Crimper
Model 9100CR23/ 9100CR26

Instructions for Use

Reference the Edwards SAPIEN Transcatheter Heart Valve with the RetroFlex 3 Delivery System Instructions for Use for full prescribing information.

Reference the Edwards SAPIEN Transcatheter Heart Valve with the Ascendra 3 Delivery System Instructions for Use for full prescribing information.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Please verify that you have the latest version of the instructions for use prior to using the device by visiting http://THVIFU.edwards.com or by calling 1.800.822.9837. In order to access the instructions for use, an IFU Code will be required.

STERILE: The Crimper is supplied sterilized by ethylene oxide.

1.0 Device Description

The Crimper is comprised of a housing and a compression mechanism, creating an aperture that is opened and closed by means of a handle. The Crimper includes a balloon gauge to verify diameter of an inflated balloon catheter. The Crimper is available in two sizes, 23 mm and 26 mm, with a corresponding balloon gauge for each size. It also includes a crimp gauge to verify collapsed diameter of the device.

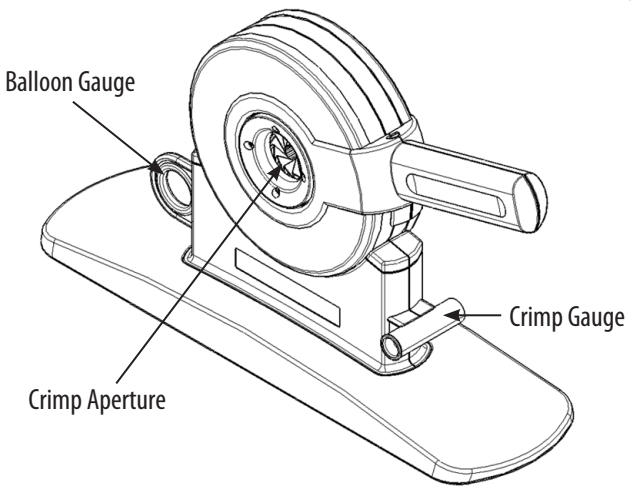

Figure 1. Crimper

2.0 Indications

The Crimper is indicated for use in preparing the Edwards SAPIEN Transcatheter Heart Valve for implantation.

3.0 Contraindications

No known contraindications.

4.0 Warnings

- The device is designed, intended, and distributed for single use only. **Do not resterilize or reuse the device.** There are no data to support the sterility, nonpyrogenicity, and functionality of the device after reprocessing.
- Do not mishandle the device or use it if the packaging or any components are not sterile, have been opened or are damaged, or the expiration date has elapsed.

5.0 Precautions

For special considerations associated with the use of this device prior to transcatheter heart valve implantation, refer to the bioprosthesis Instructions for Use.

6.0 Potential Adverse Events

No known potential adverse events.

7.0 Directions for Use

1. Remove the bioprosthesis from its package and gently place the bioprosthesis into the crimper aperture.
2. Crimp the bioprosthesis by rotating the handle to close the aperture.

8.0 How Supplied

STERILE: The Crimper is supplied sterilized by ethylene oxide.

9.0 Storage

The Crimper should be stored in a cool, dry place.

10.0 Device Disposal

Used crimpers may be handled and disposed of in the same manner as hospital waste and biohazardous materials. There are no special risks related to the disposal of these devices.

These products are manufactured and sold under one or more of the following US patent(s): US Patent No. 7,530,253 and corresponding foreign patents. Additional patents are pending.

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