

SOURCELINK™ Connectors and Spacers

SYNTHETIC ABSORBABLE SEEDING SPACER LINKS

Bulk, Non-Sterile

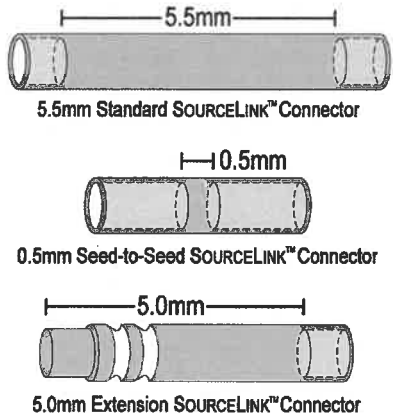
70:30 Poly(L-lactide-co-D,L-lactide)

Bard Brachytherapy, Inc.**Caution:**

Federal law restricts this device to sale by or on the order of a physician.

DESCRIPTION**Physical Characteristics**

SOURCELINK™ Connectors are synthetic absorbable monofilament seeding spacers that are designed to be assembled with BrachySource® seeds into connected trains of variable lengths and with seed-to-seed spacing as predetermined by the physician [Figure 1]. SOURCELINK™ Spacers are synthetic absorbable monofilament spacers that are placed between seeds to provide non-connected seed-to-seed spacing as predetermined by the physician. Both the SOURCELINK™ Connectors and SOURCELINK™ Spacers are composed of 70% L-lactide and 30% D,L-lactide copolymer. SOURCELINK™ Connectors are approximately 0.9mm in diameter and come in various sizes to provide accurate spacing of seeds in 0.5cm center-to-center increments. SOURCELINK™ Spacers are approximately 0.8mm in diameter and are available in lengths of 5.0mm and 5.5mm.

**In-Vivo Characteristics**

As body fluids initially come into contact with the SOURCELINK™ Connectors and SOURCELINK™ Spacers, they chemically react with the polymer to break the polymer chains through hydrolysis. The material is then metabolized.^{1,2,3}

INDICATIONS

SOURCELINK™ Connectors are indicated for use in seed spacing and linking in brachytherapy procedures. SOURCELINK™ Spacers are indicated for non-connected seed spacing in brachytherapy procedures.

CONTRAINDICATIONS

SOURCELINK™ Connectors and SOURCELINK™ Spacers, being absorbable, should not be used where permanent spacing or linking is required.

WARNINGS AND PRECAUTIONS

Warning: SOURCELINK™ Connectors and SOURCELINK™ Spacers are supplied non-sterile and must be sterilized prior to use using a validated gamma sterilization process that exposes the product to 25-40kGy. Do not steam sterilize SOURCELINK™ Connectors or SOURCELINK™ Spacers.

As with any foreign body, prolonged contact of this or any other synthetic absorbable material with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation.

Store SOURCELINK™ Connectors and SOURCELINK™ Spacers in their packaging at room temperature. Do not store SOURCELINK™ Connectors or SOURCELINK™ Spacers at temperatures that exceed 40°C. Close the cap securely between use. The product has been shipped with an indicating desiccant. Discard the SOURCELINK™ Connectors or SOURCELINK™ Spacers if the blue desiccant turns pink.

Users should be familiar with procedures and techniques involving absorbable spacers and seed train products before using the SOURCELINK™ Connectors or SOURCELINK™ Spacers.

When handling this or any other synthetic absorbable material, care should be taken to prevent any damage to the material. Avoid crushing or crimping damage to the cup ends caused by the application of forceps or tweezers.

SOURCELINK™ Connectors are designed to provide accurate spacing in increments of 0.5cm with typical 4.5mm brachytherapy sources. Use of SOURCELINK™ Connectors with brachytherapy sources of other lengths will result in atypical spacing, e.g. use of a 5.5mm Standard SOURCELINK™ with a 5mm seed will result in 1.05cm center-to-center spacing.

Where additional spacing is desired on either end of the assembled seed train, the spacing must end with the male end of the 5.0mm Extension SOURCELINK™ to avoid crushing a SOURCELINK™ cup end during compression.

ADVERSE REACTIONS

Adverse side effects associated with the use of this device include: minimal acute inflammatory tissue reaction, calculus formation in urinary and biliary tracts in the event of prolonged contact with salt solutions such as urine and bile, and transitory local irritation.

INSTRUCTIONS FOR USE

Link brachytherapy seeds using the SOURCELINK™ Connectors to accurately space the seeds in 0.5cm increments. Refer to the graphical representation of linked seeds on the reverse side.

Assembly using an implant needle and 2 Implant needle stylets

Holding the SOURCELINK™ Connectors in the center of the link where there is solid monofilament material, place unlinked SOURCELINK™ Connectors and loose seeds into an implant needle in the desired sequence. A 5.5mm Standard SOURCELINK™ will provide 1.0cm center-to-center spacing. A 0.5mm Seed-to-Seed SOURCELINK™ will provide 0.5cm center-to-center spacing. A 5.0mm Extension SOURCELINK™ will add an additional 0.5cm to the center-to-center spacing when used in conjunction with a 0.5mm Seed-to-Seed SOURCELINK™ or a 5.5mm Standard SOURCELINK™.

Using two implant needle stylets, one in each end of the implant needle, apply a gradual compressive load of approximately 1kg to the stylets to seat the seeds in the open ends of the SOURCELINK™ Connectors. You will feel a slight change in pressure as each seed is seated within the open end of a SOURCELINK™. Once all seeds are properly seated, you will feel a significant increase in resistance. All seeds are then properly seated within the SOURCELINK™ Connectors. Remove the SOURCELINK™ train from the needle and visually inspect the spacing.

Following sterilization described below, the assembled SOURCELINK™ train is ready for implant.

Assembly using a SOURCELINK™ Loader

Refer to the SOURCELINK™ Loader package insert for additional assembly instruction. Following sterilization described below, the assembled SOURCELINK™ train is ready for implant.

HOW SUPPLIED

SOURCELINK™ Connectors and SOURCELINK™ Spacers are supplied non-sterile and undyed. SOURCELINK™ Connectors and SOURCELINK™ Spacers of different sizes are packaged separately in various quantities. SOURCELINK™ Connectors and SOURCELINK™ Spacers are packaged in polyethylene jars with indicating desiccant. Discard the SOURCELINK™ Connectors or SOURCELINK™ Spacers if the blue desiccant turns pink.

STERILITY

SOURCELINK™ Connectors and SOURCELINK™ Spacers are supplied non-sterile. SOURCELINK™ Connectors and SOURCELINK™ Spacers must be sterilized prior to use using a validated gamma sterilization process that exposes the product to 25-40kGy. SOURCELINK™ Connectors and SOURCELINK™ Spacers may be resterilized by gamma irradiation one additional time at 25-40kGy.

GRAPHICAL REPRESENTATION OF LINKED SEEDS

Refer to the graphical representation of linked seeds on the reverse side.

REFERENCES

1. Domb, A.J., Kost, J., and Wiseman, D.M.; *Handbook of Biodegradable Polymers*; 1996, Harwood Academic Publishers; The Netherlands, pp. 3-27, pp. 451-471.
2. Claes, L.E., Ignatius, A.A., Rehm, K.E. and Scholz, C., *New Bioresorbable pin for the reduction of small bony fragments: design, mechanical properties and in vitro degradation, Biomaterials* (1996) 17, 1621-1626.
3. Rehm, K.E., Helling, H.J. and Claes, L.E., *Bericht der Arbeitsgruppe Biodegradabile Implantate, Aktuelle Traumatologie* (1994) 24, 70-74.

SYMBOLS USED ON LABELING



Caution



Use By



Batch number



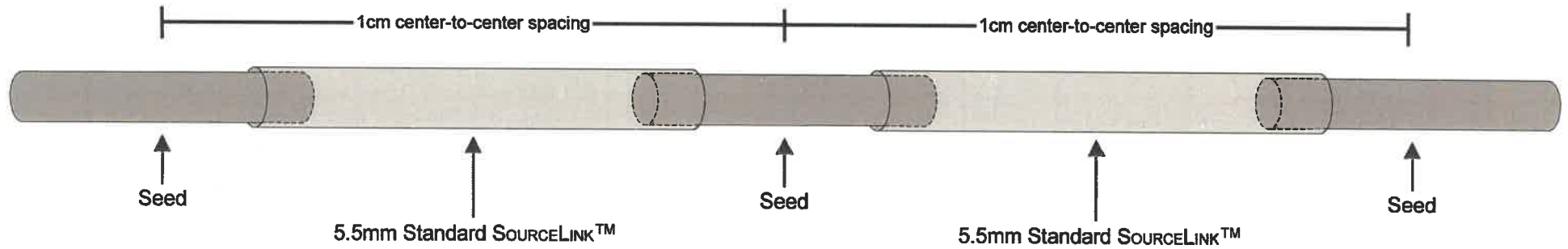
Reference Number

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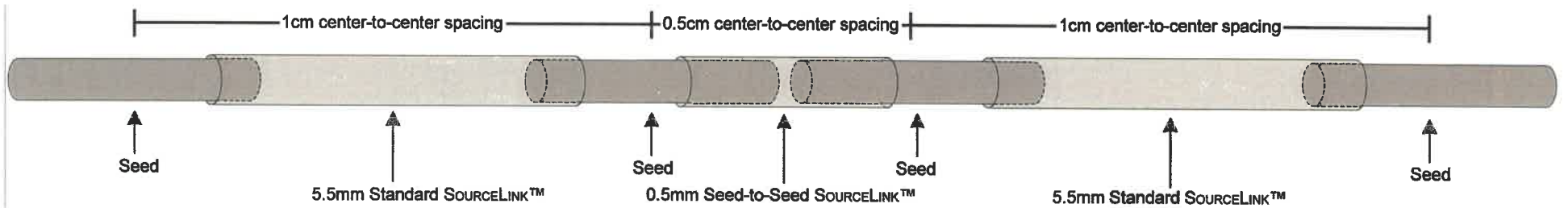
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GRAPHICAL REPRESENTATION OF LINKED SEEDS

Seeds linked with 5.5mm Standard SOURCELINK™ providing 1cm center-to-center spacing.



Seeds linked with 5.5mm Standard SOURCELINK™ and 0.5mm Seed-to-Seed SOURCELINK™, providing both 0.5cm center-to-center spacing and 1cm center-to-center spacing.



Seeds linked with 5.5mm Standard SOURCELINK™ and 5.0mm Extension SOURCELINK™, providing 2cm center-to-center spacing.

