# Example Balloon-Expandable Stent Crimping Processes

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Medical stents are mesh-like metal tubes used to prop open bodily conduits, usually arteries, to treat an abnormal constriction. **Balloon-expandable stents**, one of the two main types of stents, are expanded in the conduit by inflating a balloon. There are many types of balloon-expandable stents, each designed to treat a specific range of anatomies, most commonly the coronary artery. Balloon-expandable stents are attached to stent-delivery balloon catheters by means of a radial compression process known as **stent crimping**.

This article describes an **example crimping process** using Blockwise's workhorse equipment, the **model CX crimping machine**. Variations of the process for different stent materials are also described.

Balloon-expandable stents are usually made of stainless steel, cobalt-chromium alloy, or a polymer such as PLLA, although several other materials are also used. Metals stents sometimes have polymer coatings containing a drug.

***Please note: This information is offered to help customers understand how Blockwise stent crimping 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.***

Our example balloon-expandable crimping process can be thought of as **four main parts**, each with a purpose.

1. **Precrimping** – sizing diameter of the stent so that it is snug, but still moveable, on the balloon.
2. **Positioning** – moving the stent into the correct position on the balloon, usually between a pair of radiaopaque marker bands.
3. **Pillowing** – at a certain stent diameter set by the temperature-controlled crimping dies, inflating the balloon and holding a high pressure for a while, to allow the balloon to move outward and mold itself around and between the stent, to increase stent dislodgement force. When possible, the whole stent crimping process is usually done at an elevated temperature to increase the effectiveness of the pillowing step.

4. **Attachment** – radially compressing the stent to plastically deform the stent body, to decrease the final diameter and cause the stent to tightly grip the balloon and prevent dislodgement.

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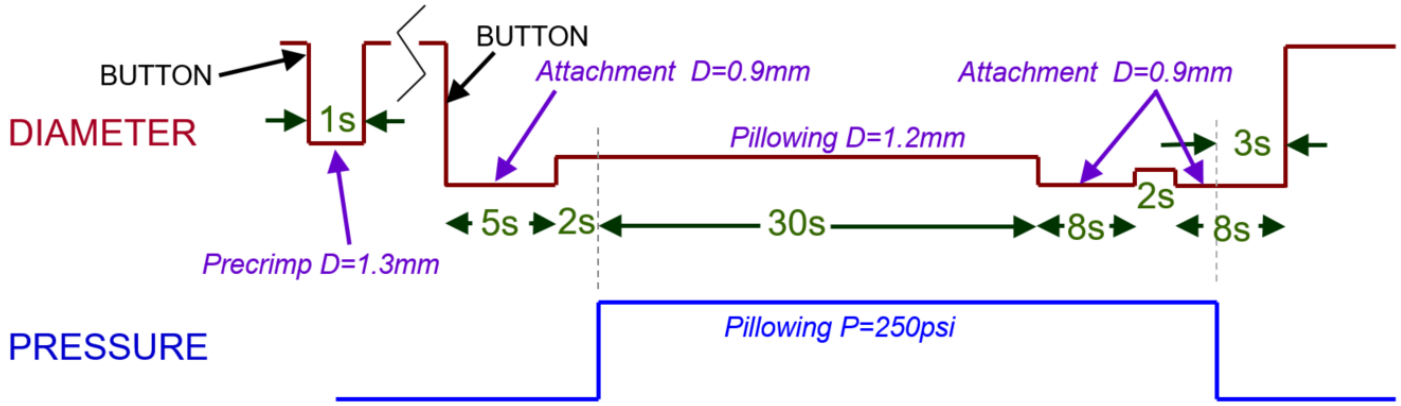
Steps 3 and 4, pillowing and attachment, are sometimes done in reverse order, or repeated, such as:

- Attachment, Pillowing
- Attachment, Pillowing, Attachment
- Pillowing, Attachment, Pillowing

Other types of steps are sometimes included, such as:

- Leak test
- Sheathing
- Temperature soaking

Shown as a pair of graphs, DIAMETER vs TIME and balloon internal PRESSURE vs TIME, a process may look like this:




This sequence of steps can be programmed as a “recipe” in a Blockwise model CX crimping machine:

*Temperature is set to **55C** and held constant through the recipe.*

| ***Step*** | ***Type*** | ***Setting*** | ***Setting2*** | ***Continue After*** | ***Time*** | ***Comment*** |
|---|---|---|---|---|---|---|
| 0 | Diameter | 15.0 mm | 3 mm/s | | | “Open-Stop” |
| 1 | Diameter | 1.25 mm | 15 mm/s | Step Complete | 1.0 s | ***Precrimp***; make stent “snug” on balloon |
| 2 | Diameter | 15.0 mm | 15 mm/s | START Button | | Open, wait for operator to ***position*** stent |
| 3 | Diameter | 0.85 mm | 5.0 mm/s | Step Complete | 5.0 s | First high-force ***attachment*** step |
| 4 | Diameter | 1.3 mm | 5.0 mm/s | Step Complete | 2.0 s | Go to diameter for Pillowing |
| 5 | Pressure | ON | 250 psi | Step Complete | 50 s | ***Pillowing*** step (dia stays 1.3 mm) |

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| | | | | | | |
|---|---|---|---|---|---|---|
| 6 | Pressure | OFF | | Step Complete | 2.0 s | Wait 2 sec for pressure to drop |
| 7 | Diameter | 0.85 mm | 5.0 mm/s | Step Complete | 8.0 s | 2nd high-force ***attachment*** crimp |
| 8 | Diameter | 1.1 mm | 5.0 mm/s | Step Complete | 2.0 s | Reduce force momentarily |
| 9 | Diameter | 0.85 mm | 5.0 mm/s | Step Complete | 8.0 s | 3rd high-force ***attachment*** step |

This simple recipe has a “Precrimping” step, and “Positioning” step, three “Attachment” steps and one “Pillowing” step. This example is similar to some recipes used to attach a Bare Metal Stent to a balloon catheter. The three most important parameters in this recipe are the “ATTACHMENT DIAMETER”, the “PILLOWING DIAMETER”, and the “TEMPERATURE”.

Main input and output parameters of this type of stent crimping process are shown here:

## Recipe

- **Temperature**
- ***Pillowing***
  - **Diameter**
  - **Balloon Pressure**
  - **Time**
- ***Attachment***
  - **Diameter (or Force)**

## Product

- **Diameter (profile)**
- **Dislodgement Force**
- **Even Crimping – No Strut Overlap**
- **Balloon Wings Not Protruding Between Struts**
- **Balloon Burst Pressure – No Damage**

Some general guidelines about how the recipe influences the product are shown in the table.

| Temperature | | |
|---|---|---|
| *Too Low* | *Good Setting* | *Too High* |
| • Poor Dislodgement Force | • Good Dislodgement Force<br>• No Balloon or Coating Damage | • Balloon Shrinkage<br>• Reduced Burst Pressure<br>• Coating or Drug Damage |

| Diameter of Pillowing | | |
|---|---|---|
| *Too Low* | *Good Setting* | *Too High* |
| • Poor Dislodgement Force | • Good Dislodgement Force<br>• Even Crimping | • Unfolded, Protruding Balloon<br>• Uneven Crimping |

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| | | |
|---|---|---|
| | • Balloon Contained Under Stent | |
| **Balloon Pressure During Pillowing** | | |
| *Too Low* | *Good Setting* | *Too High* |
| • Poor Dislodgement Force | • Good Dislodgement Force | |
| **Time of Pillowing** | | |
| Too Low | Good Setting | Too High |
| • Poor Dislodgement Force | • Good Dislodgement Force | • High Cycle Time |
| **Diameter or Force of Attachment** | | |
| *Diameter Too Low or Force Too High* | *Good Setting* | *Diameter Too High or Force Too Low* |
| • Reduced Burst Pressure<br>• Balloon Damage and Leak<br>• Uneven Crimping<br>• Stent Strut Overlap | • Good Crimped Diameter<br>• Even Crimping<br>• No Balloon Damage | • Final Diameter Too Big<br>• Poor Dislodgement Force |

Some possible variations of this process include:

- **Force-Controlled Attachment** – The attachment steps can be changed from diameter-controlled steps to force-controlled steps. Sometimes force-controlled attachment step is more forgiving of raw materials variability. (Knowledge Base article MS009 discusses this.)
- **Leak Testing** – The CX crimper's optional leak testing feature may be used to check for balloon leaks. For example, after step 9, the diameter may be increased slightly to allow air to move within the balloon, then the balloon may be pressurized to 100 psi, followed by a leak check. In a leak-check step, valves are commanded to pneumatically isolate the balloon, then the isolated air's pressure is monitored, triggering a failure if the pressure drops by more than a certain amount within a certain time.
- **Manual Sheathing** – For stents with fragile coatings, a thin-walled, tubular plastic sheath can be manually placed over the stent prior to the high-force attachment steps, protecting it from the localized high pressure of the metal dies.
- **Auto Sheathing** – The CX crimper is available with optional autosheathing feature. A thin PTFE film protects the stent from localized high pressure of the metal dies. When autosheathing is used, all of the recipe's steps in including Step 0 should be set to a small diameter to keep the film slightly overlapped. (See Knowledge Base article AS205)
- **Verify Force** – A "verify force" step can be added after the first attachment step (Step 3) to check the product's bulk. While maintaining the diameter, the actuation force is monitored, triggering a failure if it is outside the specified limits. (If the attachment steps are force-controlled type, then "Verify Diameter" step would be used.)
- **Polymer Stent** – When processing a polymer stent, the temperature should be set within the range that will not damage the stent. Also, the speed setting when compressing the stent (both precrimping and attachment) may need to be very slow to prevent fracture of the stent or coating.
- **Batch or Offline Precrimping** – The example recipe includes precrimping of the stent to make it snug on the balloon. Precrimping can also be done separately, prior to the crimping process.
    - Batches of stents can be quickly precrimped using less expensive equipment such as model RPF Fast Precrimper
    - If autosheathing is used and the initial diameter of the stent is larger than 0.9 • π • Film Width (allowing the film not to overlap) (see Knowledge Base article AS205), then the precrimping can be separated into a recipe which is run without sheathing film.
- **Crimping Over Inflated Balloon** – If a stent's design prevents it crimping stably, i.e. the stent buckles inward when crimping, then an inflated balloon catheter can be placed inside the stent during crimping.