

SOURCELINK® Loader

MANUAL RADIONUCLIDE APPLICATOR SYSTEM
Model #: 70308-A1

BARD® Brachytherapy, Inc.

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

DESCRIPTION

The SOURCELINK® Loader is designed to assemble brachytherapy seeds and SOURCELINK® Connectors into seed trains of variable lengths and with variable seed to seed spacing as predetermined by the physician. The SOURCELINK® Loader is biocompatible, composed entirely of stainless steel and Ultem™ 1000 (PEI) parts. The SOURCELINK® Loader comes equipped with the following features (Figure 1):

Assembly Groove and Ruler

The assembly groove is designed to provide a track for the compression of the seeds and SOURCELINK® Connectors. The ruler provides a means for verifying that the desired seed-to-seed spacing is obtained prior to delivery into the needle.

Releasable Slide

The slide is designed to transfer the necessary force for compression of the seeds and SOURCELINK® Connectors into a seed train. The slide is adjusted at Bard Brachytherapy, Inc. to ensure the proper compressive force is delivered every time.

Removable Stylet

The stylet is designed to compress the seeds and SOURCELINK® Connectors into a seed train and has been equipped with a luer-lock fitting for quick and easy replacement.

Seed Bin Cover

The stainless steel seed bin cover has been designed to provide shielding from the seeds placed in the seed bin for loading. The cover provides full radiation protection, while allowing for sterilant penetration. The positive closure mechanism of the cover ensures seeds will remain in the bin during handling. When moved away from the seed bin, the cover can be lifted away for easy cleaning.

Needle Adapter

A stainless steel needle adapter is provided for attaching the implant needles to the SOURCELINK® Loader. They are available in different styles to fit any style of implant needle. Refer to the SOURCELINK® Loader Spare Parts package insert for needle adapter compatibility information.

Compression Gate

The gate is designed as a base for compression of the SOURCELINK® Connectors and seeds into the assembled seed train. It has been equipped with positive stops in both the up (open) and down (closed) position.

Funnel

The stainless steel SOURCELINK® Loader funnel is designed to fit both the SOURCELINK® Connector and seed bins to make component addition to the SOURCELINK® Loader clean and safe. The funnel may be sterilized and stored in the slide handle for convenience.

A SOURCELINK® Loader Shield is also available to provide shielding to personnel from unnecessary radiation during Brachytherapy procedures.

INDICATIONS

The SOURCELINK® Loader is indicated for use with SOURCELINK® Connectors and brachytherapy seeds in the assembly of seed trains of variable lengths with predetermined spacing between the seeds for use in brachytherapy procedures.

WARNINGS AND PRECAUTIONS

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Clean and Sterilize SOURCELINK® Loader and its spare parts prior to use per the instructions provided below.

Ensure needle adapter and stylet are finger-tight. Do not make any other adjustments to the SOURCELINK® Loader.

Do not close the gate when the stylet is extended into the needle adapter.

Ensure SOURCELINK® Connectors and seeds are fully inserted in the assembly groove prior to closing the groove cover.

Close the groove cover whenever the slide is moved toward the assembly plate.

When sterilization of the SOURCELINK® Loader is performed, allow the SOURCELINK® Loader to cool prior to use to prevent melting the SOURCELINK® connectors.

Do not sterilize the SourceLink® Loader with SOURCELINK® Connectors in the SOURCELINK® Connector bin.

Do not sterilize by irradiation.

Do not expose the loader or spare parts at temperatures above 135°C.

CLEANING AND STERILIZATION

The SOURCELINK® Loader and its spare parts are supplied non-sterile and must be cleaned and sterilized prior to initial use and each subsequent use.

Limitations on processing – Repeated cleaning and steam sterilization has minimal effect on the SOURCELINK® Loader. The SOURCELINK® Loader and its spare parts should be inspected for damage or corrosion prior to use and replaced or repaired as necessary.

Use appropriate personal protective equipment (e.g. gloves, gowns, eyewear, face masks or shields, respiratory protection devices) as dictated by facility protocol.

Cleaning

1. Point of Use – No particular requirements.
2. Containment and Transportation – No particular requirements.
3. Instrument Preparation – Remove any SOURCELINK® Connectors, seeds, stylets, seed bin cover, needle adapter, and funnel.
Caution: If loose seeds are found, immediately contact Radiation Safety for safe handling and disposal of the seeds.
4. Initial Rinse – Rinse the loader and spare parts thoroughly with cool (maximum 25°C, 77°F) tap water. While rinsing, remove any excess soil by brushing with a soft bristle brush.
5. Enzymatic Presoak – Prepare enough multi-tiered enzymatic cleaning solution (Ruhof Endozime™ AW Plus or equivalent), following the manufacturer's instructions, to completely wet the SOURCELINK® Loader and spare parts. Thoroughly wet the loader and spare parts 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 spare parts 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 spare parts thoroughly with cool (maximum 25°C, 77°F) 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 after multiple cleaning attempts, contact Bard Brachytherapy, Inc. Customer Service at (800) 977-6733.
10. Drying – Allow loader and spare parts to air dry. Do not dry loader and spare parts at temperatures above 135°C.
11. Maintenance and Inspection – Verify that the SOURCELINK® Loader is free from obvious defects, damage, or corrosion. Verify that the stylet is straight. Contact Bard Brachytherapy, Inc. Customer Service at (800) 977-6733 for repairs or replacement components as necessary.

Sterilization

1. Prior to sterilization, the SOURCELINK® Loader and spare parts should be clean and dry.
2. Double wrap loader and spare parts individually with 510(k) approved hospital sterilization wrap prior to sterilization.

Caution: DO NOT sterilize by irradiation.

Caution: DO NOT process the SOURCELINK® Loader and spare parts at temperatures above 135°C.

3. Sterilize the SOURCELINK® Loader and spare parts in accordance with manufacturer's directions using the following Dynamic-air-removal Steam Sterilization (Pre-Vacuum) or Gravity Displacement cycle parameters:

Gravity Displacement Autoclave Cycle Parameters

Full Cycle Temperature	Full Cycle Exposure Time	Dry Time (in chamber)	Cool Down Time at Room/Ambient Temperature
135°C (275°F)	10 minutes	N/A	30 minutes

Pre-Vacuum Autoclave Cycle Parameters

Full Cycle Temperature	Full Cycle Exposure Time	Dry Time (in chamber)	Cool Down Time at Room/Ambient Temperature
132°C (270°F)	4 minutes	N/A	30 minutes
134°C (273°F)	3 minutes	N/A	30 minutes
134°C (273°F)	18 minutes	N/A	30 minutes
135°C (275°F)	5 minutes	N/A	30 minutes

4. Allow SOURCELINK® Loader and spare parts to cool before handling.
5. Storage – Store at room temperature.
6. When sterilizing multiple instruments in one autoclave cycle, ensure the sterilizer's maximum load is not exceeded.
7. Instrument Reassembly – After sterilization, reassemble any SOURCELINK® Connectors, seeds, stylets, seed bin cover, needle adapter, and funnel.
8. Maintenance and Inspection – Verify that the SOURCELINK® Loader is free from obvious defects, damage, or corrosion. Verify that the stylet is straight. Contact Bard Brachytherapy, Inc. Customer Service at (800) 977-6733 for repairs or replacement components as necessary.
9. The instructions above have been validated by Bard Brachytherapy, Inc. 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.

INSTRUCTIONS FOR USE

1. Retract the slide to the right until it contacts the rear plate to seat the slide compression mechanism (if unseated).
2. Attach the implant needle to the SOURCELINK® Loader by pushing the needle hub firmly onto the needle adapter.
3. Press the gate downward to close. If resistance is experienced, clear any obstruction that may be in the opening. DO NOT use excessive force.
4. Raise the groove cover and add necessary components to the SOURCELINK® Connector and seed bins.
5. Place the seeds and the SOURCELINK® Connectors in the assembly groove to obtain desired seed spacing.
6. Close the groove cover and move the slide left toward the assembly plate to compress the seeds and the SOURCELINK® Connectors. Continue motion to the left until the slide handle releases and comes to a full stop (Figure 2).
7. Retract slide to the right until it contacts the rear plate to reseat the slide compression mechanism.
8. Open groove cover to visually inspect the compressed seed train and measure seed spacing.
9. Close groove cover and raise gate upward to open.
10. Move slide left toward assembly plate until it stops to push the compressed seed train into the implant needle.
11. Retract slide to the right.

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

SPARE PARTS

Loader shields, spare stylets, and needle adapters may be obtained from Bard Brachytherapy, Inc. Customer Service, (800) 977-6733. Detailed installation instructions will be provided with the spare parts. Identify your SOURCELINK® Loader Serial Number in all correspondence.

TROUBLESHOOTING

Condition	Solution
SOURCELINK® Connectors not connected after compression	1. Ensure slide has been fully reset before compression. 2. Stylet bent – replace. 3. Extension SOURCELINK® inserted in strand backwards – discard backward Extension SOURCELINK® and the adjacent SOURCELINK® Connector and repeat assembly.
SOURCELINK® Connectors or seeds pop out of groove during compression	Close groove cover prior to compression.
Loose SOURCELINK® Connectors and seeds exit through needle adapter during compression	Ensure gate is in closed (down) position.
Assembled seed train cannot be loaded into the attached implant needle	Ensure gate is in open (up) position.
Implant needle does not stay attached to the needle adapter	Ensure needle adapter is appropriate for the implant needle used.
Completed seed train does not load smoothly into the attached implant needle	Ensure needle adapter is appropriate for the implant needle used.
Device fails visual inspection (e.g. corrosion, bent stylet) after cleaning or sterilization.	Contact Bard Brachytherapy, Inc. Customer Service at (800) 977-6733 for repair or replacement component.

TRADEMARKS

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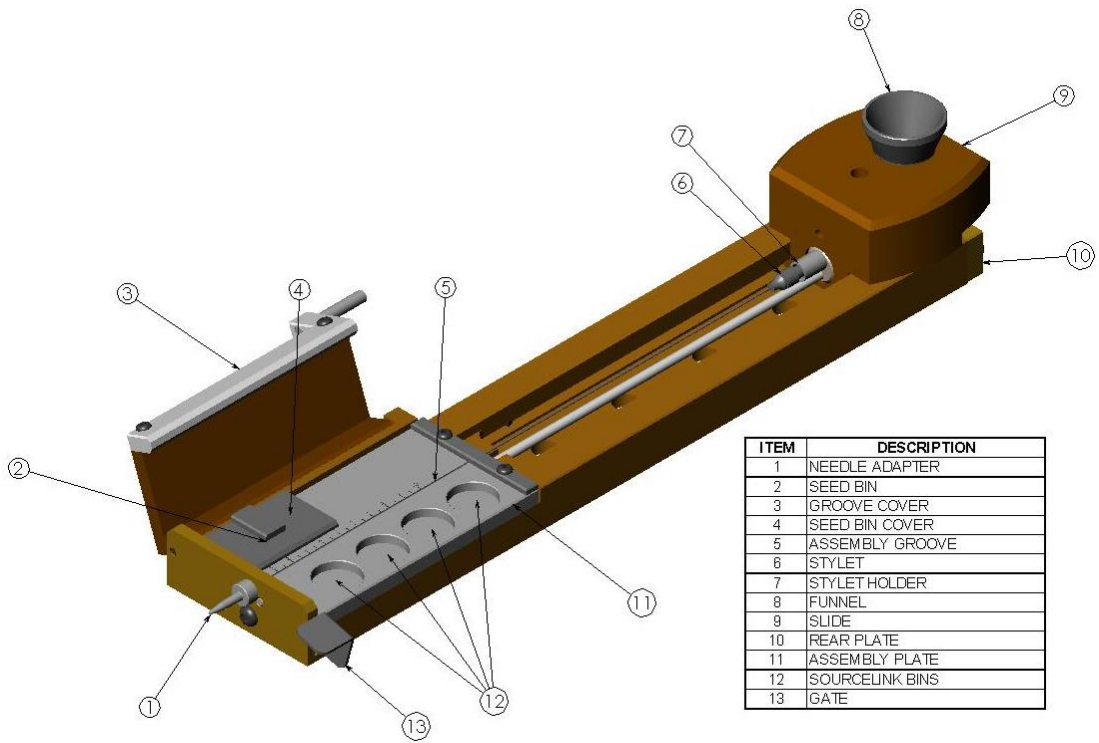


Figure 1

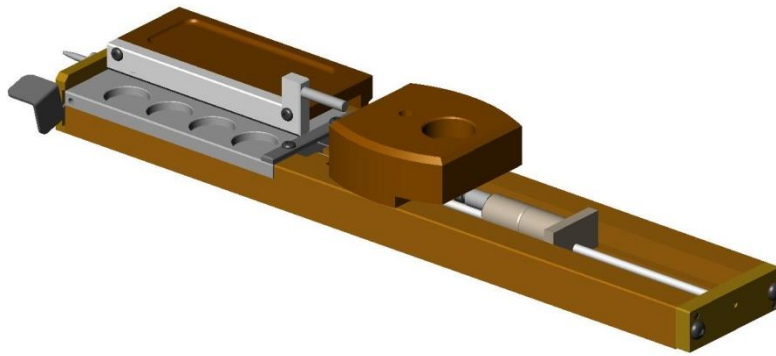


Figure 2

SYMBOLS USED ON LABELING

Symbol	Title	Reference	Explanatory Text
	Caution	ISO 15223-1 5.4.4	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Product code / Catalog number	ISO 15223-1 5.1.6	Indicates the manufacturer's catalog number so that the medical device can be identified.