The QuickLink® Delivery System is designed to be assembled with brachytherapy seeds, SourceLink™ synthetic spacers, and SourceLink™ Connectors in cartridges into seed trains of variable lengths and with variable seed-to-seed spacing as predetermined by the physician. The QuickLink® Loader is composed of stainless steel, GE Ultem® 1000 plastic, and shielding glass. SourceLink™ Connectors and SourceLink™ Spacers are synthetic absorbable monofilament seed spacing that are designed to be assembled with brachytherapy seeds into seed trains of variable lengths and with seed-to-seed spacing as predetermined by the physician [Figure 1]. They 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.

**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**

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 predetermied spacing between the seeds for use in brachytherapy procedures. SourceLink™ Connectors are indicated for use in seed spacing and linking in brachytherapy procedures. The SourceLink™ Connector spacer is used in seed approximation in brachytherapy procedures.

**CONTRAINDICATIONS**

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

**ADVERSE REACTIONS**

Adverse side effects associated with the use of SourceLink™ Connectors and SourceLink™ Spacers 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.

**HOW SUPPLIED**

The QuickLink® Delivery System loaded cartridges and components are supplied sterile. The cartridges are indicated for single use only. The QuickLink® Delivery System Loader is supplied non-sterile and must be sterilized in an autoclave before use.

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**HOW SUPPLIED**

The QuickLink® Delivery System loaded cartridges and components are supplied sterile. The cartridges are indicated for single use only. The QuickLink® Delivery System Loader is supplied non-sterile and must be sterilized in an autoclave before use.
Caution: Storage requirements are temperature dependent
Extra care should be taken to avoid exposing the QUICKLINK® cartridges containing bioabsorbable SOURCELINK™ components to excessive heat or moisture. Store unopened packages at room temperature. Discard open, unused cartridges, SOURCELINK™ Connectors, and SOURCELINK™ Spacers.

Do not store bioabsorbable components at temperatures that exceed 40°C.

Caution: Elevated temperatures following loader steam sterilization
After sterilization, allow the QUICKLINK® Delivery System loader components to cool to room temperature prior to use.

Caution: Avoid damaging the system or using damaged materials
- Never use visibly damaged, bent or broken QUICKLINK® Delivery System loaders, cartridges or components. This may cause system damage or jamming.
- Do not force cartridges into the carriage slots. The slots are keyed to accept the appropriate cartridges, and minimal effort is required to properly seat the cartridges.
- 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.
- Ensure the needle adapter and stylet are finger-tight. Do not make any other adjustments to the QUICKLINK® Delivery System.
- Do not tamper with the mechanisms that reside beneath the carriage when removing the carriage from the loader. These components are aligned to rigid specifications, and must be handled carefully to maintain proper loader functionality.
- In the event the QUICKLINK® Loader or cartridges become inoperable due to damage or malfunction, any or all components may be removed from the cartridges and implanted manually.
- Do not adjust the indicator in the cartridge when the cartridge is loaded. The indicator provides a spring bias to the components to allow for dispensing in the loader, and lifting the indicator and allowing it to snap closed can damage the components and cartridge.
- Do not re-sterilize SOURCELINK™ Connectors or SOURCELINK™ Spacers either loose or in cartridges. The components are supplied sterile and indicated for single use. If desired, radioactive seeds may be removed from a cartridge and re-sterilized. Do not re-sterilize QUICKLINK® cartridges.

Caution: Limitations on use
The QUICKLINK® Delivery System is prescription use only. Users should be familiar with procedures and techniques involving absorbable spacers and seed train products before using the SOURCELINK™ Connectors. 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.

DIRECTIONS FOR USE

1. Remove the protective tab from the bottom of the QUICKLINK® cartridge prior to use by grasping the cartridge by the cartridge body and pulling the tab out of the side of the cartridge. To prevent inadvertent dispensing of a component, do not hold the cartridge body by the green plunger when removing the tab.

2. Insert the cartridges containing seeds, SOURCELINK™ Connectors, and SOURCELINK™ Spacers into the carriage. Ensure that the cartridges are fully seated in the cartridge receptacle. The cartridge and cartridges are marked as follows to indicate the correct placement of cartridges as well as the current selection:

3. Retract the compression slide handle to the right until it contacts the rear plate to seat the slide compression mechanism (if unsnapped).

4. Attach the implant needle to the QUICKLINK® Delivery System by pushing the needle hub firmly onto the needle adapter.

5. Move the carriage to select which item to dispense by aligning the indicator with the symbol indicating the desired item.

Note: The position of the Extension SOURCELINK™ Connector in the cartridge is accurately represented by the icon. Therefore, when spacing at either end of a seed train is desired, an Extension SOURCELINK™ Connector may only be used at the leading end of the train. Spacing at the trailing end of the train must be provided by one or more spacers.

6. Push the dispense button to dispense and move the selected item into the assembly track.

Note: During normal operation, the dispense button will return to the “up” position after a component is dispensed. If a cartridge is empty, the button will come to a stop before it reaches the bottom of its range of motion. Further pressing will cause the button to release from its internal mechanism to prevent damage to the cartridge. The button may be lifted to the “up” position to reset it to the internal mechanism, and the empty cartridge may be removed and replaced.

7. Repeat items 4-5 until all items necessary to build the predetermined seed train have been dispensed.

8. Visually inspect the dispensed components, if desired, through the lead glass door prior to assembly of the seed train. Incorrect components can be removed as necessary by opening the lead glass door to access the assembly track.

9. Move the carriage to the arrow symbol indicating that the QUICKLINK® Delivery System is ready to either compress or dispense a seed train.

10. Move the handle on the releasable slide left towards the carriage to compress the seed train. Continue motion in this direction until the slide handle releases and comes to a full stop.

11. Retract the slide to the right until it contacts the rear plate to seat the slide compression mechanism.

12. The assembled seed train may be inspected through the lead glass door, and proper seed spacing confirmed using the assembly base ruler.

13. Move the handle on the releasable slide left again towards the carriage while holding the gate button down in order to dispense the seed train through the needle adapter.

14. Retract the handle of the releasable slide fully to the right.

15. Remove the loaded implant needle by pulling the needle hub away from the needle adapter.

TROUBLESHOOTING

Condition: SOURCELINK™ Connectors not connected after compression
- Ensure compression slide has been fully reset before compression;
- Stylet bent – replace;
- The seed train is incorrectly built consisting of either two female or two male ends placed adjacent to each other;
- Ensure the SOURCELINK™ Connector material is not damaged preventing compression.

Condition: SOURCELINK™ Connectors are ejected from the loader during compression
- Ensure the lead glass cover is securely closed;
- Do not press the gate button during compression, allowing ejection of unlinked components through the needle adapter.

Condition: Pushing the dispense button does not eject any items or produces a partial dispense
- Ensure that the handle is not being pulled while the dispense button is being depressed. Pulling on the handle during dispensing can cause the cartridge to become misaligned with the dispense track, resulting in a lock out or a jam;
- Ensure the selected cartridge is fully seated in the corresponding cartridge receptacle;
- Remove cartridge from carriage and reinsert back into the cartridge;
- Ensure the dispense blade is not jammed - remove the cartridge and inspect dispense blade, verify there are no loose components;
- The selected cartridge is empty - replace with a full cartridge;
- The dispense button is not fully depressed - press button fully;
- If cartridge does not dispense following troubleshooting, replace cartridge.

Condition: The assembled seed train cannot be loaded into the attached implant needle
- Ensure that you hold the gate button down while sliding the releasable slide;
- Ensure the seed train has been properly built and does not include damaged components.

Condition: Implant needle does not stay attached to the needle adapter
- Ensure needle adapter is appropriate for the implant needle used.

Condition: Completed seed train does not load smoothly into the attached implant needle
- Ensure needle adapter is appropriate for the implant needle used.
**QUICKLINK® LOADER CLEANING, LUBRICATION AND STERILIZATION**

**Note:** Limitations on processing – Repeated cleaning and steam sterilization has minimal effect on the QUICKLINK® Loader. The QUICKLINK® Loader should be inspected for damage prior to use and replaced or repaired as necessary.

**Manual Cleaning:**
1. Point of Use - No particular requirements.
2. Containment and Transportation - No particular requirements.
3. Instrument Preparation - Remove the stylet and carriage from the QUICKLINK® loader. Open the lead glass door, and ensure that it remains open throughout the cleaning procedure. Remove any QUICKLINK® cartridges, loose seeds, spacers and SOURCELINK™ components.

**Note:** If loose seeds are found, immediately contact Radiation Safety for safe handling and disposal of the seeds.

4. Initial Rinse - Rinse the loader and accessories thoroughly with cool (25°C) tap water. Remove any excess soil by brushing with a soft bristle brush. Ensure all hard to reach areas are flushed.
5. Enzymatic Presoak - Prepare enough multi-tiered enzymatic cleaner solution (Ruhof Endozime® AW Plus or equivalent), following the manufacturer's instructions, to completely wet the QUICKLINK® loader and accessories. Thoroughly wet the loader and accessories with enzymatic cleaning solution and allow them to soak for a minimum of 5 minutes. Actuate the loader while in the cleaning solution to ensure the cleaning solution reaches the hard-to-reach areas.
6. Cleaning - Using a soft bristle brush, brush all accessible areas of the loader and accessories for a minimum of one minute to remove visible evidence of debris or soil. Actuate the loader while brushing to ensure the solution reaches the hard-to-reach areas.
7. Rinse - Rinse the loader and accessories thoroughly with cool (25°C) tap water until there is no visible evidence of the cleaning solution. Actuate the loader while rinsing to ensure the rinse water reaches the hard-to-reach areas.
8. Repeat - Repeat Steps 5-7 once, for a total of 2 Presoak/Cleaning/Rinse cycles.
9. Visual Inspection - Inspect the instrument to ensure that all debris and soil has been removed. If there is any evidence of debris or soil, repeat all of the aforementioned steps until there is no evidence of debris or soil remaining. For devices that fail visual inspection, contact Bard Brachytherapy, Customer Service at (800) 977-6733.
10. Drying – Drying can be performed at temperatures below 135°C.
11. Maintenance and Inspection – Verify that the QUICKLINK® loader and carriage are free from obvious defects or damage. Verify that the stylet is straight. Verify that the lead glass door has adequate visibility. Verify that the slide compression mechanism and release are working properly. Replace the loader and/or components as necessary.

**Automated Cleaning:**
1. Point of Use - No particular requirements.
2. Containment and Transportation - No particular requirements.
3. Instrument Preparation - Remove the stylet and carriage from the QUICKLINK® loader. Open the lead glass door, and ensure that it remains open throughout the cleaning procedure. Remove any QUICKLINK® cartridges, loose seeds, spacers and SOURCELINK™ components.

**Note:** If loose seeds are found, immediately contact Radiation Safety for safe handling and disposal of the seeds.

4. Initial Rinse - Rinse the loader and accessories thoroughly with cool (25°C) tap water. Remove any excess soil by brushing with a soft bristle brush. Ensure all hard to reach areas are flushed.
5. Enzymatic Presoak - Prepare enough multi-tiered enzymatic cleaner solution (Ruhof Endozime® AW Plus or equivalent), following the manufacturer’s instructions, to completely wet the QUICKLINK® loader and accessories. Thoroughly wet the loader and accessories with enzymatic cleaning solution and allow them to soak for a minimum of 5 minutes. Actuate the loader while in the cleaning solution to ensure the cleaning solution reaches the hard-to-reach areas.
6. Manual Clean - Using a soft bristle brush, brush all accessible areas of the loader and accessories for a minimum of one minute to remove visible evidence of debris or soil. Actuate the loader while brushing to ensure the solution reaches the hard-to-reach areas.
7. Rinse - Rinse the loader and accessories thoroughly with cool (25°C) tap water until there is no visible evidence of the cleaning solution. Actuate the loader while rinsing to ensure the rinse water reaches the hard-to-reach areas.
8. Washer-Disinfector Cleaning - Place the open loader and accessories in the washer-disinfector. Process the instruments according to the following cycle:
   - **Phase:** Pre-Wash
   - **Recirculation Time (min):** 60
   - **Water temperature:** Cold tap water: 61°F (16°C) Maximum
   - **Detergent Type:** (if applicable) N/A

9. Visual Inspection - Inspect the instrument to ensure that all debris and soil has been removed. If there is any evidence of debris or soil, repeat all of the aforementioned steps until there is no evidence of debris or soil remaining. For devices that fail visual inspection, contact Bard Brachytherapy Customer Service at (800) 977-6733.
10. Drying – Drying can be performed at temperatures below 135°C.
11. Maintenance and Inspection – Verify that the QUICKLINK® loader and carriage are free from obvious defects or damage. Verify that the lead glass door has adequate visibility. Verify that the slide compression mechanism and release are working properly. Replace the loader and/or components as necessary.

**QUICKLINK® Loader Lubrication Procedure**

BAR® recommends lubricating the QUICKLINK® loader before each use. Lubricant should be applied prior to sterilization. The recommended lubricant is Milltex® Spray Lube (REF 3-700, available from Milltex Inc., York PA).

**Instructions for applying lubricant to loader**
1. Remove stylet if present and close the lead glass door if open. Always apply lubricant with lead glass door closed to prevent lubricant from getting on the dispensate track.
2. Remove carriage from loader.
3. The holes on the underside of the loader indicated by 1 (see figure below) are points where a single spray should be applied in each hole.
4. Hold lubricant spray bottle 1”-2” from surfaces 2 and 3 (see figure below) and apply with a single spray pump at each location.
5. After applying lubricant to areas indicated, any excessive lubricant should be wiped away with a lint free cloth.
6. Mount carriage back on loader and actuate back and forth.
7. Actuate compression slide handle forward and back.

**Sterilization:**

Caution: Key points for use of the QUICKLINK® Delivery System
- **DO NOT** sterilize by irradiation
- **DO NOT** process the QUICKLINK® loader and accessories at temperatures above 135°C
- **DO USE** appropriate personal protective equipment as dictated by facility protocol
- Prior to sterilization, the QUICKLINK® loader and accessories should be properly cleaned and lubricated (loader only)
- For sterilization, the QUICKLINK® loader must be sterilized with the lead glass door open

**Sterilization Preparation**
Wrap loader and accessories individually with hospital sterilization wrap and secure with autoclave tape prior to sterilization. Ensure the lead glass door of the loader is in the open position prior to wrapping.

**Sterilization conditions – The QUICKLINK® Loader and accessories should be sterilized using one of the following sterilization cycles:**

**Gravity Displacement Autoclave**

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Full Cycle Exposure Time</th>
<th>Dry Time (in chamber)</th>
<th>Cool Down Time at Room/Ambient Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>275°F (135°C)</td>
<td>10 minutes</td>
<td>N/A</td>
<td>30 minutes</td>
</tr>
</tbody>
</table>

**Pre-Vacuum Autoclave**

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Full Cycle Exposure Time</th>
<th>Dry Time (in chamber)</th>
<th>Cool Down Time at Room/Ambient Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>275°F (135°C)</td>
<td>5 minutes</td>
<td>N/A</td>
<td>30 minutes</td>
</tr>
<tr>
<td>273°F (134°C)</td>
<td>18 minutes</td>
<td>N/A</td>
<td>30 minutes</td>
</tr>
<tr>
<td>270°F (132°C)</td>
<td>4 minutes</td>
<td>N/A</td>
<td>30 minutes</td>
</tr>
<tr>
<td>265°F (130°C)</td>
<td>3 minutes</td>
<td>N/A</td>
<td>30 minutes</td>
</tr>
</tbody>
</table>

1. **Storage –** Store at room temperature.
2. **Additional information –** When sterilizing multiple instruments in one autoclave cycle, ensure the sterilizer’s maximum load is not exceeded. The instructions above have been validated by BAR® as being capable of preparing the QUICKLINK® loader for re-use. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel in the processing facility achieves the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.
3. **Instrument Reassembly –** After sterilization, replace carriage, stylet, and needle adapter accessories prior to use. Ensure carriage slides freely.
QuickLink® Loader Spare Parts

The QuickLink® Delivery System Spare Parts are intended for changing the compatibility of the QuickLink® Delivery System with various commercially available implant needles or for replacement of damaged parts. Available spare parts are described below:

**Styles:** [Part Number 70310QCC1]

The stylet is manufactured of stainless steel and designed to compress the seeds and SecureLink™ Connectors into a seed train. The stylet may become bent over time and may require replacement. It is equipped with a Luer-lock fitting and can be easily replaced if needed.

**Lead Glass:** [Part Number 70310QCA6]

The lead glass in the lead glass door is designed to protect the operator from radiation exposure. The lead glass might become clouded over time due to the sterilization process and may require replacement if visualization of the compression channel is prevented.

**Needle Adapters**

Stainless steel adapters are provided for the attachment of implant needles to the QuickLink® Delivery System. The needle adapters may be changed as necessary to accommodate different styles of implant needles. The needle adapters available are:

- **Primary Needle Adapter** [Part Number 70310QCA2]
- **Primary Needle Adapter – Locked** [Part Number 70310QCA5]

**Compatible with the following needles:**

- **BARD® BRACHYSTAR® Needles 71620X, 81620X, 171850**
- **AVID Medical P/N AV1820PN**
- **CP Medical P/N CPSS1820**
- **CP Medical P/N PSPP-1820-PDO (Point Plug PDO™)**
- **Manan Medical Products P/N 2330-18ME-20-P**
- **Manan Medical Products P/N 2340-18BE-20-P**
- **Manan Medical Products P/N 2360MUS-18BE-20**
- **Medical Device Technologies (MD Tech) P/N 500518200X**
- **Med-Tec P/N MT-BT-5001-25**
- **NeedleTech Products P/N 40052-01E**
- **NeedleTech Products P/N 40087-01E**
- **Worldwide Medical Technologies P/N PSS1820**

**Luer Needle Adapter** [Part Number 70310QCA3]

**Compatible with the following needles:**

- **AVID Medical P/N AV1820ZN (Metal Hub Zebra™)**
- **Mentor P/N 97-1030 (Metal Hub)**
- **Mentor P/N 97-1040**

**Small Hub Needle Adapter** [Part Number 70310QCA4]

**Compatible with the following needles:**

- **Medical Device Technologies (MDTech) P/N 500618200X**
- **Worldwide Medical Technologies P/N PSS1820EZ (EZ Load)**

**QuickLink® Loader Spare Parts Replacement**

**Needle Adapter Replacement**

1. Remove the needle adapter from the loader by rotating the knurled adapter base counterclockwise.
2. Retread the new needle adapter into the front plate and rotate clockwise to tighten.

**Stylet (Part Number 70310QCC1) Replacement**

1. Fully retract the compression handle to release the stylet.
2. Depress the carriage release button and remove the carriage.

**Note:** When removing the carriage from the loader, do not tamper with the mechanisms that reside beneath the carriage. These components are aligned to rigid specifications, and must be handled carefully to maintain proper loader functionality.
3. Turn the loader over to expose the underside of the loader housing.
4. Manually separate the compression handle from the compression mechanism, exposing the stylet hub.
5. Remove the stylet by rotating the knurled hub counterclockwise.
6. Feed the new stylet through the opening in the stylet support doors and into the front plate to allow the stylet hub to mate with the stylet anchor. Rotate the stylet base clockwise to tighten.
7. Return the loader to the upright position and replace the carriage.

**Lead Glass (Part Number 70310QCA6) Replacement**

1. Open the lead glass door by pushing down the door release button.
2. Use a .050” hex head wrench to remove the 8 screws from the lead glass retaining frame.
3. Remove the retaining frame and damaged glass.

**Note:** The shielding glass contains lead, and must be disposed of according to applicable laws and regulations.

4. Install the replacement glass and retaining frame and secure with the frame screws.

**Note:** The needle adapters, stylets and lead glass are the only parts of the QuickLink® Loader that are serviceable by the customer. For more extensive repair or loader replacement, contact Bard Brachytherapy Customer Service at (800) 977-6733.

**Ordering**

QuickLink® Delivery System components may be ordered from, and questions should be directed to, Bard Brachytherapy Customer Service, (800) 977-6733.

**Graphical Representation of Linked Seeds**

Refer to the graphical representation of linked seeds in Figure 3.

**Symbols Used on Labeling (QuickLink® Loader)**

- **Rx only** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- **SN Serial Number**
- **REF Catalog Number**
- **Caution** Manufacturer
- **Consult Instructions for Use** Non-Sterile

**Symbols Used on Labeling (Cartridges, Sources and SourceLink™)**

- **Rx only** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- **SN Serial Number**
- **REF Catalog Number**
- **Caution** Do not use if package is damaged.
- **Consult Instructions for Use** Single Use
- **Use By** Irradiation.
- **40°C Upper Limit of Temperature**

Certain devices used with QuickLink® are single use devices. Do not resterilize any portion of these devices. 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.

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**References**


PK0319939 12/2018
GRAPHICAL REPRESENTATION OF LINKED SEEDS

Seeds linked with 5.5mm Standard SOURCELink™ Connector, providing 1cm center-to-center spacing.

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

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

[FIGURE 3]