

Urgent[®] PC

NEUROMODULATION SYSTEM

Patient Considerations

Questions about Indications, Contraindications and Precautions

Urgent PC provides office-based neuromodulation in the treatment of Overactive Bladder and associated symptoms of urinary urgency, urinary frequency, and urge incontinence. Cogentix Medical recommends that Physicians consult the Urgent PC Instructions for Use (IFU) and use their own medical discretion when deciding whether to use Urgent PC to treat patients with any pre-existing medical conditions.

Common Questions about Patient Selection

Patient has ...	Product Labeling	Recommendation	Potential Cause or Rationale
Nerve damage that could impact either percutaneous tibial nerve or pelvic floor function	Contraindicated <i>Contraindication #1, see page 4 of IFU</i>	Physician discretion	Some nerve damage in the pelvic floor, legs/feet may affect the stimulation pathway for PTNS with Urgent PC. The physician should use their discretion in determining if a patient's nerve damage would affect treatment effectiveness.
Likelihood of excessive bleeding or is taking blood thinners	Contraindicated <i>Contraindication #1, see page 4 of IFU</i>	Physician discretion	Patients on blood thinning medication are generally at a higher risk for excessive bleeding. While the 34 gauge needle electrode is unlikely to cause excessive bleeding at the insertion site, physicians should carefully consider a patient's use of blood thinning medications before using Urgent PC.
Become pregnant or is planning to become pregnant during the course of treatment	Contraindicated <i>Contraindication #4, see page 4 of IFU</i>	Avoid	Urgent PC can stimulate the pelvic floor and may cause uterine contractions.
Dysrhythmia	Precaution <i>Precautions #2, see page 6 of IFU</i>	Physician discretion	The physician can best determine if Urgent PC treatment may affect suspected or diagnosed heart problems, especially those relating to the pacing or electrical functioning of the heart.
Pedal/ankle edema (lower extremity edema)	Undefined	Physician discretion	Urgent PC has been used effectively on patients with large or swollen ankles. Clinic best practices include: <ul style="list-style-type: none"> • Advising patients to wear support stockings before their treatments to reduce the swelling • Modifying the depth of the needle insertion • Morning appointments may be more conducive to less lower extremity edema
Parkinson's Disease (PD)	Undefined	Physician discretion	Cogentix Medical has not sponsored an Urgent PC study in this subpopulation or submitted data including patients with PD to FDA.
Multiple Sclerosis (MS)	Undefined	Physician discretion	Cogentix Medical has not sponsored an Urgent PC study in this subpopulation or submitted data including patients with MS to FDA.

Common Questions about Concurrent Treatments

Patient has ...	Product Labeling	Recommendation	Potential Cause or Rationale
Implanted Pacemaker, Defibrillator, or Stimulator (<i>Cardiac, Brain, Pain, Gastric, etc.</i>)	Contraindicated <i>Contraindication #1, see page 4 of IFU</i>	Avoid	Possible risk that electrical interference from the device could cause the pacemaker to malfunction. Cogentix Medical has not gathered any data regarding the safety of using Urgent PC with these devices to determine the risk of using them together. <i>Note: the FDA recommends similar contraindications for all battery-operated stimulation devices</i>
Non-life sustaining stimulator (such as for back pain or fecal incontinence) that can be safely turned off	Undefined	Safely turn off device while being treated with Urgent PC	Possible risk of cross electrical interaction.
Holter monitor	Contraindicated <i>Contraindication #1, see page 4 of IFU</i>	<i>Avoid, while wearing the monitor</i>	Treating a patient with any concurrent medical monitoring equipment is not recommended. If patient is otherwise a good candidate for Urgent PC therapy, they may be scheduled for treatment when the Holter monitoring is complete.
TENS unit	Undefined	No concerns, <i>if treatments are not concurrent</i>	The Urgent PC and TENS units should NOT be used at the same time, but the two therapies can be used separately by patients per their physician's recommendation.
Metal orthopedic implant	Undefined	Physician discretion	Cogentix Medical recommends that if the orthopedic hardware is confined to one foot or leg, that the Physician administers the treatment in the leg without hardware. If the patient experiences pain or discomfort during or following treatment, the physician should discontinue Urgent PC use and re-evaluate the patient for continuation of treatment. <i>Note: associated nerve damage may contraindicate patient for Urgent PC treatment.</i>

For treatment-related questions, contact your area manager or the Cogentix Medical Clinical Department at clinical@cogentixmedical.com.



Urgent PC is indicated for the treatment of Overactive Bladder and associated symptoms of urinary urgency, urinary frequency and urge incontinence. Contraindications: patients with pacemakers or implantable defibrillators, patients prone to excessive bleeding, patients with nerve damage that could impact either percutaneous tibial nerve or pelvic floor function, or patients who are pregnant or planning to become pregnant during the duration of the treatment. Precautions: Exercise caution for patients with heart problems related to pacing. Most patients don't experience side-effects. If side-effects occur, they are typically temporary and include mild pain and skin inflammation at or near the stimulation site. Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. For complete instructions for use, storage, warnings, indications, contraindications, precautions, adverse reactions and disclaimer of warranties, please refer to the insert accompanying each product or online at www.cogentixmedical.com. Urgent is a registered trademark of Cogentix Medical, Inc. © 2015 All rights reserved. 20309B 5/15

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