

Durasphere[®] EXP

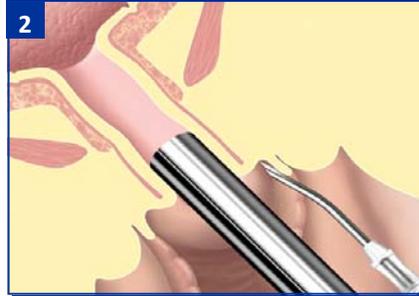
Periurethral Injection Procedure

Refer to instructions for use provided with Durasphere for complete directions.

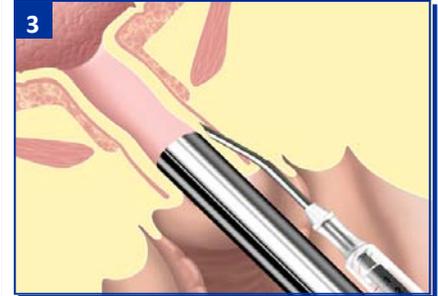
PROCEDURAL STEPS



The objective of the procedure is to obtain closure from the bladder neck to mid-urethra by injecting Durasphere until the tissue surrounding the bladder neck coacts. Using standard procedure, prepare the patient for cystoscopy.



Along the periurethral sinus, there are 2 dimples, each located at the 3 and 9 o'clock position within 1cm of the meatus. Position the needle tip at the dimple with the needle hub parallel to the scope. *NOTE: proximal half of the needle will be angled away from the scope.*



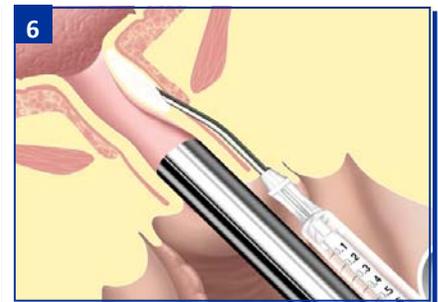
Penetrate the tissue and continue to advance the needle approximately 3cm, keeping the needle hub parallel with the scope. The 15° bend guides the tip in an arc to the submucosal tissue between the lamina propria and the muscularis.



After advancing, the needle tip should lie in the proximal urethra.



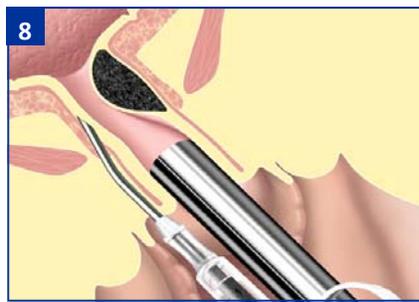
To verify placement of the needle tip in the submucosal tissue plane, look through the scope while gently wiggling the distal hub of the needle. Only the local area at the needle tip should tent.



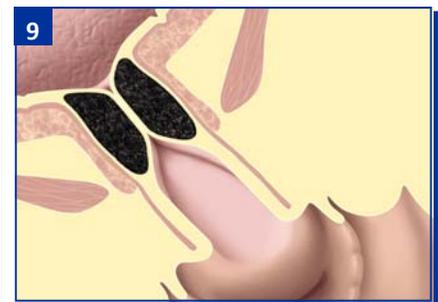
To hydrodissect, inject fluid into the site. Temporary bulking of the tissue should occur. If not seen, reposition more superficially and repeat injection of a small amount of fluid. Switch to the Durasphere syringe when the needle is in the proper position.



Begin injecting Durasphere using consistent light pressure on the plunger. While injecting, bulking of the tissue should be apparent. If circumferential closure of the bladder neck is occurring, continue to inject until complete coaptation is achieved.



If the Durasphere product is not flowing circumferentially, continue to inject into the site until the bulge has crossed the midline of the urethra. Reposition the needle on the opposing side and continue injecting. Most procedures will require 4 or more mls of Durasphere.



The objective is to obtain closure from the bladder neck to the mid-urethra. Continue to inject Durasphere until the tissue surrounding the bladder neck coacts. The bladder neck should be closed when viewing with cystoscopic irrigation on.