



Instructions for Use

PRIME™

Aortic Punch

Description:

PRIME™ Aortic Punch is a device used to make holes in the aorta during surgery. It has an ergonomic handle and easy press system for operation. The device is made of stainless steel and ABS plastic. They are available in 2.8mm, 3.6mm, 4.0mm, 4.4mm, 4.8mm, 5.2mm, 5.6mm and 6.0mm diameters.

Indications for Use:

Aortic punch is intended to punch a regular hole in the aorta to facilitate the completion of the proximal anastomosis during surgery procedures.

Contraindications:

- The device is to be used only as indicated

Warnings:

1. Please read all packaging insert warnings, precautions, and instructions before use. Failure to do so may result in severe patient injury or death.
2. Do not reuse, reprocess, or re-sterilize under any circumstance.
3. Do not use if the packaging is damaged or opened unintentionally before use. This will lead to loss of sterility.
4. Rx Only. The device must be used by trained physicians only.

Precautions:

1. For multiple perforations, the blade must be cleaned with Gauze to prevent embolism.

Instructions for Use:

1. Inspect the package and product for damage and expiration date then Open the package carefully using the aseptic technique. Catheter sizes must be selected appropriately.
2. Expose the drilling location
3. Inserts the punch tip in to incision creates.
4. After drilling, clean the blade with gauze.

Disposal:

The device can be a biological hazard if disposed incorrectly. They should be disposed using recognised medical procedures and industry best practices. Local laws and regulations should be taken into account during disposal

Potential Complications / Adverse Effects













Aortic Punches are accessories used in extracorporeal circuits. This device, as with all extracorporeal blood system devices, has possible side effects which include, but are not limited to, infections, blood loss, thrombus formation, embolic events, and dislocation. Vessel damage and complications at the puncture site may occur if the instructions for use are not followed.

Warranty and Limitations

Aortic Punches are sold in 'as is' condition. The entire risk as to the quality and performance of the product is with the buyer. ALSPL disclaims all warranties, expressed or implied, with respect to its products, including but not limited to, any implied warranty of merchantability or fitness for a particular purpose. ALSPL shall not be liable to any person for any medical expenses or any direct or consequential damages resulting from the use of any product or caused by any defect, failure, or

malfunction of any product, whether a claim for such damages is based upon warranty, contract, tort, or otherwise. No person has any authority to bind ALSPL to any representation or warranty with respect to its products.

Symbols Glossary

	Caution, Consult Indications for Use
	Date of Manufacture
	Do not re-use
	Do not use if package is damaged
	Sterilized using ethylene oxide
	Keep away from sunlight
	Batch code
	Catalogue Number
	Manufacturer
	Use-by date
	Keep dry
	Temperature Limit



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