.

If, when placing the ring, a testicle gets inside the ring, it is recommended to gently take the ring off and to start over.

This area of the body may be hairy. Use slow movements to avoid pulling your hair, which could be painful.

Don't force anything at any point. If you feel like you can't do it, reach out to your GP. The size of the ring or your anatomy may not be adapted to testicle lifting into the inguinal sac with the ring.



Getting ready

Wash your hands.

Wash the thermal ring with a gentle soap and lukewarm water, rinse it and tap it dry with a clean towel or a soft cloth.

Stand up.

Getting to know your body

Take a few moments to feel the following parts of your body to acknowledge the texture and elasticity of the tissues:

Penis: Feel the upper part, where it connects with the pubis. Locate the frenulum just below the glans or the foreskin.

Scrotum: Feel the outline of its shape, its attachment point to the perineum, to the inguinal folds et to the sides of the penis.

Perineum: Feel this area located between the anus and the attachment point to the scrotum.

Inguinal folds: Place the tip of your index finger on it. Try hooking the skin on the side of your penis. You will find that it is loose, as though there were a canal running just underneath it. Which is exactly the case. Your testes will migrate into the inguinal sac through this canal.

Pubis: Feel this area. The skin is soft and stretches easily. This is where your testes will settle for 15 hours a day.

First step: Inserting the penis into the thermal ring

Hold the ring open with the edge of your left hand.

Make sure the internal side of the ring is the one with the little bumps. If it's not, turn it inside out.

With your right hand, hold the base of your penis.

Slide it into the ring.

With your right thumb and index finger, hold the penis at the glans or foreskin.

Gently pull on it towards your head.

With your left hand, finish inserting the penis so it's completely inside the ring. The upper part of the ring must be in contact with your pubis.

It's the seem as putting a ring on someone's finger.

Second step: Partly inserting the scrotum

The right thumb and index finger are still holding the penis at the glans or foreskin while slightly pulling it upwards towards the head.

Place the left thumb and index finger on the frenulum. Let the two fingers slide all the way down your penis until they reach the edge of the ring.

With the tip of both fingers, slightly pinch the skin that you're touching at this point. You are at the base of your penis and at the start of the scrotal sac. Fold the skin of the scrotum over and pull slightly upwards towards your head.

Let your right hand go off your penis. With the right thumb and index finger, grasp the ring underneath the scrotal skin fold that you're holding with your left hand. The thumb goes on the internal side of the ring and the index finger on the external side, like a clamp.

The right hand holds this position, holding the ring and pulling slightly towards the perineum. This hand should not move at all. If needed, rest the edge of your hand on your thigh.

Gently slide the scrotal skin upwards, towards your head, until a small part of the scrotal sac is inserted into the ring where your penis already is.

Stop pulling. Don't touch your penis or scrotum any more. The ring should hold on its own.

Normally at this point you should see your penis inside the ring and just underneath the penis, a small bulge of skin from the scrotal sac.

If that's the case, continue applying the protocol. If not, stop and start over.

Place your right thumb on the internal side of the ring and the index finger on the external side, like a clamp. Both fingers are holding the lower side of the ring placed against the scrotum.

Maintain the position, holding the ring and slightly pulling on it towards the perineum. This hand should not move at all. If needed, rest the edge of your hand on your thigh.

With your left hand, pinch a piece of skin from the scrotum as close to the ring as possible, where your right thumb holding the ring is placed.

Gently pull this part of your scrotal sac upwards towards your head until another small part of your scrotal sac is inserted into the ring.

Repeat about 5 times or stop when you cannot insert any more skin from the scrotum.

Don't touch your penis or scrotum any more.

At this point, most of your scrotum is inside the ring with your penis. When feeling the space between your perineum and the bottom part of the ring, you should feel the rest of the scrotum that will need to be inserted into the ring. Your testicles are now either just below the ring in the rest of the scrotal sac that hasn't been inserted into the ring yet, or around the groin folds in the inguinal canals.

When palpating, you can place the middle finger and the ring finger of both hands on the perineum and slide them until they reach the ring. Then, still touching the ring and the skin in that area, go all the way around the ring until your fingers meet at the pubic area.

The skin with which the ring is in contact should still be soft. This means that the testicles might still have enough space and are thus not migrating into the inguinal sac.

This stage is interesting because it shows you what can happen if the ring is not correctly placed or is sliding off. Your testicles are not in the inguinal sac any more, so the temperature they are exposed to is not high enough and the spermatozoa production might start again.

The optimal position is for the testicles to be maintained in the inguinal sac, which is the only place where the temperature is high enough for the spermatozoa production to stop temporarily.

Third step: Tensioning the skin around the ring in 3 motions

- **Tensioning the lower part:**

With your left hand, spoon together everything that's been inserted into the ring.

Gently lift it against your pubis. This whole part should be in contact with the pubic area.

Hold the position. This hand should not move at all.

Slide the first phalanx of the right thumb into the part of the ring that's closest to the ground, located underneath the part that you are holding against your pubis with your left hand.

With your right thumb, gently push the ring between your legs until you reach the perineum.

With the tip of the right thumb and the edge of the ring, gently press against the perineum. Meanwhile, the left hand is still holding the skin gently and firmly against the pubis.

The left hand brings it all back against the perineum, the bottom part of the ring and the thumb, as though you wanted to cover them with the skin.

Take the right thumb out.

Let the left hand go.

Feel your perineum. The skin that is directly in contact with the ring around the perineum should be slightly stretched.

It should feel a bit difficult to fold the skin in this area. It's almost like a balloon that's a little deflated and that you wanted to pinch.

Observe your penis and the part of the scrotum that's inside the ring without touching anything. On both sides of your penis, two folds have formed at the junction of your penis and the scrotal skin that's been inserted. One side at a time, those 2 points are where you are going grasp the ring to tension the left side and the right side at the edge of the ring. The testicles will then migrate into the inguinal sac for lack of space in the inguinal canals.

- **Tensioning the left side:**

Spoon your right hand to hold together the penis and the scrotum that are both inside the ring and tilt it to the right until it touches your right thigh.

With your left hand, place the tip of your index finger between the ring and the edge of the spoon of the right hand.

Introduce the first phalanx of the left index finger at the folding point at the junction of your penis and the scrotal skin that's inside the ring.

Pull the ring to the left until the tip of your left index finger and the edge of the ring are in contact with the left inguinal fold. Gently press the tip of your index finger and the edge of the ring on the inguinal fold. Meanwhile, the right hand holds the penis and scrotum gently and firmly against the right thigh.

The right hand then brings the penis and scrotum against the left thigh, the ring and the left index finger, as though you wanted to cover them with the penis and scrotum.

Remove the left index finger.

Let go of the right hand.

The skin that's directly touching the ring at the left inguinal fold and the left side of the pubis area should be slightly tense.

It should feel a bit difficult to fold the skin in this area. It's almost like a balloon that's a little deflated and that you wanted to pinch.

- **Tensioning the right side:**

It's the same sequencing as for the left side.

Spoon your left hand to hold together the penis and the scrotum that are both inside the ring and tilt it to the left until it touches your left thigh.

With your right hand, place the tip of your index finger between the ring and the edge of the spoon of the left hand.

Introduce the first phalanx of the right index finger at the folding point at the junction of your penis and the scrotal skin that's inside the ring.

Pull the ring to the right until the tip of your right index finger and the edge of the ring are in contact with the right inguinal fold. Gently press the tip of your index finger and the edge of the ring on the inguinal fold. Meanwhile, the left hand holds the penis and scrotum gently and firmly against the left thigh.

The left hand then brings the penis and scrotum against the right thigh, the right index finger, and the edge of the ring, as though you wanted to cover them with the penis and scrotum.

Remove the right index finger.

Let go of the left hand.

The skin that's directly touching the ring at the right inguinal fold and the right side of the pubis area should be slightly tense.

It should feel a bit difficult to fold the skin in this area. It's almost like a balloon that's a little deflated and that you wanted to pinch.

Checks

Your testicles should normally be located in the pubis area at this point. They are forming two bulges above the ring. With a light palpation, make sure that's the case.

The thermal ring should be in contact with the pubis (the area just above your penis) and the perineum (the area between your anus and the scrotum).

If that's the case, continue applying the protocol. If not, stop and start over.

Take a moment to try out different positions: lying down with your knees to the chest or squatting. This will allow you to check that the testicles stay in the inguinal sac.

Wash your hands.

The device is correctly placed if the testicles are held in an upward position as shown on the picture.

Well done!! You did it!

Take the ring off and try applying the whole protocol a few more times. Bit by bit, the moves will start coming naturally.

It is recommended to wear the ring for 2 hours the first 2 days and to gradually increase your wearing time until you reach 15 hours a day after 7 days.

Removal

Wash your hands.

With your left hand, spoon together everything that's been inserted into the ring.

Gently lift it against your pubis. This whole part should be in contact with the pubic area.

Hold the position. This hand should not move at all.

With your thumb and right index finger in a clamp, grasp the part of the ring that's closest to the ground and that lies underneath the penis and scrotum held in your left hand against your pubis.

Using the clamped fingers on the right side, gently slide the ring upwards towards your head. The tension in the bottom part will be released. Part of your scrotum will slide out of the ring. At this point, the position of the ring is the same as at the end of the second placement step. Let us remind you that this position is not ideal to practice MTC.

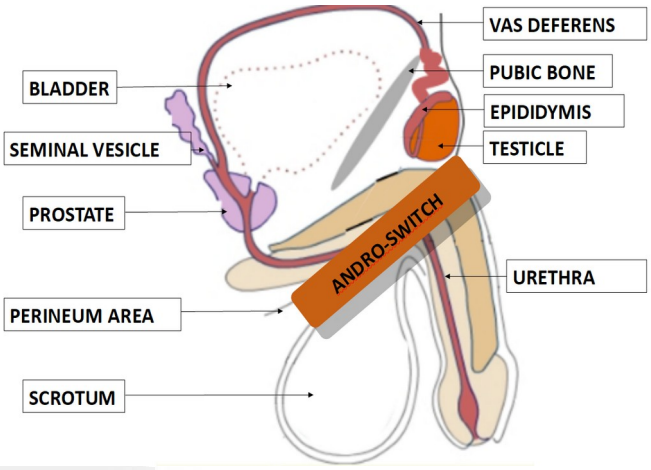
Using both hands, gently slide the thermal ring to finsih removing it.

Wash the ring with a gentle soap and lukewarm water, then rinse is before tapping it dry with a clean towel or soft cloth.

Wash your hands.

Well done!! You did it!

Try applying the whole protocol a few more times. Bit by bit, the moves will start coming naturally.



Notes:

When putting the thermal ring on and taking it off, **you won't need to touch the testicles directly.** They will naturally migrate for lack of space during placement. And when you remove the ring, they will naturally slide back down from the inguinal sac to the scrotum/

It can be placed and removed in any position.

You do not need to use a lubricant when placing, wearing or removing the device.

The qualities of the platinum-catalysed silicone, certified biocompatible (ISO 10993-10 Skin Safe), the shape of the thermal ring and the structure of its internal side create a push-up effect that allows the testes to be held upwards so they cannot settle back down into the scrotum.

The thermal ring can be covered with standard underwear.

You can urinate, have sexual intercourse, get erections and go about your daily and professional business just like you normally would.

In case you feel any pain or any other adverse reaction while wearing the thermal ring: Remove it immediately. Try again a few hours later. If the pain is still there, ask your general practitioner or your pharmacist for an opinion. Refer to the user manual to get acquainted with all information regarding ANDRO-SWITCH.

CERTIFIED ISO 10993-10 SKIN SAFE

ANDRO SWITCH

MEASURING PENIS/ RING SIZE - Instruction manual

Method

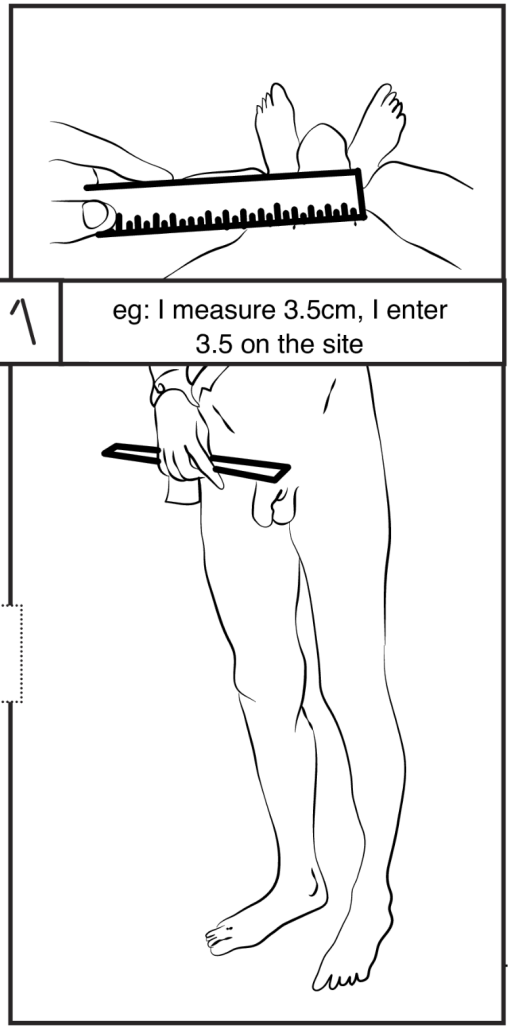
Use a ruler or a tape measure

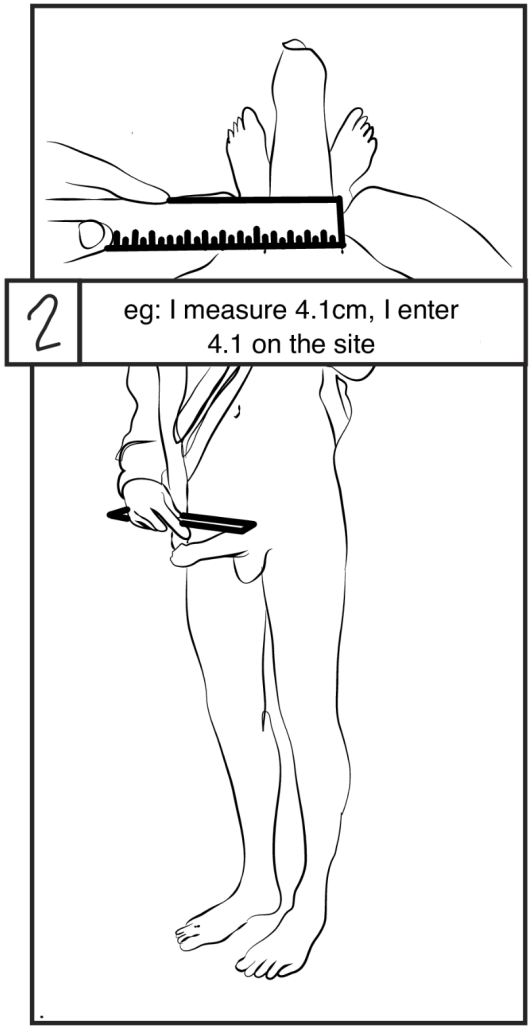
1. Standing, uncover your penis and place the ruler on top, at the base

Note the width of your penis when flaccid

2. With an erection, place the ruler at the base of your penis for a second time, and note the width

3. Those are all the measurements you need! Head to the Andro-switch lab (https://lab.androswitch.com/) to upload (anonymously) your measurements and ring size





Sizing chart

If the difference between the measurements is more than 1.2cm

Measurement of erection	Ring internal diametre	Andro-Switch basic	Andro-Switch soft
2,9 > 3,5 cm	31.5 mm	A	S (+soft)
3,5 > 4 cm	34.7 mm	N	W (+soft)
4 > 4,5 cm	35.9 mm	D	I (+soft)
4,5 > 5 cm	41.3 mm	R	T (+soft)
5 > 5,5	44.7 mm	O	C (+soft)

Andrology (2012) 22:211-215
DOI 10.1007/s12610-012-0192-1

THE EXPERT'S OPINION

A practical guide to hormonal and heat-based male contraception techniques

J.-C. Soufir · R. Mieusset

Introduction

New contraception methods for men include male hormonal contraception (MHC) and male thermal contraception (MTC). Both methods, MHC and MTC, have been tested for their inhibiting effect on spermatogenesis, their contraceptive effect and reversibility. Considering that the current data are sufficient to ensure day-to-day contraception, we found it necessary to create a practical guide to both methods that will allow physicians faced with questions regarding male contraception to provide answers and have the tools needed to apply these methods and ensure follow-up at their disposal.

MHC in nine questions (J.-C. Soufir)

For which men does MHC seem acceptable?

Men (under 45 years old) living with a stable partner and accepting that their partner (under 40 years old) is informed of their wish.

- Such men should present strong motivation determined by the following reasons:
  - preserving the health of their female partner (medical contraindication to or adverse effects of female contraception methods);
  - the wish to balance contraceptive responsibility within the couple;
- In our experience, among 30 couples who have observed MHC as a contraception method:
  - in one third of the cases, the woman had suffered from genital infections after an intrauterine device had been placed;
  - in one third of the cases, the "pills" had caused metrorrhagia, hyperlipidemia or mastodynia;
  - in the remaining third of the cases, the man wished to share the contraceptive responsibility.

Which clinical and biological assessments should be required from a man wishing to use MHC?
What are the contraindications to MHC?

Oral examination:

- Age: the man must be younger than 45 years old. Beyond that age, a vasectomy with sperm conservation is offered;
- Medical history: the treatment is contraindicated in the following cases:
  - history of phlebitis or coagulation disorders;
  - heart diseases, liver diseases (obstructive jaundice, steatosis), kidney diseases (kidney failure), neurological diseases (epilepsy...), respiratory diseases (sleep apnea), psychiatric diseases (psychosis, hyper-aggressiveness), dermatological diseases (acne), prostatic diseases;
- Family history: prostate cancer (one first-degree relative — father, brother — or two second-degree relatives);
- Additionally, the man must not:
  - present tobacco intoxication (over 5cg/day) or alcohol intoxication;

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– be treated with medications that alter androgen transport or countering their peripheral action.

During the clinical exam, he must not specifically present:

- obesity (BMI > 30)
- HBP (systolic > 150, diastolic > 9)
- acne.

The following *biological assessment* must be normal: complete blood count, HDL and LDL cholesterol, triglycerides, liver function tests (bilirubin, alkaline phosphatases, ASAT, ALAT, GGT).

Lastly, the *sperm* must me considered fertilising (sperm count higher than 15 million/ml, motility (a+b) higher than 32%, normal shape higher than 14%) according to WHO standards[1].

Which products are used for MHC, in what form and how often?

The most widely used treatment is testosterone enanthate (TE) in the form of oily, intramuscular injections with a dose of 200 mg once a week.

Treatment duration must not exceed 18 months.

On this subject, we can quote the WHO expertise (excerpt of a protocol that has been approved by the toxicology group and the advisory committee on human research):

"The 200 mg intramuscular dose of TE has been administered by different authors during various previous studies conducted on normal men. All of these studies have provided a great amount of data regarding sperm analyses, rates and serum hormone profiles and side effects. The following side effects seem to be well established: moderate tendency to put on weight (2 kg in average), slight increase in haematocrit (2%) and occasional acne or detectable gynecomastia. Such reactions have rarely lead participants to interrupt the experiment protocol. Nothing shows that this treatment could lead to prostatic hyperplasia and in any event, the men included in this study all belong to an age group (25–45 years old) in which there are no chances of prostatic failure. No report mentions acute toxicity and in particular signs of hepatic diseases when this scheme relying on TE is applied to normal men [2].

TE has been marketed worldwide for over 30 years. It has been used for therapeutic purposes often for dozens of years by thousands of men with hypogonadism, usually with a 250/220 mg dose every 10 to 14 days.

No author reported that this substance was toxic in these therapeutic schemes.*"*

At which point does a man using MHC has reached a contraceptive condition?

Once the concentration of spermatozoa is below 1 million/ml. This concentration level must be obtained between one and three months of treatment. If after three months the concentration of spermatozoa is higher than 1 million/ml, the treatment is stopped and we tell the candidate that they're not part of the good responders for ill-identified biological reasons as of yet.

Should they continue to have sperm analyses?

If the man takes his treatment appropriately, one sperm analysis per trimester is enough. This test reassures the couple and is used to make sure the treatment is correctly followed.

For how long can a man use MHC?

For 18 months according to wide-scale WHO protocols.

Is MHC reversible and within how long?

MHC is perfectly reversible. Depending on the person, getting back to the same sperm count as that preceding the treatment happens over varying timeframes. But fertility can be restored very quickly, as soon as one month after the treatment was stopped.

In our experience [3], one month after stopping the treatment 70% of the participants had a concentration of spermatozoa higher than 1 million/ml, and of those 70%, 20% had over 20 million spermatozoa/ml.

This has been quantified in an analysis conducted on 1,549 men. The average time needed to recover a 20 million/ml concentration was estimated at 3,4 months [4].

What are the side effects of MHC?

They have been well identified (see also the answer to question 3).

Under the aforementioned conditions, the effects are benign. More precisely, in a group of 157 men following the treatment [5], we decided to stop the treatment for 25 of them (16%) for the following reasons: acne ($n = 9$),

aggressivity, excessive libido (n = 3), weight gain (n = 2), lipid alteration (n = 2) or hematocrit alteration (n = 2), hypertension (n = 1), depression (n = 1), asthenia (n = 1), aphthous stomatitis (n = 1), acute prostatitis (n = 1), pneumonia (n = 1) and Gilbert's syndrome (n = 1).

Is an annual check-up necessary while on MHC?

A clinical assessment (designed to assess efficiency and side effects of the treatment) and a biological assessment carried out every 6 months seem advisable based on current evidence. The biological assessment is simple (FBC, ASAT, ALAT, GGT, blood lipids).

MTC in nine questions (R. Mieusset)

For which men does MTC seem acceptable?

All men living with a partner and accepting that their partner is orally informed of the method used, whatever the motivation behind it: the wish to balance contraceptive responsibility within the couple, preserving the health of the woman (adverse effects of or medical contraindication to female contraception methods), wish to control his fertility on the part of the man.

In our experiences on 17 couples who are using or have used MTC has a couple contraception method:

- in 6% of the cases, the woman had suffered from genital infections after an intrauterine device had been placed;
- in 18% of the cases, female hormonal contraception (pills, implant) had caused metrorrhagia or hyperlipidemia;
- in 24% of the cases, the woman wished to stop using the pill on the long run and to stop assuming the couple's contraception alone;
- in 18% of the cases, the couple used the condom and/or withdrawal or a vaginal ring and wished to switch to a male non-hormonal contraception method;
- in 34% of the cases, the man wanted to share the contraceptive responsibility without resorting to MHC.

Which clinical and biological assessments should be required from a man wishing to use MTC? What are the contraindications to MTC?

In the absence of previously conducted studies, MTC is not recommended to men whose

- *oral examination reveals the following history:*
  - Testicular descent anomalies (cryptorchidism, ectopia), treated or not; inguinal hernia, treated or not;
  - testicular cancer;
- *clinical examination shows:* grade 3 varicocele; severe obesity;

No *blood test* is required.

Lastly, the *seminogram* must be considered normal: concentration of spermatozoa higher than 15 million/ml, progressive motility greater than 32%, normal morphology depending on the method used

Which techniques are used for MTC, in what form and how often?

The most widely used method consists in raising the temperature in the testicles by about 2°C. This rise in temperature is obtained by moving the testicles from the scrotum to the superficial inguinal sac. The testicles are then held in this position using two techniques:

- surgical "suspension" of the testes [6]: this method requiring surgery does not seem acceptable to us and will not be described here;
- testicular "lifting" which we favour.

Principle: Each testicle is manually "lifted" from the scrotum to the root of the penis, close to the external orifice of the inguinal canal. The testicles must be held in this position every day during waking hours (15 hours a day).

Implementation and results Testicular lifting[1] is possible without any risks for all men meeting the defined inclusion criteria (see answer to question 2). We have made three consecutive improvements to the holding method which have resulted in a technique that can be shared and evaluated on a large scale.

First step (n = 14 men):

- the testicles are maintained with the help of snug underwear (95% cotton, 5% elastomer) in which a hole is created at the root of the penis. With a light manual pulling movement, the man can put his penis as well as the scrotal skin through this hole, which brings the testicles up in the desired position;
- after 6 to 12 months, the concentration of *mobile* spermatozoa is comprised between 1 and 3 million/ml [7].

Second step (n = 6 men):

1 The author can forward a short slideshow on the practical execution of the movement.

- a flexible rubber ring was added around the hole in order to better hold the testicles in the desired area;
- the inhibiting effect of this process is significantly higher: within 3 months, the concentration of *mobile* spermatozoa is lower than or equal to 1 million/ml [8].

Third step and current method (n = 5 men):

- the rubber ring has been replaced by elastic fabric strips sewn directly on the underwear;
- this adjustment allowed us to reach the contraceptive threshold (less than 1 million *mobile* spermatozoa/ml) within the first three months of use [9].

The contraceptive efficiency of these methods was established by two studies:

- testicular "suspension": 28 couples, 252 cycles of exposure to pregnancies: no pregnancies [6];
- testicular "lifting": 9 couples, 159 cycles of exposure to pregnancies: one pregnancy, due to improper use of the method (the underwear was not worn for seven weeks). If we exclude the cycle that resulted in a pregnancy while keeping this couple who then started using the testicular lifting technique again as their sole couple contraception method, there were no pregnancies for 158 exposure cycles [10]. *The underwear must be worn every day for a minimum of 15 hours a day. Failure to respect this minimum period of time every day or staying one day without wearing the underwear do not guarantee the inhibiting effect on spermatogenesis any more, and thus the contraceptive effect.*

At which point does a man using MTC has reached a contraceptive condition?

Once the concentration of *mobile* spermatozoa is inferior to 1 million/ml in two consecutive sperm samples taken three weeks apart. This concentration is obtained within two to four months of treatment.

Do you need to continue doing semen analysis after that?

It is advised to take a monthly test up to the sixth month, then every two months after that if the man properly applies his treatment. This test is a way of controlling that the treatment is applied properly and that the desired effect endures.

For how long can a man stay contracepted with MTC?

The maximum period is four years since reversibility in terms of sperm parameters and fertility has been observed for this period of time

Is this MTC method reversible? Within how long?

Testicular suspension After they stopped using the suspension method, the values of the spermatic parameters went back to normal for all men within 6 to 9 months. All the couples who subsequently wished to get pregnant did and no anomalies were found. No spontaneous miscarriages occurred [6].

Testicular lifting After the man stops wearing the underwear, the concentration of *mobile* spermatozoa gets back to the initial values within six to nine months. All the couples who subsequently wished to get pregnant did and no anomalies were found. No spontaneous miscarriages occurred [10]. It should be mentioned that an undesired pregnancy occurred three months after the man stopped wearing the underwear in a couple that wasn't using any other contraception method; which goes to show that the fertilising power of the spermatozoa can be effective again before all spermatic parameters are completely back to normal. Consequently, once MTC is stopped, another contraception method is *immediately* required to avoid any pregnancies.

What are the side effects of MTC?

No side effects have been observed during the application of MTC weather it was with suspension techniques (aside from surgical suspension) or testicular lifting.

Is an annual health check required when applying MTC?

No annual health check is required when applying MTC.

Conflict of interests statement: The authors declare no conflict of interest

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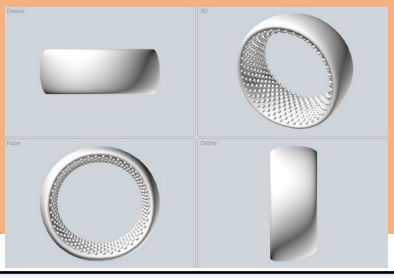
Instructions for use:

SEMINOGRAM & MALE THERMAL CONTRACEPTION



Introduction	A seminogram is a medical exam whose purpose is to analyse several parameters in a sperm sample. It consists in observing a drop of semen through a microscope in order to count the number of spermatozoa and study their characteristics. **Non-invasive and painless**, this exam is to be done regularly to ensure your sperm count remains under the **contraceptive threshold**: concentration of spermatozoa **< 1 million/ml**.
Instructions for MTC	• The first exam assesses the quality of your sperm. If it does not match the WHO standards, your general practitioner will redirect you to different contraceptive methods. • The next two analyses will be done 2 to 3 months later, then every 3 weeks after you started wearing the device. If your sperm count is < 1 million/ml, you are contracepted. If not, take the test again the following month. • During the first 6 months, the exam is to be done monthly, then quarterly. • **Caution : In case you forgot to wear the ring or were not consistent in wearing it, continue applying the protocol but use a different contraceptive method for a month, then take the test again.** • When you stop using this contraception method, use a different one then, after 3 months, take another test to make sure your fertility is back to normal according to WHO standards **with your general practitioner's guidance**.
Where can you do it?	**Contact the laboratory that is closest to you.** **By appointment only,** you can either collect a sample at home and bring it to the laboratory within an hour, or collect it directly at the premises.
Equipment	Sterile container Antiseptic wipe Sterile saline water vial
Minimum quantity	Between 0.5 and 3 ml depending on the requested exams. Can be associated with other spermiological exams.
How to get ready for it?	**General rule: observe a 3-day abstinence period.** Drink 1 litre of water the day before and a big glass of water on the same day. Urinate before collecting the sample. Wash your hands with soap and water. Rinse your hands with clear water. Disinfect your penis with the antiseptic wipe. Rinse your penis with the saline water from the sterile vial in order to wipe off all traces of disinfectant. Open the container. Masturbate and collect the ejaculate in the sterile container designed for this purpose. Carefully put the lid back on the container. The person taking delivery will stick a label with your last name, first name and date of birth on the container.

SEMINOGRAM

Reference values according to the 2010 WHO guide

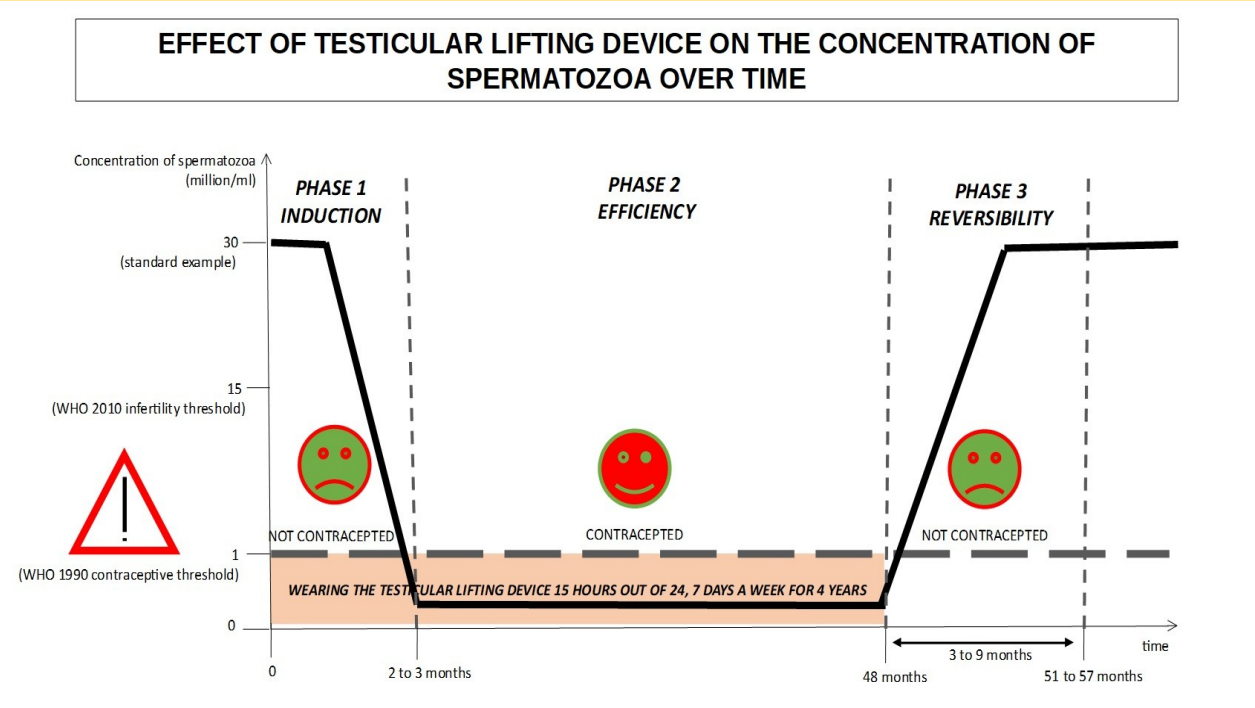
SPERM CHARACTERISTICS	*STANDARD VALUES*	*STANDARD VALUES WHILE USING THERMAL MALE CONTRACEPTION*
VOLUME	> 1.5 ml	> 1.5 ml
SPERM COUNT	> 15 million/ml (Infertility threshold)	**< 1 million/ml (Contraceptive threshold)**
PROGRESSIVE MOTILITY (A+B)	> 32%	< 10%
VITALITY (MOTILITY ONE HOUR AFTER EJACULATION)	> 58%	< 40%
NORMAL MORPHOLOGY OF THE SPERMATOZOA	> 4%	< 4%

- Practising MTC and wearing the contraceptive ring will not provide any protection against sexually transmitted diseases (STD) or infections (STI), for which the condom is the only effective barrier.
- Before using this product, please refer to your general practitioner.
- Make sure you always wear the device strictly following the instructions from the MTC protocol and those given to you by your GP. If you have any doubts, ask your GP or your pharmacist.

ANDRO SWITCH

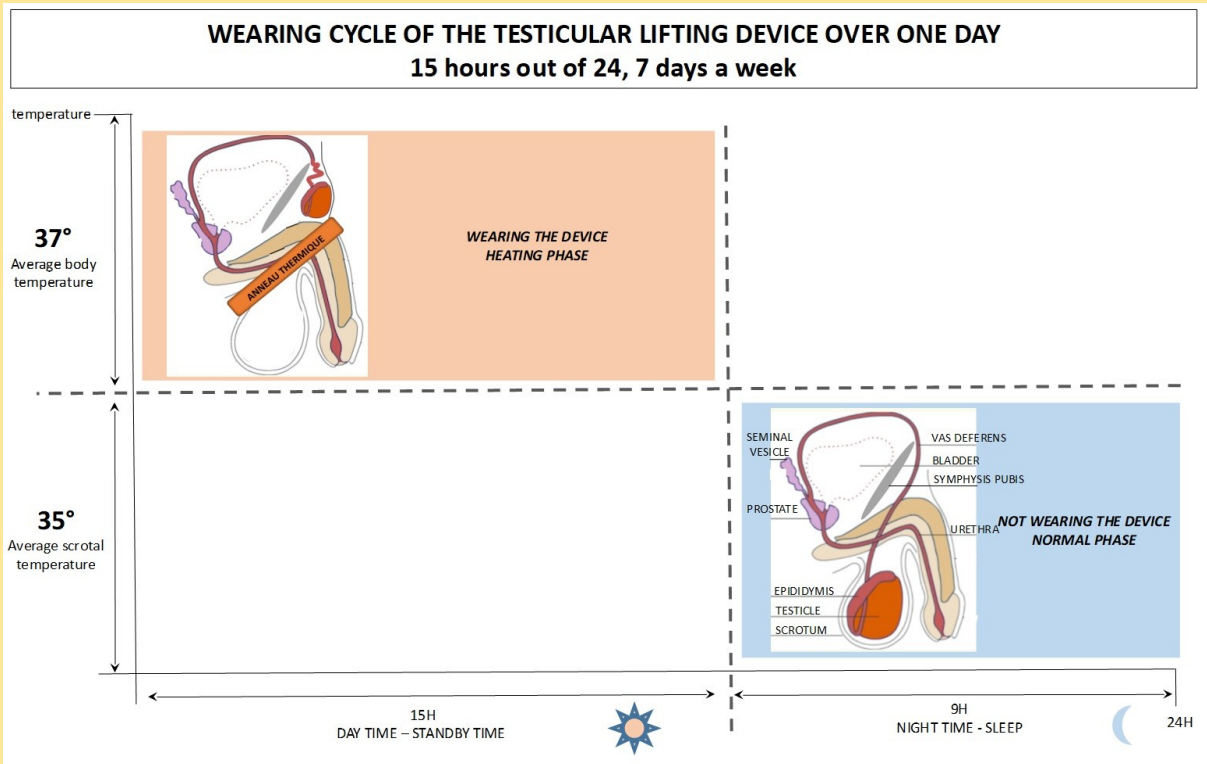
GENERAL PRINCIPLE OF THE MALE THERMAL CONTRACEPTION (MTC) METHOD WITH TESTICLE LIFTING

ANDRO SWITCH



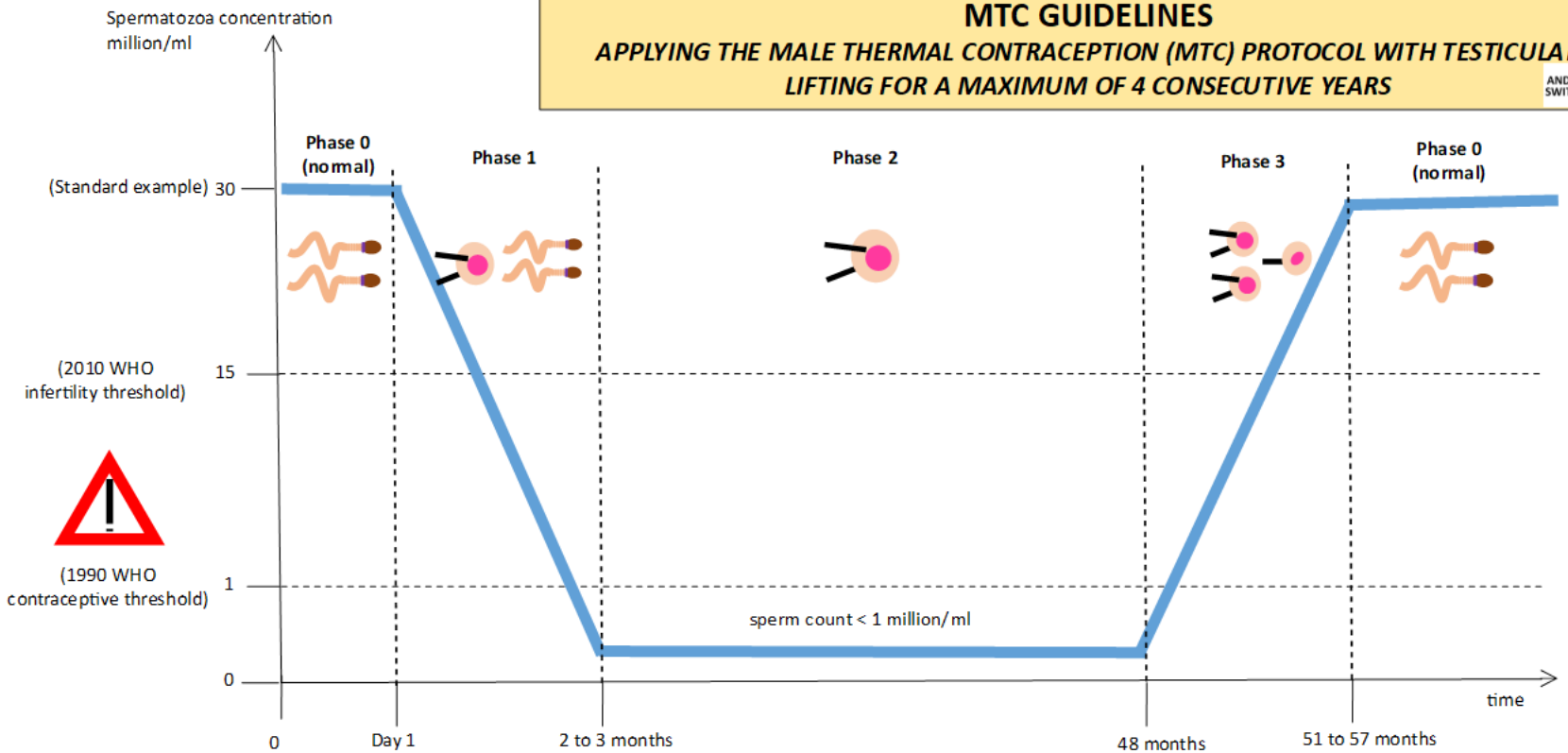
REMINDER:

- Make an appointment with your general practitioner before you start practising MTC.
- Practising MTC and wearing the contraceptive ring will not provide any protection against sexually transmitted diseases (STD) or infections (STI), against which the condom is the only effective barrier.



MTC GUIDELINES

APPLYING THE MALE THERMAL CONTRACEPTION (MTC) PROTOCOL WITH TESTICULAR LIFTING FOR A MAXIMUM OF 4 CONSECUTIVE YEARS



WEARING THE DEVICE (15 h/day, 7/7)					
EFFICENCY (Sperm count < 1 million/ml)					
USING A DIFFERENT CONTRACEPTIVE METHOD					Planning a pregnancy / Not planning any pregnancies
COMPLETE REVERSIBILITY (Normal seminogram according to the 2010 WHO standards)					
MEDICAL MONITORING general practitioner – andrologist	+	+	In case you forgot to wear the ring or wore it irregularly, continue applying the protocol and use another contraception method for one month, then do a seminogram.		+
SEMIOGRAM The test is done in a laboratory and 100% reimbursed with a prescription	✓	✓✓	Monthly check for 6 months, then quarterly		✓

Make an appointment with your general practitioner before you start practising MTC. In case of doubt or of unusual signs, see your doctor.

Practising MTC and wearing the contraceptive ring will not provide any protection against sexually transmitted diseases (STD) or infections (STI), against which the condom is the only effective barrier.

If your sperm count does not comply with the 2010 WHO standards and/or if you present any of the following contraindications: Testicular descent anomalies (cryptorchidism, ectopia) that have been treated or not; inguinal hernia, treated or not; testicular cancer; sensitivity alteration in the pubis, groin, penis or scrotum areas; strength decline in the hands; severe obesity: body mass index (BMI) ≥ 30 kg/m2; grade 3 varicocele; intra-scrotal nodule; significant hydrocele; cutaneous filariasis; elephantiasis; topical cutaneous infections in the penis, scrotum, groin and pubis areas; contact dermatitis in the penis, scrotum, groin and pubis areas; penile edema. Ask your general practitioner for advice before you start practising MTC.

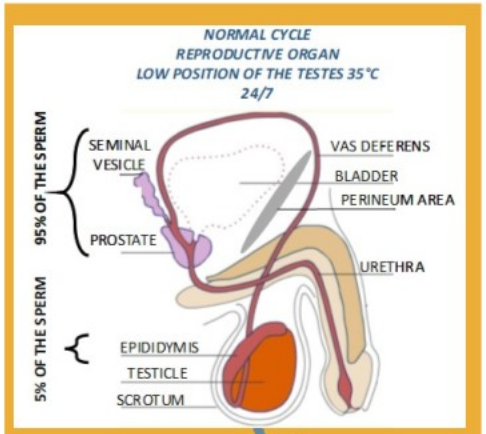
2 seminograms 3 weeks apart must show a sperm count < 1 million/ml in order to confirm the efficiency of the protocol application.

As long as your sperm count is > 1 million/ml, use another contraception method.

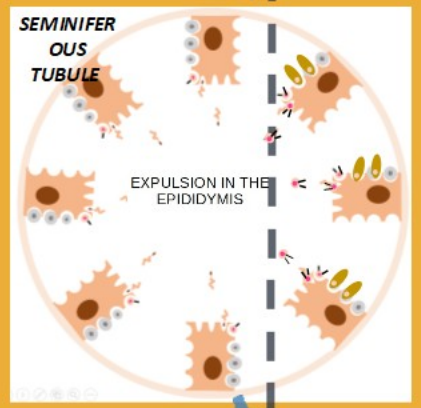
For monthly and quarterly checks, you won't need to see your doctor. You both get the results and they get back to you if necessary.

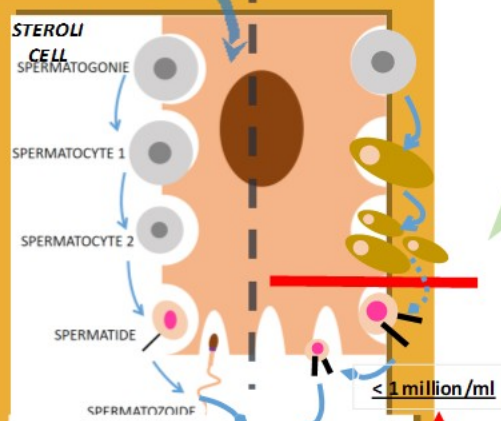
LEGEND	
NORMAL SPERMATOGONIUM AND SPERMATOCYT 1 & 2	
ABNORMAL SPERMATOGONIUM AND SPERMATOCYT 1 & 2 (ALTERED DNA)	
NORMAL SPERMATID	
ABDNORMAL SPERMATID (ALTERED CHARACTERISTICS)	
NORMAL SPERMATOZOON	

TEMPERATURE DEPENDENCE - SPERMATOGENESIS - MALE THERMAL CONTRACEPTION



NORMAL CYCLE **PHASE 2**

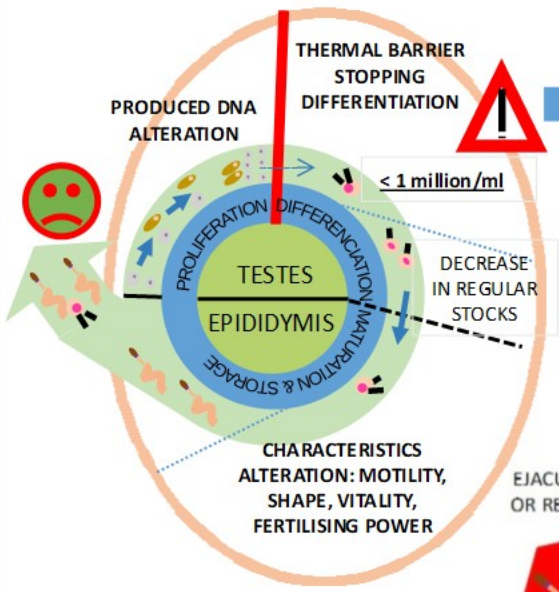




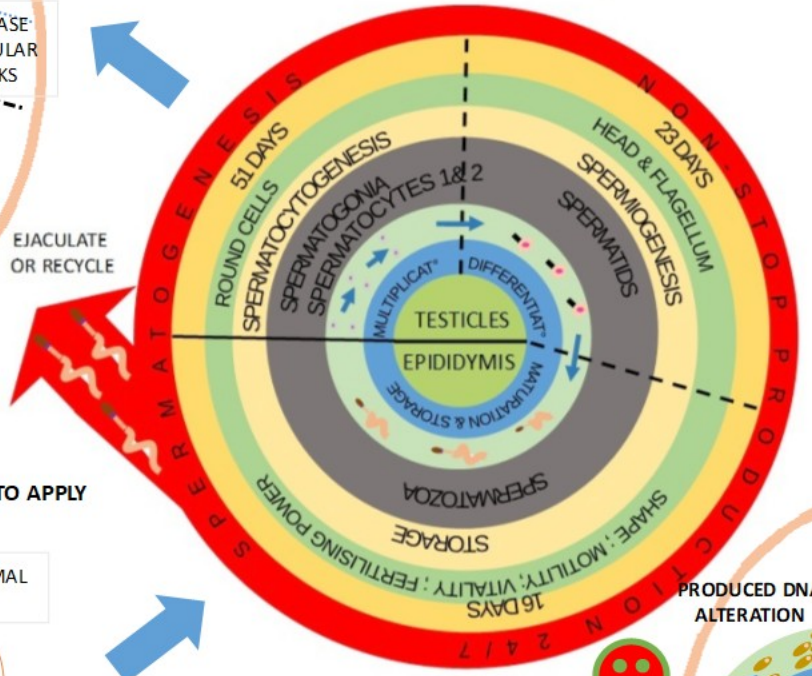
< 1 million/ml

Expulsion in the epididymis then the vas deferens then ejaculated or recycled

PHASE 1



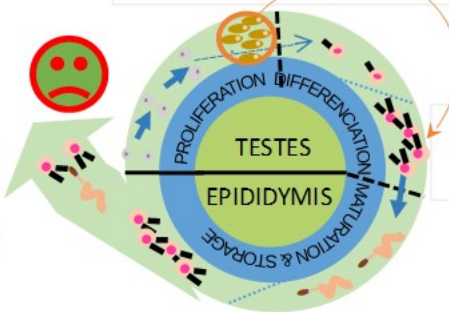
NORMAL 90-DAY CYCLE
(according to WHO 2010 values)



EJACULATE OR RECYCLE

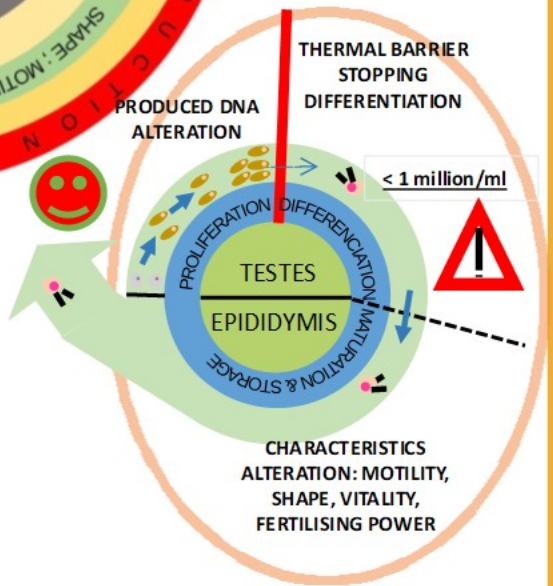
PHASE 3
STOPPED WEARING THE DEVICE OR FAILED TO APPLY THE PROTOCOL

BOUNCING EFFECT ONCE THE THERMAL BARRIER HAS BEEN LIFTED



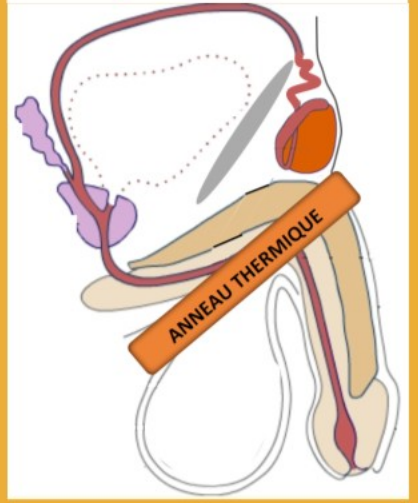
INCREASE FOLLOWED BY A DECREASE IN REGULAR STOCKS

PHASE 2



SEMIOGRAM (preceded by a 3-day abstinence period)		
SPERM CHARACTERISTICS	STANDARD VALUES (WHO 2010)	STANDARD VALUES (WITH MALE THERMAL CONTRACEPTION)
VOLUME	> 1.5 ml	> 1.5 ml
SPERM COUNT	> 15 million/ml (Infertility threshold)	**< 1 million/ml (Contraceptive threshold)**
PROGRESSIVE MOTILITY (A+B)	> 32%	< 10%
VITALITY (MOTILITY ONE HOUR AFTER EJACULATION)	> 58%	< 40%
NORMAL SPERMATOZOA MORPHOLOGY	> 4%	< 4%

PHASES 1 & 2
UPWARD POSITION OF THE TESTES 37°
15/24 HOURS - 7/7 DAYS



Dragon Skin™ Series

Addition Cure Silicone Rubber Compounds

www.smooth-on.com

Cured Material Certified Skin Safe!

PRODUCT OVERVIEW

Dragon Skin™ silicones are high performance platinum cure liquid silicone compounds that are used for a variety of applications ranging from creating skin effects and other movie special effects to making production molds for casting a variety of materials. Because of the **superior physical properties** and flexibility of Dragon Skin™ rubbers, they are also used for medical prosthetics and cushioning applications. Dragon Skin™ rubbers are also used for a variety of industrial applications and have a service temperature range of a constant -65°F to +450°F (-53°C to +232°C).

Great for Making Molds for a Variety of Applications - Available in **Shore 10A, 20A and 30A**, Dragon Skin™ silicones can be used to make exceptionally strong and tear resistant molds for casting plaster, wax, concrete (limited production run), resins and other materials.

Time Tested, Versatile Special Effects Material – Soft, super-strong and stretchy, Dragon Skin™ 10 (**Very Fast, Fast, Medium and Slow speeds**) is used around the world to make spectacular skin and creature effects. An infinite number of color effects can be achieved by adding Silc Pig™ silicone pigments or Cast Magic™ effects powders. Cured rubber can also be painted with the Psycho Paint™ system. Cured material is skin safe and certified by an independent laboratory to ISO 10993-10, Biological evaluation of medical devices, Part 10: Tests for irritation and skin sensitization.

Easy To Use – Dragon Skin™ silicones are mixed 1A:1B by weight or volume. Liquid rubber can be thinned with Silicone Thinner™ or thickened with THI-VEX™. Rubber cures at room temperature (73°F/23°C) with negligible shrinkage. ***Vacuum degassing is recommended to minimize air bubbles in cured rubber.***

TECHNICAL OVERVIEW

	Mixed Viscosity (ASTM D-2393)	Specific Gravity (g/cc) (ASTM D-1475)	Specific Volume (cu. in./lb.) (ASTM D-1475)	Pot Life (ASTM D-2471)	Cure Time	Shore A Hardness (ASTM D-2240)	Tensile Strength (ASTM D-412)	100% Modulus (ASTM D-412)	Elongation at Break % (ASTM D-412)	Die B Tear Strength (ASTM D-624)	Shrinkage (in./in.) (ASTM D-2566)
Dragon Skin™ 10 Very Fast	23,000 cps	1.07	25.8	4 min.	30 min.	10A	475 psi	22 psi	1000%	102 pli	< .001 in./in.
Dragon Skin™ 10 Fast	23,000 cps	1.07	25.8	8 min.	75 min.	10A	475 psi	22 psi	1000%	102 pli	< .001 in./in.
Dragon Skin™ 10 Medium	23,000 cps	1.07	25.8	20 min.	5 hours	10A	475 psi	22 psi	1000%	102 pli	< .001 in./in.
Dragon Skin™ 10 Slow	23,000 cps	1.07	25.8	45 min.	7 hours	10A	475 psi	22 psi	1000%	102 pli	< .001 in./in.
Dragon Skin™ 20	20,000 cps	1.08	25.6	25 min.	4 hours	20A	550 psi	49 psi	620%	120 pli	< .001 in./in.
Dragon Skin™ 30	20,000 cps	1.08	25.7	45 min.	16 hours	30A	500 psi	86 psi	364%	108 pli	< .001 in./in.

Mix Ratio: 1A:1B by volume or weight
Color: Translucent
Useful Temperature Range: -65°F to +450°F (-53°C to +232°C)
Dielectric Strength (ASTM D-147-97a)***:*** >350 volts/mil

*All values measured after 7 days at 73°F/23°C

PROCESSING RECOMMENDATIONS

PREPARATION... Safety – Use in a properly ventilated area ("room size" ventilation). Wear safety glasses, long sleeves and rubber gloves to minimize contamination risk. Wear vinyl gloves only. Latex gloves will inhibit the cure of the rubber.

Store and use material at room temperature (73°F/23°C). Warmer temperatures will drastically reduce working time and cure time. Storing material at warmer temperatures will also reduce the usable shelf life of unused material. These products have a limited shelf life and should be used as soon as possible. Mixing containers should have straight sides and a flat bottom. Mixing sticks should be flat and stiff with defined edges for scraping the sides and bottom of your mixing container.

Cure Inhibition – Addition-cure silicone rubber may be inhibited by certain contaminants in or on the pattern to be molded resulting in tackiness at the pattern interface or a total lack of cure throughout the mold. Latex, tin-cure silicone, sulfur clays, certain wood surfaces, newly cast polyester, epoxy, tin cure silicone rubber or urethane rubber may cause inhibition. If compatibility between the rubber and the surface is a concern, a small-scale test is recommended. Apply a small amount of rubber onto a non-critical area of the pattern. Inhibition has occurred if the rubber is gummy or uncured after the recommended cure time has passed.

Because no two applications are quite the same, a small test application to determine suitability for your project is recommended if performance of this material is in question.

Safety First!

The Material Safety Data Sheet (MSDS) for this or any Smooth-On product should be read prior to use and is available upon request from Smooth-On. All Smooth-On products are safe to use if directions are read and followed carefully.

Keep Out of Reach of Children

Be careful. Use only with adequate ventilation. Contact with skin and eyes may cause irritation. Flush eyes with water for 15 minutes and seek immediate medical attention. Remove from skin with waterless hand cleaner followed by soap and water.

Important: The information contained in this bulletin is considered accurate. However, no warranty is expressed or implied regarding the accuracy of the data, the results to be obtained from the use thereof, or that any such use will not infringe upon a patent. User shall determine the suitability of the product for the intended application and assume all risk and liability whatsoever in connection therewith.

Cure Inhibition – To prevent inhibition, one or more coatings of a clear acrylic lacquer applied to the model surface is usually effective. Allow any sealer to thoroughly dry before applying rubber. Note: Even with a sealer, platinum silicones will not work with modeling clays containing heavy amounts of sulfur. Do a small scale test for compatibility before using on your project.

Applying A Release Agent - Although not usually necessary, a release agent will make demolding easier when pouring into or over most surfaces. Ease Release™ 200 is a proven release agent for making molds with silicone rubber. Mann Ease Release™ products are available from Smooth-On or your Smooth-On distributor.

IMPORTANT: To ensure thorough coverage, lightly brush the release agent with a soft brush over all surfaces of the model. Follow with a light mist coating and let the release agent dry for 30 minutes.

If there is any question about the effectiveness of a sealer/release agent combination, a small-scale test should be made on an identical surface for trial.

MEASURING & MIXING...

Stir Part A and Part B thoroughly before dispensing. After dispensing required amounts of Parts A and B into mixing container (1A:1B by volume or weight), **mix thoroughly for 3 minutes making sure that you scrape the sides and bottom of the mixing container several times.** After mixing parts A and B, vacuum degassing is recommended to eliminate any entrapped air. Vacuum material for 2-3 minutes (29 inches of mercury), making sure that you leave enough room in container for product volume expansion.

POURING, CURING & MOLD PERFORMANCE...

For best results, pour your mixture in a single spot at the lowest point of the containment field. Let the rubber seek its level up and over the model. **A uniform flow will help minimize entrapped air.** The liquid rubber should level off at least 1/2" (1.3 cm) over the highest point of the model surface.

Curing / Post Curing - Allow rubber to cure as prescribed at room temperature (73°F/23°C) before demolding. Do not cure rubber where temperature is less than 65°F/18°C. **Optional:** Post curing the mold will aid in quickly attaining maximum physical and performance properties. After curing at room temperature, expose the rubber to 176°F/80°C for 2 hours and 212°F/100°C for one hour. Allow mold to cool to room temperature before using.

If Using As A Mold - When first cast, silicone rubber molds exhibit natural release characteristics. Depending on what is being cast into the mold, mold lubricity may be depleted over time and parts will begin to stick. No release agent is necessary when casting wax or gypsum. Applying a release agent such as Ease Release™ 200 (available from Smooth-On) prior to casting polyurethane, polyester and epoxy resins is recommended to prevent mold degradation.

Thickening Dragon Skin™ Silicones - **THI-VEX™** is made especially for thickening Smooth-On's silicones for vertical surface application (making brush-on molds). Different viscosities can be attained by varying the amount of THI-VEX™. See the **THI-VEX™ technical bulletin** (available from Smooth-On or your Smooth-On distributor) for full details.

Thinning Dragon Skin™ Silicones - Smooth-On's **Silicone Thinner™** will lower the viscosity of Dragon Skin™ for easier pouring and vacuum degassing. **A disadvantage** is that ultimate tear and tensile are reduced in proportion to the amount of **Silicone Thinner™** added. ***It is not recommended to exceed 10% by weight of total system (A+B).*** See the **Silicone Thinner™ technical bulletin** (available from Smooth-On or your Smooth-On distributor) for full details.

Mold Performance & Storage - The physical life of the mold depends on how you use it (materials cast, frequency, etc.). Casting abrasive materials such as concrete can quickly erode mold detail, while casting non-abrasive materials (wax) will not affect mold detail. Before storing, the mold should be cleaned with a soap solution and wiped fully dry. Two part (or more) molds should be assembled. Molds should be stored on a level surface in a cool, dry environment.

SMOOTH-ON SINCE 1895

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The new **www.smooth-on.com** is loaded with information about mold making, casting and more.

☑ GHS Compliant

Safety Data Sheet

SDS No. 823A

Section 1 - Identification

1.1 Product Identifier: Part A for: Body Double® & Body Double® SILK; Dragon Skin® Series & F/X Pro; Ecoflex® Series & Gel; Encapso® K; Equinox® Series; EZ Brush® Silicone; EZ-Spray® Silicone Series; Mold Max® Series; Mold Star® Series; OOMOO® Series; PoYo® Putty 40; Psycho Paint®; Rebound® Series; Rubber Glass®; Silicone 1515; Silicone 1603; Silicone 3030; Skin Tite®; Smooth-Sil® Series; Solaris®; SomaFoama® Series; SORTA-Clear® Series; Silicone 1708

1.2 General Use: Silicone Elastomer

1.3 Manufacturer: Smooth-On, Inc.,
5600 Lower Macungie Rd., Macungie, PA 18062
Phone (610) 252-5800, FAX (610) 252-6200
SDS@Smooth-On.com

1.4 Emergency Contact: Chem-Tel
Domestic: 800-255-3924 International: 813-248-0585

Section 2 – Hazard(s) Identification

2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to United States Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (29 CFR 1910.1200), the Canadian Workplace Hazardous Materials Information System (WHMIS) and Regulation (EC) No 1272/2008 and subsequent amendments.

2.2 GHS Label elements, including precautionary statements

Pictogram(s): none
Signal word: none

General Precautions:

P101: If medical advice is needed, have product container or label at hand.
P102: Keep out of reach of children.
P103: Read label before use.

Hazards not otherwise classified (HNOC) or not covered by GHS - none

Section 3 - Composition / Information on Ingredients

3.1 Substances

No ingredients are hazardous according to Regulation 2012 OSHA Hazard Communication Standard 29 CFR 1910.1200 criteria.

Section 4 - First Aid Measures

4.1 Description of first aid measures

Inhalation: Remove source(s) of contamination and move victim to fresh air. If breathing has stopped, give artificial respiration, then oxygen if needed. Contact physician immediately.
Eye Contact: Flush eyes with plenty of water. If irritation persists, seek medical attention.
Skin Contact: In case of skin contact, wash thoroughly with soap and water.
Ingestion: Do not induce vomiting unless instructed by a physician. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

None known.

4.3 After first aid, get appropriate in-plant, paramedic, or community medical support.

Section 5 - Fire-Fighting Measures

5.1 Extinguishing Media: Water Fog, Dry Chemical, and Carbon Dioxide Foam

5.2 Special hazards arising from the substance or mixture: None known.

5.3 Advice for firefighters: Use water spray to cool fire-exposed surfaces and to protect personnel. Shut off "fuel" to fire. If a leak or spill has not ignited, use water spray to disperse the vapors. Either allow fire to burn under controlled conditions or extinguish with foam or dry chemical. Try to cover liquid spills with foam. Because fire may produce toxic thermal decomposition products, wear a self-contained breathing apparatus (SCBA) with a full face piece operated in pressure demand or positive-pressure mode.

Section 6 - Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures: Only properly protected personnel should remain in the spill area; dike and contain spill. Stop or reduce discharge if it can be done safely**.**

6.2 Environmental precautions: No special environmental precautions required.

6.3 Methods and material for containment and cleaning up: absorb or scrape up excess into suitable container for disposal; wash area with dilute ammonia solution

6.4 Reference to other sections: if appropriate Sections 8 and 13 shall be referred to.

Section 7 - Handling and Storage

7.1 Precautions for safe handling: Use good general housekeeping procedures. Wash hands after use.

7.2 Conditions for safe storage, including any incompatibilities: Keep container(s) tightly closed and properly labeled. Store in cool, dry, well ventilated place away from heat, direct sunlight, strong oxidizers and any incompatibles. Store in approved containers and protect against physical damage. Keep containers securely sealed when not in use. Indoor storage should meet OSHA standards and appropriate fire codes. Containers that have been opened must be carefully resealed to prevent leakage. Empty containers retain residue and may be dangerous. Avoid water contamination.

7.3 Specific end use(s): These precautions are for room temperature handling. Other uses including elevated temperatures or aerosol/spray applications may require added precautions.

Section 8 - Exposure Controls / Personal Protection

8.1 Control parameters: none defined

8.2 Exposure controls:

Respiratory Protection: Should a respirator be needed, follow OSHA respirator regulations 29 CFR 1910.134 and European Standards EN 141, 143 and 371; wear an MSHA/NIOSH or European Standards EN 141, 143 and 371 approved respirators equipped with organic vapor cartridges.

Hand Protection: Wear any liquid-tight gloves such as butyl rubber, neoprene or PVC.

Eye Protection: Safety glasses with side shields per OSHA eye- and face-protection regulations 29 CFR 1910.133 and European Standard EN166. Contact lenses are not eye protective devices. Appropriate eye protection must be worn instead of, or in conjunction with contact lenses.

Other Protective Clothing/Equipment: Additional protective clothing or equipment is not normally required. Provide eye bath and safety shower.

Comments: Never eat, drink, or smoke in work areas. Practice good personal hygiene after using this material, especially before eating, drinking, smoking, using the toilet, or applying cosmetics. Wash thoroughly after handling.

Section 9 - Physical and Chemical Properties

9.1 Information on basic physical and chemical properties:

Appearance : viscous liquid
Odor/Threshold: Mild to sweet odor
pH: N.A. (non-aqueous)
Melting Point/Freezing Point: N.A.
Low/High Boiling Point: N.A.
Flash Point: >300 °F
Evaporation Rate: Not available
Flammability: f.p. at or above 200 °F
UEL/LEL: Not available

Vapor Pressure: None (Polymeric Resin)
Vapor Density (Air=1): >1
Specific Gravity (H_2O=1, at 4 °C): 1.05-1.15
Water Solubility: Insoluble
Partition coefficient: Not available
Auto-ignition temperature: Not available
Decomposition temperature: Not available
Viscosity: 5,000 – 50,000 centipoise
% Volatile: Nil

Section 10 - Stability and Reactivity

10.1 Reactivity: No hazardous reactions if stored and handled as prescribed/indicated., No corrosive effect on metal. Not fire propagating.
10.2 Chemical stability: These products are stable at room temperature in closed containers under normal storage and handling conditions.
10.3 Possibility of hazardous reactions: Hazardous polymerization cannot occur.
10.4 Conditions to avoid: none known
10.5 Incompatible materials: strong bases and acids
10.6 Hazardous decomposition products: Thermal oxidative decomposition can produce carbon oxides, gasses/vapors, and traces of incompletely burned carbon compounds.

Section 11- Toxicological Information

11.1 Information on toxicological effects:
Skin Corrosion/Irritation: no data
Serious Eye Damage/Irritation: no data
Respiratory/Skin Sensitization: no data
Germ Cell Mutagenicity: no data
Carcinogenicity: No component of these products present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by IARC, ACGIH or NTP.
Reproductive Toxicity: no data
Specific Target Organ Toxicity – Single Exposure: no data
Specific Target Organ Toxicity – Repeated Exposure: no data
Aspiration Hazard: no data
Acute Toxicity: no data
Chronic Exposure: no data
Potential Health Effects – Miscellaneous: no data

Section 12 - Ecological Information

12.1 Toxicity: no data
12.2 Persistence and Degradability: no data
12.3 Bioaccumulative Potential: no data
12.4 Mobility in Soil: no data
12.5 Results of PBT and vPvB assessment: no data
12.6 Other Adverse Effects: no data

Section 13 - Disposal Considerations

13.1 Waste treatment methods: Under RCRA it is the responsibility of the user of the product to determine at the time of disposal whether the product meets RCRA criteria for hazardous waste. Waste management should be in full compliance with federal, state and local laws.
Empty containers retain product residue which may exhibit hazards of material, therefore to not pressurize, cut, glaze, weld or use for any other purposes. Return drums to reclamation centers for proper cleaning and reuse.

Section 14 - Transport Information

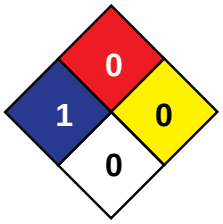
Not regulated by DOT, IATA or IMDG
14.1 UN number: none
14.2 UN proper shipping name: none
14.3 Transport hazard class(es): not applicable
14.4 Packing group: not applicable
14.5 Environmental hazards: none known
14.6 Special precautions for user: none known
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: not applicable

Section 15 - Regulatory Information

15.1 Safety health and environmental regulations/legislation specific for the substance or mixture:
In the United States (EPA Regulations):
TSCA Inventory Status (40 CFR710): All components of this formulation are listed in the TSCA Inventory.
SARA 302 Components: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.
SARA 313 Components: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 313.
SARA 311/312 Hazards: none
California Proposition 65**:** This product does not intentionally contain any chemicals known to the state of California to cause cancer, birth defects or other reproductive harm.
15.2 Chemical safety assessment: No chemical safety assessment has been carried out for this substance/mixture by the supplier.

16 - Other Information

HMIS	
H	1
F	0
R	0



NFPA

Revision: 7
Date Prepared: March 2, 2017

Glossary: ACGIH-American Conference of Governmental Industrial Hygienists; ANSI-American National Standards Institute; Canadian TDG-Canadian Transportation of Dangerous Goods; CAS-Chemical Abstract Service; Chemtrec-Chemical Transportation Emergency Center (US); CHIP-Chemical Hazard Information and Packaging; DSL-Domestic Substances List; EC-Equivalent Concentration; EH40 (UK)-HSE Guidance Note EH40 Occupational Exposure Limits; EPCRA-Emergency Planning and Community Right-To-Know Act; ESL-Effects screening levels; GHS-Globally Harmonized System of Classification and Labelling of Chemicals; HMIS-Hazardous Material Information Service; IATA-International Air Transport Association; IMDG-International Maritime Dangerous Goods Code; LC-Lethal Concentration; LD-Lethal Dose; LEL-Lower Explosion Level; NFPA-National Fire Protection Association; OEL-Occupational Exposure Limit; OSHA-Occupational Safety and Health Administration, US Dept. of Labor; PEL-Permissible Exposure Limit; SARA (Title III)-Superfund Amendments and Reauthorization Act; SARA 313-Superfund Amendments and Reauthorization Act, Section 313; SCBA-Self-Contained Breathing Apparatus; STEL-Short Term Exposure Limit; TCEQ-Texas Commission on Environmental Quality; TLV-Threshold Limit Value; TSCA-Toxic Substances Control Act Public Law 94-469; TWA-Time Weighted Value; UEL-Upper Explosion Level; US DOT-US Department of Transportation; WHMIS-Workplace Hazardous Materials Information System.

Disclaimer: The information contained in this Safety Data Sheet (SDS) is considered accurate as of the version date. However, no warranty is expressed or implied regarding the accuracy of the data. Since the use of this product is not within the control of Smooth-On Inc., it is the user's obligation to determine the suitability of the product for its intended application and assumes all risk and liability for its safe use.

This SDS is prepared to comply with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as prescribed by the United States (US) Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (29 CFR 1910.1200), the Canadian Workplace Hazardous Materials Information System (WHMIS), and European Union Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 (REACH).

Classifications of the chemical in accordance with 29 CFR 1910.1200, signal word, hazard and precautionary statement(s), symbol(s) and other information are based on listed concentration of each hazardous ingredient. Unlisted ingredients are not "hazardous" per the OSHA Hazard Communication Standard (29 CFR 1910.1200), WHMIS and EC No 1907/2006 and are considered trade secrets under US Federal Law (29 CFR and 40 CFR), Canadian Law (Health Canada Legislation), and European Union Directives.

☑ GHS Compliant

Safety Data Sheet

SDS No. 823B

Section 1 - Identification

1.1 Product Identifier: Part B for: Body Double® & Body Double® SILK; Dragon Skin® Series & F/X Pro; Ecoflex® Series & Gel; Encapso® K; Equinox® Series; EZ Brush® Silicone; EZ-Spray® Silicone Series; Psycho Paint®; Mold Star® Series; OOMOO® Series; Rebound® Series; Rubber Glass®; Skin Tite®; Smooth-Sil® Series; Soma Foama® 15 and 25; Solaris®; SORTA-Clear® Series; Silicone 1603; Silicone 1708

1.2 General Use: Silicone Elastomer Crosslinker

1.3 Manufacturer: Smooth-On, Inc.,
5600 Lower Macungie Rd., Macungie, PA 18062
Phone (610) 252-5800, FAX (610) 252-6200
SDS@Smooth-On.com

Emergency Contact: Chem-Tel
Domestic: 800-255-3924 International: 813-248-0585

Section 2 – Hazard(s) Identification

2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to United States Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (29 CFR 1910.1200), the Canadian Workplace Hazardous Materials Information System (WHMIS) and Regulation (EC) No 1272/2008 and subsequent amendments.

2.2 GHS Label elements, including precautionary statements

Pictogram(s): none

Signal word: none

General Precautions:

P101: If medical advice is needed, have product container or label at hand.
P102: Keep out of reach of children.
P103: Read label before use.

Hazards not otherwise classified (HNOC) or not covered by GHS - none

Section 3 - Composition / Information on Ingredients

3.1 Substances

No ingredients are hazardous according to Regulation 2012 OSHA Hazard Communication Standard 29 CFR 1910.1200 criteria.

Section 4 - First Aid Measures

4.1 Description of first aid measures

Inhalation: Remove source(s) of contamination and move victim to fresh air. If breathing has stopped, give artificial respiration, then oxygen if needed. Contact physician immediately.

Eye Contact: Flush eyes with plenty of water. If irritation persists, seek medical attention.

Skin Contact: In case of skin contact, wash thoroughly with soap and water.

Ingestion: Do not induce vomiting unless instructed by a physician. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

None known.

4.3 After first aid, get appropriate in-plant, paramedic, or community medical support.

Section 5 - Fire-Fighting Measures

5.1 Extinguishing Media: Water Fog, Dry Chemical, and Carbon Dioxide Foam
5.2 Special hazards arising from the substance or mixture: None known.
5.3 Advice for firefighters: Use water spray to cool fire-exposed surfaces and to protect personnel. Shut off "fuel" to fire. If a leak or spill has not ignited, use water spray to disperse the vapors. Either allow fire to burn under controlled conditions or extinguish with foam or dry chemical. Try to cover liquid spills with foam. Because fire may produce toxic thermal decomposition products, wear a self-contained breathing apparatus (SCBA) with a full face piece operated in pressure demand or positive-pressure mode.

Section 6 - Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures: Only properly protected personnel should remain in the spill area; dike and contain spill. Stop or reduce discharge if it can be done safely**.**
6.2 Environmental precautions: No special environmental precautions required.
6.3 Methods and material for containment and cleaning up: absorb or scrape up excess into suitable container for disposal; wash area with dilute ammonia solution
6.4 Reference to other sections: if appropriate Sections 8 and 13 shall be referred to.

Section 7 - Handling and Storage

7.1 Precautions for safe handling: Use good general housekeeping procedures. Wash hands after use.
7.2 Conditions for safe storage, including any incompatibilities: Keep container(s) tightly closed and properly labeled. Store in cool, dry, well ventilated place away from heat, direct sunlight, strong oxidizers and any incompatibles. Store in approved containers and protect against physical damage. Keep containers securely sealed when not in use. Indoor storage should meet OSHA standards and appropriate fire codes. Containers that have been opened must be carefully resealed to prevent leakage. Empty containers retain residue and may be dangerous. Avoid water contamination.
7.3 Specific end use(s): These precautions are for room temperature handling. Other uses including elevated temperatures or aerosol/spray applications may require added precautions.

Section 8 - Exposure Controls / Personal Protection

8.1 Control parameters: none defined
8.2 Exposure controls:
Respiratory Protection: Should a respirator be needed, follow OSHA respirator regulations 29 CFR 1910.134 and European Standards EN 141, 143 and 371; wear an MSHA/NIOSH or European Standards EN 141, 143 and 371 approved respirators equipped with organic vapor cartridges.
Hand Protection: Wear any liquid-tight gloves such as butyl rubber, neoprene or PVC.
Eye Protection: Safety glasses with side shields per OSHA eye- and face-protection regulations 29 CFR 1910.133 and European Standard EN166. Contact lenses are not eye protective devices. Appropriate eye protection must be worn instead of, or in conjunction with contact lenses.
Other Protective Clothing/Equipment: Additional protective clothing or equipment is not normally required. Provide eye bath and safety shower.
Comments: Never eat, drink, or smoke in work areas. Practice good personal hygiene after using this material, especially before eating, drinking, smoking, using the toilet, or applying cosmetics. Wash thoroughly after handling.

Section 9 - Physical and Chemical Properties

9.1 Information on basic physical and chemical properties:

Appearance : viscous liquid
Odor/Threshold: Mild to sweet odor
pH: N.A. (non-aqueous)
Melting Point/Freezing Point: N.A.
Low/High Boiling Point: N.A.
Flash Point: >300 °F
Evaporation Rate: Not available
Flammability: f.p. at or above 200 °F
UEL/LEL: Not available

Vapor Pressure: None (Polymeric Resin)
Vapor Density (Air=1): >1
Specific Gravity (H_2O=1, at 4 °C): 1.07
Water Solubility: Insoluble
Partition coefficient: Not available
Auto-ignition temperature: Not available
Decomposition temperature: Not available
Viscosity: 5,000 – 50,000 centipoise
% Volatile: Nil

Section 10 - Stability and Reactivity

10.1 Reactivity: No hazardous reactions if stored and handled as prescribed/indicated., No corrosive effect on metal. Not fire propagating.
10.2 Chemical stability: These products are stable at room temperature in closed containers under normal storage and handling conditions.
10.3 Possibility of hazardous reactions: Hazardous polymerization cannot occur.
10.4 Conditions to avoid: none known
10.5 Incompatible materials: strong bases and acids
10.6 Hazardous decomposition products: Thermal oxidative decomposition can produce carbon oxides, gasses/vapors, and traces of incompletely burned carbon compounds.

Section 11- Toxicological Information

11.1 Information on toxicological effects:
Skin Corrosion/Irritation: no data
Serious Eye Damage/Irritation: no data
Respiratory/Skin Sensitization: no data
Germ Cell Mutagenicity: no data
Carcinogenicity: No component of these products present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by IARC, ACGIH or NTP.
Reproductive Toxicity: no data
Specific Target Organ Toxicity – Single Exposure: no data
Specific Target Organ Toxicity – Repeated Exposure: no data
Aspiration Hazard: no data
Acute Toxicity: no data
Chronic Exposure: no data
Potential Health Effects – Miscellaneous: no data

Section 12 - Ecological Information

12.1 Toxicity: no data
12.2 Persistence and Degradability: no data
12.3 Bioaccumulative Potential: no data
12.4 Mobility in Soil: no data
12.5 Results of PBT and vPvB assessment: no data
12.6 Other Adverse Effects: no data

Section 13 - Disposal Considerations

13.1 Waste treatment methods: Under RCRA it is the responsibility of the user of the product to determine at the time of disposal whether the product meets RCRA criteria for hazardous waste. Waste management should be in full compliance with federal, state and local laws.
Empty containers retain product residue which may exhibit hazards of material, therefore to not pressurize, cut, glaze, weld or use for any other purposes. Return drums to reclamation centers for proper cleaning and reuse.

Section 14 - Transport Information

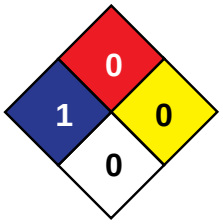
Not regulated by DOT, IATA or IMDG
14.1 UN number: none
14.2 UN proper shipping name: none
14.3 Transport hazard class(es): not applicable
14.4 Packing group: not applicable
14.5 Environmental hazards: none known
14.6 Special precautions for user: none known
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: not applicable

Section 15 - Regulatory Information

15.1 Safety health and environmental regulations/legislation specific for the substance or mixture:
In the United States (EPA Regulations):
TSCA Inventory Status (40 CFR710): All components of this formulation are listed in the TSCA Inventory.
SARA 302 Components: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.
SARA 313 Components: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 313.
SARA 311/312 Hazards: none
California Proposition 65**:** This product does not intentionally contain any chemicals known to the state of California to cause cancer, birth defects or other reproductive harm.
15.2 Chemical safety assessment: No chemical safety assessment has been carried out for this substance/mixture by the supplier.

16 - Other Information

HMIS	
H	1
F	0
R	0



NFPA

Revision: 8
Date Prepared: March 2, 2017

Glossary: ACGIH-American Conference of Governmental Industrial Hygienists; ANSI-American National Standards Institute; Canadian TDG-Canadian Transportation of Dangerous Goods; CAS-Chemical Abstract Service; Chemtrec-Chemical Transportation Emergency Center (US); CHIP-Chemical Hazard Information and Packaging; DSL-Domestic Substances List; EC-Equivalent Concentration; EH40 (UK)-HSE Guidance Note EH40 Occupational Exposure Limits; EPCRA-Emergency Planning and Community Right-To-Know Act; ESL-Effects screening levels; GHS-Globally Harmonized System of Classification and Labelling of Chemicals; HMIS-Hazardous Material Information Service; IATA-International Air Transport Association; IMDG-International Maritime Dangerous Goods Code; LC-Lethal Concentration; LD-Lethal Dose; LEL-Lower Explosion Level; NFPA-National Fire Protection Association; OEL-Occupational Exposure Limit; OSHA-Occupational Safety and Health Administration, US Dept. of Labor; PEL-Permissible Exposure Limit; SARA (Title III)-Superfund Amendments and Reauthorization Act; SARA 313-Superfund Amendments and Reauthorization Act, Section 313; SCBA-Self-Contained Breathing Apparatus; STEL-Short Term Exposure Limit; TCEQ-Texas Commission on Environmental Quality; TLV-Threshold Limit Value; TSCA-Toxic Substances Control Act Public Law 94-469; TWA-Time Weighted Value; UEL-Upper Explosion Level; US DOT-US Department of Transportation; WHMIS-Workplace Hazardous Materials Information System.

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Classifications of the chemical in accordance with 29 CFR 1910.1200, signal word, hazard and precautionary statement(s), symbol(s) and other information are based on listed concentration of each hazardous ingredient. Unlisted ingredients are not "hazardous" per the OSHA Hazard Communication Standard (29 CFR 1910.1200), WHMIS and EC No 1907/2006 and are considered trade secrets under US Federal Law (29 CFR and 40 CFR), Canadian Law (Health Canada Legislation), and European Union Directives.

QAI LABORATORIES
CERTIFICATION TESTING INSPECTION

1325 North 108th E. Ave.
Tulsa, OK 74116
918.437.8333 ph. | 918.437.8487 fx.

CLIENT: **SMOOTH-ON INC.**
5600 Lower Macungie Road
Lower Macungie, PA 18062

Test Report No: TJ5491	Date: April 24, 2018

SAMPLE ID: The test samples are identified as **"DRAGON SKIN 10"**

SAMPLING DETAIL: Test samples were submitted to the laboratory directly by the client. No special sampling conditions or sample preparation were observed by QAI.

DATE OF RECEIPT: Samples were received at QAI on April 03, 2018

TESTING PERIOD: April 11, 2018

AUTHORIZATION: Proposal 18SP031901 approved on March 29, 2018

TEST PROCEDURE: The submitted sample was tested in accordance with the procedures outlines in UL-94 (2006), "Tests for Flammability of Plastic Materials for Parts and Devices in Appliances" (Horizontal Burning Test, HB Section 7)

TEST RESULTS: Results can be found on the following pages and apply only to the sample tested.

CLASSIFICATION: The sample resulted in a Classification of HB according to section 7.1.3 of UL94.

Prepared By

L. Casey Holcomb
Fire Testing Technician

Signed for and on behalf of QAI Laboratories, Inc.

Fire Lab Project Manager

TEST RESULTS:

SAMPLE ID	Passed 25-mm Length	Reached 100-mm Length	Time[1] (min:sec)	Linear Burn Rate[2] (mm/min)
Dragon skin 1	No	No	00:00	0
Dragon skin 2	No	No	00:00	0
Dragon skin 3	No	No	00:00	0
AVERAGE	No	No	00:00	**0**

[1] – References the time to across from the 25-mm mark to the 75-mm mark
[2] – References the Time[1] per 50-mm length burn

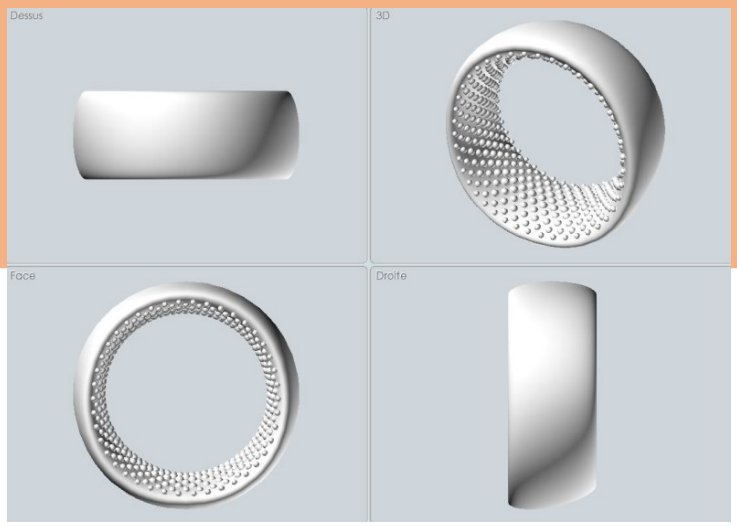
Additional notes: The sample measured 125mm x 13mm x 13mm. The minimum required thickness from the referenced standard is 3.0mm. Sample tested as submitted.

****

END OF REPORT

User manual

ANDRO-SWITCH



For the first time worldwide, THOREME creates an innovating sex toy that combines great technicality and exquisite design. It is the first sex toy that's just perfect for men. It is discreet and easy to use. It feels incredible and brings the testicles closer to the body to raise their temperature.

Ergonomic and inventive, the ANDRO-SWITCH thermal ring is designed to adapt to your anatomy. It complies with directive 2004/108 from 15/12/2004. The high-quality platinum-catalysed silicone, **certified biocompatible (ISO 10993-10 Skin Safe)** allows for comfortable use and its super stretch features ensures perfect adjustment each and every time. It is soft, hygienic, non-porous, odourless, hypoallergenic, resistant, and easy to clean.

The thermal ring brings the testicles closer to the body to raise their temperature. It also offers incredible sensations that will stimulate and satisfy you more than ever.

Before you go any further in discovering the "ANDRO-SWITCH" thermal ring, please read this manual carefully.

CERTIFIED ISO 10993-10 SKIN SAFE

ANDRO SWITCH

Device description

Important information to be aware of regarding the **male thermal contraception (MTC) method with testicular lifting** and the use of the thermal ring:

- Practising MTC and wearing the contraceptive ring will not provide any protection against sexually transmitted diseases (STD) or infections (STI), against which the condom is the only effective barrier.
- It is among the most reliable reversible contraception methods when correctly applied.
- MTC is a topical, non-hormonal and long-term male contraception.
- Use it with caution and see your doctor if you feel any pain or notice any unusual sign.
- Appropriate cleaning and care can extend the products shelf life.
- Before using this product, see your general practitioner.
- Please read this manual carefully and follow the safety instructions detailed below before you start wearing the thermal ring or using this contraception method.
- Keep this manual. You may need to re-read it.
- If you have any other questions, ask your doctor or pharmacist.
- This product is yours and yours only. Don't give it to anyone else. It could be harmful to them.
- If you feel any secondary effect or adverse reaction, reach out to your doctor or pharmacist. This also applies to any secondary effect not specified in this manual. See section 5.
- The thermal ring is, as of now, not a medical contraceptive device. Currently, it is only an innovative product specifically designed to temporarily hold the testes in a supra-scrotal position for wellness purposes. Testicular lifting is not a medical practice (it happens naturally when you are cold, for instance), unlike contraception. Using it to apply the MTC protocol is your and your doctor's full responsibility.

What will you find in this manual?

Which documents will you need?

THOREME puts the following PDF documents at your disposal, downloadable for free:

- Complete product sheet: ANDRO-SWITCH
- Instructions for use: PLACEMENT & REMOVAL ANDRO-SWITCH
- My ANDRO-SWITCH size
- ANDRO-SWITCH & MTC Infography
- R. Mieusset & JC. Soufir, Practical guide to male thermal or hormonal contraception ANDRO-SWITCH
- Instructions for use: SEMINOGRAM & MALE THERMAL CONTRACEPTION (MTC)
- DRAGON_SKIN: technical data & certifications
- User manual: ANDRO-SWITCH
- ANDRO-SWITCH PACK (includes all the above documents)

Make sure you always have these documents on hand. They will allow you to grasp all the subtleties of MTC and of the thermal ring itself and will constitute a wealth of information that you will need to refer to while practising MTC.

They are all available on the Slow Contraception Facebook page:

https://www.facebook.com/slow.contraception/

What is the thermal ring and in which cases is it used?

Wearing a thermal ring is designed to bring the testes optimally closer to the body. It can be used for wellness purposes. Raising the temperature of the testicles to that of the body leads to temporary and reversible infertility.

Is it discreet?

The Andro-switch thermal ring is completely invisible underneath your clothes. Is is 100% discreet.

Is it easy?

Once you have understood how to put the ring on and have grasped the MTC protocol, this contraception method is pretty easy to use.

Can I use it outside of MTC?

Of course! Remember that it is a wellness sex toy before anything else. Nothing keeps you from using it as such as long as you follow the instructions from the manual.

Remember that the thermal ring must be washed before and after each use during sexual intercourse with lukewarm water and soap.

How many thermal rings do I need?

MTC is a daily practice. If you've forgotten to wear it for 24 hours or more, it is advised to use another contraception method. Have a new seminogram done a month later. Depending on the results and with your doctor's approval, you can start using MTC only again.

If you lose your thermal ring, the same problem will arise.

This is why it is recommended to always have 2 thermal rings on hand.

What do I need to know before I start wearing the thermal ring?

General notes:

Before you start wearing the thermal ring, you will need to provide your general practitioner with information regarding your health and medical history and that of your relatives. The doctor will carry out a clinical examination and prescribe you a seminogram as well as other analyses or exams depending on your personal situation.

No blood test is required.

The results of a seminogram are considered normal when the concentration of spermatozoa is higher than 15 million/ml, progressive motility greater than 32% and the shapes are normal, depending on the method used[1]. For more details, please refer to the table in section 7. If it's not the case for you, your doctor will present you with alternative contraception methods that are more suitable to your specific situation.

This manual describes several situations that require you stop wearing the thermal ring as well as circumstances in which the efficiency of the thermal ring may decrease. In such cases, you should abstain from sexual intercourse or use other contraception methods, such as condoms.

Wearing the thermal ring or practising male thermal contraception will not provide any protection against HIV/AIDS or other sexually transmitted diseases (STD).

Never wear the thermal ring:

If you find yourself in one of the situations listed below or suffer from mental and/or physical disabilities, you must not wear the thermal ring. If this is the case, you must inform your general practitioner. They will present you with alternative contraception methods that suit your situation better or with other possible options to use the thermal ring depending on your situation.

During the oral examination, it is found that you have a history of:

- Testicular descent anomalies (cryptorchidism, ectopia), treated or not;
- Inguinal hernia, treated or not;
- Testicular cancer;
- Sensitivity alteration in the pubis, groin, penis or scrotum areas;
- Strength decline in the hands.

The clinical examination shows that:

- You suffer from severe obesity; Your Body Mass Index (BMI) is ≥ 30 kg/m2;
- You suffer from grade 3 varicocele;
- You have an intra-scrotal nodule;
- You have a significant hydrocele;
- You suffer from cutaneous filariasis or elephantiasis;
- You have topical cutaneous infections in the penis, scrotum, groin and pubis areas;
- You have contact dermatitis in the penis, scrotum, groin and pubis areas;
- You have a penile edema.

[1] WHO (2010) Laboratory manual for the examination and processing of human semen, Fifth edition, WHO press, World Health Organisation, Switzerland

What do I need to know before I start practicing male thermal contraception and wearing Andro-switch?

Make sure you always strictly follow the instructions from the MTC protocol described below and those given to you by your doctor while wearing the ring. In case of doubt, ask your general practitioner or pharmacist.

Protocol

The most widely used method consists in raising the temperature of the testicles by about 2°C. This raise in temperature is obtained by shifting the testicles from the scrotum into the superficial inguinal sac. The testicles are then held in this position using the testicular lifting technique. Raising the temperature of the testicles to that of the body leads to temporary and reversible infertility.[2]

Principle: each testicle is manually lifted from the scrotum to the root of the penis, close to the external orifice of the inguinal canal. The testicles must be held in this position every day during waking hours (15 hours a day).

Execution: testicular lifting is possible without any risks for all men meeting the defined inclusion criteria.

The heating process must be applied every day for 15 consecutive hours. The minimum period of 12 hours should remain exceptional and maximum wearing time is 16 hours. Non-observance of the minimum daily period or not wearing the thermal ring for a whole day does not guarantee the inhibiting effect on spermatogenesis and thus the contraceptive effect. It is not advised to wear the thermal ring over 16 hours a day, or only exceptionally and with your general practitioner's approval.

Effective contraception: once the concentration of spermatozoa is below 1 million/ml in two consecutive sperm analyses three weeks apart. This level of concentration is obtained between 2 to 4 months of wearing the thermal ring. The 1 million/ml threshold was defined in 2007 for thermal, chemical and hormonal contraception methods[3][4]. Below this threshold, you are considered contracepted.

Consequently, it is necessary to use another contraception method as long as the concentration of spermatozoa is higher than 1 million/ml.

Medical follow-up: no blood analysis is mandatory. However, the first seminogram you do must be considered normal: concentration of spermatozoa higher than 15 million/ml, progressive motility greater than 32%, normal morphology depending on the method used[5]. For more details, please refer to the table in section 7. If it's not the case for you, your doctor will present you with alternative contraception methods that are more suitable to your specific situation.

It is advised to have a monthly seminogram done up until the sixth month, than every three months afterwards if the user properly applies the protocol. This simple and quick test is used to control that the thermal ring is correctly worn and that the desired effect endures. It is advised to observe a three-day abstinence period before a seminogram. No annual medical check-up is required when practicing MTC.

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[2] Male thermal contraception protocol in nine questions (R. Mieusset)
http://www.contraceptionmasculine.fr/les-methodes/la-cmt/

[3] World Health Organization Task Force on Methods for the Regu- lation of Male Fertility, Gui-Yuan Z, Guo-Zhu L, et al. Contraceptive efficacy of testosterone-induced azoospermia in normal men. Lancet 1990;336:955-9.

[4] Jean-Claude 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*, vol. 27, 13 January 2017, p. 3

[5] WHO (2010) Laboratory manual for the examination and processing of human semen, Fifth edition, WHO press, World Health Organisation, Switzerland

Length of male thermal contraception: the maximum period is four years since reversibility in terms of sperm parameters and fertility has been proven for this length of time. Beyond that, please check with your doctor first.

Reversibility: when you stop wearing the ring, spermatozoa production starts again. The concentration of spermatozoa gets back to the standard values established by WHO[6] between six to nine months. All the couples who have consequently wished to get pregnant have been able to do so and no anomalies have been found. No spontaneous miscarriages have occurred. It should be noted that an unwanted pregnancy has occurred three months after the protocol was stopped for a couple who wasn't using any contraception method[7]. This goes to to show that the fertilizing potential of the spermatozoa can be activated before the spermatic parameters are fully back to normal.

Consequently, as soon as you stop applying the MTC protocol or wearing the thermal ring, another contraception method is immediately necessary in order to avoid any unwanted pregnancies.

Oversight: in case you forgot to wear the ring for over a day or you have a doubt, it is recommended to check the concentration of spermatozoa with a seminogram. It is advised to double the contraception with other methods as long as the sample results don't point to a concentration of spermatozoa that is lower than 1 million/ml.

Pregnancy

Don't use the thermal ring if you and your partner are planning a pregnancy in the very short term.

Every pregnancy possibility must be excluded before you start applying the MTC protocol with the thermal ring. Should a pregnancy occur while practising MTC, see your doctor as soon as possible.

Can MTC or wearing the thermal ring impact my sex life?

You will still get erections and orgasms while wearing the thermal ring and practising MTC.
The amount of sperm you ejaculate is about the same but it doesn't contain as many spermatozoa as it used to (contraceptive threshold: concentration of spermatozoa < 1 million/ml).
Your hormones and manliness remain unaffected.
Your sex drive and ability to have sexual intercourse remain unaffected as well.
The only change is that you cannot conceive a child for a given period of time. If your decision is carefully pondered and you do not feel forced to do it, then you probably won't regret your choice.

Do I need anyone's consent?

It is recommended to discuss MTC and the thermal ring with your partner beforehand. This decisions affects both of you.
This said, your partner is not required to give their consent.
You can chose to practise MTC and to wear the ring if you don't have a partner or if you don't have children.
See you doctor before you start practising MTC and wearing the thermal ring.

Why should I chose MTC?

It is a topical non-hormonal and long-term male contraception method.
It can be used if you do not wish to have children or do not wish to have any more children, all the while being temporary and reversible.
Whatever your reasons, MTC and wearing the thermal ring are easy to use.

[6] WHO (2010) Laboratory manual for the examination and processing of human semen, Fifth edition, WHO press, World Health Organisation, Switzerland
[7] http://www.contraceptionmasculine.fr/les-methodes/la-cmt/

Driving vehicles and operating machines

If it is proved that you are using vehicles or machine that could lead to testicular trauma, see your doctor before you start wearing the device.

No other precaution is required.

Sports & leisure

For any sports that can cause testicular trauma or direct testicular contusion such as contact sports or combat sports where you risk getting hit with a knee or a foot or team sports where you risk getting hit with a ball, please refer to your doctor before wearing the ring while practising.

For any sports requiring a medical certificate, see your doctor before you start wearing the device:

- Sports that are practised in a specific environment :
    - Mountain climbing;
    - Underwater diving;
    - Caving;
- Competitive sports where the fight can end notably or exclusively with one of the opponents getting in a position that keeps them from defending themselves or even renders them unconscious after they've been hit;
- Sports that include the use of firearms or air guns;
- Competitive sports that include the use of ground motor vehicles, except for remotely operated model cars;
- Sports including the use of an aircraft except for aeromodelling;
- Rugby union, rugby league and rugby sevens.
- Any sport discipline or activity involving the use of a climbing harness, harness, pelvis belt.

If you have any questions regarding the use of the thermal ring, ask your general practitioner or pharmacist for more information.

Additional information regarding specific populations

Children and young adults

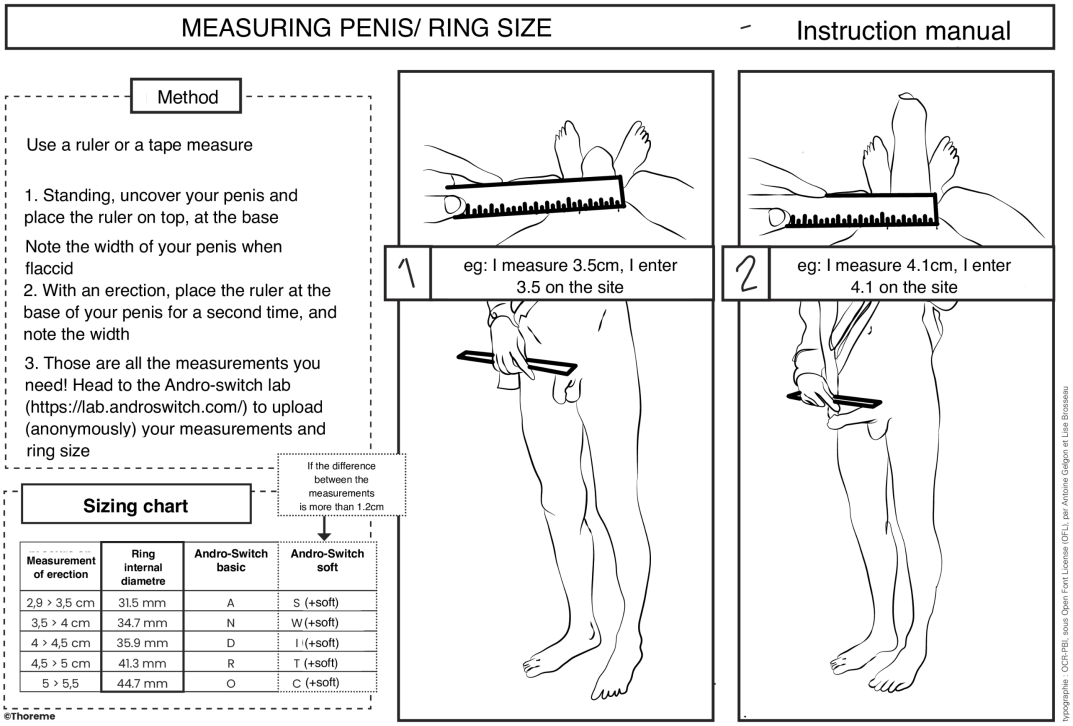
The thermal ring is not intended for young boys. Your doctor will discuss with you other contraception methods that are more suitable.

Keep the thermal ring out of the reach of children.

How to wear the thermal ring?

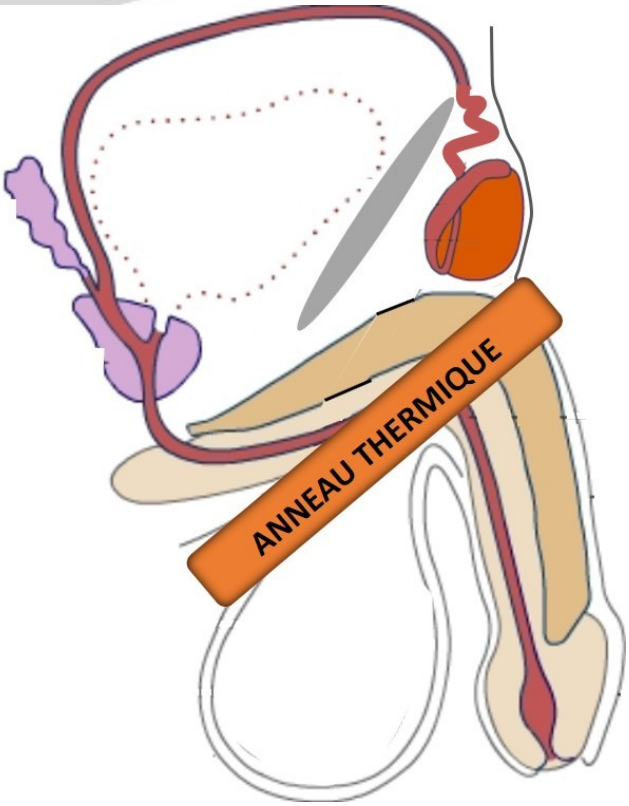
Which size should I choose?

To choose the size that fits you best, please follow the instructions hereafter:



Placement

Wash your hands. Wash the thermal ring with a gentle soap and lukewarm water, the rinse it and tap it dry with a clean towel or soft cloth. Insert the penis into the thermal ring. Then, gently slide the scrotal skin until it is completely inserted into the ring and the ring is in contact with the pubis (the area just above the penis) and the perineum (the area between your anus and scrotum). Lacking space, the testes will then naturally move up into the inguinal sac, at the root of the penis, where they will enter a heating phase.



It is absolutely necessary to check that the testicles are in the inguinal sac with a light palpation. That is, that they are above the thermal ring.

The qualities of the platinum-catalysed silicone, certified biocompatible (ISO 10993-10

Skin Safe), the shape of the thermal ring and the structure of its internal side create a push-up effect that allows the testes to be held upwards so they cannot settle back down into the scrotum. You can wear any standard underwear with the ring on.

Wash your hands.

The device is correctly placed if the testes are held up as shown on the illustration.

Removal

Wash your hands.

Gently slide the thermal ring to take it off.

Wash the thermal ring with a gentle soap and lukewarm water, the rinse it and tap it dry with a clean towel or soft cloth.

Wash your hands.

Note:

The thermal ring has an internal and external side. **The internal side is uneven and presents specifically designed bumps** They create a **non-slip** effect which will keep the device from slipping and a **breathable** effect to evacuate moisture.

When putting the thermal ring on and taking it off, you won't need to touch the testicles directly. When placing the ring, they naturally move upwards for lack of space. When removing the ring, they naturally slide back down from the inguinal sac to the scrotum. It can be placed and removed in any positions.

If you accidentally let a testicle slide into the thermal ring, gently remove the device and start over.

You do not need to shave to be able to wear the ring. Its release internal surface and the qualities of the silicone we use are specifically designed to adapt to you.

To get acquainted with the testicular lifting protocol with the thermal ring, please refer to the document entitled “Instructions for use: PLACEMENT & REMOVAL ANDRO-SWITCH” which can be downloaded free of charge here:

https://www.fichier-pdf.fr/2018/09/25/mode-demploi-pose-et-retrait-dandro-switch/

First use

If you are using the thermal ring for the very first time, it is advised to start out following the steps below:

Day 1 and 2: 2 hours/24 h

Day 3 and 4: 4 hours/24 h

Day 5 and 6: 10 hours/24 h

Day 7 and onwards : 15 hours/ 24 h

Note: The correct use of the thermal ring and the application of the MTC protocol does not guarantee a contraceptive effect from day one.

Caution

Do not use the thermal ring:

- Under the influence of alcohol, narcotics, psychoactive substances and illegal drugs as they may alter your ability to make sound judgements.
- If you suffer from irritation or topical infection of the skin. Please treat them before you start wearing the ring as extended contact between the ring and the skin could aggravate irritations and infections of the skin in the penis, scrotum, groin and pubis areas.
- If your sensitivity in the penis, scrotum, groin or pubis areas is altered, as you won't feel the pain in case there is a problem.
- If you observe a strength decline in the hands, as it will make it difficult for you to place and remove the thermal ring appropriately.

Using other contraception methods in addition to the thermal ring is not contraindicated.

If the thermal ring is correctly installed and if the size fits your morphology, it should stay in place for the whole wearing period.

If you feel that a testicle has moved back down or that the thermal ring has moved, check its position and that of your testicles.

You can urinate, have sexual intercourse, get erections and go about your daily and professional business just like you normally would.

If you have worn the ring longer than 16 hours a day: it is not advised to wear the thermal ring over 16 hours a day on a regular basis. However, it can happen exceptionally and with your general practitioner's approval.

If you have forgotten to wear the thermal ring for one day out of a 30-day period: the thermal ring must be worn every day in order to guarantee its contraceptive efficiency. Start applying the MTC protocol on the following like you usually do.

If you have forgotten to wear the thermal ring more than one day out of a 30-day period: contact your doctor or pharmacist for advice. It is recommended to use an additional contraception method while your make sure you are still below the contraceptive threshold according to the protocol explained in section 3.

In case you feel any pain while wearing the ring: Stop wearing it immediately. Try again a few hours later. If pain persists, contact your doctor or pharmacist for advice.

If you have any other questions regarding the use of this device, ask your doctore or pharmacist for more information.

What are the potential adverse effects?

As for any contraception methods or extended contact of a product with the skin, it can come with adverse effects but not everyone will experience them. If you feel any adverse effect, particularly if the effect is severe and persistent, or if you notice a change in your health that you think could be linked to this contraception method, inform your doctor.

Male thermal contraception & adverse effects

Reversible alteration of the chromatin's integrity & reversible alteration of the number of chromosomes in 2 to 3 spermatogenesis cycles once you stop applying the protocol.

Male thermal contraception & frequent side effects

Reversible testicular volume reduction by a few percent, reversible in 2 to 3 spermatogenesis cycles once you stop applying the protocol.

Thermal ring & adverse effects

No adverse effect was observed while wearing the thermal ring.

Thermal ring & side effects

There can be a risk of infection due to extended contact between the ring and the skin, but no infection has actually been observed.
There can be a risk of itching, especially when removing the thermal ring.
Do not use the thermal ring on swollen or inflamed areas or if you have small lesions in the penis, scrotum, groin and pubis areas.

Stop wearing the ring if you feel any pain or discomfort and contact your doctor or pharmacist for advice.

No increase in the risk of testicular torsion or testicular cancer has been highlighted.

It has however been shown that the the chromatin's integrity of the spermatozoa produced during the 15-hours-a-day heating phase was altered due to exposure to body heat[8].

Chromatin is the structure inside of which DNA is packed and compacted in the limited volume of the nucleus of eukaryotic cells.

Heat alters the nuclear quality of the spermatozoa that are produced during the 15-hours-a-day heating phase. This is why it is necessary to use an additional contraception method when you start practising MTC and until you have reached the 1 million/ml threshold, which takes a few weeks, but also when you stop practising MTC and until your seminogram results fall back into the 2010 WHO standards, which takes a few months.

[8] Ahmad G, Moinard N, Lamare C, Mieusset R, Bujan L. Mild testicular and epididymal hyperthermia alters sperm chromatin integrity in men. Fertil Steril. 2012;97:546–53 (https://www.fertstert.org/article/S0015-0282(11)02909-8/pdf)

Reporting side effects

If you feel any side effects, do mention it to your general practitioner or pharmacist. This also applies to any side effect that is not in this manual.

How to store the thermal ring

Keep this device out of the reach and sight of children.

You can throw it out with domestic waste. This will contribute to protecting the environment.

Thermal ring care

Follow and apply the steps below before you start using this product:

- By taking good care of your ring, you will extend its shelf life.
- Clean the product carefully before and after each use. Scrub the thermal ring with a gentle, fragrance-free soap and lukewarm water, then rinse well with clear water to avoid any irritations caused by residue. Tap it dry with a clean towel or soft cloth.

Reminder: when cleaning the ring, do not use any cleaning agents containing alcohol, petroleum or acetone. Avoid exposing the product to direct sunlight or high temperatures. The product should be stored in a clean and dry environment and contact with plastic materials should be avoided.

Once a month, sterilise the ring using one of the following methods:

Boiling water

This is the oldest method: our grand-mothers used it but it is still up to date.

- Fill a pressure cooker or saucepan
- with water up to three-quarters and let it boil for at least fifteen minutes.
- Soak the product in the water for 5 minutes (if longer it might warp).
- Using a clamp, take it out of the water.

Heat steriliser

There are two systems available.

- The first uses a microwave. It is made of a stand, a container and a lid and is quick and easy to use. Just pour a little water into the container, close the lid and place it the microwave at maximum power. The heating time (from 5 to 20 minutes) depends on the maximum temperature of your appliance, but know that such sterilisers are getting quicker and quicker. The principle is the same as that of a heating chamber, where steam is used for sterilisation. A clamp is usually provided to extract the ring. As long as the lid remains closed, the sterilisation effect will last for 24 hours. Note: do not sterilise several products at once.
- The electric steriliser: it is bulkier than the first option but uses the same principle (steam sterilisation). Sterilisation takes about 10 to 20 minutes depending on the model.

Cold sterilisation

This is the easiest method. You just place the product in a clean container filled with cold water and put a chemical tablet used to sterilise baby equipment in it (it is best to follow the instruction manual). Those tablets are safe for human health and made of sodium hypochlorite. Make sure the product is completely soaked. Sterilising with this method usually takes about 30 minutes. Don’t forget to rinse the ring before use.

Storing the thermal ring

The thermal ring should be stored at a temperature below 100°C.

Once you are done using it, carefully clean and dry your thermal ring and store it in a clean and dry place away from light.

Do not expose directly to flames.

Do not store your thermal ring in a plastic bag or an airtight container.

If you follow the cleaning and storing instructions, you will be able to use your thermal ring for several years.

If you notice any changes in the aspect of the material or warping of the thermal ring, or if your ring tears or become sticky, it needs to be replaced.

As time goes by, some stains may appear. This does not mean your thermal ring is not hygienic any more or that its function is altered.

If you wish to remove the stains, soak the thermal ring in a sterilising solution (used to sterilise baby equipment and available in pharmacies). Let it soak for the minimum recommended amount of time and follow the dilution instructions provided by the manufacturer. Rinse thoroughly with clear water. Your thermal ring is ready for its next use.

Lubricants and the thermal ring

Placing, wearing or removing the device do not require the use of a lubricant.

If while using the ring you wish to use a lubricant, it needs to be water-based because the use of a silicone-based lubricant could create an organic surface.

Do not use massage oil or hand cream as a lubricant, as it could damage the product.

Is it normal if my thermal ring smells?

Your thermal ring shouldn't normally have a strong smell. The thermal ring may develop odours if:

- You keep it on a lot longer than the recommended 15 hours;
- You don't wash it on a daily basis;
- You boil it in a saucepan that had food residue on its surface.

It none of these options apply, you should mention this to your doctor or pharmacist.

To remove the smell:

1. Soak your thermal ring in a sterilising solution similar to those used to sterilise baby bottle nipples, diluted according the the manufacturer’s instructions for the minimum amount of time recommended (usually 7 to 10 minutes).
2. Rinse thoroughly with clear water.

Additional information

Material & quality

The annular ring is entirely made out of one of the best qualities of platinum-catalysed silicone, certified biocompatible (ISO 10993-10 Skin Safe). It is flexible and clinically tested for extended skin contact.

Hypoallergenic, latex-free, it does not contain any colouring, BPA, phtalates, plastic, bleaching agents or toxins.

It is strictly intended for personal use.

All technical product information are to be found in the PDF file entitled
DRAGON_SKIN: technical data & certifications
and in the following PDF file:
ANDRO-SWITCH Pack

Package contents and other information

The package contains your ANDRO-SWITCH thermal ring. To lessen the environmental impact of the package, you will be sent an e-mail with the instructions for use as well an any additional information.

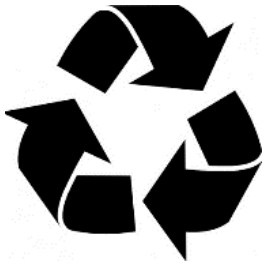
SEMINOGRAM (preceded by a 3-day abstinence period)		
SPERM CARACTERISTICS	STANDARD VALUES (WHO 2010)	STANDARD VALUES (WITH MALE THERMAL CONTRACEPTION)
VOLUME	> 1.5 ml	> 1.5 ml
NUMERATION	> 15 million/ml (infertility threshold)	**< 1 million/ml** **(contraception threshold)**
PROGRESSIVE MOTILITY (A+B)	> 32%	< 10%
VITALITY (MOTILITY ONE HOUR AFTER EJACULATION)	> 58%	< 40%
NORMAL MORPHOLOGY OF THE SPERMATOZOA	> 4%	< 4%

Manufacturer

Thoreme

contact@thoreme.org

This user manual was last revised on 29 July 2020.



ANDRO SWITCH