

N-DO INJECTOR SYSTEM APPLICATION

CURVED NEEDLE FOR INJECTION OF BOTOX INTO THE BLADDER

INTRODUCTION

The mechanism of action of Botulinum Toxin is expressed by blocking the transmission of ACTH (acetyl–choline), mediator of muscle contraction of the moto-neuron ending nerve. The result is the relaxation of the innervated muscle fiber after local injection. The therapeutic effect is resolved through a relaxation of the affected muscle and generally promotes the solution of problems related to the pathophysiology of the organ concerned.

FOR THE BLADDER there are two indications:

- IDIOPATHIC OVERACTIVE BLADDER with symptoms of urinary incontinence, urgency and frequency, in adult patients who do not have an adequate response or are intolerant to anticholinergic drugs
- NEUROGENIC HYPERACTIVITY of the bladder detrusor due to stabilized lesion of the spinal cord, starting from the cervical regions to the lower levels or multiple sclerosis.

THE APPLICATION OF BOTULINUM TOXIN (BOTOX) INTO THE BLADDER IS RECOMMENDED BY EUROPEAN GUIDELINES (EAU) AND ITALIAN GUIDELINES (SIU).

DOSAGE AND ADMINISTRATION METHOD:

- In OVERACTIVE BLADDER are injected 100 Units/10ml with a needle guided by a cystoscope in the detrusor muscle fro about 2mm in order to perform 20 wheals distant 1 cm apart.
- In NEUROGENIC BLADDER are injected 200 Units/30 ml with a needle guided by a cystoscope in the detrusor muscle in order to perform 30 wheals with the same procedure.

N-DO INJECT CURVED NEEDLE ROLE:

- Botulinum toxin is a substance that has to be used with a lot of caution when calibrating precisely the dosages and when is administered in exactly 2 mm in the detrusor wall and not in the trine or at the base of the bladder.
- N-DO INJECT needles are reliable by an operator and patient safety point of view.
- Allow to operate in fluency and safety of regulatory parameters by the only manufacture of botulinum toxin (Botox - Allergan).
- Allows to declare that N-DO SYSTEM IS UNIQUE AND NOT PRODUCIBLE BY OTHERS.
- Since the N-DO INJECTOR has the following unique features in comparison with other needles:
 - CURVED NITINOL NEEDLE, allowing for maneuvers without angular impediments within the bladder lumen.
 - HANDLE-SLIDER with red signal (needle off) and green (needle in)
 - NEEDLE WITH GRADUATE OUTPUT with 2mm steps for each advancement. In this situation a single click of 2mm will allow the exact depth of arrival of the toxin.
 - ALLOWS TO PROGRAM A TOTAL OF 30 NJECTIONS
 - GRADUATED SHEATH that wraps the cannula needle holder, allowing the operator to control the depth of the N-DO INJECTOR locally
 - 4 Fr GAUGE OF THE CANNULA NEEDLE HOLDER
 - 45 CM LENGHT OF THE CANNULA NEEDLE HOLDER
 - Female Luer-Lock CONNECTOR TUBE for standard syringe, CURVED NEEDLE till 16mm lenght

FOR THE ABOVE IT IS REQUESTED THE ACQUISITION FOR THE UROLOGY DEPARTMENT.