Example Self-Expanding Stent Loading Process

Blockwise Engineering LLC

A medical stent is a mesh-like metal tube used as a scaffolding for constricted arteries, or other bodily conduits. **Self-Expanding Stents**, one of the two main types of stents, are usually manufactured from the superelastic alloy Nickel Titanium, or Nitinol.

These stents are manufactured at their final diameter and then compressed and constrained at a smaller diameter conducive to delivery. After deployment, they self-expand back to their original diameter. The process of compressing and constraining this type of stent is known as "stent loading".

This article describes an example stent loading process using Blockwise's LX loading machine, as well as some of the numerous variables that can be considered when creating a recipe.

Please note: This information is offered to help customers understand how Blockwise stent loading machines might be used in their manufacturing processes. The information about manufacturing processes is based on the author's anecdotal experience, not scientific work. Knowledgeable process engineers often disagree about this information. Choice of process steps and settings depends on the product requirements, design, materials, and other processes. To make the examples more concrete, actual numbers are shown here. In a real manufacturing process, these process steps and numbers must be carefully selected by the medical device manufacturing engineers after analysis, experiments, trials, and process validation.
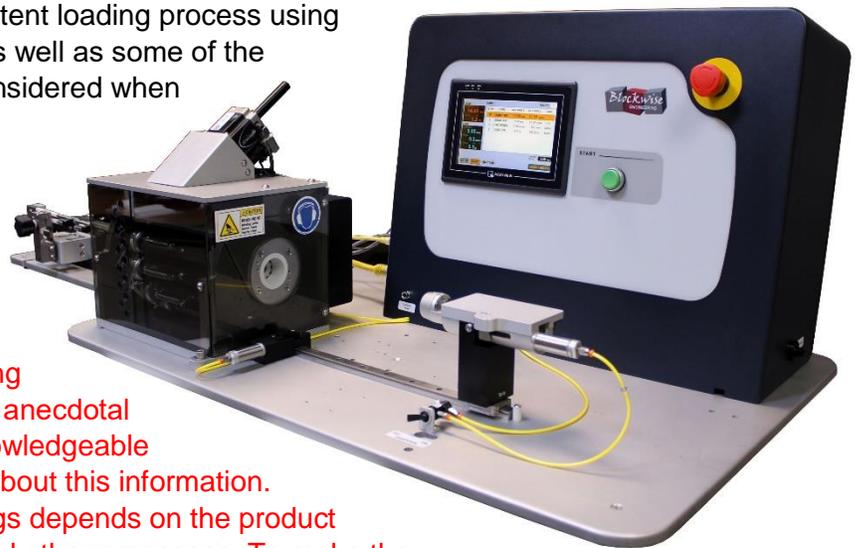
The stent loading process can generally be categorized into two processes: *crimping* and *loading*. *Crimping* involves all of the steps required to attain and maintain a final diameter that will allow the stent to be loaded into the delivery device. Likewise, *loading* involves all of the steps and tools necessary to transfer the stent from the compression mechanism into the delivery device.

STEP	TYPE	SETTING 1	SETTING 2		CONTINUE AFTER	TIME [sec]	
0	DIAMETER	14.00 mm	10.00 mm/s				Crimping Step(s)
1	DIAMETER	2.00 mm	3.00 mm/s	Step Options	START BUTTON		
2	COOL	ON	-30.0 c		STEP DONE	3.0	
3	LOAD FORCE	10.0 N	105.0 mm	Step Options	STEP DONE	0.0	Loading Step(s)

Example Self-Expanding Stent Loading Process

Blockwise Engineering LLC

www.blockwise.com

CRIMPING

Choosing How to Control Compression

Blockwise's LX loading machine offers two step types for controlling how the stent is compressed:

Diameter Control: The *diameter* step type moves the compression actuator until the encoder-measured diameter equals the set diameter. Using this method, the machine controls the diameter while the force applied to the stent is determined by the variables of the product itself.

STEP	TYPE	SETTING 1	SETTING 2	CONTINUE AFTER	TIME [sec]
0	DIAMETER	14.00 mm	10.00 mm/s		
1	DIAMETER	2.00 mm	3.00 mm/s	Step Options	START BUTTON

Force Control: Conversely, the *force* step type moves the compression station in the closing direction until the transducer-measured compression (actuator) force equals the set force. Using this method, the machine controls the force applied to the stent, while the final diameter is determined by the variables of the product itself.

STEP	TYPE	SETTING 1	SETTING 2	CONTINUE AFTER	TIME [sec]
0	DIAMETER	14.00 mm	10.00 mm/s		
1	FORCE	50.0 N	3.00 mm/s	Step Options	START BUTTON

For more information regarding the use of diameter control or force control, please refer to Knowledge Base article MS009 Crimping: Diameter Control vs Force Control.

Example Self-Expanding Stent Loading Process

Other Common Crimping Techniques

During a typical stent loading process, it is common to only partially crimp the stent and then pause to perform some other task, such as inserting a push rod or the inner shaft of the delivery device. This can be accomplished by adding a *diameter* step equal to, or smaller than, the expanded diameter of the stent and choosing a *continue after: start button* setting for that step. The station will crimp to the selected diameter and then hold that diameter until the start button is pressed, giving the operator time to perform any necessary tasks.

STEP	TYPE	SETTING 1	SETTING 2		CONTINUE AFTER	TIME [sec]
0	DIAMETER	14.00 mm	10.00 mm/s			
1	DIAMETER	8.00 mm	5.00 mm/s	Step Options	START BUTTON	
2	DIAMETER	2.00 mm	3.00 mm/s	Step Options	STEP DONE	0.0

Choosing the *Start Button* option will allow the user time to setup to the pushrod or align the catheter before continuing the recipe

Another possible variation of the crimp step is to actually over-crimp the stent. This can be helpful when loading covered stents or utilizing nitrogen cooling. This method simply incorporates an extra step, or series of steps, that uses either diameter or force control to crimp the stent smaller than the final target diameter.

Using A *Cool* Step to Maintain Diameter

Nitrogen cooling is often a very useful step in the stent loading process because of the shape memory properties of Nitinol stents. Utilizing a *cool* step helps to maintain the small crimped diameter of the stent and reduce friction during the loading process.

Blockwise's LX loading machine offers options for both nitrogen injection while the stent is in the compression station (Nitrogen Chilling System R286) as well as, the more commonly used, nitrogen injection while the stent is being pushed from the station (Catheter Cooling System R691). To incorporate nitrogen cooling in the loading recipe, a *cool* step can be added after the stent has reached its final diameter, but before the loading process begins. The *cool* step also allows the user to set the target temperature and a time delay, during which the nitrogen will continue to flow through the gripper. The *cooling duty cycle*, found on the "Modify Recipe

STEP	TYPE	SETTING 1	SETTING 2		CONTINUE AFTER	TIME [sec]
0	DIAMETER	14.00 mm	10.00 mm/s			
1	DIAMETER	2.00 mm	3.00 mm/s	Step Options	START BUTTON	
2	COOL	ON	-30.0 c		STEP DONE	3.0
3	LOAD FORCE	10.0 N	105.0 mm	Step Options	STEP DONE	0.0

In this recipe, the *cool* step follows the final crimp but precedes the load step. The temperature is set to -100° c and has a delay of 3 seconds before it continues on to the loading step.

Example Self-Expanding Stent Loading Process

Parameters" screen will also need to be set. The nitrogen will pulse on and off at the set duty cycle for the remainder of the recipe, or until cooling is turned off.

For more information regarding the various screens on the LX machine, please refer to Knowledge Base article R706 LX Loader Screens and Recipe Setup.

LOADING

Choosing How to Control Loading

Blockwise's LX loading machine with the Automated Pushrod System (R383) offers two step types for controlling how the stent is pushed from the station into the delivery device:

Speed Control: The *load speed* step type moves the pushrod at the set speed until the travel distance indicated in setting 2 is reached. To maintain the set speed, this step type will apply the required force, up to the *load force limit during speed* setting chosen on the "Modify Recipe Parameters" screen.

STEP	TYPE	SETTING 1	SETTING 2		CONTINUE AFTER	TIME [sec]
0	DIAMETER	14.00 mm	10.00 mm/s			
1	DIAMETER	2.00 mm	3.00 mm/s	Step Options	START BUTTON	
2	LOAD SPEED	10.00 mm/s	105.0 mm	Step Options	STEP DONE	0.0

Force control: The *load force* step type moves the pushrod at the set force until the travel distance indicated in setting 2 is reached. The speed is modulated to try to maintain the set force. The user is able to choose a minimum (*loader stall speed*) and a maximum (*load speed limit during force*) loading speed on the "Modify Recipe Parameters" screen.

STEP	TYPE	SETTING 1	SETTING 2		CONTINUE AFTER	TIME [sec]
0	DIAMETER	14.00 mm	10.00 mm/s			
1	DIAMETER	2.00 mm	3.00 mm/s	Step Options	START BUTTON	
2	LOAD FORCE	10.0 N	105.0 mm	Step Options	STEP DONE	0.0

For more information regarding the various screens on the LX machine, please refer to Knowledge Base article R706 LX Loader Screens and Recipe Setup.

Example Self-Expanding Stent Loading Process

Blockwise Engineering LLC

www.blockwise.com

RFG225 Powerfeed Compression Station

Automated Pushrod System (R383)
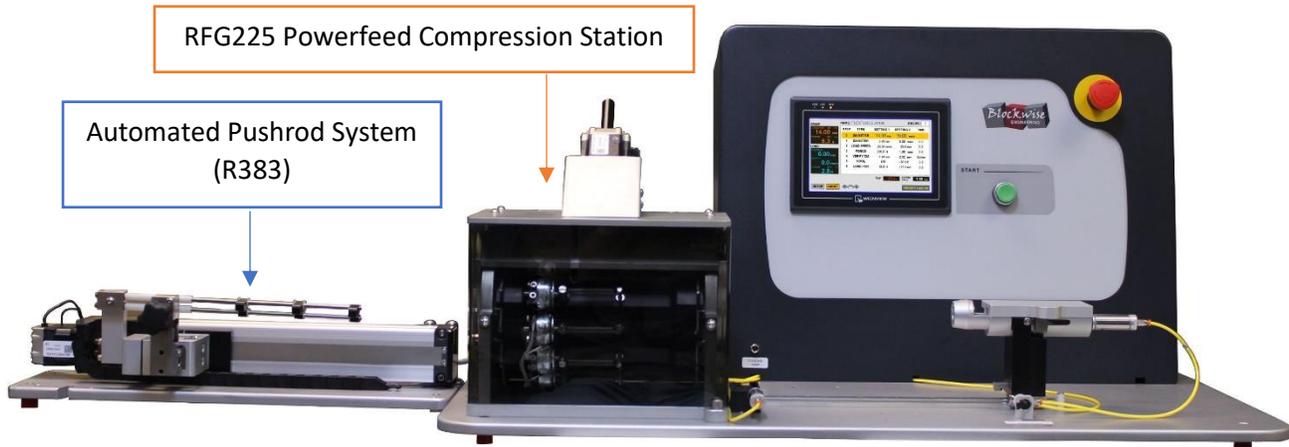
Other Options for Assisting Loading

Pushing a stent out of the compression station and into the delivery device is not always a straightforward process. There are a few other considerations that can help reduce friction and the force required to load the stent. These can be especially crucial on longer or other hard-to-load stents.

Tooling: Choosing the correct style of pushrod, or using a mandrel, can have varied effects on the loading process and should be taken into careful consideration. For more information on choosing the correct tooling, please refer to Knowledge Base article R705 Self-Expanding Stent Loading Tooling.

Powerfeed: Blockwise's LX loader offers a compelling feature known as the "Powerfeed". When enabled, dies move back and forth along the axis of the stent in a way that propels the stent through the compression station. This essentially eliminates the issue of friction between the stent and compression station. The powerfeed option can be turned on/off using the *Step Options* button on both *Load Force* and *Load Speed* steps.