



Edwards Lifesciences

Edwards Crimper Model 9350CR

Instructions for Use

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.

This product should be used by physicians trained and experienced in interventional techniques.

1.0 Device Description

The Edwards Crimper is comprised of a housing and a compression mechanism, creating an aperture that is opened and closed by means of a handle. The Edwards Crimper includes a 2-piece Crimp Stopper (packaged with the delivery system) used to correctly crimp the Transcatheter Heart Valve (THV).

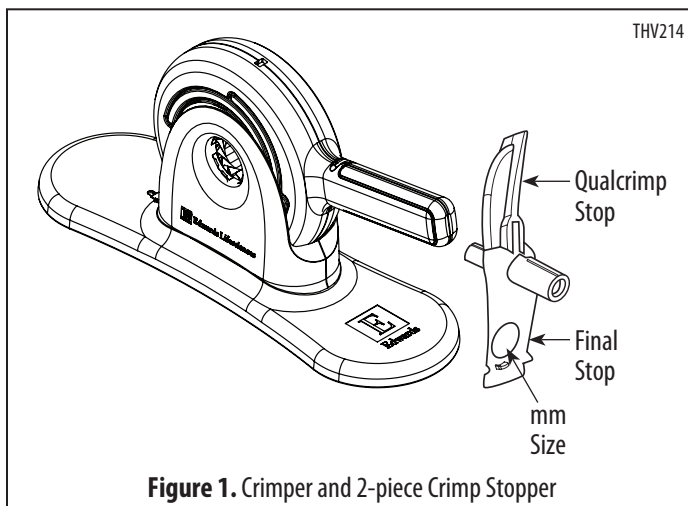


Figure 1. Crimper and 2-piece Crimp Stopper

2.0 Indications

The Edwards Crimper is indicated for use in preparing the Edwards SAPIEN XT 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.
- Do not use the device 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 THV implantation, refer to the SAPIEN XT transcatheter heart valve Instructions for Use.

6.0 Potential Adverse Events

No known potential adverse events.

7.0 Directions for Use

1. Remove the THV from its package, prepare and gently place the THV into the crimper aperture, and crimp the THV per the SAPIEN XT Instructions for Use.

8.0 How Supplied

STERILE: The Edwards Crimper is supplied sterilized by ethylene oxide.

9.0 Storage

The Edwards 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; 7,895,876; and corresponding foreign patents. Additional patents are pending.



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