vPATCH User Guide

Premature Ejaculation Management

VIRILITY MEDICAL

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Table of Contents

Chapter 1: Introduction

Description

The vPATCH device is a single-use disposable patch designed to manage premature ejaculation. The patch contains electrodes to provide EMS (electrical muscle stimulation) on the perineal muscles to help the user control ejaculation.

vPATCH works by delivering short-duration, low-intensity EMS to the perineal muscles and nerves during intercourse. The stimulation contracts the pelvic floor muscles, which delays rhythmic contraction of ejaculation. This increases the time between arousal and ejaculation.

vPATCH is available in two intensity levels; High Intensity and Low Intensity.

Contraindications

Never use vPATCH if you:

- have been diagnosed with, or are receiving treatment for, pelvic cancer
- have an implanted electronic device
- suffer from perineal dermatological diseases, irritations, or lesions

Warnings and Precautions

- Consult your physician if you:
  - experience any pain in the area
  - require any muscle rehabilitation in the area
  - have diabetes with peripheral neuropathy.
  - have had genital or anorectal surgery.
- Do not apply the vPATCH to any area other than the male perineum.
- The vPATCH is intended for a single-use. If the vPATCH shall be reused, it might be ineffective.
- The vPATCH is a single-user device (do not transfer between users).
- Potential adverse reactions include redness, discomfort, and localized pain.
- Do not use the patch if its temperature rises. Deactivate it and use quick removal tips to avoid skin burn.
- Do not use the patch in water or in a humid environment (such as a jacuzzi, bath, shower, etc.).
- Cease stimulation if allergic reaction occurs.
- For use by adults aged 18–60.

Disclaimers

The vPATCH has not been tested on:

- usage with a pregnant partner
- users with past occurrences of ejaculation before vaginal penetration

Note

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

System Components

The vPATCH device is provided in packages containing:

- a case to hold four units (1)
- storage bag to hold 1 unit (1)
- vPATCH devices (4)

1 Stimulating Electrodes (skin side)

2 Quick-removal Tips

3 Scrotum Side-positioning Edge

4 Anus Side-positioning Edge

5 Removable liner

6 Main Power Button

Chapter 2: Instructions

General Usage and Safety Guidelines

Follow these guidelines for the safe and effective use of vPATCH device:

- Do not apply any kind of solvents or cleaning agents to the patch.
- Do not use in an oxygen-rich environment.
- Do not use near electromagnetic radiation.
- Do not use within 1.5 meters of shortwave or unshielded microwave devices.
- Do not use while sleeping.
- Do not use while driving, operating machinery, or any other activity.
- Do not place the patch on other objects.
- Keep out of reach of children.
- Do not allow any contamination of the patch.
- Do not attempt to reuse a patch.
- Do not remove from moisture-sealed packaging or remove liner until ready to use.
- Store in a dry, room temperate environment.
- It is recommended not use more than two vPATCH devices per day.

Applying the Patch

For best results, follow these directions.

1. Select the vPATCH with the desired intensity (High or Low).

Note

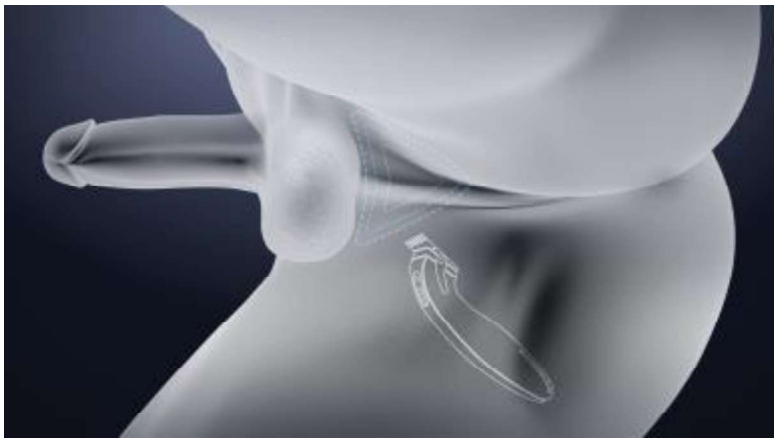
If this is your first time using vPATCH, select Low intensity.

If the intensity is too low, select the High Intensity device.

2. Trim perineal hair to 2–4 mm length with hand-held electric clippers.

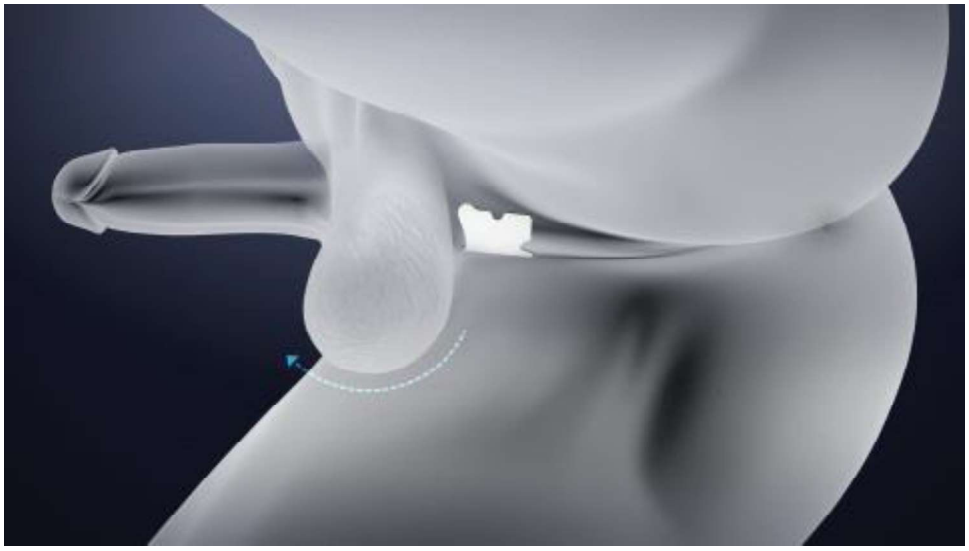
Note

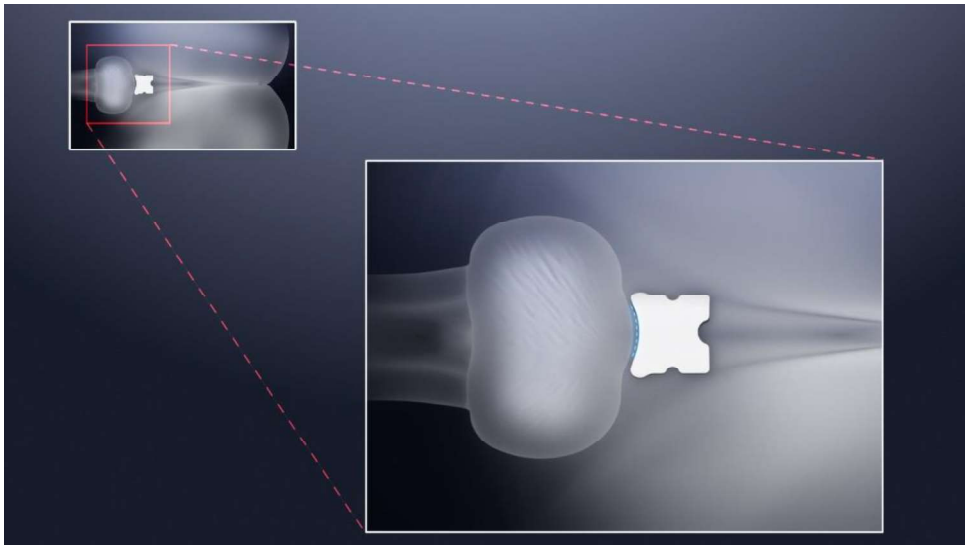
Do ***not*** shave the perineum area. Shaved skin may encourage skin irritations.



3. Wash and clean the skin to remove any oils. Dry thoroughly.
4. Make sure that there are no cuts, abrasions, or lesions in the area.
5. Remove the liner and gently bend the patch in a U-shape.

6. Gently lift the scrotum to expose the perineum. Apply the patch to the centerline of the perineum symmetrically along both sides. The Scrotal Positioning Edge should be positioned adjacent to the posterior aspect of the scrotum. The Anal Positioning Edge should be placed clear of the anus.

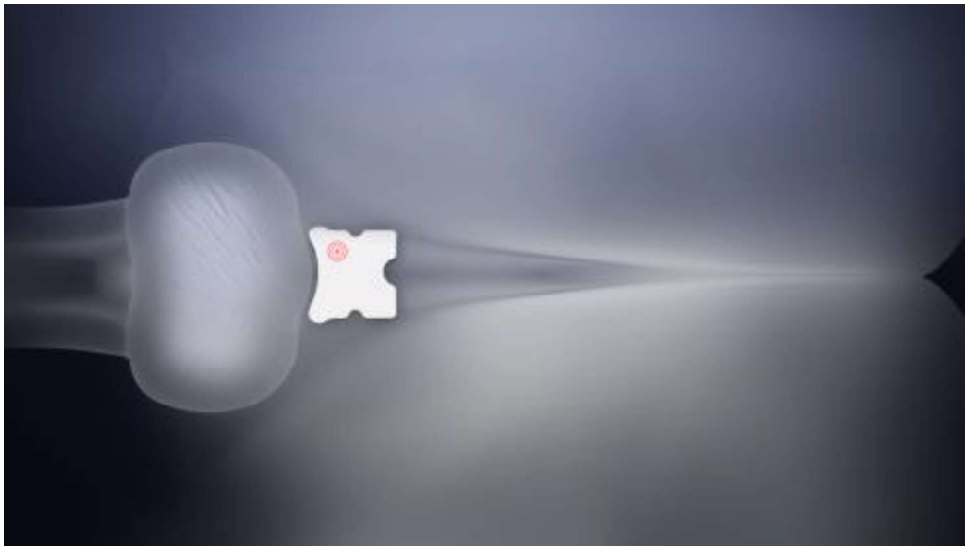




7. Push the power button once for one second to turn on. The stimulation begins and reaches the configured intensity level.

Note

The vPATCH device will operate for a maximum of 15 minutes (continuously or cumulatively).



Caution

If you experience major discomfort or pain, stop the stimulation immediately. (Hold the power button down for at least 2 seconds.) Use quick removal tips to remove the patch.

Removal and Disposal

After usage, remove the patch as follows:

1. Hold down the power button for 2 seconds to stop stimulation.

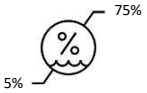
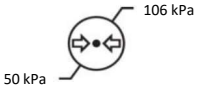
Caution

Do ***not*** remove the patch while it is still activated. Always turn it off before removing.

2. Grasp the non-stick tips to gently peel the patch away.
3. Return the patch to its packaging and dispose of in regular (non-recycled) waste.

Chapter 3: References

Product Specifications

Dimensions	Width 42 mm; Length 38 mm; Thickness 4.8 mm		
Weight	Approximately 4 grams		
Materials (that come in contact with skin)	Adhesive hydrogel Polyolefin Foam Single Coated Medical Tape		
Shelf Life	12 months when in original packaging		
	Temperature	Humidity	Atmospheric Pressure
Operational			
Storage			
Transportation			
Power Source	LR721 Silver-oxide 2x 1.5VDC non-rechargeable		
No. of Channels	1		
Stimulation Current	HIGH Intensity: 14.3mA±10%; LOW Intensity: 9.9mA±10%		
Maximal Stimulation Voltage	HIGH voltage: 90v±10%; LOW voltage: 60v±10%		
Waveform	Symmetrical Biphasic Pulse		
Pulse Duration	400µs±10%		
Frequency	30Hz±10%		
Electrodes	Hydrogel electrodes, minimal size 475mm^2		
Range of Impedance	1kΩ-6kΩ±10%		
Current Density	Exceeds 2mA/cm^2		

Electromagnetic Emissions

Declaration – Electromagnetic Emissions		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group1 Class A	The vPATCH uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	Class A	The vPATCH is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating vPATCH or shielding the location.
Voltage Fluctuations and Flickers IEC 61000-3-3:2013	Complies	

Declaration – Electromagnetic Immunity			
IMMUNITY Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2, 4, 8, 15kV air	8 kV contact 2, 4, 8, 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	2 kV for power supply lines N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV line(s) to line(s) 2 kV line(s) to earth 2 kV Signal input/output to earth	1 kV line(s) to line(s) 2 kV line(s) to earth N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	0% UT; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the vPATCH requires continued operation during power mains interruptions, it is recommended that the vPATCH be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 (A/m)	30 (A/m)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Declaration – Electromagnetic Immunity			
IMMUNITY Test	**IEC 60601 TEST LEVEL**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted RF IEC 61000-4-6	3V, 6V	3Vrms, 6V	Portable and mobile RF communications equipment should be used no closer to any part of vPATCH, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3,5}{V_1}]\sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m	3V/m	$d = [\frac{12}{V_2}]\sqrt{P}$ $d = [\frac{12}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{23}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. D Interference may occur in the vicinity of equipment marked with the following symbol: 
	3V from 0.15 to 80MHz; 6V from 0.15 to 80MHz and 80% AM at 1kHz	3V from 0.15 to 80MHz; 6V from 0.15 to 80MHz and 80% AM at 1kHz	
	3V/m from 80MHz to 2.7GHz	3V/m from 80MHz to 2.7GHz	

Symbols on Product Labeling

Symbol	Standard Number and Title	Symbol Number	Symbol Title	Description
	ISO 15223-1	5.1.3	Date of manufacture	Indicates the date the device was manufactured.
	ISO 15223-1	5.1.4	Use-by date	Indicates the date after which the medical device is not to be used.
	ISO 15223-1	5.4.2	Do not reuse	Indicates a medical device that is intended for one use, or for use on a single user during a single procedure.
	ISO 15223-1	5.4.4	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

Symbol	Standard Number and Title	Symbol Number	Symbol Title	Description
	ISO 15223-1	5.4.3	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO 15223-1	5.1.5	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1	5.1.6	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified.
	ISO 15223-1	5.1.1	Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1	5.3.7	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 15223-1	5.3.8	Storage humidity range	Indicates the range of humidity to which the medical device can be safely exposed.
	ISO 15223-1	5.3.9	Atmospheric Pressure	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	ISO 15223-1	5.2.8	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	ISO 15223-1	5.7.10	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information
	ISO 15223-1	5.7.7	Medical device	Indicates the item is a medical device
	ISO 7010	M002	Refer to Instruction Manual	Signifies that the instruction manual/booklet must be read
	ISO 15223-1	5.2.7	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process.
	ISO 7000	-	Quantity	Indicates the amount of product included
	IEC 60529	-	Degrees of protection provided by enclosures (IP Code)	Protected against solid objects over 12.5mm (e.g., a finger) and protected against falling drops of water, if the case is disposed at any angle up to 15 degrees from vertical
	ISO 15223-1	5.3.4	Keep Dry	Indicates a medical device that needs to be protected from moisture
	IEC 60417	5333	Type BF applied part	Identifies a type BF applied part complying with IEC 60601-1
	-	-	RoHS Compliant	Indicates a product meets the restrictions on ten hazardous materials such as lead, mercury, and cadmium

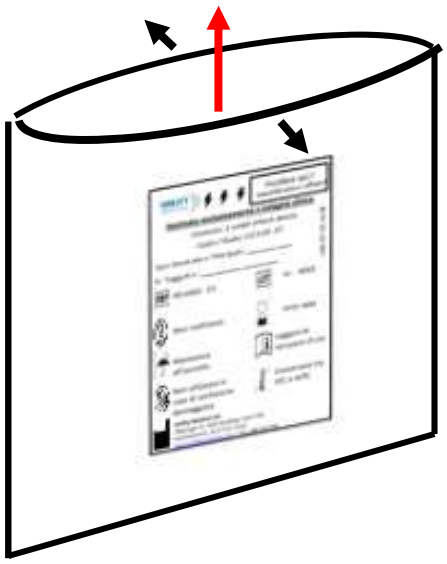
vPATCH Quick Guide

Premature Ejaculation Management

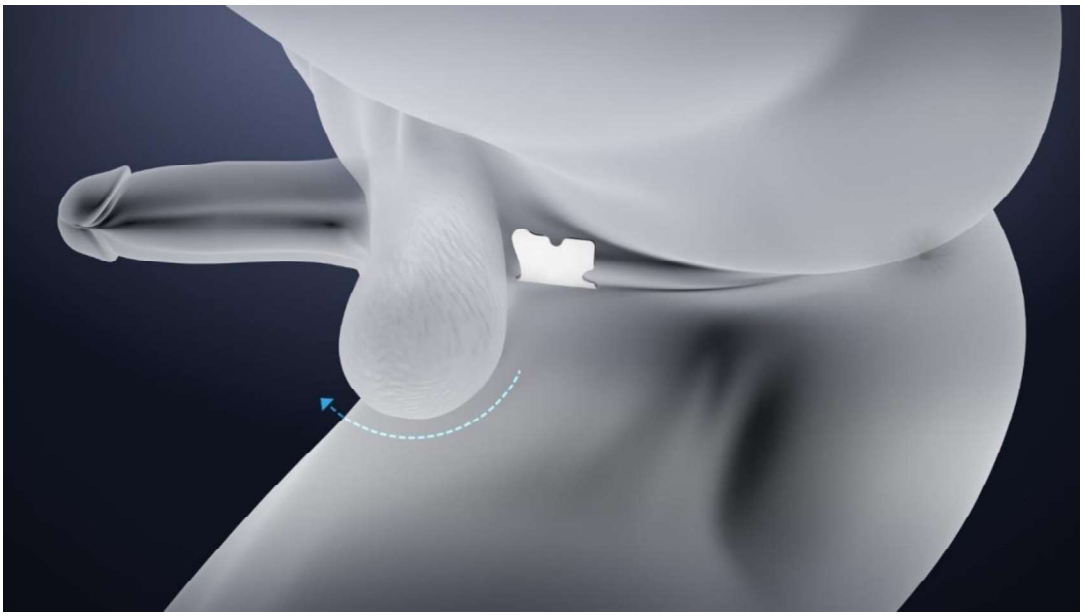
Step 1: Choose intensity

HIGH Intensity or **LOW Intensity**

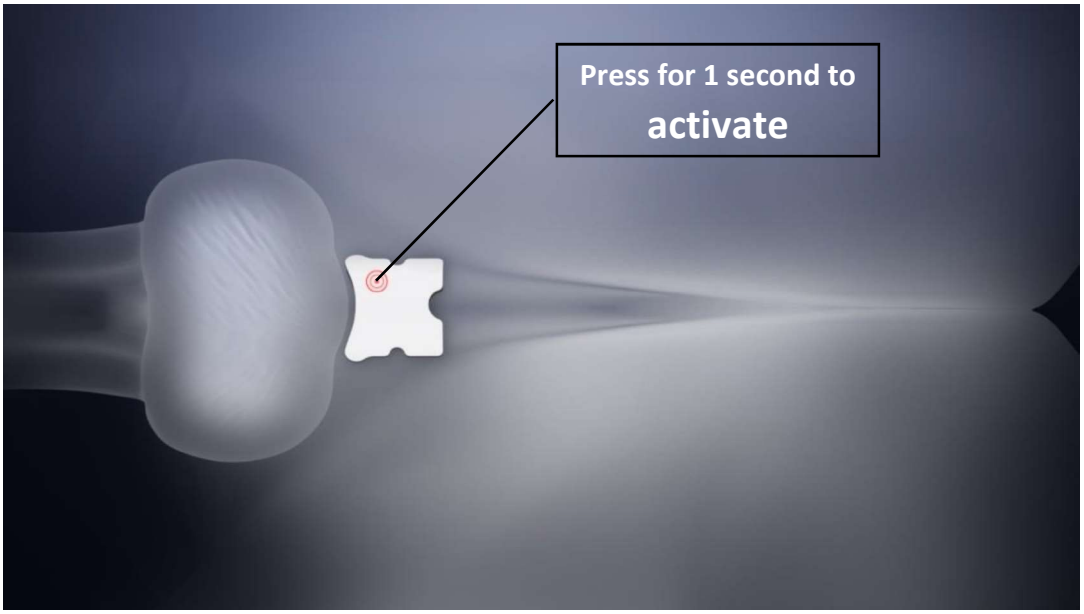
Step 2: Open Bag



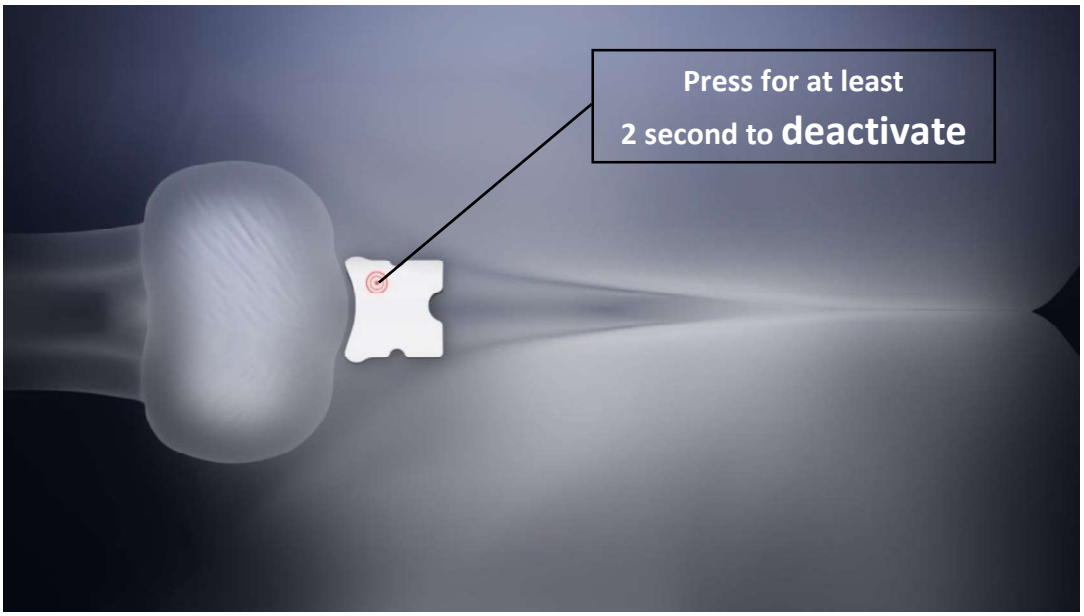
Step 3: Lift the scrotum and apply the patch to the perineum



Step 4: Activate the patch before intercourse by pushing the activation button for 1 second



Step 5: Once done, deactivate the patch by pushing the activation button for more than 2 second


Press for at least
2 second to deactivate

Step 6: Gently peel off the patch

Step 7: Return the patch to its packaging and dispose of in regular waste