

METHOD OF USE

READ BEFORE USE

Table of Contents

Page

1. DEFINITION	10
2. DESCRIPTION	10
3. INDICATIONS	10
4. PERSONALIZE Andropenis®	11
5. FITTING Andropenis®	12
6. PENILE CURVATURE AND PEYRONIE'S DISEASE	14
7. METHOD OF USE OF Andropeyronie® (FOR PENILE CURVATURE AND PEYRONIE'S DISEASE)	15
8. METHOD OF USE OF Andropeyronie® Surgery Edition (FOR UROLOGICAL POST SURGERY)	16
9. METHOD OF USE OF Andropenis® (FOR PENIS ENLARGEMENT)	17
10. PRECAUTIONS OF USE	18
11. OINTMENTS	19

NOTE:

Andropenis® has the following models: **Andropenis Gold®** (made with gold, Deluxe version), **Andropenis Mini®** (for penises smaller than 8 CM in an erect state), **Andropeyronie®** (made from aluminium, adapted for curvature correction), **Andropeyronie® Surgery Edition** (made from aluminium, adapted for posyt-surgery usage) and **Androextender®** (made from aluminium, basic version). The user instructions are the same for all models.



fig. 1

1. DEFINITION

Andropenis® is a medical device which attaches externally to the penis. In combination with penile tissues, it produces a lightweight traction on the penis through a progressive and adaptive force that is adapted to patient needs. It is indicated for esthetical and medical uses. Note: Before its first use, visit your Doctor and follow his indications.

2. DESCRIPTION

Andropenis® is composed of a plastic base ring, two metal shafts with internal springs, and an upper plastic support with a silicone band. The plastic pieces are made of POM (a synthetic material that is not affected by combustible fluids such as alcohol). The band is of medical grade silicone. The metal shafts of **Andropenis®** gold are made of brass covered with a layer of 24-carat gold. The springs are made of stainless steel and the shafts of surgical grade aluminium.

Note: All materials and components of the device, are manufactured under quality management standards (ISO:13485:2003 and ISO 9001:2008), they are biocompatible, and non cito-toxic (associated ISO 10993), its use does not involve any health risks.

COMPONENTS (fig. 1): 1-plastic base ring, 2-rounded hinge nut, 3-threaded bar, 4-threaded adjustable shaft, 5-metal shaft, 6-screw, 7-spring, 8-screw to secure the spring, 9-large 4 cm rod (1.6"), 10-medium 2 cm rod (0.8"), 11-small 0.5 cm rod (0.2"), 12-smallest rod 0.3 cm (0.1"), 13-upper plastic support, 14-silicone band, 15-protective cushion, 16-silicone rings.

NOTE: It is advisable to gently rub a small drop of oil, with the help of a cloth, between pieces 4 and 5 to allow easier sliding (see OIL).

3. INDICATIONS

- ✎ Treatment of Peyronie's disease and correction of other congenital penile curvatures.
- ✎ Treatment of male hypogonadism with micropenis or small penis.
- ✎ Aesthetic treatment for penile lengthening and thickening.
- ✎ Post-surgical treatment of some urological surgeries (prostatectomy, penile surgery, trauma, penile fracture, etc.) to avoid penile shortening due to scar retraction.
- ✎ External penile rigidity device to create or maintain sufficient penile rigidity for sexual intercourse.

Contraindications: Patients with uncontrolled diabetes, genital herpes, sexually transmitted diseases, urethritis and acute cystitis, acute prostatitis, abdominal hernia, dermatitis, testicular cancer, lymphatic cancer, lymphoma, paraplegics, quadriplegics and patients taking anticoagulant treatment. The results will be less or non-existent if the levels of testosterone are low, or at the lower end of the spectrum. We do not recommend this for the use of people under the age of 18.

Side effects: **Andropenis®** has been designed specifically for a medical use and its utilization does not involve any secondary effects, as long as it is correctly used under the indications that are exposed in the instructions manual.

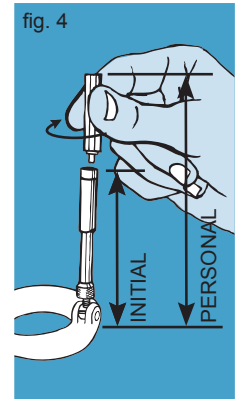
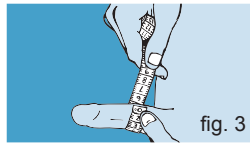
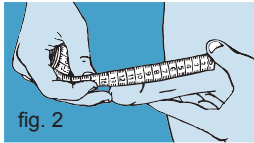
4. PERSONALIZE Andropenis®

The initial size of **Andropenis®** is 8 cm (3.1"). The size of the device is measured from the lower part of the plastic ring to the end of the metal shaft (fig.4, INITIAL).

Personalize your **Andropenis®** according to the size of your penis.

Using a tape measure, measure the length and circumference of the penis in flaccid state and then erect (fig. 2 and 3).

Calculate the personal size of **Andropenis®** by subtracting 4 cm (1.6") from the size of your penis in erection.



Example: 14.7 cm. – 4 cm. = 10.7 cm. > **Andropenis®** personal size = 10.7 cm

Now, prepare the device so that it corresponds to your personal size.

First, detach the upper plastic support by lifting it upwards (fig 5), then add as many shafts as needed to reach the personal size of **Andropenis®** (fig. 4, PERSONAL).



Example: Personal size of 10.7 cm. = **Andropenis®** initial size (8 cm.) + piece 10 (2 cm.) + piece 11 (0.5 cm.).

Note: The initial size of Andropenis Mini is 7 cm. If you have this version start the period of adaptation at that measurement (7 cm) and hold that measurement for 15 days: the first day, use the device for 3 hours, as the days pass gradually increase usage time. After the first 15-days increase usage time as indicated in the tables of use (see below).

5. FITTING Andropenis®

Insert one of the silicone band models (Piece 14) that best fits within the appropriate protective pad according to the size of the penis (Piece 15). The use of the protective cushion is **COMPULSORY**. Introduce the ends of the silicone band into the holes at the back side of the upper plastic support (piece 13), so that the band forms a loop.

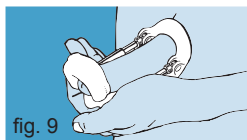
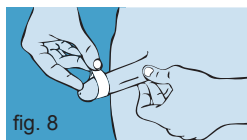
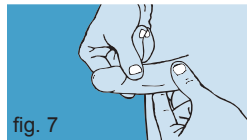
With the penis flaccid, slide all the foreskin (uncircumcised men), onto the shaft (fig. 7) and place the silicone ring below the crown of the glans where it meets the shaft of the penis (fig. 8).

The glans should not come into direct contact with the device. Next, stretch the penis away from the body so that it is lengthened whilst flaccid.

Take the base ring (piece 1), maintaining the narrowest part of the ring facing upwards. Fit the penis through the base ring (piece 1), and rest it in the depression of the upper plastic support (piece 13). Place the left hand on the upper support (piece 13) and push the device against your body, compressing the internal springs (fig. 9).

While keeping the left hand in position, use the fingers of your right hand to pull the glans through the loop formed by the silicone band (fig. 10).

Place the thumb of the left hand on top of the glans to maintain the penis in place while gradually shortening the silicone loop by pulling on both ends of the band with the right hand (fig. 11).



Slowly pull the skin on both sides of the penis towards your body to avoid pinching the skin or leaving a fold over the groove of the glans (fig 12).

The silicone loop should be fitted on and in line with the groove of the glans without hurting but tight enough to keep the glans from slipping out. Carefully secure the silicone band in the fasteners on the underside of the upper support (piece 13) by, stretching the tape each time you press within the recesses. Tighten but do not pull downwards in order to avoid pinching the penis.

Double check there is no skin over the groove nor underneath the silicone band, if there is, pull the skin towards the body to avoid it being pinched.

To remove **Andropenis®**, compress the springs by pushing down against the body, release the silicone band (piece 14) from the fasteners in the upper support (piece 13), and increase the size of the silicone loop to release the penis.

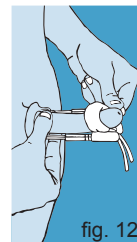
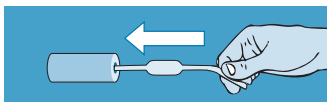


fig. 12



fig. 13

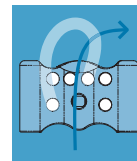
Andropenis® has a fastening system of the glans by a band called **Androcomfort® band**. There are two available models **Androcomfort® band** and **Androsilicone® band**. **Androcomfort® band** system allows even more convenient use of **Andropenis®**. It is placed between the glans and shaft of the penis, the coronal sulcus area-prepuce.



Andropenis® has a silicone ring that functions as a cushioning system called **Androring®**. It lies between the glans and shaft of the penis, the coronal sulcus-prepuce.



Andropeyronie® has a superior plastic part (**Androsupport**) adapted for the correction of penile curvatures (see the annexed "Androsupport Usage Guide").

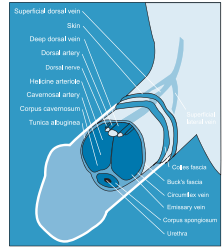


6. PENILE CURVATURE AND PEYRONIE'S DISEASE

Basic Medical Information: The penis is formed of two columns of sponge-like tissue called the corpus cavernosa and a conduit, called the urethra, where the urine exits the body. These corpa cavernosa are surrounded by a sleeve of elastic tissue called the tunica albuginea.

There are 2 types of penile curvature:

- ❑ **Peyronie's disease** (can appear at any age).
- ❑ **Congenital penis curvature** (usually detected in young men).



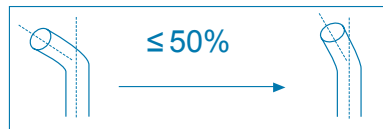
Peyronie's disease, or penile hardening, is a process whose cause is unknown, and characterized by a fibrous (hard) band on the tunica albuginea of the penis. These bands tend to be unilateral (on one side of the penis) and as a result the penis acquires a curve in erection.

The most common symptoms are deformation of the penis, pain during erection, and erectile dysfunction. Its prevalence is approximately 1% of the male Caucasian population. 75% of cases occur in men aged 45 to 60.

Medical treatment options:

- ❑ **Verapamil:** Injections into the fibrous plaque to block the production of collagen. (Studies are being undertaken on Interferon injections)
- ❑ **Andropeyronie®:** non implantable prosthesis applied to the penis which exerts a traction force and creates a reduction in curvature of up to 50%.
- ❑ **Vitamin E or Colchicine:** Taken orally as an aid.
- ❑ **Combined Treatment: Andropenis®** plus Verapamil plus vitamin E. The combination of these methods has been proposed as a medical outpatient protocol for the treatment of Peyronie's disease. Always consult your urologist before commencing any treatment regime.
- ❑ **Surgery:** removal of the fibrous plaque. Shortening of the penis or external prosthesis implantation is always a side effect of this treatment, to avoid this, a penile extender should be employed (**Andropeyronie® Surgery Edition**).

Congenital penile curvature detected in young men. This condition originates because the corpus cavernosa grow more than the urethra; causing the erection to curve downwards or to one side. Treatment options are surgery and/or application of **Andropeyronie®** for a period of 6 months.



7. METHOD OF USE OF Andropeyronie® (FOR PENILE CURVATURE AND PEYRONIE'S DISEASE)

The common treatment, excepts for different medical prescription, consists of 2 periods:

- ☒ An adaptation period, lasting 15 days.
- ☒ An evolution period, consisting of 3 separate phases: Initial evolution phase (1st and 2nd month), intermediate phase (3rd and 4th month) and final evolution phase, which begins in the 5th month.

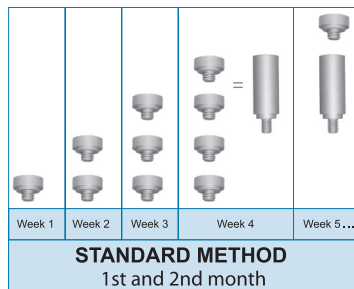
Any deviation from the treatment program could alter the results achieved (consult your doctor).

	DEVICE SIZE	Daily duration
	Adaptation period	
First 5 days	Initial size	3 hours
Day 6 - 10	Add a small 0.5cm shaft (piece 11).	6 hours
Day 11 - 15	Add a small 0.5cm shaft (piece 11).	8 hours
	Evolution period	
1st and 2nd month	Add a small 0.5cm shaft (piece 11) every 7 days	9 hours
3rd and 4th month	Add a small 0.5cm shaft (piece 11) every 10 days	9 hours
From the 5th month	Add a small 0.5cm shaft (piece 11) every 15 days	9 hours

Note: for your own comfort, from the 5th month onward, it is possible to first add a 0.3 cm shaft (piece 12) and a few days later change it for a 0.5cm shaft (piece 11) to make the traction more progressive.

The first day, as practice, fit and remove the device 10 times in a row. In case of curvature, it is recommended fitting the device away from the curvature. Every 2 hours, the device will need to be removed for a few minutes to allow the tissues to relax. After the 5th month, this rest period should be observed every 1.5 hours. Use this rest period to lightly massage the penis. Wash the device with PH neutral soap and water every 4 days.

Be patient and consistent with the treatment, this is the key to achieving your objectives. The first results will be observed 1.5 months into the treatment (the 15 day adaptation period followed by 1 the first month of treatment).



8. METHOD OF USE Andropeyronie® Surgery Edition (FOR UROLOGICAL POST SURGERY)

If the surgery is simple, it is recommended to begin use of **Andropeyronie® Surgery Edition** 15 days after surgery.

If the surgery is very complex, it is recommended to begin use of **Andropeyronie® Surgery Edition** 1 month after surgery.

Always consult your surgeon so he can advise how long after surgery to begin using **Andropeyronie® Surgery Edition** and the duration of use.

The common treatment, excepts for different medical prescription, consists of 2 periods:

- An adaptation period, lasting 15 days.
- An evolution period, consisting of 2 separate phases: Initial evolution phase (1st and 2nd month), and final evolution phase, which begins in the 3rd month.

Any deviation from the treatment program should be first discussed with your surgeon.

	DEVICE SIZE	Daily duration
	Adaptation period	
First 5 days	Initial size	3 hours
Day 6 - 10	Add a small 0.5cm shaft (piece 11).	6 hours
Day 11 - 15	Add a small 0.5cm shaft (piece 11).	8 hours
	Evolution period	
1st and 2nd month	Add a small 0.5cm shaft (piece 11) every 7 days	8 hours
From the 3rd month	Add a small 0.5cm shaft (piece 11) each month	8 hours

Note: for your own comfort, from the 5th month onward, it is possible to first add a 0.30 cm shaft (piece 12) and a few days later change it for a 0.5cm shaft (piece 11) to make the traction more progressive.

The first day, as practice, fit and remove the device 10 times in a row. It is recommended locating the device in the upwards position one day, to one side the following day, and to the other side the next day. Every 2 hours, the device will need to be removed for a few minutes to allow the tissues to relax. After the 5th month, this rest period should be observed every 1.5 hours. Use this rest period to lightly massage the penis. Wash the device with soap and water every 4 days. Be patient and consistent with the treatment, this is the key to achieving your objectives. The first results will be observed 1.5 months into the treatment (the 15-day adaptation period followed by 1 the first month of treatment).



9. METHOD OF USE OF Andropenis® (FOR PENIS ENLARGEMENT)

The common treatment, excepts for different medical prescription, consists of 2 periods:

- ☒ An adaptation period, lasting 15 days.
- ☒ An evolution period, consisting of 3 separate phases: Initial evolution phase (1st and 2nd month), intermediate phase (3rd and 4th month) and final evolution phase, which begins in the 5th month.

Any deviation from the treatment program could alter the results achieved (consult your doctor).

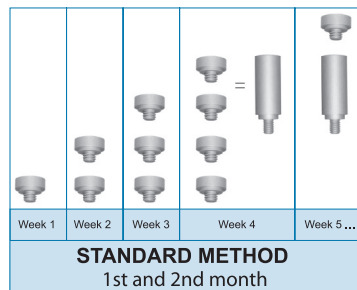
The medical practice recommends electing among the two models in use:

	STANDARD METHOD			SPECIAL METHOD	
	DEVICE SIZE	DAILY DURATION		DEVICE SIZE	DAILY DURATION
	Adaptation period			Adaptation period	
First 5 days	Initial size	3 hours	First 5 days	Initial size	4 hours
Day 6 - 10	Add a small 0.5cm shaft (piece 11)	6 hours	Day 6 - 10	Add a small 0.5cm shaft (piece 11).	4 hours
Day 11 - 15	Add a small 0.5cm shaft (piece 11)	8 hours	Day 11 - 15	Add a small 0.5cm shaft (piece 11).	4 hours
	Evolution period			Evolution period	
1st and 2nd month	Add a small 0.5cm shaft (piece 11) every 7 days	9 hours	1st and 2nd month	Add a small 0.5cm shaft (piece 11) every 3 days	4 hours
From the 3rd month	Add a small 0.5cm shaft (piece 11) every 10 days	9 hours	From the 3rd month	Add a small 0.5cm shaft (piece 11) every 10 days	4 hours
From the 5th month	Add a small 0.5cm shaft (piece 11) every 15 days	9 hours	From the 5th month	Add a small 0.5cm shaft (piece 11) every 15 days	4 hours

Note: for your own comfort, from the 5th month onward, it is possible to first add a 0.30 cm shaft (piece 12) and a few days later, change it for a 0.5cm shaft (piece 11) to make the traction more progressive.

The first day, as practice, fit and remove the device 10 times in a row. It is recommended fitting the device in the upwards position one day, to one side the following day, and to the other side the next day. Every 2 hours, the device will need to be removed for a few minutes to allow the tissues to relax. After the 5th month, this rest period should be observed every 1.5 hours. Use this rest period to lightly massage the penis. Wash the device with PH neutral soap and water every 4 days.

Be patient and consistent with the treatment, this is the key to achieving your objectives. The first results will be observed 1.5 months into the treatment (the 15 day adaptation period followed by 1 the first month of treatment).



10. PRECAUTIONS OF USE

Even though there is usually no discomfort, some days the device may feel uncomfortable. Do not worry, keep using the device. However, if necessary, you may interrupt the treatment for one day.

If you experience pain or discomfort, bluish discoloration or numbness of the glans, remove the device and massage the penis. By doing so penis colour will return to normal and the unpleasant sensations will disappear. If you feel discomfort at the base of the glans, you should try wearing cotton or gauze to protect this sensitive area.

If you have not been able to wear the device for 15 to 30 days, start treatment at 1 cm (0.4") less than the size of the device at that time. After 5 days, increase of 0.5 cm (0.2") and repeat the increment of 0.5 cm (0.2") after again 5 more days. After this 10 day adaptation period resume with the chosen mode.

When you take off the device you may notice a tingling sensation, for which you should not worry either. It is due to the tissues relaxing after a period of tension.

Penile bruising, penile skin reaction in the distal part of the shaft (site of application of the silicone band) and at the base of the penis (site of application of the plastic ring), pain, penile dyschromic changes, numbness of glands, tingling sensation, edema or fluid retention in the glands, wound, irritation, inflammation and discomfort are identified as residual risks. If any of these residual risks occur while using the device, we strongly recommend to discontinue using it, and follow the recommendations for the corresponding case, exposed in Section 11 of present instruction manual.

- ❏ Do not use **Andropenis®**: while sleeping, while partaking in strenuous physical activity or sport. While under the effects of recreational drugs or alcohol. If you have an ulcer, sexually transmitted disease or wound in the genital area. If you have decreased hand strength or difficulty manipulating the device. During sexual intercourse.
- ❏ Maintain strict hygiene standards whilst using the device.
- ❏ Remove the device to urinate or defecate.
- ❏ If you have an erection whilst using the device, do not worry: it will simply feel a little tighter.
- ❏ If you see white areas on the glans, do not worry: These are areas of edema or fluid retention possibly due to the loop being too tight. Massage the area and they will disappear.

If you develop white spots on your glans, it is necessary to see a doctor, since you may have developed a fungal infection. Personal hygiene is very important. Keep the device clean.

IMPORTANT: The use of medication for stimulating hair growth or to make your hair stronger, medication to treat depression, sleeping pills, tranquillizers and sedatives can significantly diminish the effectiveness of **Andropenis®**.

Inability to achieve an erection that is sufficient for sexual intercourse may be a sign of a serious medical problem. Consult your physician to avoid a potentially harmful delay in diagnosis.

11. OINTMENTS

The fastening system of **Andropenis®** to the glans could lead, in rare cases, to irritation or discomfort in the area. To prevent this it is recommended to use precaution's and the component **Androcomfort® band** provided. If you see any irritation, we recommend a series of ointments, you can buy pre-emptively, however, we recommend you to visit your doctor.

ANTI-IRRITATION / ANTIBIOTIC OINTMENT

In case of minor irritation, penile bruising or penile skin reaction in the distal part of the shaft (site of application of the silicone band) or at the base of the penis (site of application of the plastic ring): Apply ointment during the evening and use the device during the day until the symptoms disappear, if these symptoms persist contact your physician.

HEALING OINTMENT / ZINC OXIDE

If you develop a wound or ulcer:

- ❗ Do not use the device for 4 days. Apply anti-irritation ointment twice daily, morning and afternoon, and the healing ointment at night. If the wound persists, stop using the device and contact your physician.

ANTI-INFLAMMATION OINTMENT

If any inflammation or edema appears in the glans or at the base of the penis or in the pubic area, apply an anti-inflammation ointment such as "Cortaid". The anti-inflammation ointment will also be a valid treatment for fluid retention in the glans.

HYDRATING CREAM

If you feel discomfort in the shaft of the penis, massage the penis with a hydrating cream for 5 minutes each night using gentle stretching motions

WARNING

If any of the above mentioned symptoms persist after three days, you feel any pain or perceive any redness, swelling or fever, contact your doctor immediately.

Contraindications to the use of the apparatus with ointments or creams to the penis that contain topical anesthetics (lidocaine, xylocaine, ...).

The use of this product meets the specific needs of each patient for medical and surgical application's, it is not a general purpose machine requiring the concurrence of a specialist in your first placement and supervision of a physician for the remainder of the treatment. The device is commonly used in cosmetic application's, in this case, medical advice and supervision is only suggested as an option. Should the patient notice any abnormality during use, they must consult a doctor.