

Percutaneous Tibial Nerve Stimulation (PTNS) Performed with the Urgent[®] PC *Procedure Overview*

Urgent PC Overview

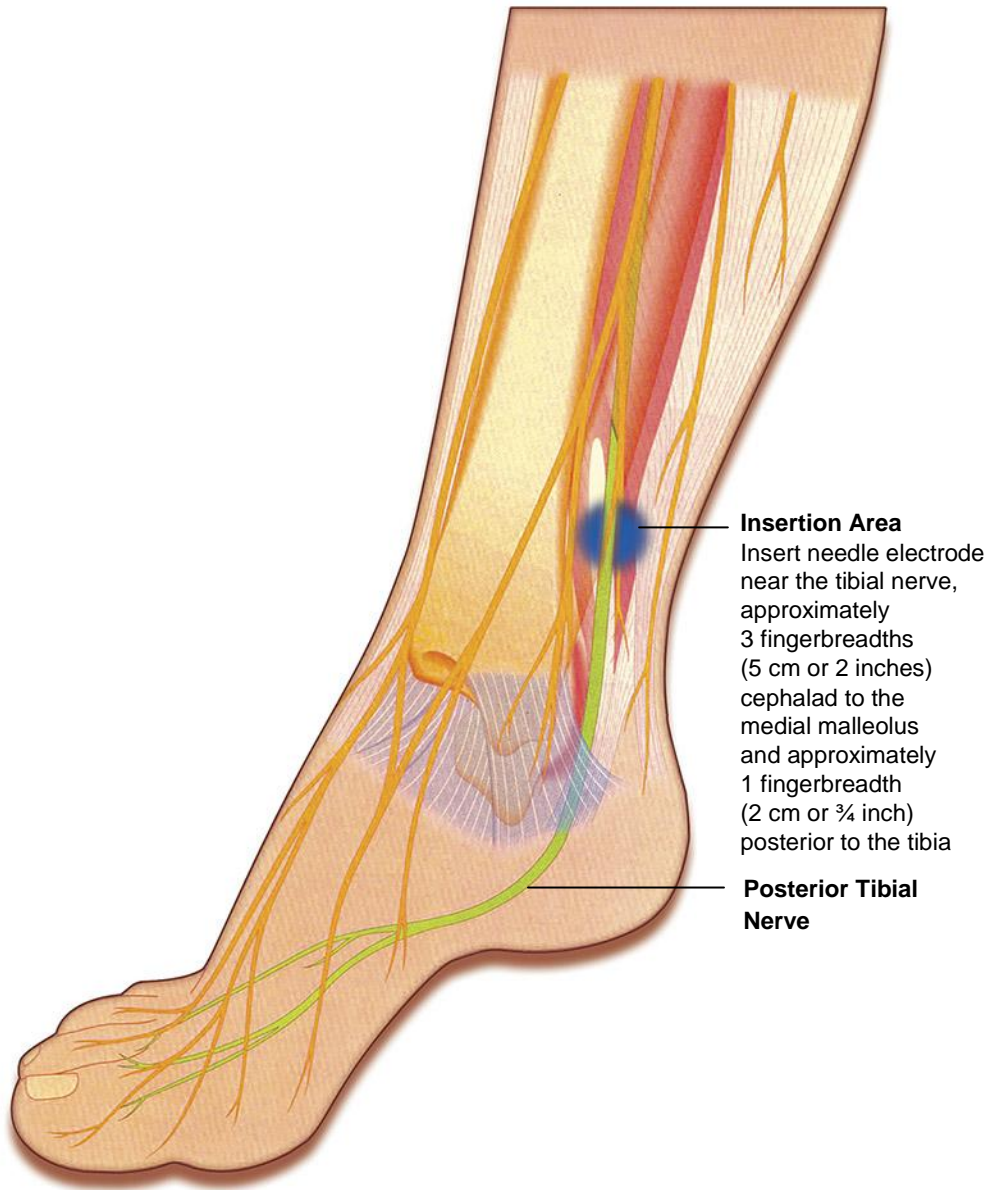
The Urgent PC system is a minimally invasive nerve stimulation device designed for office-based treatment of urinary urgency, urinary frequency and urge incontinence. Stimulation is delivered through a slim, needle electrode temporarily inserted above the ankle. This stimulation targets specific nerves and disrupts the signals that lead to urinary urgency, urinary frequency and urge incontinence.



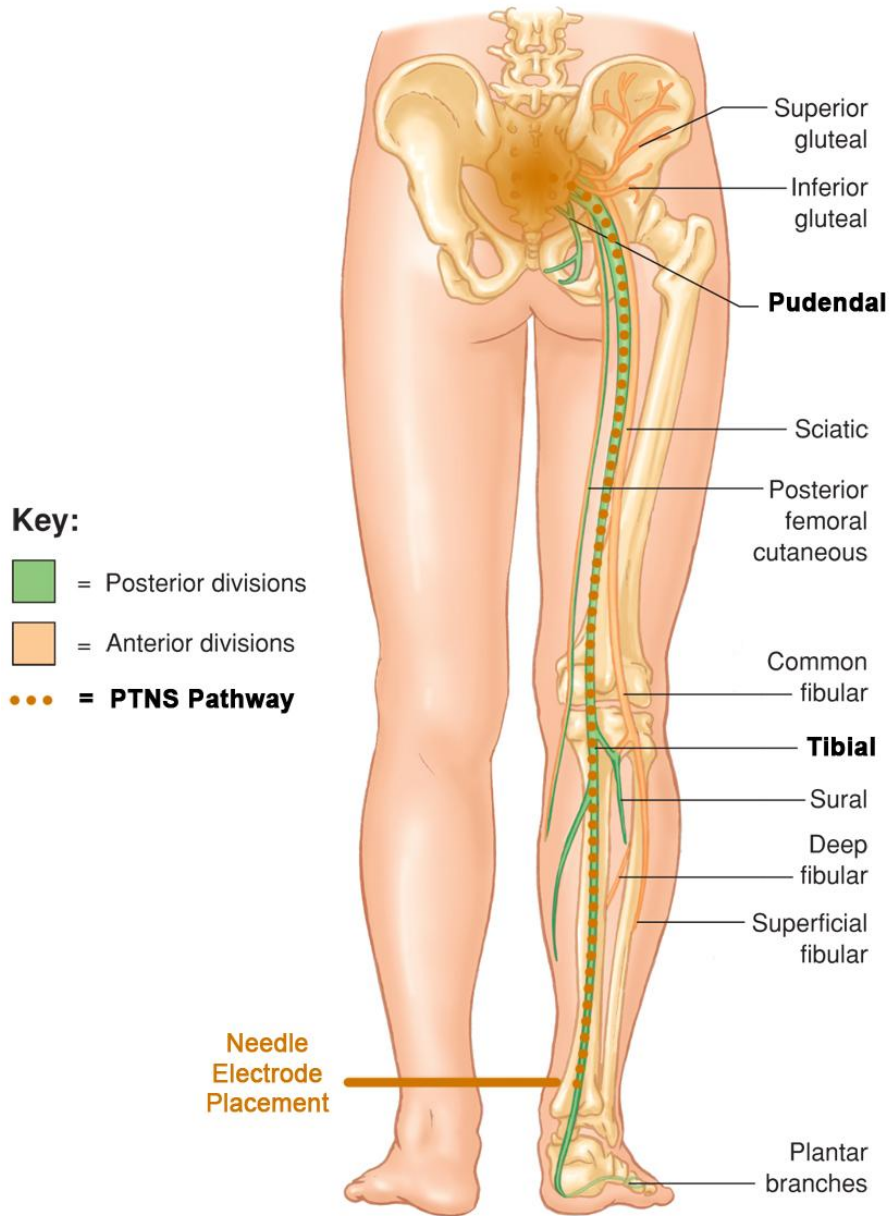
Treatment Overview

Percutaneous Tibial Nerve Stimulation (PTNS), performed with the Urgent PC involves placing a thin Needle Electrode into the lower, inner aspect of either leg slightly cephalad to the medial malleolus. A Surface Electrode is placed over the medial aspect of the calcaneus on the same leg. The Lead Wire is first connected to the Stimulator (External Pulse Generator), and then the Needle Electrode Clip is connected to the Needle Electrode. The Stimulator (External Pulse Generator) produces an adjustable electrical pulse that travels to the sacral nerve plexus via the tibial nerve. Among other functions, the sacral nerve plexus regulates bladder and pelvic floor function.

Needle Electrode Placement



PTNS Pathway to Sacral Plexus



The patient is typically treated once per week for 30 minutes for a period of 12 weeks. No decision to discontinue treatment should be made until the patient completes the 12 treatments. For patients responding to treatment, the time between treatment sessions may be slowly increased after the initial 12 treatments, with the patient closely monitored for the return of symptoms. If symptoms reappear or increase in severity, the patient's treatment schedule should revert to the last previously effective treatment schedule.

TREATMENT PROTOCOL FOR EACH TREATMENT SESSION

1. Check Battery Level

- Before beginning any treatment session, it is advisable to check the battery level. To check the battery level, turn on the Stimulator (External Pulse Generator) by pressing and holding the Power Button for approximately 2 seconds. An audible tone will sound and icons will appear on the screen. Battery replacement is recommended when there is only one line remaining in the Battery Level icon. To conserve battery power, the Stimulator (External Pulse Generator) may be turned off during patient preparation.

Note: The system is designed to prohibit the start of Test mode if there is insufficient battery life remaining to complete the treatment.

2. Insert the Needle Electrode



- Locate the insertion site for the Needle Electrode by identifying the location on the lower inner aspect of either leg that is approximately three fingerbreadths (5 cm or 2") cephalad to the medial malleolus and approximately one fingerbreadth (2 cm or 3/4") posterior to the tibia.
- To prepare the Needle Electrode insertion site, open the Lead Set packaging. Remove and open the Alcohol Pad. Use the Alcohol Pad to clean the skin area surrounding the identified insertion site.
- Place the patient in a comfortable position, supine or sitting, for easy access to the insertion site; for example, the patient may sit with the soles of the feet together and knees abducted and flexed. Open the sterile Needle Electrode package and remove the Needle Electrode/guide tube assembly.
- Place the Needle Electrode/guide tube assembly over the identified and cleaned insertion site in a position that creates a 60-degree angle between the Needle Electrode and the ankle. Remove the stop plug in the guide tube to release the Needle Electrode.



- Gently tap the Needle Electrode head to pierce the skin. Once the Needle Electrode has penetrated the skin, remove the guide tube and advance the Needle Electrode using a rotating motion to facilitate entry. *Note: it is important to maintain a 60-degree angle with the Needle Electrode while advancing it in a path that is parallel to the tibia. When appropriately inserted, approximately 2 cm (3/4") of the Needle Electrode will be inserted in the leg.*

3. Connect Lead Wire to the Stimulator (External Pulse Generator)



- Plug the one-way fit connector of the Lead Wire into the Stimulator's (External Pulse Generator's) connection site. Verify that the one-way fit connector is inserted correctly.

4. Attach the Surface Electrode

- Remove the adhesive backing from the Surface Electrode.
- Place the Surface Electrode near the medial aspect of the calcaneus on the same leg as the Needle Electrode insertion.

5. Attach Needle Electrode Clip



- Depress the plunger on the Needle Electrode Clip to expose the connection hook at the tip. Loop the connection hook around the Needle Electrode and release.

6. Determine Current Setting for Therapy

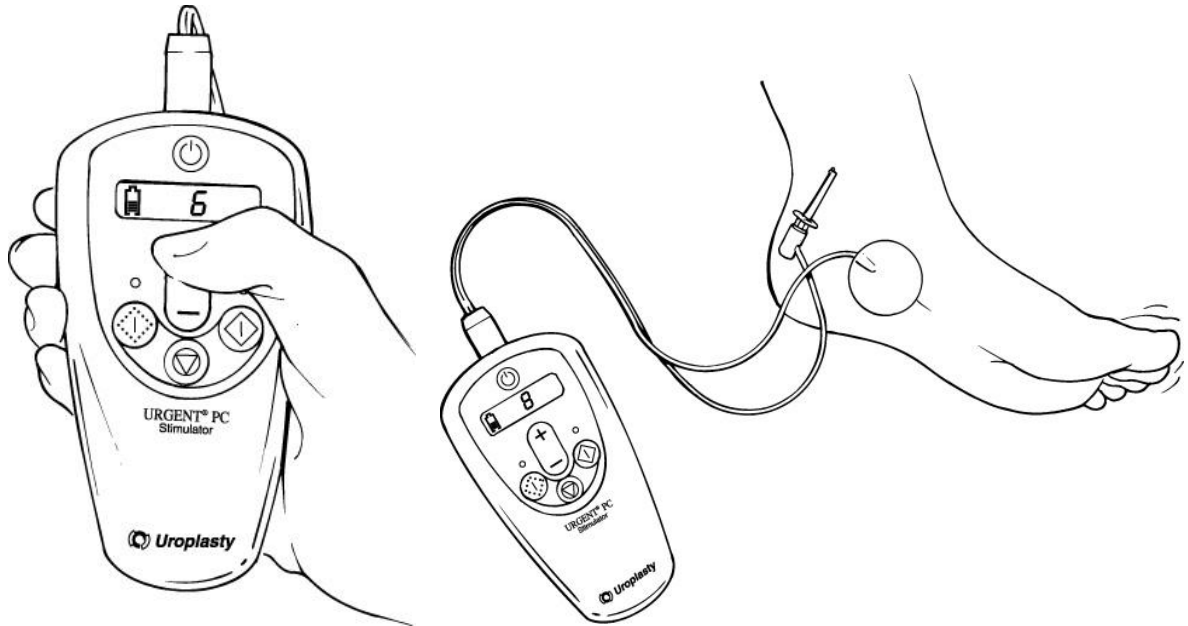
- Turn on the Stimulator (External Pulse Generator) by pressing and holding the Power button for approximately 2 seconds. An audible tone will sound and symbols will appear on the screen.

Note: If the Lead Status icon is blinking, ensure that the Lead Wire connector is secure in the Stimulator's (External Pulse Generator's) connection site.

- Enter Test mode by pressing and holding the Test button for approximately 2 seconds. The default setting for Test mode is level 0 (0mA current).

Note: If the Inactive Current icon appears, current is not flowing through the Lead Set. Check the security of the Lead Wire connector, the adherence of the Surface Electrode, and the placement of the Needle Electrode Clip.

- Using the Current Adjustment button, slowly increase the current while observing the patient's foot for a response. Patient response is generally a toe flex or fan, or an extension of the entire foot.



- Once a patient response is observed, reduce current setting by one level and begin Therapy mode.
- If the incremental adjustment of amplitude fails to elicit toe flex or fan, press the Stop button and reposition the Needle Electrode slightly. Re-enter Test mode using the preceding instructions.
- If repositioning the Needle Electrode and repeating the current step-up procedure fails to elicit patient response, discard the Needle Electrode. Open the second Needle Electrode included in the Lead Set and repeat the procedure on the other leg.

7. Conduct therapy

- After completing Test mode, Therapy mode can be entered by either:
 - 1) Pressing the Stop button to end Test mode and then pressing the Therapy button to start Therapy mode.
 - or 2) Pressing the Therapy button while the Test mode is still active.

Note: Test mode is a prerequisite to Therapy mode.

- To ensure optimal treatment, the default current setting for Therapy mode will be the final current setting in Test mode. However, the Current Adjustment button can be used to increase or decrease the current level at any time during Therapy mode.

- Therapy mode time is automatically set for 30 minutes.
- When the therapy time has elapsed, Therapy mode will automatically end, the current will be inactive, and the Stimulator (External Pulse Generator) will emit a series of three beeps.

8. Complete Treatment Session

- Turn off the Stimulator (External Pulse Generator) by holding down the Power button for approximately 2 seconds.
- Remove the Needle Electrode Clip from the Needle Electrode.
- Using a smooth, fluid motion, quickly remove the Needle Electrode from the leg. If bleeding occurs, apply slight pressure and bandage.
- Disconnect the Lead Wire from the Stimulator (External Pulse Generator) and properly dispose of Lead Set components.
- The treatment session is now complete.

TREATMENT FREQUENCY

- Conduct 12 treatments, typically once per week.
- After the initial 12 treatments, slowly increase the time between treatments, with the patient closely monitored for the return of symptoms.
- If symptoms reappear or increase in severity, the patient's treatment schedule should revert to the last previously effective treatment schedule.