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

EC REP

MDSS GmbH
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CE
2797

0400-0325 REV. A 2024-05

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 the Surgical division of 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 Glenoid Tap

WARNINGS	The instruments are supplied in sterile packaging. The sterility information is indicated on the device labels. Improper use of the Glenoid Tap can lead to damage to the tissue, destruction of the device components and injury to the operator, patient or third parties. 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	Glenoid Tap must be discarded after one use. Do not clean, disinfect, or sterilize the Glenoid Tap. Sterilization of Glenoid Tap 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 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 Glenoid Tap is designed to prepare the glenoid bone for implant placement.

Component	Material	Applicable ASTM Standard
AltiVate Reverse® Glenoid Cannulated Tap, 6.5mm	420 Stainless Steel	ASTM F899
AltiVate Reverse® Glenoid Cannulated Tap, 8.0mm	420 Stainless Steel	ASTM F899
AltiVate Reverse® Glenoid Non-Cannulated Tap, 6.5mm	420 Stainless Steel	ASTM F899
AltiVate Reverse® Glenoid Non-Cannulated Tap, 8.0mm	420 Stainless Steel	ASTM F899

3. Indications
The Glenoid Tap is indicated for preparing the glenoid bone for implant placement.

4. Intended Use
The Glenoid Tap is intended to be used in a surgical setting by trained professionals in accordance with the Instructions for Use and applicable Surgical Technique Guide. The Glenoid Tap is intended for single use only.

5. Contraindications
There are no contraindications specific to the Glenoid Tap. 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 and threads 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.
Reuse, reprocessing, or resterilization can compromise device performance, patient safety, or compliance with relevant specifications.
Reference the applicable implant IFU for additional Precautions and Warnings.

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
- Adverse Tissue Reaction
- Tissue damage as a result of surgical trauma

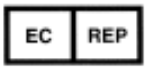
Reference the applicable implant IFU for additional Adverse Effects.

Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the relevant Competent Authority as defined in EU 2017/745.

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

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

Icon Key:

Symbol	Standard Reference	Symbol Title	Explanatory Text
	ISO 15223-1, 5.4.2	Single use - do not re-use	Indicates device is intended for single-use and cannot be re-used.
	ISO 15223-1, 5.1.4	Expiration 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	Lot Number/Batch Code	Followed by text indicating the Lot or Batch number. Can be used for traceability
	ISO 15223-1, 5.2.4	Sterility symbol: R: Sterile Using Irradiation	Indicates the device has been sterilized using an irradiation method, such as gamma.
	ISO 15223-1, 5.4.3	See “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 of items in package	Indicates the quantity of items in package
	ISO 15223-1, 5.1.2	Authorized Representative in European Community	Indicates the Authorized Representative in EU.

	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	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, 5.7.7	Medical Device	Indicates the item is a medical device.
	ISO 15223-1, 5.1.11	Country Code of Manufacture - US	Identifies the country of manufacture. “CC” is replaced by the ISO 3166-1 code.