

Tooling for Self-Expanding Stent Loading



Pushrods and Mandrels

When loading self-expanding stents, a pushrod and/or mandrel can be used to help push the stent out of the compression mechanism, as well as provide support for the stent as it is compressed. There are several variables to consider when making your pushrod or mandrel.

Material

For both pushrods and mandrels, Blockwise typically uses 304V stainless steel wire or hypodermic tubing, depending on the style of pushrod being created.

Determining Pushrod Style and Use of Mandrel

There are two styles of pushrod that can be used for stent loading, based on the type of stent and device being loaded into. A mandrel can also be used separate from, or in combination with a pushrod, again depending on the stent and device.

Single Diameter Pushrods

This style of pushrod is used solely for transferring force to the end of the stent in order to push it through the compression mechanism and into the device. It consists of a single diameter rod with a flat, non-rounded end to use as a stable pushing surface.

Stepped Pushrods

The stepped pushrod serves as both a pushing device, as well as a mandrel for added stability while pushing the stent. This type of pushrod consists of multiple diameters, usually two: a larger diameter for transferring force to the end of the stent, and a smaller diameter that will support the stent walls during the loading.

Mandrels

A separate mandrel can be used to either provide support for the stent during the crimping or loading stage, as well as act as a guide during the loading process. A mandrel usually consists of a single diameter wire that can fit the inner diameter of the crimped stent.

If used during the compression stage, a mandrel can help to stabilize the stent walls as they are being compressed. If the user is crimping the stent onto a mandrel, it is critical to ensure correct sizing so as to prevent damage to the stent or the compression mechanism from excessive force. A mandrel can also provide support to the stent during the loading stage.

When used as a guide, a mandrel can help to ensure that the stent is accurately aligned with the device and/or the pushrod. Again, sizing of the mandrel is critical to avoid damaging the stent or compression mechanism.

Tooling for Self-Expanding Stent Loading

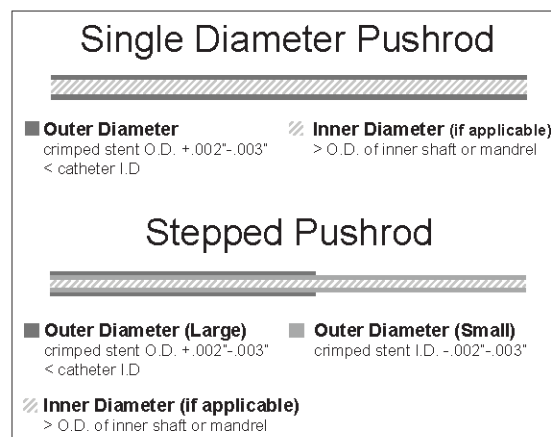


Determining Sizing

To determine the sizing for the pushrod and/or mandrel, several dimensions will need to be measured. Typically, these dimensions can be found using calipers or micrometer and a set of pin gauges.

- Device dimensions
 - I.D. of catheter or sheath
 - O.D. of inner shaft if applicable
 - I.D. of inner shaft if applicable
- Stent dimensions
 - Final crimp diameter
 - I.D. of compressed stent

See the diagram to correctly size the pushrod. Typically, it is recommended to allow .002" - .003" clearance.



Creating the Pushrod or Mandrel

Preparing the End

When preparing a single diameter pushrod, it is critical to create a flat pushing surface with no burrs or sharp or rounded edges.

Burrs and sharp edges on the pushrod can cause gouging on the dies of the compression mechanism, or inside the stent or delivery device.

Conversely, if the end of the pushrod is too rounded, it will not provide an effective pushing surface and can either damage the end of the stent, or else slip inside the stent and create excessive force between the stent walls and compression mechanism.



When preparing a stepped pushrod, the above advice is still applicable to the end of the larger diameter rod. However, for the end of the smaller, mandrel part of the rod, a rounded end is ideal. A rounded tip will help the smaller portion of the rod to easily slip into the stent while it is compressed.

Preparing a Stepped Pushrod

To create a stepped pushrod, two separate sized tubes or rods will need to be bonded together. Typically, this can be done by gluing a larger diameter hypodermic tube onto a smaller diameter wire or hypo-tube (depending on whether or not the entire pushrod should be tubular to accommodate a guidewire or inner shaft on the delivery device). Blockwise uses Loctite® 620 slip fit retaining compound for this purpose.

Tooling for Self-Expanding Stent Loading



Cleaning and Inspection of the Pushrod or Mandrel Before Use

To prevent damage to the stent or compression mechanism, it is important to ensure that the pushrod or mandrel is thoroughly cleaned and inspected before use. This includes checking for any burrs or sharp edges on the outer surface of the pushrod or mandrel, as well as through the inside of a tubular pushrod. It is recommended that a properly sized pin be run through a tubular pushrod before use to clear out any debris, as well as check for burrs.

Clamshell Gripper Tooling – Bushings and Grips



Alignment Bushing

Material

For the gripper alignment bushings, Blockwise uses Ertalyte® TX.

Determining the Style

There are two different styles of bushing that can be used based on the device and stent being loaded.

Straight Bushings

A straight bushing has only a single diameter through-hole, which aligns the end of the tube flush with the face of the compression mechanism dies. The stent will transfer directly from the compression mechanism into the catheter or sheath. This style of bushing has the benefit of being simple to manufacture, but does not provide the ability to cool the stent during the loading process as a stepped bushing does.

Stepped Bushings

Tooling for Self-Expanding Stent Loading



Blockwise Engineering LLC

www.blockwise.com

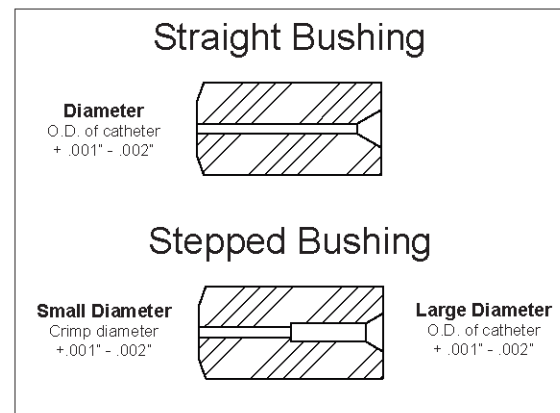
A stepped bushing has a through-hole with two different diameters, and allows for the use of liquid nitrogen to cool the stent before loading into the device. The stent will enter the smaller diameter first, which has cooling ports to allow the flow of nitrogen to the stent. The larger diameter holds the catheter or sheath in place so that the stent can then be loaded after cooling. When manufacturing this style bushing it is important to ensure that the hole is straight to prevent any misalignment of the stent and device.

Determining Size

To determine the sizing for the bushing, several dimensions will need to be measured. Typically, these dimensions can be found using calipers or micrometer and a set of pin gauges.

- Device dimensions
 - I.D. of catheter or sheath
 - O.D. of catheter or sheath
- Stent dimensions
 - Final crimp diameter

See the diagram to correctly size the bushing. Typically, it is recommended to allow .001" - .002" clearance.



Grips

Material

For the grips, Blockwise uses Xiameter® RTV-4230-E silicone rubber.

Determining Size

The O.D. of the catheter or sheath will need to be measured to correctly size the grips for the clamshell gripper. The grips should be sized approximately .005" - .010" smaller than the O.D. of the tube. When manufacturing the grips, the centerline should be offset by .010" to ensure that tube sets firmly into the bottom grip, while the top grip provides enough force when locked to prevent slippage. See the diagram below for correct sizing.

