

Configuring Zero-G™ Self-Expanding Stent Crimper / Loader Machines



Blockwise Engineering, LLC
<http://www.blockwise.com>

The **Zero-G™ Crimping / Loading Machine Models RZF and RZG** (patent pending) are used to radially compress self-expanding stents and push them into the lumen of a sheath or catheter assembly. Both machines include a Zero-G™ radial compression station (patent pending), a PLC controller, and optionally a sheath holder, and a pushrod carrier. The Zero-G™ mechanism provides a wide diameter range with no gaps between the dies.

Typically, the stent is crimped by the compression station then pushed by a pushrod out the of the compression station and into the sheath or catheter. Commonly, the stent is crimped to an intermediate position and chilled prior to being fully crimped.

There are a number of options for tailoring a Zero-G™ compression machine to fit your self-expanding stent crimping and loading application. This guide is intended to help you sort through these options and choose a machine configuration that will best meet your needs.

Compression Actuator Type

The two basic machine models, RZF and RZG, are differentiated by the power source used for radial compression

Pneumatic Actuator – Machine Model Numbers RZF62, RZF124, RZF200, RZF225 –

Compression force is provided by pneumatic actuator with an adjustable closed-stop screw. Sequencing control is provided by a PLC controller with LCD operator interface screen. Foot switch toggles compression station between open and closed states. Crimping force limit is controlled by a pressure regulator with digital gauge. The number in the part number specifies the working length of the compression dies in mm, for example, RZF124 has a working length of 124mm long. (This is the length of the cylindrical opening in the compression station.)

OR

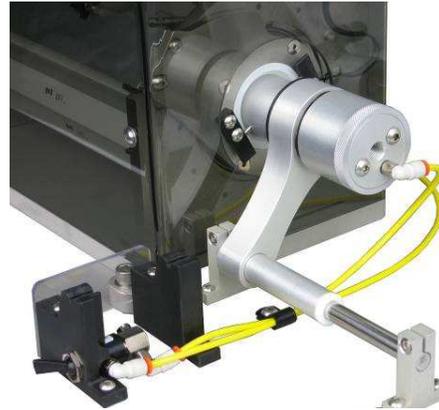
Stepper Motor – Machine Model Numbers RZG62, RZG124, RZG200, RZG225 - compression force is provided by a stepper motor mounted to the station. Sequencing control is provided by a PLC controller with LCD operator interface screen. The PLC implements a closed-loop position (diameter) control using feedback from an LVDT attached to the station, and also commands the sequencing between up to 8 diameter stops, which are stored in “recipes”. The opening diameter is displayed by the PLC. A force transducer on the actuator comes standard and is used to compensate for compliance in the compression station, providing a more accurate control of the actual opening diameter. The number in the part number specifies the working length of the compression dies in mm, for example, RZG225 has a working length of 225mm long.

Options:

Sheath Holder – PN: R220 Holds a sheath or catheter next to the dies for loading self-expanding stents. The holder uses a series of rubber donuts to firmly hold the sheath while spreading out the radially-inward force on the sheath, providing a high axial holding force with minimal inward deflection of the sheath wall or chance of sheath crushing. The sheath holder aligns the sheath precisely with the stent with no adjustment necessary. An optional alignment bushing with a built in funnel can eliminate the need to form lead-in funnels on the tip of your catheter. The diameter of the inner opening is custom sized for your product and can accommodate a relatively large range of diameters.



Sheath Holder PN: R220
Also shown: one internal donut



Sheath holder locked in compression head

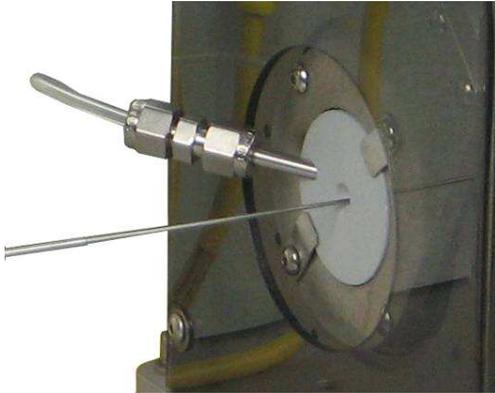
Pushrod Guide – PN: R052 Pushrod is mounted via a self-centering clamp to a linear slide. The operator pushes on a handle, moving the stent out of the compression station and into the sheath. Micrometer adjustment provides fine control for end stop of pushrod travel.

Pushrod Force Transducer – PN: R285 Integrated force sensor provides real time and peak push force for each loading cycle. Reading is shown on the PLC display. Unit is easily calibrated using hanging weights.

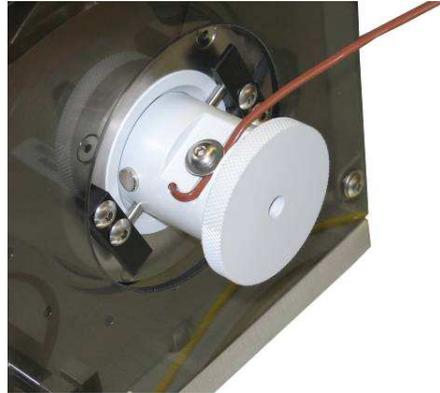


Pushrod Guide PN: R052 with Force Readout PN: R285

Nitrogen Chilling system – PN: R286 Controls the flow of cold nitrogen gas from the customer's 22 psi liquid nitrogen dewar. Cold N2 gas is injected into the opening of the compression station while the exhaust temperature is monitored and controlled by a temperature sensor and temperature controller. A cryogenic solenoid valve is held open until the temperature setpoint is reached. A small amount of N2 bypasses the valve and is used to purge the inside of the compression station to prevent condensation and frost.



Chilling System PN: R286
Injection point of N2 gas



Temperature Sensor

Digital Diameter Readout – PN: R287 Digital Indicator provides readout of opening diameter. The surface that the indicator measures is shaped to linearize the relationship between the opening diameter and the travel of the indicator. A simple formula is programmed into the indicator which allows the indicator to display the actual opening diameter of the compression head. (This option is available only on the RZF series. The RZG series displays the diameter on the PLC.)



Digital Readout of Opening Diameter – PN: R287

Example Configurations:

**RZG62 - Stepper Motor Actuated Model
62mm Length**

- with following options:
 - R052 Pushrod Guide
 - R285 Pushrod Force Transducer
 - R286 Nitrogen Chilling System
 - Custom Sheath Holder



**RZF62 - Pneumatically Actuated Model
62mm Length**

- with following options:
 - R220 Sheath Holder
 - R052 Pushrod Guide
 - R285 Pushrod Force Transducer



General Specifications:

Die Lengths Available:	62 mm, 124 mm, 225 mm, 300 mm
Compression Station Opening Diameter Range:	0 to 31.0 mm
Die Material	Ertalyte TX (PET with fluoropolymer)
Die-to-Die Gap	Zero at all opening diameters
Maximum Total Radial Force Available	1200 N (270 lbf)
Number of Compression Dies	12
Machine Dimensions	24" deep x 24" high, width depends on working length, from 24" to 36"
Sequence Control	PLC with LCD operator interface panel
Chilling Temperature	-50 C to room temperature
Service Connections	AC power 110 to 240 V, compressed air 5 to 7 bar