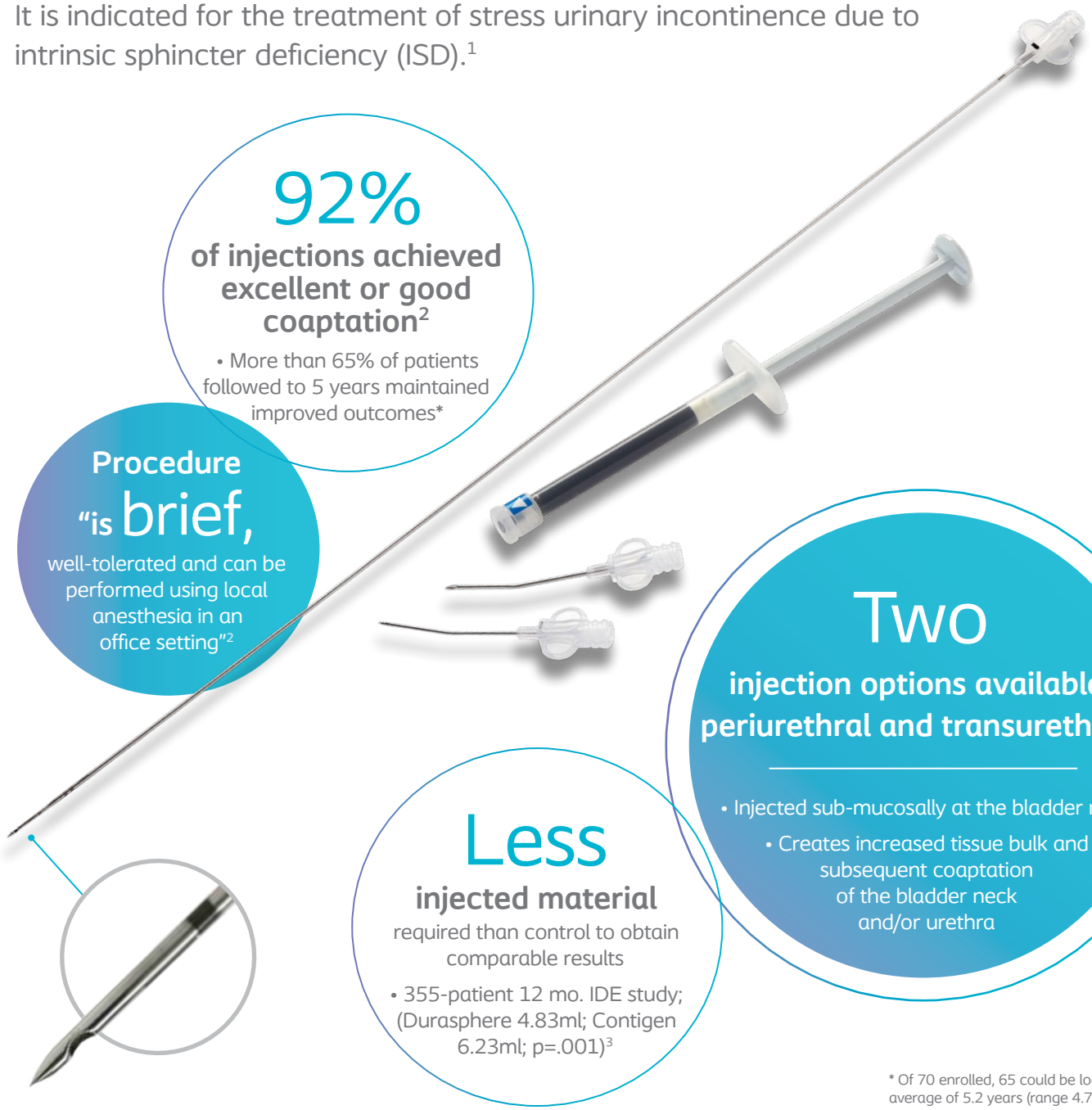
Durasphere® EXP

Injectable Bulking Agent

FEMALE STRESS URINARY INCONTINENCE

PURPOSEFUL OPTIONS

Durasphere® EXP is an injectable bulking agent containing pyrolytic carbon-coated graphite beads suspended in a water-based carrier gel. It is indicated for the treatment of stress urinary incontinence due to intrinsic sphincter deficiency (ISD).[1]



92%

of injections achieved excellent or good coaptation[2]

- More than 65% of patients followed to 5 years maintained improved outcomes*

Procedure "is brief, well-tolerated and can be performed using local anesthesia in an office setting"[2]

Two

injection options available: periurethral and transurethral[1]

- Injected sub-mucosally at the bladder neck
- Creates increased tissue bulk and subsequent coaptation of the bladder neck and/or urethra

Less

injected material required than control to obtain comparable results

- 355-patient 12 mo. IDE study; (Durasphere 4.83ml; Contigen 6.23ml; p=.001)[3]

* Of 70 enrolled, 65 could be located at an average of 5.2 years (range 4.7 - 6 years)

Coloplast Delivers Confidence

It all started in 1954 with Elise Sorensen, a nurse who wanted to help her sister regain confidence and control. After having an ostomy operation, her sister was afraid to go out in public for fear of leakage. Elise worked with engineer Aage Louis-Hansen to develop the world's first adhesive ostomy bag for greater protection and control. Today, Coloplast is an environmentally conscious global leader in ostomy care, wound and skin care, and urology care products that improve lives for millions of people around the world.

To Order Call Toll Free 800.258.3476

This product may be ordered directly from Coloplast.

Transurethral Technique

Product	Description	Order Number
Durasphere® EXP	Syringe: 1 ml	890-215
	Needle: 15 inch, pencil point tip; 20 gauge	890-209

Periurethral Technique

Product	Description	Order Number
Durasphere® EXP	Syringe: 3 ml	890-216
	Needle: 1.5 inch, spinal tip; 18 gauge	890-204

DURASPHERE® EXP – INJECTABLE BULKING AGENT

Indication:

Durasphere is indicated for use in the treatment of adult women with stress urinary incontinence (SUI) due to intrinsic sphincteric deficiency (ISD).

Contraindications:

Durasphere must not be used in patients with acute cystitis, urethritis, or other acute genitourinary infection.

The use of Durasphere with needles other than those recommended in the DFU may result in Durasphere beads clogging the injection needle.

Warnings:

Do not inject Durasphere into blood vessels. Injection of Durasphere into blood vessels may cause vascular occlusion, platelet aggregation, infarction or embolic phenomena.

Durasphere should not be used in patients with bladder neck or urethral strictures until such strictures have been corrected. Use of Durasphere on uncorrected strictures may cause occlusion.

The safety and effectiveness of Durasphere treatment during pregnancy has not been established. The effect of Durasphere on subsequent pregnancy and delivery, and the impact of subsequent pregnancy on the effectiveness of Durasphere, is unknown. Therefore, the risks and benefits of the device in women of childbearing potential could be carefully assessed.

Durasphere containing pyrolytic carbon coated graphite beads is not visible under X-ray and requires magnetic resonance imaging (MRI) for visualization.

Precautions:

The treatment procedure and instrumentation associated with the injection of Durasphere carry a small risk of infection and/or bleeding, as do similar urologic procedures. The usual precautions associated with urologic procedures, specifically cystoscopy, should be followed.

Durasphere is supplied steam sterilized in sealed package and is intended for single use only. Carefully examine the unit to verify that neither the contents nor the sterile package has been damaged in shipment. Do not use if damaged. Immediately return damaged product to Carbon Medical Technologies.

Do not re-sterilize. This may damage or distort contents. Unless the packaging is damaged, Durasphere will remain sterile until used.

Do not expose to organic solvents, ionizing radiation or ultraviolet light. This may damage or distort contents.

Rotate inventory so that product is used prior to the last day of the labeled month of the expiration date on package label.

After use, treatment syringes and needles may be potential biohazards. Handle accordingly and dispose of in accordance with accepted medical practice and applicable local, state and federal requirements.

Potential Complications:

Potential complications include acute retention, dysuria, urinary urgency, urinary tract infection, hematuria, non-acute retention, outlet obstruction (slow prolonged stream), excreted bulking material, GI (nausea, vomiting, diarrhea), genitourinary (infection, tenderness), urinary frequency, overbulking/abscess/cyst, infection, worsening of incontinence (onset of urge), neurological (headache), pelvic pain, allergic reaction to antibiotic, and fever.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, precautions, and adverse events refer to the product's Instructions for Use. Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company website at www.coloplast.us.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

References
1 Data on file at Coloplast.
2 Madjar et al; New Periurethral Bulking Agent for Stress Urinary Incontinence: Modified Technique and Early Results; Journal of Urology, 2001.
3 Lightner et al; A New Injecable Bulking Agent for Treatment of Stress Urinary Incontinence: Results of a Multicenter, Randomized, Controlled, Double-Blind Study of Durasphere®; Journal of Urology, 2001.

Ostomy Care
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