

INSTRUCTIONS

1. DEFINITION

Andropenis® is a medical device which attaches externally to the penis, exerting a gradual and adaptive traction force on the penis. It is recommended for medical, aesthetic and surgical applications.

2. DESCRIPTION

Andropenis® is composed of a plastic base ring, two metal rods 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 rods of **Andropenis®** gold are made of brass covered with a layer of 24 carat gold. The springs are made of stainless steel and the rods of surgical aluminium.

COMPONENTS (fig. 1): 1 plastic base ring, 2 metal axis, 3 Threaded bar, 4 threaded adjustable rod, 5 metal rod, 6 screw, 7 spring, 8 screw to secure the spring, 9 large 4cm 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 (andro-top).

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. APPLICATIONS

- ☒ Treatment of Peyronie's disease and correction of other congenital penile curvatures.
- ☒ Non-surgical treatment to increase length and girth.
- ☒ Post-surgical treatment of some urological surgeries (prostatectomy, penile surgery, traumatism, etc.) to avoid penile shortening due to scar retraction.

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 and quadriplegics.

Side effects: There are no side effects as long as the instructions are followed correctly.

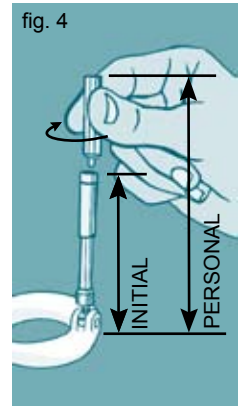
4. PERSONALISE Andropenis®

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 rod (fig.4, INITIAL).

Personalise 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 rods 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.).

5. FITTING Andropenis®

Take the silicone band (piece 14) and thread it through protective cushion (andro-top, piece 15). The use of the andro-top 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).



We recommend covering the penis with cotton wool or a bandage (fig. 8). 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 glands 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 decreasing silicon 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 fit the groove of the glans groove without hurting but tight enough to keep the glands from slipping out. Carefully secure the silicone band in the fasteners on the underside of the upper support (piece 13). 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 silicon 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 silicon band (piece 14) from the fasteners in the upper support(piece 13), and increase the size of the silicon loop to release the penis.

6. PENILE CURVATURE AND PEYRONIE'S DISEASE

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).

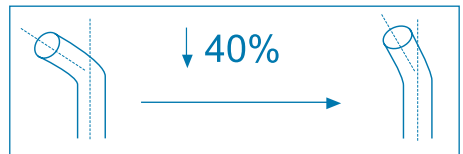
Peyronie's disease, or penile hardening, is a process whose cause is unknown, and characterised by a fibrous (hard) band on the tunica albuginea of the penis. These bands tend to be unilateral (on one side of the penis) and as a result the penis acquires a curve in erection.

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.

Treatment options:

- 📌 **Verapamil**: Injections into the fibrous plaque to block the production of collagen. (Studies are being undertaken on Interferon injections)
- 📌 **Andropenis®**: external prosthesis applied to the penis which exerts a traction force and creates a reduction in curvature of up to 40%.
- 📌 **Vitamin E o Colchicina**: 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 is always a side effect of this treatment, to avoid this, a penile extender should be employed (Andropenis®).

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



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

The treatment 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.

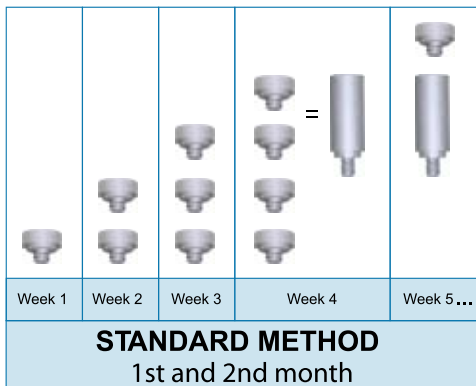
Any deviation from the treatment program could alter the results achieved.

	DEVICE SIZE	Daily duration
	Adaptation period	
First 5 days	Initial size	3 hours
Day 6 - 10	Add a small 0.5cm rod (piece 11).	6 hours
Day 11 - 15	Add a small 0.5cm rod (piece 11).	8 hours
	Evolution period	
1st and 2nd month	Add a small 0.5cm rod (piece 11) every 7 days	9 hours
3rd and 4th month	Add a small 0.5cm rod (piece 11) every 10 days	9 hours
From the 5th month	Add a small 0.5cm rod (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 rod (piece 12) and a few days later change it for a 0.5cm rod (piece 11) to make the traction more progressive.

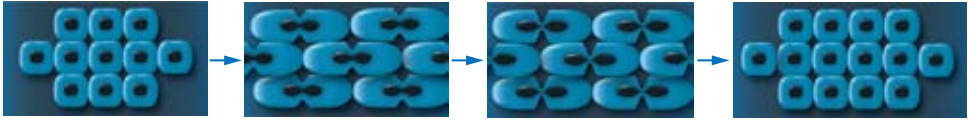
The first day, as practice, fit and remove the device 10 times in a row. In case of curvature, it is recommended locating the device away from the curvature. Every 2 hours, the device will need to be removed for a few minutes to allow the tissues to relax. After the 5th month, this rest period should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

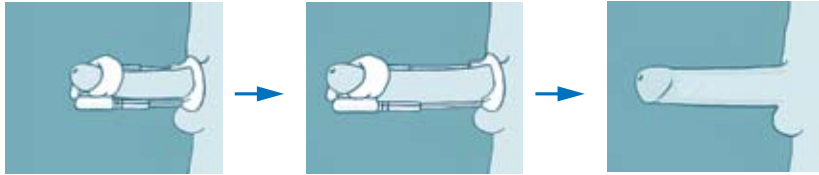


8. Andropenis® FOR PENILE ENLARGEMENT:

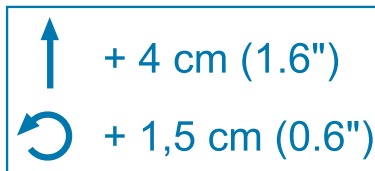
Andropenis® is based on the principle of traction which results in the expansion of human tissue by gradual stretching, and then allowing the body to remodel itself naturally.



It has been widely used in cosmetic surgery to repair and cover skin defects such as burns and large wound areas; and in orthopaedic surgery to enlarge the diaphysis of bones and phalanges (Bryant's traction, Buck's traction in hip fractures, Dunlop's traction in humeral fractures and Russell's traction). In ancient cultures the principle of traction was also applied to enlarge different parts of the body, like the neck of the Giraffe women of the Paduang tribe in Burma, or the lips and ears of other African and Amazonian tribes.



The **Andropenis®** extender creates a smooth gentle expansion by applying a continuous traction force of from 600 to 1,500 grams on the penis over sustained periods of time. This traction force causes an adaptive reaction of the penile tissue components at a structural level, increasing cellular multiplication. In other words, the expanding force opens up spaces between penile cells, triggering a growth or healing response in the cavernous body of the penis. The adjacent cells begin to divide and reform, expanding to fill the space. With continued use, millions of new cells can be generated, significantly adding size and tissue to the area.



9. METHOD OF USE (FOR PENILE ENLARGEMENT)

The treatment 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.

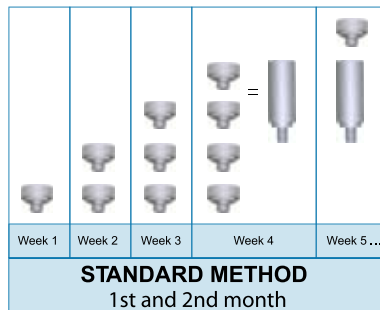
You may choose between 2 treatment methods:

	STANDARD METHOD			SPECIAL METHOD	
	DEVICE SIZE	DAILY DURATION		DEVICE SIZE	DURACIÓN DIARIA
	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 rod (piece 11)	6 hours	Day 6 - 10	Add a small 0.5cm rod (piece 11).	4 hours
Day 11 - 15	Add a small 0.5cm rod (piece 11)	8 hours	Day 11 - 15	Add a small 0.5cm rod (piece 11).	4 hours
	Evolution period			Evolution period	
1st and 2nd month	Add a small 0.5cm rod (piece 11) every 7 days	9 hours	1st and 2nd month	Add a small 0.5cm rod (piece 11) every 3 days	4 hours
From the 3rd month	Add a small 0.5cm rod (piece 11) every 10 days	9 hours	From the 3rd month	Add a small 0.5cm rod (piece 11) every 10 days	4 hours
From the 5th month	Add a small 0.5cm rod (piece 11) every 15 days	9 hours	From the 5th month	Add a small 0.5cm rod (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 rod (piece 12) and a few days later change it for a 0.5cm rod (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).



10. UROLOGICAL POST SURGERY

Andropenis® is recommended for post-surgical application in the following operations to avoid side effects of penile shortening resulting from scar retraction of the tissues.

Prostate: From the age of 40, the prostate begins to grow. This growth can be benign (hyperplasia) or malignant (cancer). **Andropenis®** is used post-surgery for:

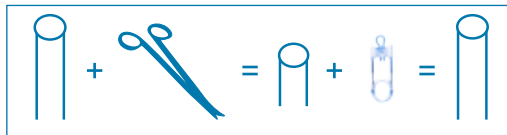
- Stage T1 or T2 prostate cancer surgery (radical laparoscopic prostatectomy or robotic prostatectomy).
- Benign hypertrophic prostate surgery (by photo-vaporisation using green laser technology, trans-urethral resection, or open surgery).

Penis: There is a high frequency of penile surgery to improve deformities, correct congenital defects or traumatic lesions. **Andropenis®** is used post surgery for:

- Curvature correction surgery
- Peyronie's disease correction surgery
- Penis enlargement surgery
- Intra-penile implant surgery
- Surgery for traumatic lesions
- Hypospadias correction surgery
- Surgery to correct male urethral stretching

Bladder: In children, congenital defects are corrected through surgery. In adults, bladder surgery is used for cancer lesions, traumatism or to improve severe urinary incontinence. **Andropenis®** is used post surgery for:

- Bladder exstrophy surgery in young boys
- Male bladder cancer surgery
- Male urinary incontinence surgery
- Male traumatic bladder lesion surgery



11. METHOD OF USE (UROLOGICAL POST SURGERY)

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

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

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

The treatment 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 rod (piece 11).	6 hours
Day 11 - 15	Add a small 0.5cm rod (piece 11).	8 hours
	Evolution period	
1st and 2nd month	Add a small 0.5cm rod (piece 11) every 7 days	8 hours
From the 3rd month	Add a small 0.5cm rod (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 rod (piece 12) and a few days later change it for a 0.5cm rod (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).

12. PRECAUTIONS

Even though there is usually no discomfort, some days your penis 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, blue-ish discoloration or numbness of the glans, remove the device and massage the penis. By doing so the penis colour will return to normal and the unpleasant sensations will disappear. If you feel discomfort at the base of the glans, you must wear 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 relaxation after a period of tension.

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, sexual transmitted disease or wound in the genital area

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 oedema 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 make your hair stronger, medication to treat depression, sleeping pills, tranquilizers and sedatives can significantly diminish the effectiveness of **Andropenis®**.

13. OINTMENTS

Ointments may be purchased as a preventative measure:

ANTI-IRRITATION OINTMENT

You can have it prepared by your pharmacist or purchase it ready-made. It should contain, per gram, 0.0035 grams of Neomycin Sulphate.

In Europe, it is available under the name “Blastostimuline”. In the USA it is known as “Neosporin”, “Bacitracin” or “Neosporin ointment”.

It is used as follows:

- ☒ In case of irritation: Apply Blastostimuline or Neosporin during the evening and use the device during the day until the symptoms have disappeared.
- ☒ In case of persistent irritation: Contact your physician.

HEALING OINTMENT

It can be prepared by your pharmacist or purchased ready-made. It should contain, per 100 grams: 27 grams of Zinc Oxide. In Europe it is available under the name “Mitosyl”.

If you develop a wound or ulcer:

- ☒ Do not use the device for 4 days. Apply the anti-irritation ointment twice daily, morning and afternoon, and the healing ointment at night.

ANTI-INFLAMMATION OINTMENT

If any serious inflammation occurs at the base of the penis or in the pubic area, apply an anti-inflammation ointment. In Europe you can use “Hirudoid”, and in the USA an ointment called “Cortaid” would be adequate.

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