

ALIGN[®]


URETHRAL SUPPORT SYSTEM

ALIGN[®] TO

TRANSOBTURATOR URETHRAL SUPPORT SYSTEM

Make the
connection.





The ALIGN® Urethral Support System and ALIGN® TO Transobturator Urethral Support System are members of the Bard family of products—where insight and ingenuity meet research and agile thinking to create products, practices, and opportunities that serve both physicians and patients equally. At Bard we know that beyond knowledge lies intuition—the right questions, the right connections, and the means to revolutionize the future of women’s health treatment options.

From our research to your operating room, with the ALIGN® Support System, Bard connects your experience with our expertise. Built to make good even better. Designed to make what was useful, intuitive and integral.



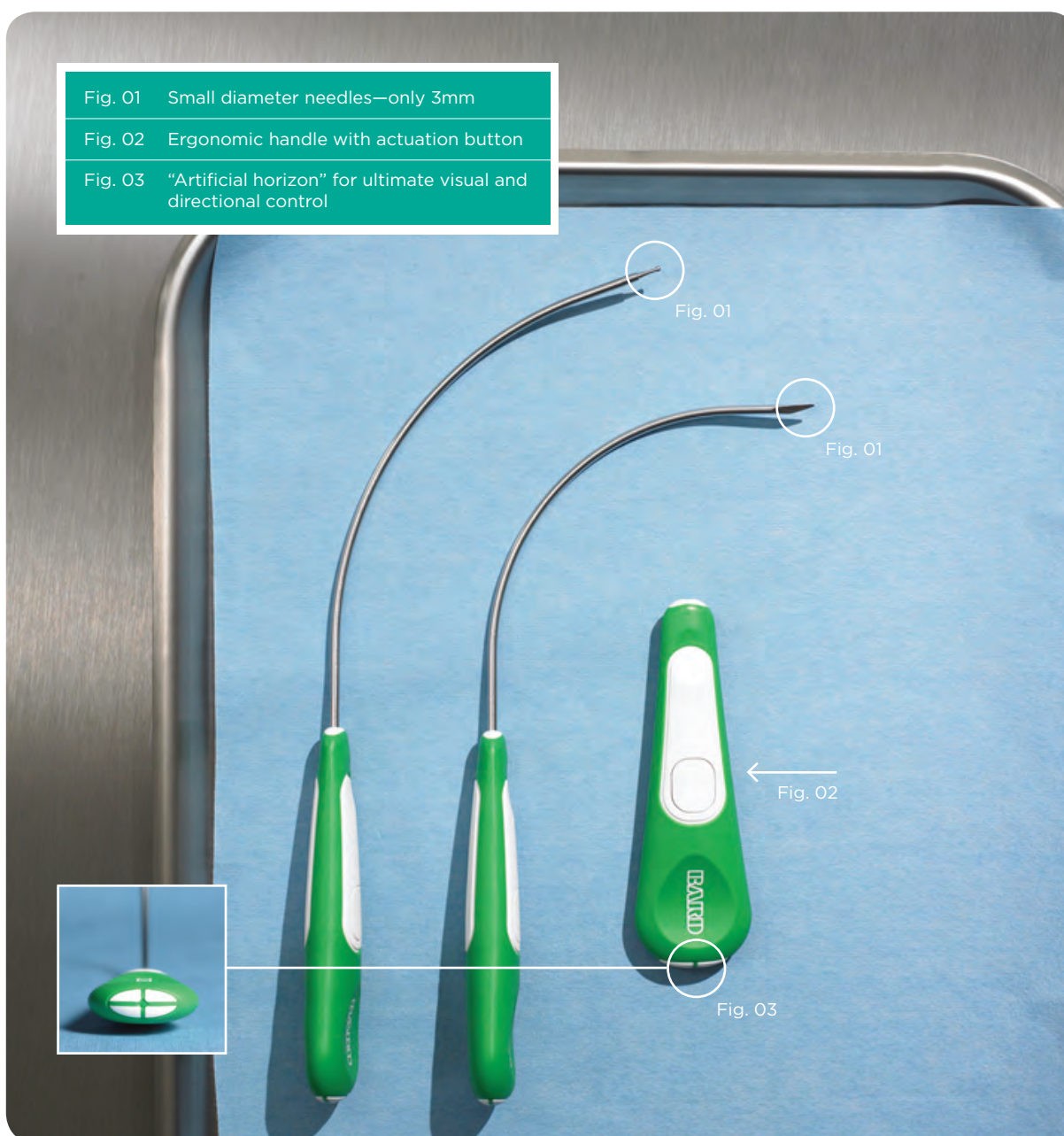
The mesh implant of ALIGN® Urethral Support System is designed with a dimensionally stable knit throughout the entire length of the graft. The implant is lightweight due to reduced density as compared to TVT®, and provides large pores to encourage tissue ingrowth.* The combination of stability and tension-free, self-anchoring support means resistance to deformation during placement.*



*Data on file as compared to URETEX® Mesh and TVT® System.

Mesh detail

Retropubic and Suprapubic introducers of the ALIGN® System have strong, low profile, small diameter 3mm needles. Built-in artificial horizons provide visual and directional aid for simple “pass, connect, and go” needle passage. Instrument handles are designed with the human hand in mind and feature ergonomically-placed finger depressions with easy to grasp rubberized grips.*



Suprapubic Needle and Introducer / Retropubic Needle and Introducer / Introducer

*Data on file based upon physician focus group and interviews.

The ALIGN® System's halo needle features an innovative multi-radius curve. The unique "S-curve" accommodates patient tissue, allowing for versatility and easy needle tip exteriorization based upon physician feedback. The needle operates in a single plane and features a spherical tip specifically designed for mid-urethral sling placement.



The ALIGN® System's sheath system, with intuitive push-on connectors allows seamless connection to the implant. The dual-colored tubing system encourages easy visualization during cystoscopy. Smart developments like a mid-point peel tab with an easy-release function help influence accuracy and controlled placement.



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Order Information		
Product Code	Description	Needle Type
BRD100R	ALIGN® R Urethral Support System	Retropubic
BRD200S	ALIGN® S Urethral Support System	Suprapubic
BRD300RS	ALIGN® RS Urethral Support System	Retropubic & Suprapubic
BRD400HK	ALIGN® TO Urethral Support System	Hook
BRD500HL	ALIGN® TO Urethral Support System	Halo
BRD600HH	ALIGN® TO Urethral Support System	Hook & Halo

Summary for ALIGN® Urethral Support System:

- Indication.** This product is indicated for the treatment of female stress urinary incontinence resulting for urethral hypermobility and/or intrinsic sphincter deficiency.
- Contraindications.** The use of ALIGN® Urethral Support System is contraindicated for patients experiencing urinary tract infection, anticoagulant therapy, infection in the operative field, and/or those who are pregnant.
- Warnings.** The procedure and instrumentation associated with the surgical placement of the ALIGN® Urethral Support System carry an inherent risk of infection and bleeding, as do similar urological procedures. The use of surgical staples or other mechanisms of attachment can damage the polypropylene mesh sling.
- Precautions.**
 - Accepted surgical practice must be followed for the management of contaminated or infected wounds. Postoperative retropubic bleeding may occur in some patients and must be controlled prior to patient release.
 - The implant procedure requires diligent attention to anatomical structure and care to avoid puncture of large vessels, nerves, bladder, and any viscera during introducer needle passage. Cystoscopy should be performed to confirm bladder integrity or recognize a bladder perforation. Proper placement of the mesh sling requires that it lies flat at mid-urethra with minimal or no tension under the urethra. Patients should be advised that pregnancy following a mesh sling implant procedure may negatively affect the success of the procedure and incontinence may reoccur.
- Potential Complications.** As with any surgical procedure, inherent risks are present. Complications associated with the proper implantation of ALIGN® Urethral Support System may include postoperative hematoma, urinary retention, bladder outlet obstruction, and voiding dysfunctions resulting from over-correction with the implant. Perforations or lacerations of vessels, nerves, bladder or any viscera may occur during the implantation procedure. Irritation may occur at the operative wound site and may elicit a foreign body response that leads to inflammation, infection or erosion of implant.

Please consult product insert for more detailed safety information and instructions for use.

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1206-05 R06/12 THP P06/12 2.5M