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ACT Adjustable Continence Therapy For Women
Patient Information Leaflet
(To Accompany Implant Card: 900164 LBL)

Read this patient information leaflet carefully. It contains important information about your implants.

If you have further questions, contact your doctor. Keep this leaflet in a safe place.

Introduction

Your doctor must give you an implant card and patient information leaflet. You will receive an implant card for each side of your body a device is implanted. Carry the implant card with you at all times. This patient information leaflet contains extra information.

What are My Implant Card and Patient Information Leaflet for?

Your implant card and patient information leaflet help you.

- Know which ACT devices are in your body.
- Find important information about your ACT devices.
- Show that you may need special care in some situations, like airport checks.
- Help emergency workers understand special care you may need.

Website Where Updated Patient Information Can Be Found

Updates to this patient information leaflet might be needed. Updates can be found on the website https://www.uromedica-inc.com. Use the catalogue number printed on your implant card to access the information.

Information for Safe Use

Your doctor should advise you regarding exercises, therapies, and any limits to your activities. It is important that you follow your doctor's instructions regarding recovery and attend all follow-up appointments.

Healing takes time. Your doctor will tell you what to expect.

Not following your doctor's advice may result in complications.

All surgery carries risks and can lead to undesirable effects. For ACT these can include.

- Allergic response.
- Anesthetic [pain killer] risks.
- Device calcification [hardening due to calcium buildup].
- Device failure.
- Device wear.
- Erosion of the device at the bladder, labia [folds of skin around the vaginal opening], urethra [tube through which urine leaves the body], vagina.
- Explant of one or both devices.
- False channel creation.
- Perforation [a small hole] (e.g. bladder, urethra [tube through which urine leaves the body], vagina).
- Pain or discomfort.
- Procedure or device adjustment not able to be completed.
- Device infection.
- Device migration [movement].

- Urinary complications (e.g. urinary difficulty, frequency, or urgency, worsening incontinence [loss of bladder control]*).
- Urinary retention [inability to fully empty the bladder].
- Urinary tract infection.
- Vascular problems (e.g. bleeding, hematoma [a collection of blood], induration [thickening or hardening of tissue], inflammation [swelling]).
- Wound infection.

*"Worsening incontinence" means the patient feels their incontinence [loss of bladder control is getting worse].

Contact your doctor if you are experiencing these, or any other, undesirable effects.

Magnetic Resonance Imaging (MRI) Safety Information

The ACT device has metal inside (it does not touch you). If you are asked to undergo an MRI scan, provide this information to your doctor or medical team.

Non-clinical testing demonstrated that the ACT device is MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions.

- Static magnetic field is 1.5 or 3 Tesla only.
- Maximum spatial gradient magnetic field is 5,000 Gauss/cm (50-T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning (per pulse sequence) in Normal Operating Mode.

Under the scan conditions defined above, the ACT device is expected to produce a maximum temperature rise of 1.5°C after 15 minutes of continuous scanning (per pulse sequence).

In non-clinical testing, the image artifact caused by the ACT device extends approximately 10mm imaged using a gradient echo pulse sequence and a 3 Tesla MR system.

Travel Information

The ACT device has metal inside (it does not touch you). This may be detected during airport security checks. When travelling by air it is recommended to inform a member of security about your implant prior to screening.

Expected Device Lifetime

The expected lifetime of the ACT device is 10 years.

Follow-Up

Attend all follow-up appointments.

The ACT device may need volume adjustment by your doctor from time to time.

Materials in Contact with Your Body

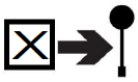
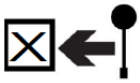
The ACT device has metal inside (it does not touch you). Only the silicone outer touches your body.

Location of Device Implanted

Marked box tells you the side of your body the device is implanted.

Explanation / Translation of Symbols

The table below will help you understand the symbols used on your implant card.

	Patient name or patient identification, translations……
	Date of implantation, translations….
	Name and address of the implanting healthcare institution / provider, translations….
	Device name, translations….
	Name and address of the manufacturer, translations….
	Information website for patients, translations….
	Lot number, translations….
	Unique device identifier, translations…
	Catalogue number, translations…
	MRI conditional, translations…
	Device implanted on right side of body, translations
	Device implanted on left side of body, translations…

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