



Your Total Prostate Brachytherapy Solutions

With the resources of a global oncology leader and innovator



As your Partner, we provide you with seeds, delivery systems and needles, but also with the needed equipment and accessories to safely and accurately perform any Brachytherapy procedure



BD

Advancing the
world of health

Brachy seeds, connectors and caps



BrachySource™

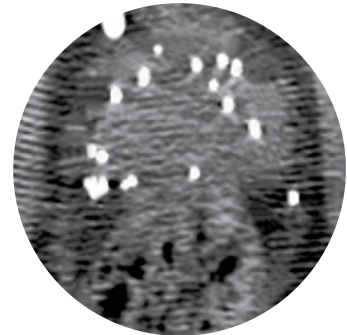
Iodine-125 Seed



Innovative design, reliable dosimetry and remarkable visibility

From the company that offers you the most comprehensive array of brachytherapy products and services available today, comes an advancement in seed technology and performance: the BrachySource™ I-125 implant.

A combination of innovative design, consistently reliable dosimetry and remarkable visibility make BrachySource™ I-125 implant an ideal choice for your brachytherapy patients. You can be confident that every BrachySource™ I-125 implant order is backed by the total support and seed management services required by clinicians who must meet the time-critical demands of brachytherapy.



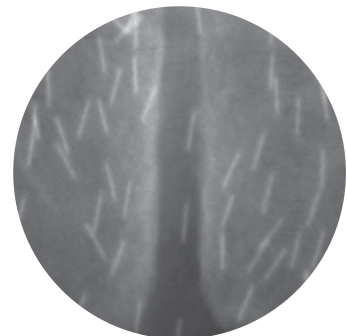
Clear CT visualization

Innovative design

- 3.8mm gold radiopaque marker.
- For greater radiation safety, BrachySource™ I-125 implants feature a titanium hull approximately 50% thicker than a leading brand of iodine-125 seed.
- 100% assay helps assure a consistently accurate activity level.

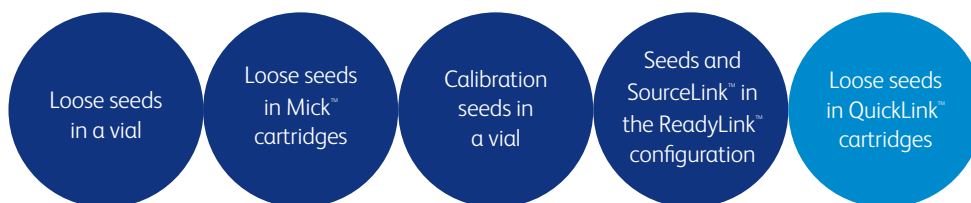
Exceptional quality

- Unique gold-core radiopaque marker inside each seed is 30% longer than a leading brand of iodine-125 seed, producing exceptional radiopacity under fluoroscopy.
- Minimal CT distortion and shadowing facilitates accurate post-implant dosimetry.



Exceptional fluoroscopic visibility

Delivered the way you want them



Supplied sterile (Gamma irradiation)



Connectors

A customized approach to performing stranded implants



The SourceLink™ System offers a customized approach to performing stranded implants. It addresses the challenges associated with current stranded products as well as provides the flexibility of seed and spacer implant techniques.

Functional characteristics

- The bioabsorbable SourceLink™ connectors are offered in three different lengths, which allow for variable spacing.
- SourceLink™ connectors easily lock together and snap apart from seeds, allowing easy loading and changes.
- Composed of 70:30 poly (L-lactide-co-D, L-lactide). Used routinely in bioabsorbable-implanted devices. Complete degradation of the materials does not occur for 18 to 24 months.
- Unlike stranded seed products that must be purchased in sets of ten, SourceLink™ connectors come ready to use individually, helping to eliminate waste in excess seeds.
- SourceLink™ material remains structurally intact for 170 days, allowing most of the dose to be delivered to the gland while the source is still held in its place of original placement.
- Works well in the needles: SourceLink™ connectors have a high column strength and do not readily absorb moisture.

SourceLink™ connectors in pre-loaded needles are available for customers who want product that is delivered ready for implant. The product arrives with Iodine seeds and SourceLink™ connectors configured to your plan.

All pre-loaded needle configurations are prepared under strict quality guidelines and shipped in lead-free packaging.

Brachy seeds, connectors and caps



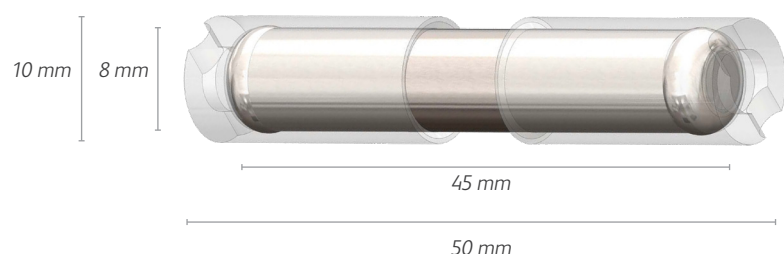
SourceCap™

Bioabsorbable Caps

A unique geometry creates increased resistance to motion, resulting in increased fixity at and following placement

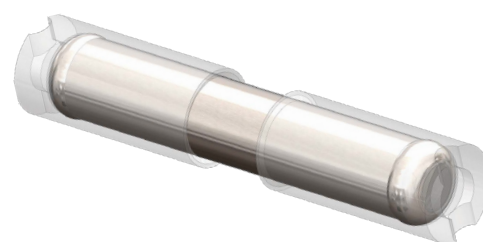
An advanced approach to performing seed implants. The key to delivering quality prostate brachytherapy is placing the sources where you need them and keeping them there.

The Sourcecap™ Bioabsorbable endcaps are designed to maximize resistance to movement while being compatible with your current delivery techniques. Sourcecap™ endcaps can be utilized with either BrachySource™ Iodine or Theraseed™ Palladium implants, and can be used with your existing applicators or be custom loaded in needles.



SourceCaps™ bioabsorbable endcaps

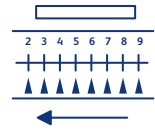
- Manufactured using bioabsorbable 70:30 poly (L-lactide-co-D, L-lactide) material (same as SourceLink™ System). The Sourcecap™ endcap material remains structurally intact for 170 days allowing most of the dose to be delivered to the gland with the sources still in place.
- 0.5 cm overall length to allow 1.0 cm standard and 0.5 cm seed-seed spacing
- Increased overall diameter and surface area to better “grip” tissue within the needle track.
- Seeds with Sourcecap™ endcaps can be delivered with existing applicator equipment or in preloaded needle configurations.
- The Sourcecap™ endcap material has no impact on the seed dosimetry



Delivery systems

ReadyLink™

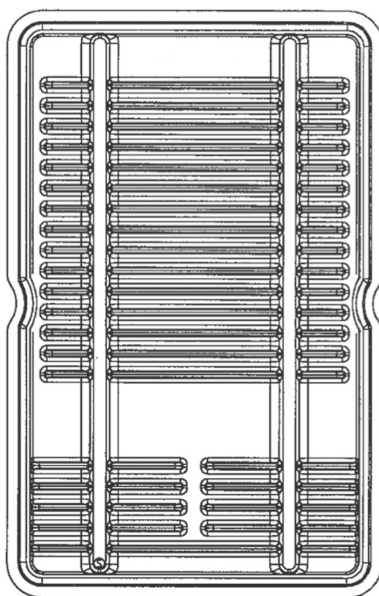
Delivery System



Combines the benefits of SourceLink™ connectors with the flexibility of on-site loading

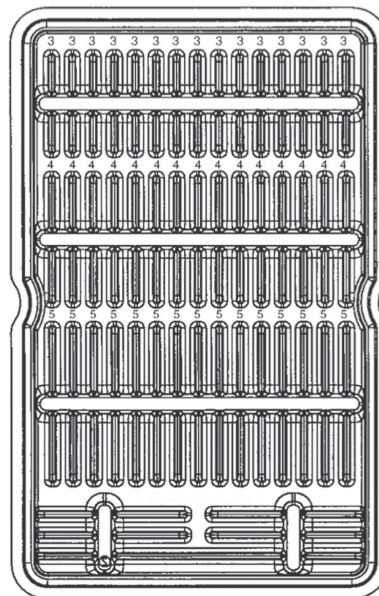
ReadyLink™ Delivery System is a next generation connected product that combines the benefits of SourceLink™ Connector System with the flexibility of on-site loading. The ReadyLink™ system offers customers 3 different loading options, standard, variable, and prescription to meet your various technique and logistical needs.

- Convenience of multiple delivery options
- Allows on-site needle loading
- Visual confirmation of load configurations
- Single shipment package with tweezers included



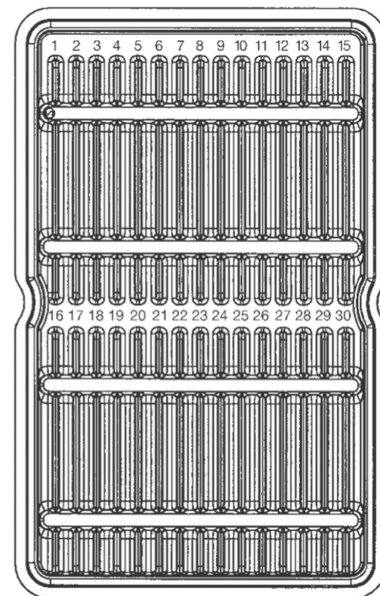
Standard

The standard tray allows for up to 15 trains of 10 seeds with standard spacing



Variable

The variable tray allows for up to 15 each standard spaced trains with 3, 4, or 5 seeds each



Prescription

The prescription tray allows for up to 30 needle loads configured in the customer manner

Delivery systems

QuickLink™

Delivery System

Offers the ultimate in connected seed versatility: combining the intraoperative procedure with a linked source

Taking the best of two approaches creating an **evolution in treatment** that means a revolution in patient care.

Offer your patients the most advanced brachytherapy treatment. The QuickLink™ Delivery System brings together connected sources with real-time planning opportunities. It's the best of both worlds.

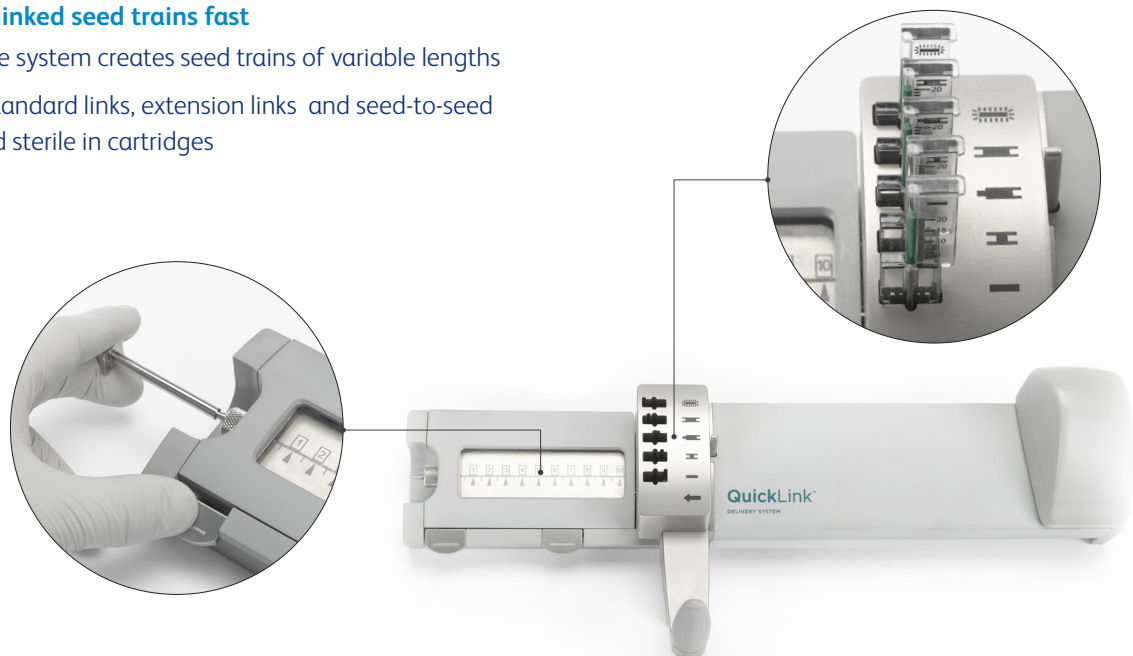
The QuickLink™ Delivery System makes building custom seed trains quick, simple, and safe. Quick enough to make real-time linked brachytherapy a viable option.

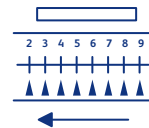
The QuickLink™ Delivery System delivers you the ultimate in brachytherapy control. Fully hands-on, mechanical, intuitive, and simple to use. This is a brachytherapy revolution. Faster. More efficient. Easier to create.

Take control.

Cartridges: Make linked seed trains fast

- Dial-and-dispense system creates seed trains of variable lengths
- Seeds, spacers, standard links, extension links and seed-to-seed links are delivered sterile in cartridges





Control outcomes

More targeted treatment, better results. The QuickLink™ Delivery System brings linked brachytherapy to a new frontier. Dynamic, fast, intuitive, and versatile, it opens the door to true, real-time linked brachytherapy. **Plan, build the train, and implant, all in the operating room, all in one efficient session.**

The QuickLink™ Delivery System delivers the benefits of a connected implant, with the advantages of real-time planning:

- Simple and intuitive for efficient loading
- Creates custom needle loads with variable spacing
- Requires no handling of individual seeds
- Allows easy verification of seed and link configurations
- For use only with SourceLink™ Connectors

Control errors

No automation. No glitches. The QuickLink™ Delivery System is fully manual, putting you in control. The cartridge and dial-and-dispense system allows you to remain very connected to the process—and enables each link and seed to be added to the current train with the simple push of a button. In addition, the proprietary SourceLink™ connector design allows you to easily alter configurations to meet a changing plan.

Finally, because there is no handling of individual seeds with the QuickLink™ Delivery System, radioactive exposure is minimized.

Control time

No counting. No handling. The QuickLink™ Delivery System is cartridge-based, and the dial-and-dispense mechanism is fast and intuitive. Seeds, links and spacers are already loaded in cartridges, limiting handling exposure. Easy-to-read indicators let you know how many seeds or links remain in each cartridge. The dial-and-dispense system makes linked seed trains fast and simple to create.

Finally, QuickLink™ cartridges are delivered sterile, requiring less preparation time.

Brachytherapy needles



BrachyStar™

Brachytherapy needle

Helping you achieve more precise, efficient implant delivery

Every BrachyStar™ Needle is designed to help you achieve one important goal: **an efficient and clinically effective brachytherapy procedure.** All needles are engineered for exceptional performance, featuring ultra-sharp tips and polished surfaces for smooth entry and exit. A broad selection of needle configurations and sizes assures an ideal match with procedural needs and personal preferences.



BrachyStar™ Implant Needles

Designed to help you achieve more precise, efficient implant delivery

- Double bevel tip promotes smooth insertion and tracking
- Optimizes stiffness/flexibility ratio to allow excellent tracking and precise placement
- Both 17G and 18G available



BrachyStar™ FastFill™ Needles

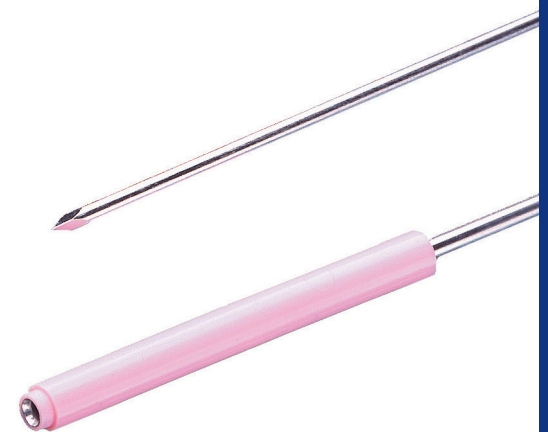
Designed to minimize prep time with fast spacer loading and pre-loaded plugs

- FastFill™ Plugged Needle eliminates need to plug needle prior to loading
- Double level tip promotes smooth insertion and straight tracking through fibrous tissue
- 18 G available

BrachyStar™ Applicator Seed Implant Needles

Specially designed for use with the Mick™ applicator.

- Trocar tip and cannula bevel provide for smooth insertion and straight tracking through fibrous tissue.
- Steel cannula “flare” to facilitate smooth seed insertion.
- Echogenic cannula tip.
- Shallow cutting angle on trocar.
- Proximal steel flare.
- Both 18 G and 17 G available.
- Ultraglide finish inside and outside of needle.





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Advancing the
world of health™

Instructions for use (IFUs)

BrachySource™ Seed Implants, Sterile

Indications for Use: BrachySource™ Seed Implants are indicated for permanent interstitial treatment of localized early-stage prostate tumors. BrachySource™ Seed Implants are indicated to treat residual tumors following completion of a course of external radiation therapy and for recurrent tumors. BrachySource™ Seed Implants loaded in Mick™ cartridges are designed for use with the Mick™ 200-TPV Applicator and with Bard® BrachyStar™ brachytherapy applicator needles.

Contraindications: As with other brachytherapy sources, treatment of tumors in generally poor condition [e.g., ulcerated] is not recommended with BrachySource™ Seed Implants due to the potential of brachytherapy source migration.

Warnings: BrachySource™ Seed Implants contain radioactive materials. BrachySource™ Seed Implants, like all radioactive materials, must be handled with care. Appropriate safety measures should be used to minimize exposure to clinical personnel. Personnel monitoring is required. Typically, a film badge or TLD dosimeter worn on the body and a ring badge(s) is adequate. Care should be taken to minimize radiation exposure to patients and other individuals consistent with proper therapeutic management. During the implantation procedure, all practical

steps should be employed to maintain radioactive exposure as low as reasonably achievable. In circumstances such as surgery when protective barriers are not practical, operators must rely upon proper use of applicators, distance and speed to minimize radiation exposure. Initiate radiation surveys on all components upon completion of the seed implant. Applicable safety standards for personnel and the general public should be followed.

Never implant visibly damaged BrachySource™ Seed Implants. BrachySource™ Seed Implants should never be handled roughly or forced into any implant device, magazine or needle. Such force may damage the wall of the brachytherapy source, potentially causing release of I-125 into the environment or tissues surrounding an implanted brachytherapy source. BrachySource™ Seed Implants that have been visibly damaged in any way should be sealed in a container and the area monitored for potential I-125 contamination.

Biohazard: After use, the BrachySource™ Seed Implants and Mick™ cartridges are potential biohazards. Handle and dispose of in accordance with acceptable medical practice and with applicable laws and regulations.

BrachySource™ I-125 Implants with SourceCap™ Bioabsorbable Caps

Indications for Use: BrachySource™ Seed Implants with SourceCap™ Bioabsorbable Caps are indicated for permanent interstitial treatment of localized early-stage prostate tumors. BrachySource™ Seed Implants are indicated to treat residual tumors following completion of a course of external radiation therapy and for recurrent tumors.

Contraindications: As with other brachytherapy sources, treatment of tumors in generally poor condition [e.g., ulcerated] is not recommended with BrachySource™ Seed Implants with SourceCap™ Bioabsorbable Caps due to the potential of brachytherapy source migration. SourceCap™ Bioabsorbable Caps being bioabsorbable, should not be used where permanent spacing is required.

Warnings: BrachySource™ Seed Implants with SourceCap™ Bioabsorbable Caps contain radioactive materials. BrachySource™ Seed Implants with SourceCap™ Bioabsorbable Caps, like all radioactive materials, must be handled with care. Appropriate safety measures should be used to minimize exposure to clinical personnel. Personnel monitoring is required. Typically, a film badge or TLD dosimeter worn on the body and a ring badge(s) is adequate. Care should be taken to minimize radiation exposure to patients and other individuals consistent with proper therapeutic management. During the implantation procedure, all practical steps should be employed to maintain radioactive exposure as low as reasonably achievable. In circumstances such as surgery when protective barriers are not practical, operators must rely upon proper use of applicators, distance, and speed to minimize radiation exposure.^{6,7,8,9} Any manipulation of the seeds or the

needles should be performed behind shielding of adequate thickness. The seeds should be handled with forceps only, and with as much distance as practical between the seed and the operator. Initiate radiation surveys on all components upon completion of the seed implant.

Never implant visibly damaged BrachySource™ Seed Implants with SourceCap™ Bioabsorbable Caps. BrachySource™ Seed Implants with SourceCap™ Bioabsorbable Caps should never be handled roughly or forced into any implant device, magazine or needle. Such force may damage the wall of the brachytherapy source, potentially causing release of I-125 into the tissues surrounding an implanted brachytherapy source or into the environment. BrachySource™ Seed Implants that have been visibly damaged in any way should be sealed in a container and the area monitored for potential I-125 contamination.

SourceCap™ Bioabsorbable Caps. 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. Do not store the seed / SourceCap™ assemblies at temperatures above 40°C.

Mick™ Cartridges. Do not handle Mick™ cartridges by the spring-loaded plunger. Do not exceed the maximum loading capacity per cartridges (15 seeds). Do not overtighten the round Mick™ cartridges head. Do not let seeds drop into cartridges groove. Do not use force on seeds or cartridges. Do not force cartridges into applicator, and do not forcibly remove cartridges from applicator.

ReadyLink™ Delivery System with BrachySource® I-125 Implants

Indications for Use: SourceLink™ Connectors are indicated for use in seed spacing and linking in brachytherapy procedures.

Contraindications: SourceLink™ Connectors that are absorbable, should not be used where permanent spacing or linking is required.

Warnings: SourceLink™ Connectors. 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.

QuickLink™ Delivery System

Indications for Use: The QuickLink™ Delivery System is indicated for use with SourceLink™ Connectors, spacers and brachytherapy seeds in the assembly of seed trains of variable lengths and predetermined spacing between the seeds for use in brachytherapy procedures. SourceLink™ Connectors are indicated for use in seed spacing and linking in brachytherapy procedures. The BioSpacer™ seeding spacer is for use in seed approximation in brachytherapy procedures.

Contraindications: SourceLink™ Connectors, being absorbable, should not be used where permanent spacing or linking is required. The BioSpacer™ seeding spacer, being absorbable, should not be used where extended approximation of tissue is required.

Warnings: Potential calculus formation with absorbable materials. As with any foreign body, prolonged contact of synthetic absorbable material, including SourceLink™ Connectors and BioSpacer™ Seeding Spacers, with salt solutions, such as those found in the biliary or urinary tracts, may result in calculus formation.

Potential biohazard: After use, the QuickLink™ Delivery System components may become biohazardous. Handle per accepted medical practice and within applicable laws and regulations. The QuickLink™ Delivery System loader is reusable, and the loader components must be thoroughly cleaned and sterilized prior to use and between uses.

Radioactive materials / Lead components: The QuickLink™ Delivery System components and the contained brachytherapy seeds should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclide brachytherapy sources and whose training and experience have been approved by the appropriate authorities authorized to license the use of radioactive materials. Use appropriate radiation safety protection practices when working with the QuickLink™ Delivery System components that contain radioactive materials. Initiate radiation surveys on the QuickLink™ Delivery System components at the completion of the brachytherapy procedure to ensure complete removal of radioactive materials. The shielding glass contains lead and must be disposed of according to local regulations.

BrachyStar™ Brachytherapy Applicator Seed Implant Needle

Indications for Use: For placement of radioactive seeds in transperineal implant procedures.

Warnings: After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and with applicable laws and regulations.

This is a single use device. Do not re-sterilize any portion of this device. Reuse and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness, or death of the patient.

Please consult BD product labels and inserts for any indications, contraindications, hazards, warnings, cautions and instructions for use.

Ordering information

QuickLink™ Delivery System

Loader and accessories

Catalogue No.	Description
70310QCA1	QuickLink™ loader
70310SGA5	QuickLink™ relay rack
70310SGA4	QuickLink™ relay for BrachyStar™ needles, clipped
70310SGA6	QuickLink™ relay stylet
70310QCC1	QuickLink™ stylet
70310QCA6	QuickLink™ replacement glass
70310QCA5	QuickLink™ primary adapter, locked

Seeds and connectors

Catalogue No.	Description	Pack size
1251QCSC	I-125 QuickLink™ cartridge, sterile	Single
70301QC20	QuickLink™ standard link cartridge (SourceLink™ connector)	20 per cartridge
70302QC10	QuickLink™ seed-to-seed link cartridge (SourceLink™ connector)	10 per cartridge
70301QC5	QuickLink™ standard link cartridge (SourceLink™ connector)	5 per cartridge
70302QC5	QuickLink™ seed-to-seed link cartridge, SourceLink™ Connector	5 per cartridge
70303QC10	QuickLink™ extension link cartridge (SourceLink™ connector)	10 per cartridge
70303QC20	QuickLink™ extension link cartridge (SourceLink™ connector)	20 per cartridge

Needles

Catalogue No.	Description	Pack size
718205	Bard® BrachyStar™ Brachytherapy seed implant needle 18 G	50 per case
718201	Bard® BrachyStar™ Brachytherapy seed implant needle 18 G	10 per case

Mick™ Applicator

Accessories

Catalogue No.	Description
1251CCEF	BrachySource™ seed implants loaded in disposable shielded Mick™ magazines, sterile

Seeds

Catalogue No.	Description
PS1251CCE	I-125 QuickLink™ cartridge, sterile
PS1251KCE	BrachySource™ seed implants single, calibrated, BrachySource™ seed implants, sterile
PS1251LCE	BrachySource™ seed implants loose seeds, sterile

Needles

Catalogue No.	Description	Pack size
718205	Bard® BrachyStar™ brachytherapy seed implant needle 18 G	50 per case
718201	Bard® BrachyStar™ brachytherapy seed implant needle 18 G	10 per case
918205	Bard® BrachyStar™ brachytherapy applicator needle 18 G	50 per case
918201	Bard® BrachyStar™ brachytherapy applicator needle 18 G	10 per case
917205	Bard® BrachyStar™ brachytherapy applicator needle 17 G	50 per case
917201	Bard® BrachyStar™ brachytherapy applicator needle 17 G	10 per case

ReadyLink™ Delivery System

Seeds

Catalogue No.	Description
1251RLCE	BrachySource™ seed implants ReadyLink™ delivery systems

Needles

Catalogue No.	Description	Pack size
718205	Bard® BrachyStar™ brachytherapy seed implant needle 18 G	50 per case
718201	Bard® BrachyStar™ brachytherapy seed implant needle 18 G	10 per case
918205	Bard® BrachyStar™ brachytherapy applicator needle 18 G	50 per case
918201	Bard® BrachyStar™ brachytherapy applicator needle 18 G	10 per case
917205	Bard® BrachyStar™ brachytherapy applicator needle 17 G	50 per case
917201	Bard® BrachyStar™ brachytherapy applicator needle 17 G	10 per case

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