Encore Medical, L.P.
9800 Metric Blvd.
Austin, TX 78758-5445 USA

0400-0315 REV. A 2022-09

A printable copy of the IFU for this device can be located at: www.djosurgicalifus.com. A paper copy can be requested via phone at +1-800-520-8976.

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1. Product Handling
Devices not returned to Enovis™ should be treated as biohazardous material and disposed of in accordance with local laws and regulations.

Recommendation for the Care and Handling for Enovis™ Single Use Sterile Packed Cross Pin

WARNINGS	The instruments are supplied in sterile packaging. The sterility information is indicated on the device labels. Improper use of the Cross Pin can lead to damage to the tissue, destruction of the device components and injury to the operator, patient or third parties. Avoid excessive contact pressure. This can result in breakage, damage of the device, or extreme heat generation which increases the risk of thermal necrosis. Avoid jamming of the device during operation. Do not use as a lever. Prior to use, inspect package for damage that may compromise sterility. If packaging has been opened or damaged upon receipt, contact the manufacturer's representative. Do not use the product if the sterile package is damaged. Single use devices must be disposed of in compliance with all applicable local, state, and federal laws and regulations concerning medical waste.
CAUTION	Federal Law (USA) restricts this device to sale by or on the order of a physician.

Instructions For Use

CLEANING, DISINFECTION, AND STERILIZATION	Cross Pin must be discarded after one use. Do not clean, disinfect, or sterilize the Cross Pin. Sterilization of Cross Pin has been performed by gamma radiation at the minimum dose of 25 kGy to achieve a Sterility Assurance Level (SAL) of 10^{-6}.
STORAGE/INSTRUMENT CARE	Sterilized instruments and instruments in sterile packages must be stored away from dust, moisture and any source of contamination and should always be stored unopened in their respective protective containers.
CONTACT INFORMATION	**Enovis™** **ATTN: Customer Service** **9800 Metric Boulevard** **Austin TX, 78758 USA** **+ 1-800-456-8696**

2. Product Description
The Cross Pin is designed to temporarily stabilize guides on bones.

Component	Material	Applicable ASTM Standard
AltiVate® Anatomic Shoulder AG Half-Wedge Cross Pin, Sterile	AISI 316LVM DIN 1.4441	ASTM F138, ASTM F899

3. Indications for Use
The Cross Pin is indicated for use as instrument to temporarily stabilize guides on bones.

4. Intended Use
The Cross Pin is intended to be used in a surgical setting by trained professionals in accordance with the Instructions for Use and applicable Surgical Technique Guide.

5. Contraindications
There are no contraindications specific to the Cross Pin. Reference the applicable implant IFU for contraindications.

6. Precautions and Warnings
Use aseptic technique to open package for delivery of device into sterile field.
To avoid injury and infection, wear gloves or finger protection when inserting or removing the instruments from the hand piece. The tips of the instruments are sharp. The use of a device in any manner or medical procedure other than those for which it is designed and indicated may result in damage or breakage.

7. Preoperative Planning and Postoperative Care
Reference the applicable implant IFU for Preoperative Planning and Postoperative Care.

8. Adverse Effects
All known reactions on orthopedic treatment have to be considered carefully. Adverse events may include:
- Infection
- Tissue damage as a result of surgical trauma

9. Lifetime of Device
Cross Pin is single use only. The Cross Pin is designed to withstand the wear of a single surgery, when used as intended.

10. Trademarks and Patents
AltiVate® is a registered trademark of Encore Medical, L.P.

Enovis™ is a trademark of Enovis Corporation.

Symbol Glossary:

Symbol	Standard Reference	Symbol Title	Explanatory Text
	ISO 15223-1, 5.4.2	Do not re-use	Indicates device is intended for single-use and cannot be re-used.
	ISO 15223-1, 5.1.4	Use-by Date	Followed by text indicating the expiration date.
	ISO 15223-1, 5.3.4	Keep Dry	Indicates that the device should be kept dry.
	ISO 15223-1, 5.1.5	Batch Code	Followed by text indicating the Lot or Batch number. Can be used for traceability.
	ISO 15223-1, 5.2.4	Sterilized Using Irradiation	Indicates the device has been sterilized using an irradiation method, such as gamma.
	ISO 15223-1, 5.4.3	Consult Instructions for Use or Consult Electronic Instructions for Use	Indicates the need for the user to consult the instructions for use. For electronic IFU, the symbol is accompanied by a URL or QR code.
	ISO 15223-1, 5.1.1	Manufacturer	Followed by the name and address of the medical device manufacturer.
	N/A	Quantity	Indicates the quantity of items in package.
	ISO 15223-1, 5.1.6	Catalog Number	Indicates the manufacturers catalog number so that the device can be identified.
	ISO 15223-1, 5.2.8	Do not use if package is damaged	Indicates that a device should not be used if the package has been damaged or opened and that IFU should be consulted for additional information.
℞ Only	21 CFR 801.109	Caution: Federal Law restricts this device to sale by or on the order of a physician	Indicates the device is professional use only or prescription.
	ISO 15223-1, 5.1.11	Country Code of Manufacture	Identifies the country of manufacture. “CC” is replaced by the ISO 3166-1 code.