

Selig Group Technology Department

Inventory Management - Product Tracing and Best Practices

All Selig products regardless of form (That is, Selig Roll/Reel/Tape or Selig Manufactured Pre-Cut Closure Liners/Wads)

Selig Sealing Products, Inc. (Selig) products are often used as food contact packaging articles. Special care is therefore advised in the handling and storage of these closure liner products that shall include protection of the products while in customer inventory from sources of contamination or other conditions that may render the product unsafe for its intended use. The customer is further advised of the importance of liner inventory management best practices to ensure that all liner products are used in a logical sequence that is consistent with current good manufacturing practices (cGMP) and prior to product expiry.

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Technical Information – Inventory Management - Product Tracing and Best Practices

Customer Notice

Selig strongly encourages its customers to review both their manufacturing processes and their applications of Selig products from the standpoint of Good Manufacturing and the use of First In First Out inventory practices to ensure that Selig products are used only in ways for which they are intended and tested. Selig customer service personnel are available to answer your questions and to provide reasonable technical support. Selig product literature, including technical data sheets, should be consulted prior to use of Selig products. Current product technical data sheets are available from Selig.

Inventory Management - First In, First Out (FIFO)

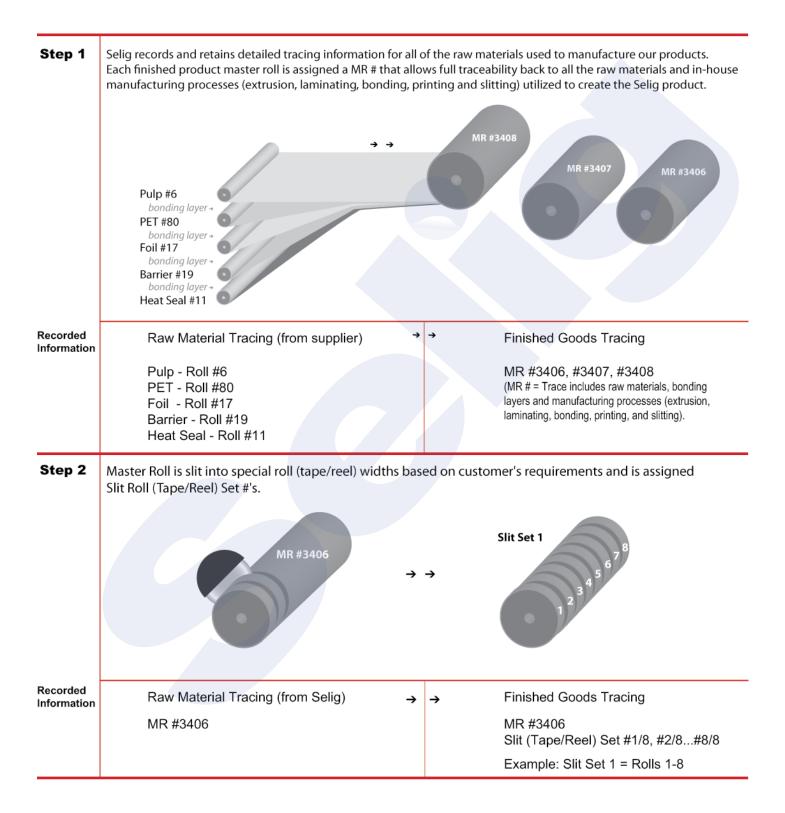
- Selig's defines "product lot" as the individual roll/reel or tape number for a given order number.
- 2) Selig pre-cut liner or wadding "product lot" is defined according to product order number and carton number.
- 3) The Selig order, lot number, and date of manufacture may be found on every product roll/reel or tape label or carton number.
- 4) Selig advises that each liner order shall be managed according to First In, First Out (FIFO) inventory practice.
- 5) FIFO inventory management may be simply referred to as the liner order that is received first is processed first and what liner order is received next waits in inventory on hold until the first liner order is entirely processed.
- 6) The use of FIFO is consistent with industry best practices such as cGMP for material handling.
- 7) Guidance on the proper storage and handling of Selig products in their various forms is available by referring to Selig Technical Information Bulletins both dated February 2015 (Roll form: RD091708C) and (Converted Form: RD011207E) that is available on the Selig website or by contacting the Selig Customer Service Department.
- 8) To assure optimum performance, Selig products are best if used or converted in sixty (60) days from date of receipt by customer.

Product Lot Traceability

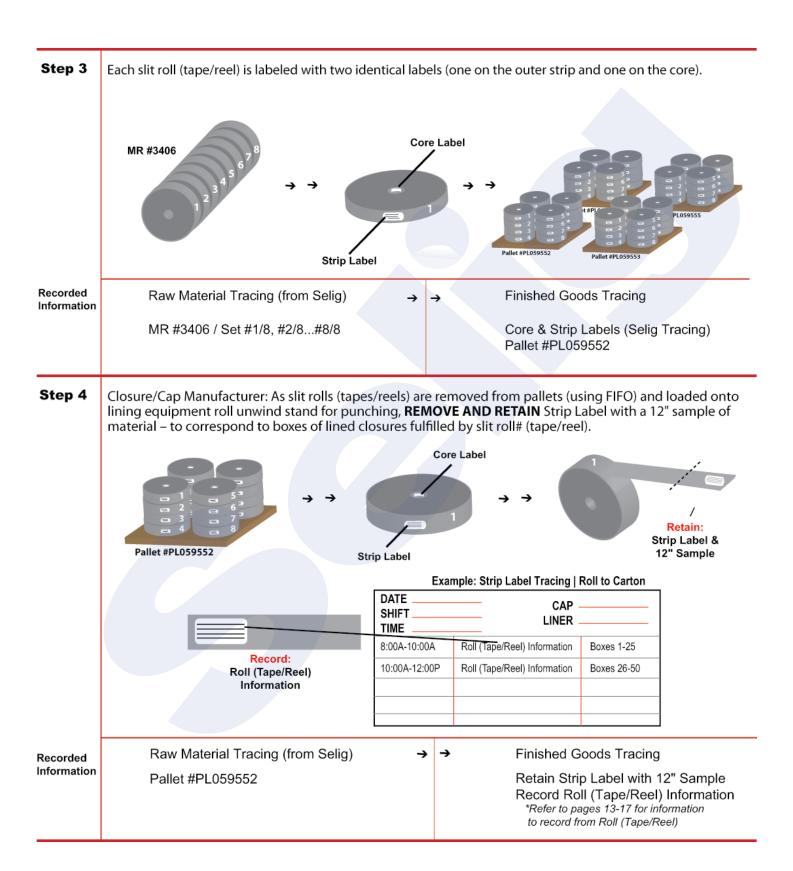
- 1) Selig maintains 100% traceability of each raw component and finished product lot.
- 2) Selig advises that liner orders shall not be intermixed within closure lots to maintain liner traceability.
- 3) Selig strongly recommends that each closure lot not exceed a Selig liner order.
- 4) Where more than one closure lot is satisfied by one Selig liner order, then the closure lot size should be selected while adhering to point (2) above.
- 5) Selig recommends that a reasonable closure lot size should not exceed 250,000 closures.
- 6) Liner order traceability should be maintained by the customer by recording Selig liner individual roll/tape/bail or reel numbers or liner carton numbers used in the production of each lined closure carton or case.
- 7) To protect the traceability chain for both the closure and liner lots, every lined closure carton or case should be provided with a discrete individual identification mark that is to be referenced and documented by the packaging end-user for component and product tracing.
- 8) Each end-user of lined closures should be advised by Selig customers of the importance of continuing the package traceability chain by using FIFO inventory practices, not intermixing lined closure lots, and the documentation requirements for use of lined closure cartons or cases.
- 9) Selig recommends that lined closure lots should be processed by the end-user in a manner consistent with the above practices.



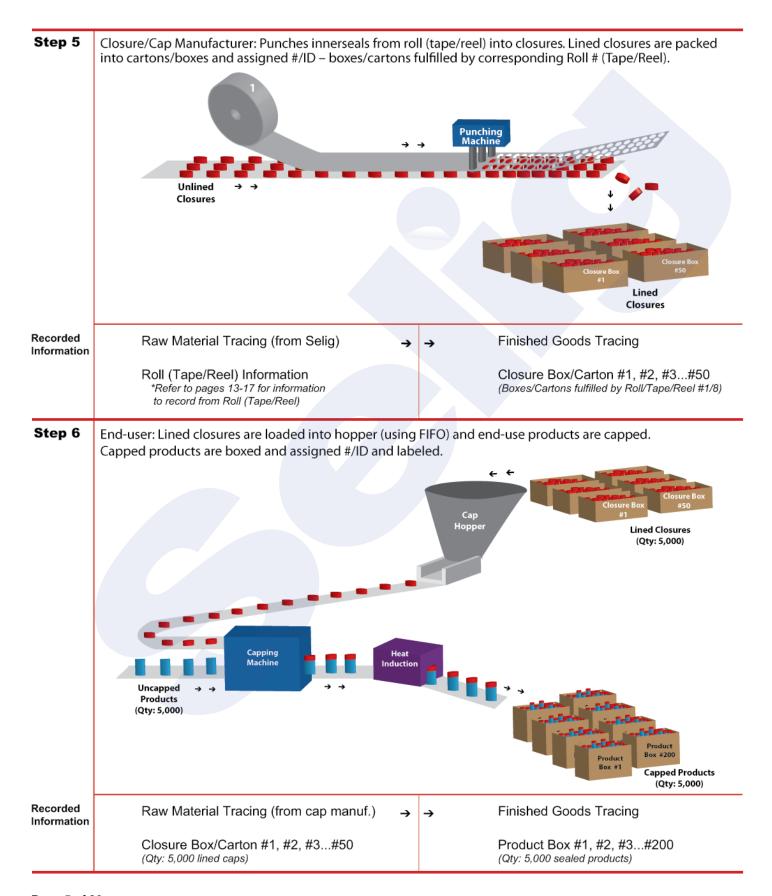
Roll (Liner/Reel) Tracing Procedure













Step 7 End-user: Finished products/packages are loaded onto pallets and assigned #/ID. Pallet #2 Pallet #8 Pallet #1 (Box #28-54) (Box #174-200) (Box #1-27) Recorded Raw Material Tracing (End-user) Finished Goods Tracing Information Product Box #1, #2, #3...#200 Product Pallet #1, #2, #3...#8 (Qty: 5,000 sealed products) (Qty: 5,000 sealed products) Example: Pallet #1 = Box #1-27 Pallet #2 = Box #28-54 Pallet #3 = Box #55-81 Pallet #8 = Box #174-200

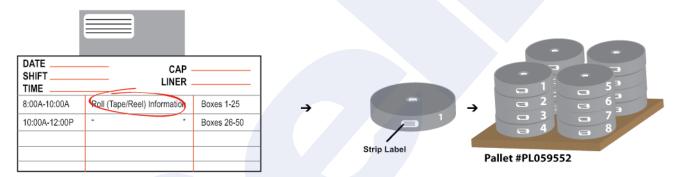


Reverse Tracing Sample | End-Use Products to Raw Materials - Roll (Tape/Reel)

Tracing: End-User to Closure/Cap Manufacturer



Closure/Cap Manufacturer to Selig Product

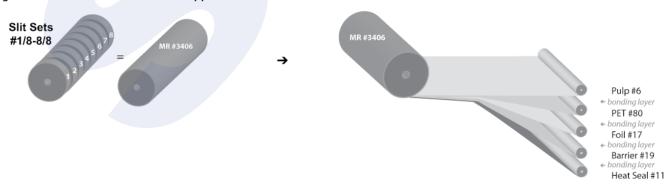


Step 4: Closure Boxes #1-50 were filled by closures punched with liner material from Slit Set #1/8 / Pallet #PL059552.

Step 5: Provide critical Strip Label information to Selig for tracing.

*Refer to pages 13-17 for critical Strip Label information.

Selig Product to In-House Processes & Supplier's Raw Materials



Step 6: Slit Sets #1/8-8/8 were slit from Master Roll (MR) #3406.

Step 7: MR #3406-3408 used raw materials: Pulp #6, PET #80, Foil #17, Barrier #19 and Heat Seal #11

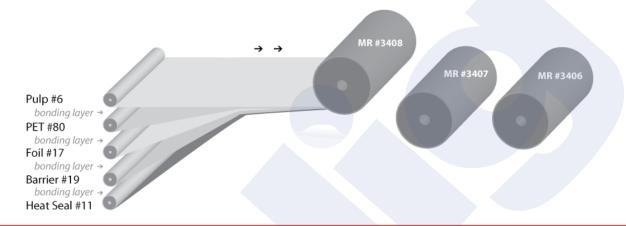
(MR#: Traces raw materials, bonding layers and Selig's in-house manufacturing processes (extrusion, laminating, bonding, printing and slitting).



Pre-cut Disc (Liner/Wad) Tracing Procedure

Step 1

Selig records and retains detailed tracing information for all of the raw materials used to manufacture our products. Each finished product master roll is assigned a MR # that allows full traceability back to all the raw materials and in-house manufacturing processes (extrusion, laminating, bonding, printing and slitting) utilized to create the Selig product.



Recorded Information

Raw Material Tracing (from supplier)

Pulp - Roll #6

PET - Roll #80

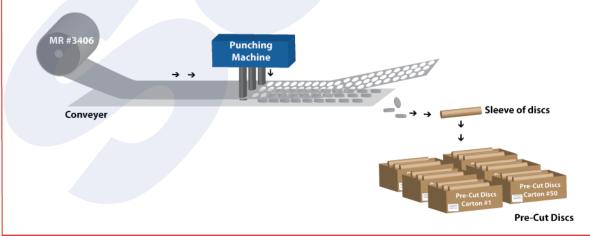
Foil - Roll #17

Barrier - Roll #19 Heat Seal - Roll #11 Finished Goods Tracing

MR #3406, #3407, #3408 (MR # = Trace includes raw materials, bonding layers and manufacturing processes (extrusion, laminating, bonding, printing, and slitting).

Step 2

Pre-Cut Discs (liners/wads) with diameters based on customer's requirements are punched from Master Roll (tape/reel), packed into sleeves, boxed and assigned #/ID – connecting cartons of pre-cut discs (liners/wads) fulfilled by corresponding MR#.



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Recorded Information

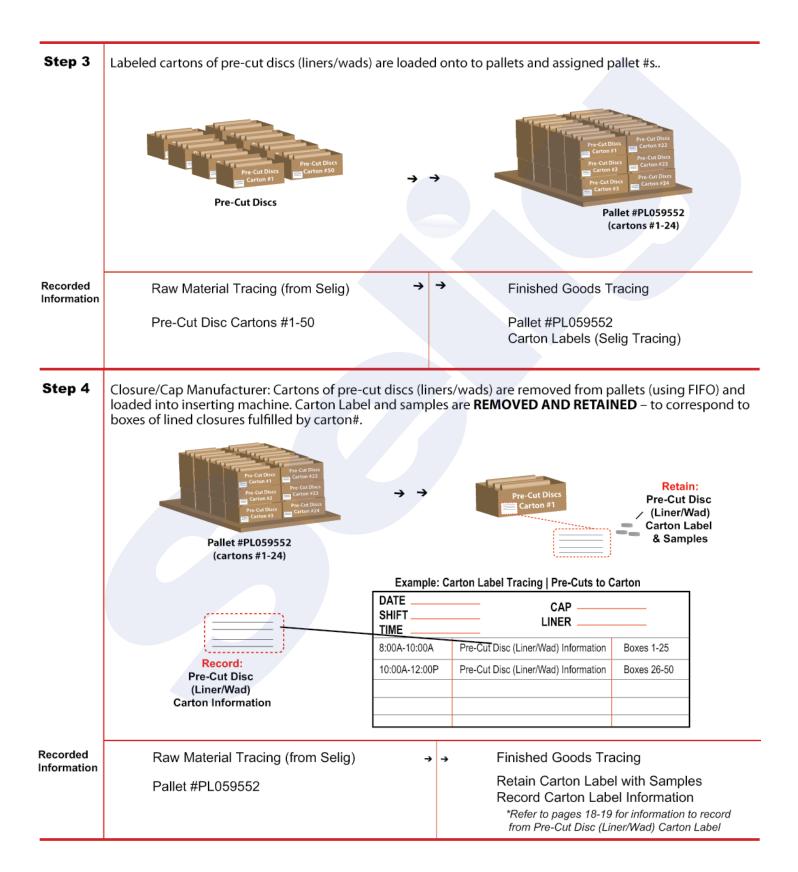
Raw Material Tracing (from Selig)

MR #3406

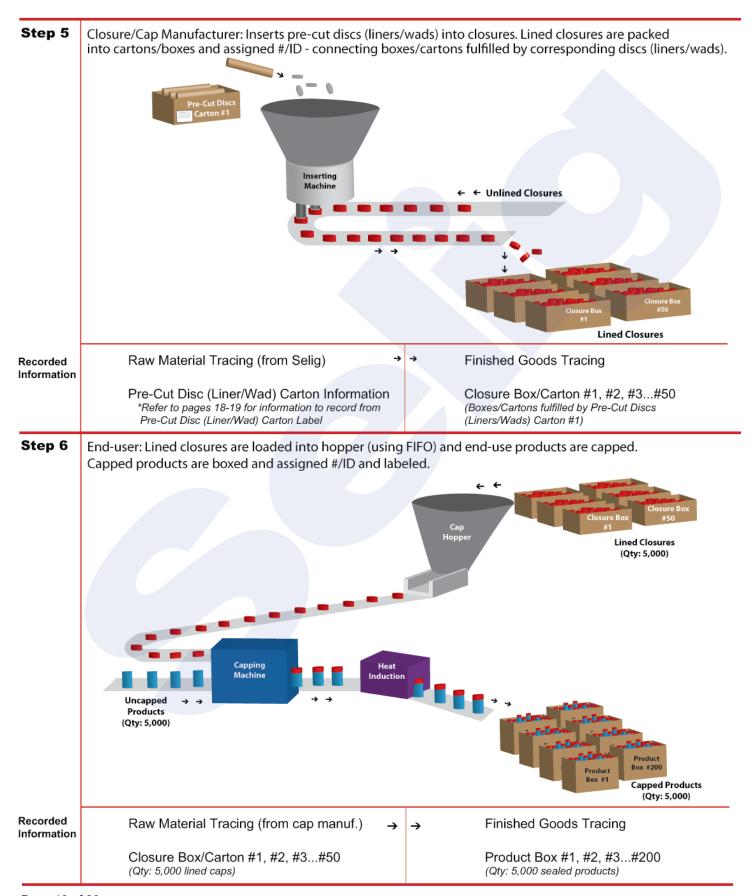
Finished Goods Tracing

Pre-Cut Discs Carton #1, #2, #3...#50 (Cartons filled by MR #3406)











Step 7 End-user: Finished products/packages are loaded onto pallets and assigned #/ID. Pallet #1 Pallet #2 Pallet #8 (Box #28-54) (Box #174-200) (Box #1-27) Recorded Raw Material Tracing (End-user) Finished Goods Tracing Information Product Box #1, #2, #3...#200 Product Pallet #1, #2, #3...#8 (Qty: 5,000 sealed products) (Qty: 5,000 sealed products) Example: Pallet #1 = Box #1-27 Pallet #2 = Box #28-54 Pallet #3 = Box #55-81 Pallet #8 = Box #174-200



Reverse Tracing Sample | End-Use Products to Raw Materials - Pre-Cut Disc (Liner/Wad)

Tracing: End-User to Closure/Cap Manufacturer



Step 1: Weak seal product from Pallet #1 / Product Box #27

Step 2: Product Boxes #1-200 capped with lined closures from Closure Boxes #1-50

Step 3: Provide Closure Box #/IDs to Closure/Cap manufacturer for tracing.

Closure/Cap Manufacturer to Selig Product

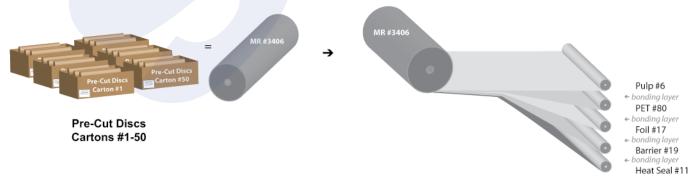


Step 4: Closure Boxes #1-50 were filled by closures lined with pre-cut discs (liners/wads) from Carton #1 / Pallet #PL059552.

Step 5: Provide critical Pre-Cut Discs Carton Label information to Selig for tracing.

*Refer to pages 18-19 for critical Pre-Cut Disc (Liner/Wad) Carton Label information.

Selig Product to In-House Processes & Supplier's Raw Materials



Step 6: Pre-Cut Discs (liners/wads) Cartons #1-50 were punched from Master Roll (MR) #3406.

Step 7: MR #3406-3408 used raw materials: Pulp #6, PET #80, Foil #17, Barrier #19 and Heat Seal #11

(MR#: Traces raw materials, bonding layers and Selig's in-house manufacturing processes (extrusion, laminating, bonding, printing and slitting).



Roll/Tape/Reel Labels and Locations

Every roll (tape/reel) contains two identical labels located on the core and the outside strip:

Product Core Label: The information contained on this label will allow you to systemically trace the precise raw material that corresponds to a specific batch of your closures. Never remove this label from the core of a product roll (tape/reel).

Strip Label: The information contained on this label is identical to the Product Core Label. However, this label should be trimmed off the roll (tape/reel) with approximately 12 inches of product to retain as a sample for your records.



Product Core Label

Contains same information as Strip Label.

Strip Label

Contains the following:

- Roll Identification #
- Ship/Dispatch Date
- Product Expiration Date
- Product Description (Name, Code or Brand)

Refer to the following pages (14-17) to view sample labels for Roll (Tape/Reel) manufactured from each Selig location.



Facility: Forrest, IL - USA



Key Information – Product Strip Label

Contains same information on inner Core Label.

- 1. LOT #: Critical information to record for full traceability.
- **2. PRODUCT EXPIRATION DATE:** Use before this date. Products used after the expiration date or that have been improperly stored or handled shall be deemed "Out of Condition" and if used, is the sole responsibility of the customer.



Facility: Aurora - Canada



Key Information – Product Strip Label

Contains same information on inner Core Label.

- 1. LOT #: Critical information to record for full traceability.
- **2. PRODUCT EXPIRATION DATE:** Use before this date. Products used after the expiration date or that have been improperly stored or handled shall be deemed "Out of Condition" and if used, is the sole responsibility of the customer.



Facilities: Slough - UK



Key Information – Product Strip Label

Contains same information on inner Core Label.

- 1. SELIG ORDER: Critical information to record for full traceability.
- 2. LOT #: Critical information to record for full traceability.
- **3. PRODUCT EXPIRATION DATE / EXPIRY:** Use before this date. Products used after the expiration date or that have been improperly stored or handled shall be deemed "Out of Condition" and if used, is the sole responsibility of the customer.



Facility: Niederglatt - CH



Key Information – Product Strip Label

Contains same information on inner Core Label.

- 1. LOT #: Critical information to record for full traceability.
- **2. PRODUCT EXPIRATION DATE:** Use before this date. Products used after the expiration date or that have been improperly stored or handled shall be deemed "Out of Condition" and if used, is the sole responsibility of the customer.



Technical Information - Inventory Management - Product Tracing and Best Practices

Pre-Cut Disc (Liner/Wad) Carton Labels and Locations Every carton of pre-cut discs (liners/wads) contains a label located on the carton:

Pre-Cut Disc (Liner/Wad) Carton Label: The information contained on this label will allow you to systemically trace the precise raw material that corresponds to a specific batch of your closures. **This label should be retained with samples of product for your records.**



Pre-Cut Disc (Liner/Wad) Carton Label

Contains the following:

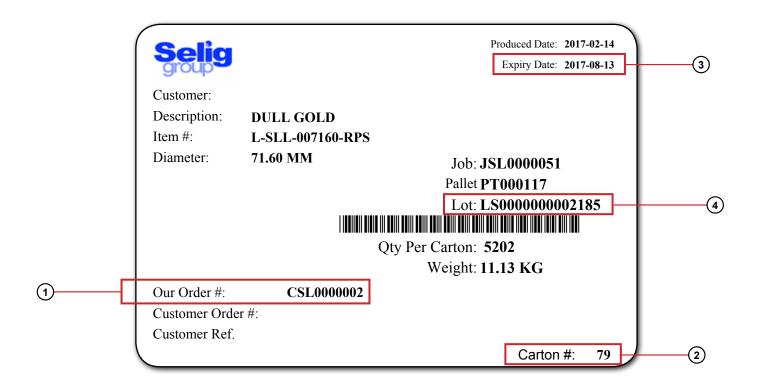
- Carton #
- Order Number
- Diameter
- Ship/Dispatch Date
- Product Expiration Date

Refer to the following page (19) to view sample label for Pre-Cuts manufactured from Selig's Slough, UK location.



Product Pre-cut Disc (Liner/Wad) Carton Label

Facility: Slough - UK



Key Information – Product Carton Label

- 1. OUR ORDER: Critical information to record for full traceability.
- 2. CARTON #: Critical information to record for full traceability.
- **3. PRODUCT EXPIRATION DATE / EXPIRY DATE:** Use before this date. Products used after the expiration date or that have been improperly stored or handled shall be deemed "Out of Condition" and if used, is the sole responsibility of the customer.
- 4. LOT #: Critical information to record for full traceability

Selig group

Technical Information - Inventory Management - Product Tracing and Best Practices

Selig Medical Application Policy

Selig will not knowingly sell or sample any product ("Product") into any commercial or developmental application that is intended for:

- (a) permanent (Long term) contact with internal body fluids or internal body tissues. Long term is a use which exceeds 72 continuous hours:
- (b) use in cardiac prosthetic devices regardless of the length of time involved; (Cardiac prosthetic devices include, but are not limited to, pacemaker leads and devices, artificial hearts, heart valves, intra-aortic balloons and control systems, and ventricular bypass assisted devices);
- (c) use as a critical component in medical devices that support or sustain human life; or
- (d) use in applications designed specifically for pregnant women or designed specifically to promote or interfere with human reproduction.

Additionally, all Products intended for use in pharmaceutical applications, other than pharmaceutical packaging, must pass the current Pharmaceutical Liability Guidelines.

- For the products sold by the Selig, new business opportunities require a business assessment prior to sale or sampling of Selig
 products.
- Authorized distributors and resellers will adhere to this medical policy.
- Selig does not endorse or claim suitability of their products for specific medical applications. It is the responsibility of the medical
 device or pharmaceutical manufacturer to determine that the Selig product is safe, lawful, and technically suitable for the intended
 use. SELIG MAKES NO WARRANTIES, EXPRESS OR IMPLIED, CONCERNING THE SUITABILITY OF ANY SELIG PRODUCT
 FOR USE IN MEDICAL APPLICATIONS.

Disclaimer

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NOTICE: If products are described as "experimental" or "developmental": (1) product specifications may not be fully determined; (2) analysis of caution in handling and use are required; and (3) there is greater potential for Selig to change specifications and/or discontinue production.

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